

BEFORE THE PATENT TRIAL AND APPEAL BOARD
UNITED STATES PATENT AND TRADEMARK OFFICE

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3			
4	MEDTRONIC, INC.,)	
5)	Case IPR2014-00034
6	Plaintiff,)	Case IPR2014-00073
7)	Case IPR2014-00074
8	VS.)	Case IPR2014-00075
9)	Case IPR2014-00081
10	NUVASIVE, INC.,)	Case IPR2014-00087
11)	
12	Defendant.)	
13	_____)	

DEPOSITION OF PATRICK S. MILES
San Diego, California
Thursday, September 4, 2014

Job No: 83789

Reported by: NIKKI ROY

CSR No. 3052

MSD 1037 Medtronic, Inc. v. NuVasive, Inc. IPR2014-00075
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1 Deposition of PATRICK S. MILES, taken on behalf
2 of the Plaintiff, at 3111 Camino Del Rio North,
3 Suite 400, San Diego, California, on Thursday,
4 September 4, 2014 at 9:12 a.m., before NIKKI
5 ROY, CSR No. 3052.

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7
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9
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8 ALSO PRESENT:

9 TOM CAVANAUGH, Videographer

10 JAMES GARRETT, NuVasive

11 JONATHAN SPANGLER, NuVasive

I N D E X

WITNESS	EXAMINATION	PAGE
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	MR. MILLER	196

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1 I N D E X (CONTINUED):

2

QUESTIONS INSTRUCTED NOT TO ANSWER

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(None)

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INFORMATION REQUESTED

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(None)

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1 SAN DIEGO, CALIFORNIA, THURSDAY, SEPTEMBER 4, 2014

2 9:12 A.M.

3
4 THE VIDEOGRAPHER: Good morning. This is
5 the start of tape labeled number 1 of the videotaped
6 deposition of Patrick S. Miles in the matter of
7 Medtronic Incorporated versus NuVasive Incorporated
8 held before the Trial and Appeal Board of the Patent
9 and Trademark Office, case numbers IPR2014-00034,
10 IPR2014-00073, IPR2014-00074, IPR2014-00075,
11 IPR2014-00081 and case number IPR2014-00087.

12 This deposition is being held at Regus, 3111
13 Camino Del Rio North, Suite 400, San Diego,
14 California, on September 4, 2014, at approximately
15 9:12 a.m. My that name is Tom Cavanaugh from TSG
16 Reporting Incorporated. I am the legal video
17 specialist. The court reporter is Nikki Roy in
18 association with TSG Reporting.

19 Will counsel please introduce yourselves.

20 MR. OLIVER: Justin Oliver, Fitzpatrick
21 Celia for Medtronic.

22 MR. MILLER: Todd Miller of Fish &
23 Richardson on behalf of NuVasive, Inc. and Mr. Miles.

24 With me today is Stephen Schaefer and Jim
25 Garrett, James Garrett and Jonathan Spangler of

1 NuVasive, Inc.

2 My understanding also from counsel from
3 Medtronic is that there is a live real time feed of
4 this transcript to attorneys of the law firm of
5 Kirkland & Ellis.

6 THE VIDEOGRAPHER: Thank you.

7 Will the court reporter please swear in the
8 witness.

9
10 PATRICK S. MILES

11 called as a deponent and sworn in by
12 the deposition officer, was examined
13 and testified as follows:

14
15 EXAMINATION

16 BY MR. OLIVER:

17 Q. Good morning, Mr. Miles. How are you?

18 A. I'm well.

19 Q. Just a few starting questions.

20 Have you ever had your deposition taken
21 before today?

22 A. I have.

23 Q. About how many times?

24 A. About five.

25 Q. Okay. I'm going to ask you questions, which

1 you'll answer under oath.

2 Do you understand what it means to be under
3 oath?

4 A. I do.

5 Q. Okay. And if at any time you don't
6 understand one of my questions, please say so, and
7 I'll make my best efforts to clarify the question.

8 Is that acceptable?

9 A. It is.

10 Q. Okay. And understand that Mr. Miller may
11 object to some of my questions, but absent an
12 objection to privilege of which he instructs you not
13 to answer, you will continue to answer the questions.

14 Do you understand that?

15 A. I understand.

16 Q. Okay. Also, I'll suggest we take a break
17 every once in a while just to give us a chance to
18 refresh. If you need a break at any time, please let
19 me know, unless it's not during a particular
20 question.

21 Is that all right?

22 A. Yes.

23 Q. Is there any reason you will not be able to
24 give truthful and accurate testimony here today?

25 A. No.

1 Q. Okay. And what did you do to prepare for
2 this deposition?

3 A. I reviewed documents.

4 Q. Okay. And did you meet with anyone in
5 reviewing these documents?

6 A. Yes.

7 Q. And were those attorneys?

8 A. Yes.

9 Q. And about how many times did you meet with
10 them?

11 A. Twice.

12 Q. Okay. And outside your preparation sessions
13 with the attorneys, did you review any documents on
14 your own?

15 A. Yes.

16 Q. And what documents were those?

17 MR. MILLER: I'll object. You can lay the
18 foundation as to who identified the documents for
19 Mr. Miles and whether those were documents provided
20 by counsel. Otherwise, it's work product.

21 BY MR. OLIVER:

22 Q. Are there any public documents that you
23 reviewed on your own?

24 A. Any public documents?

25 Q. Patents?

1 MR. MILLER: Other than documents provided
2 to you by counsel.

3 THE WITNESS: No.

4 BY MR. OLIVER:

5 Q. Okay. And who's your current employer?

6 A. NuVasive, Inc.

7 Q. Are you employed by anyone else?

8 A. No.

9 Q. And what's your title at NuVasive?

10 A. President of Global Products and Services.

11 Q. And what does that entail?

12 MR. MILLER: Objection; form.

13 BY MR. OLIVER:

14 Q. I'll restate the question.

15 What are your responsibilities in that role?

16 MR. MILLER: Same objection.

17 THE WITNESS: The areas of my responsibility
18 are marketing, product development, surgeon
19 education, research.

20 BY MR. OLIVER:

21 Q. Okay. And you submitted six declarations in
22 six IPR proceedings; is that correct?

23 A. Yes.

24 Q. And just for convenience I'm going to give
25 you a binder here that has Exhibits 2024 from each of

1 the six IPRs identified on the record already.

2 Is it correct that those declarations are
3 similar, except for the fact they were submitted in
4 different IPRs?

5 A. Are you speaking of these six?

6 Q. Yes.

7 A. Let me review the six.

8 Q. Mr. Miles, rather than have you read all six
9 declarations, do you recall preparing these
10 declarations?

11 A. Let me review the declarations, and I'll let
12 you know if I remember.

13 Q. Did you sign those declarations on the last
14 page?

15 A. I've got to review the declaration to
16 determine if I -- if I signed them.

17 Q. Okay. Can you turn to the last page --

18 A. Yes.

19 Q. -- of the first declaration, please?

20 A. Yes.

21 Q. Is that your signature?

22 A. Yes, this is my signature on page -- would
23 this be 29 or 31?

24 Q. This is your declaration, so those are the
25 page numbers provided by NuVasive. I mean, we can

1 use --

2 A. I'm asking you as it relates to the page
3 number that you'd like to refer to --

4 Q. Why don't we refer to the bottom page
5 number, the smaller one, throughout the deposition.

6 A. That would -- that would be page 31.

7 Q. Correct.

8 MR. MILLER: Mr. Miles, I don't think
9 there's a question pending at this point.

10 BY MR. OLIVER:

11 Q. Yes. Mr. Miles, let's talk about some --
12 your declaration refers to "commercial offered XLIF
13 procedure."

14 Are you familiar with the XLIF procedure?

15 A. I am.

16 Q. And what does XLIF stand for?

17 A. Extreme lateral interbody fusion.

18 Q. And what does "extreme lateral" mean?

19 A. It means lateral to midline.

20 Q. Okay. And the midline would be midline of
21 the patient's back?

22 A. Yes, depending upon the context of what
23 we're discussing.

24 Q. Okay. So how would you describe it relative
25 to -- it's also referred to as 90 degrees; is that

1 correct?

2 A. It has been described as 90 degrees.

3 Q. Okay. And that would mean zero degree is --
4 if the patient is laying on his or her belly, that
5 would be zero degrees of the midline of the patient's
6 back?

7 MR. MILLER: Objection; form.

8 THE WITNESS: If -- if the patient is laying
9 on their belly, depending upon what the discussion is
10 about, zero degrees is at the -- at the due -- due
11 back or at the due front and 90 at the -- at the --
12 at the side. Is that what you're asking?

13 BY MR. OLIVER:

14 Q. Yes.

15 A. Sure.

16 Q. Okay. And zero degree would be a posterior
17 approach in that situation?

18 MR. MILLER: Objection; form.

19 THE WITNESS: You can consider zero at
20 posterior or anterior.

21 BY MR. OLIVER:

22 Q. Okay. And then 90 degree would be the
23 extreme lateral?

24 MR. MILLER: Objection; form.

25 THE WITNESS: As we describe XLIF --

1 BY MR. OLIVER:

2 Q. Uh-huh.

3 A. -- it is -- it is a directly lateral or
4 90 degrees from midline.

5 Q. Okay. And then there are also approaches in
6 between the posterior and the lateral approach; is
7 that correct?

8 A. Yes.

9 Q. And they are referred to as postero-lateral?

10 MR. MILLER: Objection; form.

11 THE WITNESS: Yes.

12 BY MR. OLIVER:

13 Q. Okay. And the term extreme lateral, has
14 that also been referred to as direct lateral?

15 A. It's been -- it's been referred to as -- as
16 many things.

17 Q. Is direct lateral one of those things?

18 A. Yes.

19 Q. Okay. What about true lateral?

20 A. Yes.

21 Q. And far lateral?

22 A. Oftentimes, far lateral is not a connotation
23 for direct lateral.

24 Q. And what would far lateral be?

25 A. Postero-lateral normally.

1 Q. Far lateral would mean postero-lateral?

2 A. In the context of surgery, yes.

3 Q. At what angle would that be if we talked
4 about the zero degree and 90 degree?

5 MR. MILLER: Objection; form.

6 THE WITNESS: Between 45 and 65 degrees.

7 BY MR. OLIVER:

8 Q. Okay. Are you familiar with Dr. Obenchain?

9 MR. MILLER: Objection; form.

10 THE WITNESS: Yes.

11 BY MR. OLIVER:

12 Q. Okay. And do you know that Dr. Obenchain
13 has referred to the direct lateral as a 9:00 o'clock
14 approach. Have you heard that used before?

15 A. I don't.

16 Q. You don't know. Okay.

17 A. I've never heard it called a 9:00 o'clock
18 approach.

19 Q. Okay. So you've stated that XLIF stands for
20 "extreme lateral interbody fusion."

21 What is meant by "interbody fusion"?

22 A. Bone growth from end plate to end plate.

23 Q. And are implants used to achieve fusion?

24 MR. MILLER: Objection; form.

25 THE WITNESS: At times.

1 BY MR. OLIVER:

2 Q. Okay. Does NuVasive sell an intervertebral
3 implant for its XLIF procedure?

4 A. Yes.

5 Q. And is that referred to as the CoRoent?

6 A. Please restate the question.

7 Q. Does NuVasive sell an implant -- an
8 intervertebral implant called the CoRoent?

9 A. Yes.

10 Q. Okay. And that is inserted during an XLIF
11 procedure?

12 A. It's inserted via multiple procedures.

13 Q. XLIF being one of them?

14 A. Yes.

15 Q. Okay. If you could turn to paragraph 16 of
16 your declaration on page 12, the second bullet point
17 refers to a large load-bearing interbody
18 construction; is that correct?

19 A. The second bullet point. There's one bullet
20 point on the page. Are we talking about the big
21 number or the small number?

22 Q. The small number. We're going to refer
23 to --

24 A. Here's the small number at the bottom of the
25 page, and there's one bullet point.

1 Q. Page 12?

2 A. Page 16.

3 Q. Paragraph 16, page 12.

4 A. My paragraphs aren't numbered.

5 Q. You didn't number the paragraphs in this
6 declaration?

7 A. I'm looking at the page number.

8 Q. Okay.

9 A. So what's your question?

10 Q. The second bullet point, it says "The large
11 load bearing interbody construction."

12 Do you see that, the second bullet point?

13 A. I do.

14 Q. Is that referring to an implant?

15 A. In the context that's being described, it's
16 referring in context to the procedure.

17 Q. Does the procedure have a large load-bearing
18 interbody construction?

19 A. No.

20 Q. Does an implant have a large load-bearing
21 interbody construction?

22 A. If you're asking me if it has an implant, it
23 has an implant.

24 Q. I'm asking what you meant by "large
25 load-bearing interbody construction." Are you

1 referring to an implant there?

2 A. Yes.

3 Q. Okay. Were you involved in the design of
4 the CoRoent XL implant?

5 MR. MILLER: Objection; form.

6 THE WITNESS: What do you mean involved?

7 BY MR. OLIVER:

8 Q. Did you help design the implant?

9 MR. MILLER: Same objection.

10 THE WITNESS: If you could be more
11 descriptive with regard to what "design" means.

12 BY MR. OLIVER:

13 Q. Come up with features. Did you help
14 determine what features the implant would have?

15 A. I would -- I would characterize my input as
16 requirements writing.

17 Q. And what requirements would those be?

18 MR. MILLER: Objection; form.

19 Sorry. Go ahead.

20 THE WITNESS: At 10 years, it would be tough
21 for me to specify the exact requirements.

22 BY MR. OLIVER:

23 Q. The exact requirements for what, for what
24 the implant would have structurally?

25 MR. MILLER: Objection; form.

1 THE WITNESS: You asked specifically what
2 requirements, and I said I'd have a tough time
3 remembering. So what's your next question.

4 BY MR. OLIVER:

5 Q. What features of the implant did you help
6 design? Do you know?

7 A. I don't recall.

8 Q. Okay. What was the purpose of NuVasive
9 introducing the CoRoent XL implant?

10 MR. MILLER: Objection; form, scope.

11 THE WITNESS: Inter -- to create an
12 environment for interbody fusion.

13 BY MR. OLIVER:

14 Q. And what was needed to provide interbody
15 fusion?

16 MR. MILLER: Objection; form, scope.

17 THE WITNESS: There's a multitude of
18 variables that are required for interbody fusion.

19 Are you -- are you specifically looking for
20 one thing?

21 BY MR. OLIVER:

22 Q. No. Which -- would it include disk height,
23 restoring disk height?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: I would suggest that -- you

1 know, I'm not an expert on the biology of fusion and
2 don't -- I can't completely characterize if disk
3 height restoration creates fusion.

4 BY MR. OLIVER:

5 Q. What was the purpose of the implant
6 regardless of fusion? What's the -- what's trying to
7 be achieved by insertion of the implant other than
8 fusion?

9 MR. MILLER: Objection; form and scope.

10 (Whereupon at 9:27 a.m. Sharre
11 Lotfollahi entered the deposition
12 proceedings.)

13 THE WITNESS: The intended utility of the
14 implant was stability.

15 BY MR. OLIVER:

16 Q. Stability. Okay. Was the CoRoent XL
17 specifically designed for the XLIF procedure?

18 MR. MILLER: Objection; form and scope.

19 THE WITNESS: It was specifically designed
20 for -- the CoRoent XL was specifically designed for
21 the XLIF procedure.

22 BY MR. OLIVER:

23 Q. Okay. What was the first length the CoRoent
24 XL came in or lengths rather?

25 MR. MILLER: Objection; scope.

1 THE WITNESS: To the best of my
2 recollection, 40 and 45.

3 BY MR. OLIVER:

4 Q. Okay. And why did the CoRoent XL come in
5 40- and 45-millimeter length?

6 MR. MILLER: Objection; form and scope.

7 THE WITNESS: To create stability.

8 BY MR. OLIVER:

9 Q. And how did the length create stability?

10 MR. MILLER: Objection; form and scope.

11 THE WITNESS: They were intended to sit on
12 the ring apotheosis.

13 THE DEPOSITION OFFICER: I'm sorry. They
14 were intended to?

15 THE WITNESS: To sit on the ring apotheosis.

16 BY MR. OLIVER:

17 Q. Does that refer to the cortical rim of the
18 vertebral bone?

19 MR. MILLER: Objection; form, expert and
20 scope.

21 THE WITNESS: There is a cortical rim within
22 the vertebral body, yes.

23 BY MR. OLIVER:

24 Q. Okay. And when you said it was -- the
25 length was intended to sit on the cortical

1 apotheosis, what did you mean by that?

2 MR. MILLER: Objection; mischaracterizes,
3 form and scope.

4 THE WITNESS: Please repeat the question.

5 BY MR. OLIVER:

6 Q. Can you -- you state the implants were
7 intended to sit on the ring apotheosis; is that
8 correct?

9 A. If that's what I stated, that's correct.

10 Q. And what did you mean by that?

11 A. I mean that the implant was to create
12 stability, and it creates stability sitting on the
13 ring apotheosis.

14 Q. And how does the length correspond to it
15 sitting on that rim?

16 MR. MILLER: Objection; scope, expert.

17 THE WITNESS: It depends upon how it's
18 placed.

19 BY MR. OLIVER:

20 Q. And how is it placed? How is the XLIF
21 placed or -- excuse me -- the CoRoent placed?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: As I said, there's multiple
24 CoRoent implants, and so it depends upon what CoRoent
25 implant you're talking about.

1 BY MR. OLIVER:

2 Q. How about the XL?

3 A. The XL?

4 MR. MILLER: Can we have a single question?

5 BY MR. OLIVER:

6 Q. So for the XL implants --

7 A. Uh-huh.

8 Q. -- you say it was -- how -- it was intended
9 to sit in a certain way. How was it intended to sit?

10 MR. MILLER: Objection; form and scope.

11 THE WITNESS: On the ring apotheosis.

12 BY MR. OLIVER:

13 Q. Okay. And is -- why the -- what's the
14 length of the XL implant?

15 MR. MILLER: Objection; form and scope.

16 THE WITNESS: I stated 40 to 45 were the
17 first CoRoent implants.

18 BY MR. OLIVER:

19 Q. Okay.

20 A. XL implant.

21 Q. And those were intended to sit on that ring?

22 A. They were -- they were intended to provide
23 stability.

24 Q. And you said that was achieved by sitting on
25 the ring?

1 A. Sitting on a portion of the ring.

2 Q. Okay. And the ring, is that on the outer
3 portion of the vertebrae?

4 MR. MILLER: Objection; expert, scope.

5 THE WITNESS: Is the ring on the outer
6 portion of the vertebra? Typically, yes?

7 BY MR. OLIVER:

8 Q. Yes.

9 A. Typically, yes.

10 Q. And what's the width of the CoRoent XL
11 implant?

12 MR. MILLER: Objection; form and scope.
13 Actually, withdrawn. Objection; scope.

14 THE WITNESS: In what time period are you
15 talking about?

16 BY MR. OLIVER:

17 Q. The last three years.

18 A. 30, 26, 22, 18, 16.

19 Q. Okay. Can the CoRoent XL be inserted
20 interiorly?

21 A. Yes.

22 MR. MILLER: Objection.

23 THE WITNESS: Sorry.

24 MR. MILLER: Objection; scope, and
25 objection; expert.

1 BY MR. OLIVER:

2 Q. Can the CoRoent XL be inserted posteriorly?

3 MR. MILLER: Objection' expert. Objection;
4 scope.

5 THE WITNESS: Yes.

6 BY MR. OLIVER:

7 Q. Can a CoRoent XL be inserted in a TLIF
8 procedure?

9 MR. MILLER: Objection; expert and scope.
10 Yeah, it is. Go ahead and answer.

11 THE WITNESS: It's -- it's nonsensical.
12 The -- can it be placed posterior? Yes. Can it be
13 placed via TLIF approach? Yes. You know, safely,
14 no.

15 BY MR. OLIVER:

16 Q. Okay. Can the CoRoent XL be inserted
17 obliquely?

18 MR. MILLER: I'm sorry. Can I have the
19 question back?

20 BY MR. OLIVER:

21 Q. Can the CoRoent XL be inserted obliquely?

22 MR. MILLER: Objection; expert and scope and
23 form.

24 THE WITNESS: You could put it in virtually
25 any direction you want to. It's not going to be safe

1 and so --

2 BY MR. OLIVER:

3 Q. In front of you, you have a binder that has
4 many of the exhibits relied on in your declaration.
5 One of those exhibits is Exhibit 2038, this binder
6 here. These are all the exhibits.

7 Can you turn to Exhibit 2038. Do you
8 recognize that document?

9 A. It looks like it's a NuVasive 10-K.

10 Q. Okay. And it's a NuVasive 10-K from 2013;
11 is that correct?

12 A. It appears as such.

13 Q. And since you cite to in your declaration,
14 is it fair to understand that you are generally aware
15 of what a NuVasive 10-K is?

16 A. Yes, generally.

17 Q. And what is it?

18 A. It's a SEC document.

19 Q. Filed by publicly traded corporations?

20 A. Yes.

21 Q. Okay. And NuVasive files one every year as
22 a publicly traded corporation?

23 A. Yes.

24 Q. Okay. Are you aware that there are certain
25 legal penalties for lying in an SEC filing?

1 MR. MILLER: Objection; scope, form.

2 THE WITNESS: Please restate the question.

3 BY MR. OLIVER:

4 Q. Is it your understanding that NuVasive is
5 truthful in its filings with the SEC?

6 A. Yes.

7 Q. Okay. If you could turn to page 4 of that
8 document, there's a section entitled "Overview."
9 Do you see that?

10 A. I do.

11 Q. And if you go down eight lines, there's a
12 line that begins -- begins "IRM support."

13 Do you see that line? Excuse me. Yes,
14 that's the line.

15 A. I do.

16 Q. In that line, it refers to "specialized
17 implants." Do you see that?

18 A. I do.

19 Q. Can you tell me what's specialized about
20 NuVasive implants?

21 MR. MILLER: Objection; form and scope.

22 THE WITNESS: I'd like to read it just so I
23 understand the context of the discussion here or the
24 question.

25 Can you repeat the question, please?

1 BY MR. OLIVER:

2 Q. What makes NuVasive's implants specialized?

3 MR. MILLER: Objection; form and scope.

4 THE WITNESS: I would say predominantly the
5 intent of defining what the -- what the utility is
6 and -- and creating features that are reflective of
7 what the surgical requirements are.

8 BY MR. OLIVER:

9 Q. What about the CoRoent implant, what makes
10 that different than other implants that were
11 available before it?

12 MR. MILLER: Objection; form and scope.

13 THE WITNESS: You're asking about specific
14 implants or --

15 BY MR. OLIVER:

16 Q. The CoRoent implant, the CoRoent XL.

17 A. The CoRoent XL implant, what makes it --
18 what makes it --

19 Q. Specialized. What makes it different than
20 implants that came before it?

21 MR. MILLER: Objection; form and scope.

22 THE WITNESS: What makes it specialized, I
23 would say is its attempt at fulfilling the
24 requirements of surgery.

25 ///

1 BY MR. OLIVER:

2 Q. That's a specialized feature of the implant
3 itself?

4 A. Yes.

5 Q. What features of the -- what features of the
6 design of the implant achieve that?

7 MR. MILLER: Objection; form and scope.

8 And just pause after the question so I can
9 interpose my objections.

10 THE WITNESS: It-- it becomes a difficult
11 question to answer based upon the number of -- of
12 implants and what the specific utility is, I guess.
13 I'm trying to help you get to an answer, but the
14 question is vague and broad.

15 BY MR. OLIVER:

16 Q. Let me provide you with another document.
17 We can talk about that in the same context.

18 There are some documents here that have been
19 marked. If you could turn in that new binder to
20 Exhibit 1025.

21 MR. SCHAEFER: I think we're way out of
22 scope here. This is Steve Schaefer on the record.

23 MR. OLIVER: If you're going to object to
24 scope, you can say "objection as to scope."

25 MR. MILLER: We're going to call the board

1 if --

2 MR. SCHAEFER: Yes.

3 MR. MILLER: So I'll take it, Steve. So I
4 have given you a lot of leeway here hoping you were
5 just laying a foundation and were going to connect
6 the dots with what we're here for, which is
7 Mr. Miles's declaration in the instant actions.

8 You are now putting in front of Mr. Miles a
9 declaration in a different action, which relates to
10 implants, which has been your questions for the last
11 40 minutes.

12 MR. OLIVER: To the extent that his
13 statements in other proceedings are inconsistent with
14 his statements in this proceeding, it's relevant.

15 MR. MILLER: His statements in other
16 proceedings that have nothing to do with this
17 proceeding are not relevant.

18 MR. OLIVER: They are relevant. It goes to
19 secondary considerations.

20 MR. SCHAEFER: Let me -- let me just make
21 clear, is it your intent to obtain testimony for
22 these implant IPR proceedings?

23 MR. OLIVER: My intent is to show
24 discrepancies for purposes of this proceeding between
25 what he said in other proceedings and what he's

1 saying in this proceeding.

2 MR. SCHAEFER: Okay. The reason I ask is --
3 and you may not know because you're not counsel of
4 record in those other proceedings -- but Medtronic
5 made the decision not to depose Mr. Miles in those
6 other proceedings, and it has a response to and if
7 the purpose of this is --

8 MR. OLIVER: If you want to go off the
9 record and call the board, we'll call the board;
10 otherwise, you're taking up time for this deposition.

11 MR. SCHAEFER: The point is -- and I'll make
12 it on the record to make it clear -- this -- the
13 purpose of this deposition is not for these other IPR
14 matters. That's not what it was noticed for.

15 MR. MILLER: If your intention is to use
16 this declaration to show a contradiction with
17 Mr. Miles's declaration in this proceeding, we'll
18 allow that.

19 If your purpose is to simply elicit
20 testimony about the subject matter of this other
21 unrelated declaration, we will call the board.

22 MR. OLIVER: That's fine.

23 Can we go back to the questions?

24 Q. All right. So you have Exhibit 1025?

25 A. Could we take a brief break?

1 MR. OLIVER: Sure.

2 MR. MILLER: Sure. Is there a question
3 pending?

4 THE VIDEOGRAPHER: All agreed to go off the
5 record, we're off the record at 9:43 a.m.

6 (Recess held 9:43 a.m. to 9:51 a.m.)

7 THE VIDEOGRAPHER: We are -- we're back on
8 the record at 9:51 a.m.

9 BY MR. OLIVER:

10 Q. So we're looking at Exhibit 1025, which is a
11 declaration you filed in a separate IPR,
12 IPR2013-00506.

13 Can you look at paragraph 7 of that
14 declaration, page 4? Do you see the first paragraph
15 of -- excuse me -- the first sentence of paragraph 7
16 says (reading):

17 Initially, NuVasive's XLIF --
18 XLIF solution was met with
19 substantial skepticism within the
20 spinal orthopedic community,
21 including concern over the size of
22 the implants.

23 What was the skepticism with respect to the
24 size of the implants?

25 A. Will you please repeat exactly where you

1 are?

2 Q. Paragraph 7 on page 4, first full sentence?

3 MR. MILLER: And if you need the question
4 read back --

5 I'll object now to form and scope.

6 (Document reviewed by witness.)

7 BY MR. OLIVER:

8 Q. Do you need me to repeat the question?

9 A. I'm reviewing the document.

10 Okay. Please repeat the question.

11 Q. What was the skepticism expressed with
12 respect to the size of the implants?

13 MR. MILLER: Objection; form and scope.

14 THE WITNESS: Yeah, the sentence reads
15 "substantial skepticism within the spinal community
16 including," so it was an element of -- of the
17 skepticism.

18 BY MR. OLIVER:

19 Q. And what was the concern with respect to the
20 size of the implant that you were referring to?

21 MR. MILLER: Objection; form and scope.

22 THE WITNESS: To the best of my
23 recollection, I would say that it would be a lack of
24 familiarity with the shape and the -- and the size.

25 ///

1 BY MR. OLIVER:

2 Q. Okay. And can you turn to the next page,
3 paragraph 9. The first full sentence reads
4 (reading):

5 NuVasive's CoRoent XL implants
6 have enjoyed commercial success.

7 Can you describe the commercial success of
8 the CoRoent XL implant that you're referring to
9 there?

10 MR. MILLER: Objection; form and scope.

11 THE WITNESS: In what context would you like
12 me to describe commercial success?

13 BY MR. OLIVER:

14 Q. Well, what you believe was the commercial
15 success of the CoRoent XL implant.

16 MR. MILLER: Objection; form and scope.

17 THE WITNESS: I would say the association of
18 the CoRoent XL implant and XLIF in general has
19 enjoyed market acceptance.

20 BY MR. OLIVER:

21 Q. Okay. And just market acceptance is your
22 definition of commercial success?

23 MR. MILLER: Objection; form and scope.

24 THE WITNESS: Significant market acceptance
25 is -- is probably a more accurate description of

1 mine.

2 BY MR. OLIVER:

3 Q. And what makes the market acceptance
4 significant?

5 MR. MILLER: Objection; form and scope.

6 THE WITNESS: If we're talking about
7 significant market acceptance, what does that mean to
8 me?

9 BY MR. OLIVER:

10 Q. Yes.

11 A. It means that there becomes a reproducible
12 experience in the hands of many surgeons to apply the
13 technology.

14 Q. Okay. Can you turn to page 7 of that
15 declaration, paragraph 10? In the second full
16 sentence, you state, for example, (reading):

17 After NuVasive pioneered the
18 market for lateral transpsoas
19 interbody fusion surgeries with the
20 CoRoent XL implant.

21 Do you see that sentence?

22 MR. MILLER: For the record, that's a
23 reading of half the sentence.

24 MR. OLIVER: You can read the whole sentence
25 for the record if you'd like. I was just trying to

1 direct the witness to the specific sentence.

2 MR. MILLER: So the question is do you see
3 it.

4 THE WITNESS: Yes.

5 BY MR. OLIVER:

6 Q. Okay. When you stated in paragraph 10 that
7 NuVasive pioneered the market for lateral transpsoas
8 interbody fusion with the CoRoent XL implant, how did
9 the implant pioneer the market?

10 MR. MILLER: Objection; form and scope.

11 THE WITNESS: The context of this sentence
12 is about pioneering a surgical approach, and the
13 implant is part of that surgical approach.

14 BY MR. OLIVER:

15 Q. So what part --

16 A. Or procedure.

17 Q. -- of the approach -- how was the -- strike
18 that question.

19 How did the CoRoent XL implant aid in the
20 pioneering of that market for the lateral transpsoas
21 interbody fusion?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: The -- repeat the question,
24 please.

25 ///

1 BY MR. OLIVER:

2 Q. You state that NuVasive pioneered the market
3 for lateral transposas interbody fusion with the
4 CoRoent.

5 What role did the CoRoent XL implant play in
6 pioneering that market?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: The implant itself was one of
9 the associated tools to create predictability of a
10 surgery, so I'm not sure I understand exactly what
11 you're asking me.

12 BY MR. OLIVER:

13 Q. Were there features of the implant that
14 provided that predictability?

15 MR. MILLER: Objection; form and scope.

16 THE WITNESS: There were features of every
17 element of the -- of what we designed and developed
18 that --

19 BY MR. OLIVER:

20 Q. Okay.

21 A. -- made it special.

22 Q. What were the features of the implant,
23 specifically, the CoRoent XL implant, that made it
24 special?

25 MR. MILLER: Objection; form and scope.

1 THE WITNESS: That it responded to the
2 requirements of the respective surgery.

3 BY MR. OLIVER:

4 Q. And how did it do that?

5 MR. MILLER: Objection; form and scope.

6 THE WITNESS: You would have to tell me
7 exactly what implant you're describing.

8 BY MR. OLIVER:

9 Q. The CoRoent XL implant.

10 A. There are multiple CoRoent XL implants.

11 Q. Different sizes?

12 A. Yes.

13 Q. Okay. Can you give me an example of one?

14 A. One of -- one of many. In terms of a size,
15 do you want a size?

16 Q. Sure.

17 A. 10 by 22 by 55.

18 Q. Okay. And what features of that particular
19 implant were specialized so as to pioneer the market
20 for lateral transpsoas interbody fusion?

21 MR. MILLER: Objection; form and scope.

22 THE WITNESS: One of them was that there is
23 an anti-expulsion mechanism.

24 BY MR. OLIVER:

25 Q. And what's an anti-expulsion mechanism?

1 A. In the -- a screw that engaged the
2 intervertebral body.

3 Q. Is there a screw that engaged the
4 intervertebral body?

5 A. Yes.

6 Q. What features did you personally design of
7 the CoRoent XL implant?

8 MR. MILLER: Objection; form and scope.

9 THE WITNESS: 10 years ago, I wrote the
10 requirements for it. I don't specifically recall the
11 individual contributions to the specific implants in
12 2004 or 5.

13 BY MR. OLIVER:

14 Q. And turn to page 8 of that declaration,
15 still within the same paragraph 10. Do you see in
16 the second and third lines, it says (reading):

17 The total CoRoent XL implant
18 revenues from 2005 through 2013
19 totaled hundreds of millions of
20 dollars.

21 Do you see that?

22 A. Yes.

23 Q. Yes. When you refer to the hundreds of
24 millions of dollars of revenue, does that include all
25 interbody fusion products?

1 MR. MILLER: Objection; form and scope.

2 THE WITNESS: I'd say the intended
3 reflection of that statement is the entire portfolio
4 of CoRoent XL.

5 BY MR. OLIVER:

6 Q. Does it exclude, for instance, biologics?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: The intended reflection of
9 that communication was to demonstrate commercial
10 success, which is the end of that sentence, and so
11 the intention was to -- to communicate that -- that
12 the acceptance of the procedure was very high.

13 BY MR. OLIVER:

14 Q. I'm asking specifically about the number you
15 mention you mentioned, hundreds of millions of
16 dollars. Is that for implant sales alone or does it
17 include other sales?

18 MR. MILLER: Objection; scope.

19 THE WITNESS: I don't recall exactly whether
20 the hundreds of millions of dollars meaning have we
21 sold -- have we sold -- have we created a lot of
22 revenue from the procedure? We have. You know, the
23 intent was that oftentimes the currency of what
24 people pay for is the implant, and so I think I was
25 intending to say there was great commercial success

1 based upon a revenue contribution.

2 BY MR. OLIVER:

3 Q. Okay. And revenue contribution from the
4 implant?

5 MR. MILLER: Objection; form and scope.

6 THE WITNESS: The intent of that comment was
7 to communicate commercial success. And -- and did we
8 generate revenue with a myriad of implants? We did.
9 Beyond that, I -- I'm not sure exactly what you're
10 getting at.

11 BY MR. OLIVER:

12 Q. Okay. That's fine.

13 Can you turn to, in the binder in front of
14 you, Exhibit 1032. Can you identify this document?

15 A. It appears like a 10-K.

16 Q. From NuVasive?

17 A. It appears as such.

18 Q. And it's from 2005; is that correct?

19 A. Yes.

20 Q. Can you turn to page 18 of that document?

21 The middle paragraph there, beginning "Our fixation
22 system," do you see that?

23 A. I do.

24 Q. It states, (reading):

25 Our fixation systems have been

1 uniquely designed to be delivered
2 through our MaXcess System to provide
3 stabilization at the posterior spine.
4 "Fixation systems," does that refer to
5 implants?

6 MR. MILLER: Objection; form and scope.

7 THE WITNESS: It could refer to --

8 Pedicle fixation could refer to interbody
9 fixation. I'm not sure exactly what the intended
10 communication is here.

11 BY MR. OLIVER:

12 Q. Okay. The next sentence says (reading):

13 These systems enable minimally
14 destructive placement of implants and
15 are intended to reduce operating time
16 and patient morbidity.

17 Can you tell me how the fixation systems and
18 MaXcess system reduce operating time and patient
19 morbidity?

20 A. Yes.

21 MR. MILLER: Objection; form.

22 THE WITNESS: Sorry.

23 MR. MILLER: Go ahead.

24 BY MR. OLIVER:

25 Q. How about operating time? Can you tell me

1 how they -- how do those two systems, fixation
2 systems and the MaXcess system, reduce operating
3 time?

4 MR. MILLER: Objection; form.

5 THE WITNESS: Can you be more specific with
6 regard to what -- I could describe their utility, if
7 that's what you'd like.

8 BY MR. OLIVER:

9 Q. I'm just curious, since this is a NuVasive
10 document, what is meant by fixation systems and
11 MaXcess systems reducing operating time?

12 MR. MILLER: Objection; form.

13 THE WITNESS: I didn't -- I didn't write the
14 document, so I can't speculate as to -- as to -- as
15 to what was meant, but I'm happy to describe
16 functionally how MaXcess and implants reduce
17 operative times.

18 BY MR. OLIVER:

19 Q. That's fine. Can you do that, please?

20 A. Sure. When you utilize MaXcess, depending
21 upon its application, there is the opportunity to
22 define a specific operative corridor. And when --
23 when you say we improve operative times, you're
24 improving it compared to something else. And so as
25 compared to say a tube, your ability to customize the

1 exposure accommodates oftentimes a much more
2 expeditious experience than picking around in a tube.
3 So the reflection of reducing operative times is in
4 comparison to something. So if you'd like to
5 describe to me how you'd like me to compare it, then
6 I would.

7 Q. Just to be clear, the MaXcess system is a
8 retractor system; is that correct?

9 A. That's correct.

10 Q. Okay. And is it reusable? Is it used in
11 more than one operation?

12 A. It depends upon what element you're
13 describing, that you're talking about.

14 Q. The system or are there portions of the
15 system that are reused?

16 A. Yes.

17 Q. And which portions are those?

18 A. The handles, the blades, and the body.

19 Q. Okay. And are those portions typically
20 loaned to hospitals for use in multiple surgeries?

21 A. They could be loaned. They could be
22 consigned. They're made available.

23 Q. Okay. And what's the most common way that
24 they're made available to hospitals?

25 MR. MILLER: Objection; scope.

1 THE WITNESS: I'd say loaned or consigned.

2 BY MR. OLIVER:

3 Q. Okay. And when you say "consigned," do you
4 mean -- what do you mean by that?

5 MR. MILLER: Objection; scope.

6 THE WITNESS: I mean they're placed in the
7 hospital.

8 BY MR. OLIVER:

9 Q. Do you charge the hospital at that time when
10 you place them?

11 MR. MILLER: Objection; scope.

12 THE WITNESS: It depends.

13 BY MR. OLIVER:

14 Q. Is it more often that you don't charge
15 hospitals when you provide the MaXcess system or that
16 you do?

17 MR. MILLER: I need that one back.

18 MR. OLIVER: I'll repeat it.

19 BY MR. OLIVER:

20 Q. When you -- is it -- when you provide the
21 MaXcess retractor system to hospitals, do you more
22 often provide it in a loaning situation or other
23 uncharge situation?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: We either -- we either loan or

1 consign the, you know, the retractor most -- most
2 often. And there's a multitude of variables as it
3 relates to how we get paid for its utility.

4 BY MR. OLIVER:

5 Q. How do you get paid for its utility?

6 MR. MILLER: Objection; scope.

7 THE WITNESS: We can sell the disposables
8 that are used with the retractor. We can sell
9 implants that are used with the retractor. So -- so
10 there's a multitude of ways that we generate revenue
11 associated with the retractor.

12 BY MR. OLIVER:

13 Q. Okay. We referred earlier to the XLIF
14 procedure, and that is extreme lateral interbody
15 fusion; is that correct?

16 A. That's the acronym, yes.

17 Q. And extreme lateral is approximately a
18 90-degree approach if zero is the midline of the
19 patient's back?

20 MR. MILLER: Objection; form.

21 THE WITNESS: It depends upon what time
22 period you're talking about.

23 BY MR. OLIVER:

24 Q. Okay. So is it correct there was an XLIF 60
25 procedure?

1 A. Yes.

2 Q. And that was around 2001 when it was
3 introduced?

4 A. What do you mean by "introduced"?

5 Q. When did NuVasive offer the XLIF 60?

6 MR. MILLER: Objection; form.

7 THE WITNESS: We made available in a very
8 limited way XLIF 60 in the 2001, 2002 time frame.

9 BY MR. OLIVER:

10 Q. Okay. And XLIF, the current XLIF that's
11 offered from -- when did XLIF 90 -- that's the
12 90-degree approach -- when did that -- when was that
13 first offered?

14 MR. MILLER: Objection; form.

15 THE WITNESS: It was -- it was initially
16 commercial launched in 2003.

17 BY MR. OLIVER:

18 Q. 2003. And since the launch of the XLIF
19 90-degree approach, have you offered the XLIF 60?

20 A. Not to my knowledge.

21 Q. Okay. Now, we already stated that the
22 90-degree referred to the degrees off the midline of
23 the patient's back.

24 Is -- can you describe what the 60-degree
25 approach is?

1 MR. MILLER: Objection; form,
2 mischaracterizes.

3 THE WITNESS: Yes. We -- we stated that
4 it's from the front or from the back, 90 degrees from
5 the front or from the back.

6 And so your question was can I characterize
7 the 60-degree?

8 BY MR. OLIVER:

9 Q. Yes.

10 A. Okay. I would say that it was 60 degrees
11 from the back.

12 Q. From the midline of the patient's back?

13 A. Correct.

14 Q. So if zero degrees is the midline of the
15 patient's back, it would be 60 degrees from the
16 midline of the patient's back?

17 MR. MILLER: Objection; form.

18 THE WITNESS: Approximately.

19 BY MR. OLIVER:

20 Q. Approximately. Okay.

21 And do you recall testifying about the
22 XLIF 60 procedure during a patent infringement
23 litigation between Medtronic and NuVasive?

24 A. Yes, I do, vaguely.

25 Q. Okay. And during that testimony, did you

1 characterize the XLIF 60 as a postero-lateral
2 approach?

3 A. I don't specifically recall.

4 MR. MILLER: Just interpose a scope
5 objection.

6 THE WITNESS: I don't specifically recall.

7 BY MR. OLIVER:

8 Q. Is the XLIF 60 a postero-lateral approach?

9 A. I would say in common vernacular, it could
10 be characterized as a postero-lateral approach.

11 Q. Okay. And why did NuVasive switch from the
12 XLIF 60-degree approach to the XLIF 90-degree
13 approach?

14 MR. MILLER: Objection; form.

15 THE WITNESS: There wasn't -- there wasn't
16 a -- I didn't deem there to be a business in XLIF 60.

17 BY MR. OLIVER:

18 Q. Why not?

19 MR. MILLER: Objection; form. I'm sorry.
20 Objection; scope.

21 Go ahead.

22 THE WITNESS: I didn't believe it could be
23 reproducible by a wide array of surgeons.

24 BY MR. OLIVER:

25 Q. Did you believe -- did you believe it to be

1 safe?

2 MR. MILLER: Objection; form.

3 THE WITNESS: I'd say there's two -- in what
4 specific patient type?

5 BY MR. OLIVER:

6 Q. Did you believe that the XLIF 60 was safe
7 and reproducible from the common surgeon?

8 A. I didn't believe that the XLIF 60 was safe
9 and reproducible enough to a wide enough audience of
10 surgeons to create a business.

11 Q. Okay. And both the XLIF 60-degree approach
12 and XLIF 90-degree approach were transpsoas; is that
13 correct?

14 MR. MILLER: Objection; form.

15 THE WITNESS: I think what you'd have to do,
16 if you genuinely want to get at that question, is
17 define exactly what level of the spine and exactly
18 what procedure you're talking about.

19 BY MR. OLIVER:

20 Q. Let's say L4-L5 fusion procedure.

21 MR. MILLER: And what is the question?

22 BY MR. OLIVER:

23 Q. Were both the XLIF 60-degree approach and
24 XLIF 90-degree approach transpsoas?

25 MR. MILLER: Objection; form.

1 THE WITNESS: Depends upon the anatomy of
2 the patient.

3 BY MR. OLIVER:

4 Q. Were there XLIF 60 procedures that were
5 transpsoas?

6 MR. MILLER: Objection; form.

7 THE WITNESS: I couldn't speculate.

8 When there's a dilator in a body, it becomes
9 a little difficult to tell if a dilator is in a psoas
10 or not.

11 BY MR. OLIVER:

12 Q. You're not aware of any XLIF 60 procedures
13 that may have been transpsoas?

14 MR. MILLER: Objection; form.

15 THE WITNESS: It's -- it's a bit of a
16 nonsensical question. It becomes very to tell from a
17 60-degree midline, depending upon the level and the
18 patient's anatomy, if you are in the psoas or not
19 from a 60-degree off midline. So it's a question I
20 can't answer.

21 BY MR. OLIVER:

22 Q. Did you use nerve -- did NuVasive use nerve
23 monitoring in the XLIF 60 approach?

24 A. Yes.

25 Q. And what was the purpose of the nerve

1 monitoring?

2 A. To avoid nerves.

3 Q. Nerves in which parts of the body?

4 A. In the spine.

5 Q. In the spine.

6 What about the psoas muscle?

7 A. Yes. The intended utility for nerve
8 physiology is to avoid nerves. If a surgeon is
9 navigating via a small incision, it's best to have
10 adjunctive technology.

11 Q. Okay. So was there any discussion of using
12 nerve detection for detecting nerves in the psoas
13 muscle in the XLIF 60 procedure?

14 MR. MILLER: Objection; form.

15 THE WITNESS: Not to my recollection.

16 BY MR. OLIVER:

17 Q. Did you safely implant a CoRoent XL via an
18 XLIF 60 approach?

19 MR. MILLER: Objection; form, expert.

20 THE WITNESS: I would be speculating based
21 upon the level and the number of variables that
22 you're describing.

23 BY MR. OLIVER:

24 Q. Are there levels that you could implant the
25 CoRoent XL?

1 MR. MILLER: Objection; form, expert.

2 THE WITNESS: I would suggest, much like the
3 procedure itself, the XLIF 60 didn't accommodate
4 predictability across a wide audience of surgeons,
5 and so could you? There's a lot of things you can
6 do, but I can't speculate whether you should or you
7 could in a procedure that foundationally we deemed
8 not predictable to a wide audience.

9 BY MR. OLIVER:

10 Q. When you switched or when NuVasive switched
11 from the XLIF 60 to the XLIF 90, is it correct that a
12 Dr. Luis Pimenta first suggested to NuVasive the
13 90-degree approach?

14 MR. MILLER: Objection; form.

15 THE WITNESS: I don't specifically recall.

16 BY MR. OLIVER:

17 Q. You don't recall?

18 A. If he was the first one. There was -- you
19 asked if he was the first one. I can't recall that.

20 Q. Was he one that suggested the direct lateral
21 approach to you?

22 A. He was one of, yes.

23 Q. Who were others?

24 A. Paul McAfee, John Regan.

25 Q. You stated the XLIF 90 was introduced

1 commercially in 2003; is that correct?

2 A. I did state that, yes.

3 Q. Since 2003, the X -- the XLIF has referred
4 to the 90-degree approach; is that correct?

5 MR. MILLER: Objection; form.

6 THE WITNESS: To the best of my
7 recollection --

8 BY MR. OLIVER:

9 Q. Okay.

10 A. -- yes.

11 Q. So in 2004, 2005, when someone referred
12 to -- when a doctor referred to as an XLIF, were they
13 referring most typically to XLIF 90?

14 MR. MILLER: Objection; form.

15 THE WITNESS: I'm not sure. There was a
16 chapter published on XLIF 60, and so I recall people
17 asking about XLIF 60, and I don't recall the timing
18 of that publication or when we dropped the 60 or 90
19 nomenclature. So it's tough for me to recall.

20 BY MR. OLIVER:

21 Q. You discussed in your declaration various
22 praise for the XLIF procedure. When you were talking
23 about the praise for the XLIF procedure, was it for
24 the XLIF 90 or XLIF 60?

25 A. It was for the XLIF 90.

1 Q. Okay. You mention a Dr. John -- was it
2 Regan or Regan?

3 A. Regan.

4 Q. Okay. Do you know that he and others were
5 performing transpsoas approaches in the late 1990s?

6 A. I know that John Regan was on our board at
7 the time, and I --

8 Q. At what time?

9 A. At the 2001 through 2000 and approximately 3
10 time frame. So I'm extremely familiar with regard to
11 what he described that he was doing both in the
12 literature and directly to me.

13 Q. And what did he describe that -- in the
14 literature?

15 MR. MILLER: Objection; form.

16 THE WITNESS: What he described to me and
17 what he published in the literature was -- an
18 endoscopic retroperitoneal approach was
19 foundationally what his focus was.

20 BY MR. OLIVER:

21 Q. And did that proceed through the psoas
22 muscle?

23 A. Often it peeled the psoas -- peeled the
24 psoas off the spine, again, depending upon what level
25 you're talking about.

1 Q. Did it ever proceed through the psoas
2 muscle?

3 A. I can't speculate as to -- if he did
4 surgeries through the psoas, there was -- there
5 was -- I can't -- I would tell you it was uncommon if
6 he did.

7 Q. Okay. When he was doing these procedures in
8 the 1990s, was he using implants other than the
9 CoRoent implant?

10 A. He must have as NuVasive, depending upon
11 when you're talking about in the '90s didn't even
12 exist.

13 Q. Before NuVasive introduced the XLIF 60 and
14 XLIF 90, was the lateral approach reimbursable from
15 most insurance companies?

16 MR. MILLER: Objection; form and scope.

17 THE WITNESS: And to this day, there's no
18 such thing as reimbursement for the lateral approach.

19 BY MR. OLIVER:

20 Q. How is the XLIF reimbursed?

21 A. Anterior column surgery.

22 Q. Anterior column. So it's an anterior
23 approach reimbursement?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: There's no such thing as

1 reimbursement for procedures. They're described
2 based upon their anatomic location.

3 BY MR. OLIVER:

4 Q. Okay. So why is the XLIF approved as an
5 anterior approach?

6 MR. MILLER: Objection; form and scope.

7 THE WITNESS: It's considered anterior
8 column surgery based upon it dealing with the
9 intervertebral body, the anterior portion of the
10 intervertebral body.

11 BY MR. OLIVER:

12 Q. Can you turn back to Exhibit 2038?

13 MR. MILLER: That's in that binder.

14 BY MR. OLIVER:

15 Q. If you can turn to page 69 of that exhibit,
16 the paragraph -- the third paragraph down begins "At
17 various times."

18 Do you see that paragraph?

19 A. Yes.

20 Q. The second full sentence states (reading):

21 We have worked with our surgeons,
22 customers in the North America Spine
23 Society, NASS, who, in turn, have
24 worked with these insurance providers
25 in an effort to supply information,

1 explanation of clinical data they
2 require to categorize the XLIF
3 procedure as a procedure entitled to
4 reimbursement under the policies.

5 Is that a true statement?

6 A. If put in proper context, it is.

7 Q. What's the proper context?

8 A. The proper context was that people who
9 invested in our company would be interested in
10 whether procedures that we marketed were -- availed
11 some reimbursement for both surgeon and hospital, and
12 so that was the intended utility of it.

13 Q. How did NuVasive work with its surgeons'
14 customers to achieve that goal?

15 MR. MILLER: Objection; form and scope.

16 THE WITNESS: Can you clarify the question?

17 BY MR. OLIVER:

18 Q. Well, it says in the document that NuVasive
19 worked with surgeon customers and NASS, in turn,
20 worked with insurance providers in an effort to
21 supply information, explanation and clinical data
22 they required to categorize the XLIF procedure.

23 If you were working with those surgeons, if
24 NuVasive was working with those surgeons, how were
25 they working with their surgeons to provide that

1 information and ensure that the XLIF was entitled to
2 reimbursement?

3 MR. MILLER: Objection; form and scope.

4 THE WITNESS: Practically speaking, I would
5 call surgeons who had previously opined in the
6 literature on this very subject and requested that
7 they avail clarification to the insurance carrier.

8 BY MR. OLIVER:

9 Q. Clarification of what?

10 A. Clarification of what --

11 MR. MILLER: Let me just -- objection; form
12 and scope.

13 Go ahead.

14 THE WITNESS: Clarification of what the XLIF
15 procedure was.

16 BY MR. MILLER:

17 Q. And why was that clarification needed to
18 obtain reimbursement?

19 MR. MILLER: Objection; form and scope.

20 THE WITNESS: The insurance carriers in
21 our -- from our perspective, were confused with
22 regard to what the proprietary acronym XLIF meant
23 as -- as they have to translate what a proprietary
24 surgery is into exactly what it does. There appeared
25 some confusion there.

1 BY MR. OLIVER:

2 Q. Okay. Other than the XLIF procedure, are
3 there other approaches to the spine that NuVasive
4 offers to customers?

5 A. Do we -- do we provide other spine
6 procedures? Is that your question or --

7 Q. Do you provide products and support for
8 other spine procedures?

9 A. Yes.

10 Q. What other approaches to the spine do you
11 provide support for?

12 A. What other procedures do we provide support
13 for? Is that the question?

14 Q. Yes.

15 A. ACDF, ALIF, PLIF, TLIF, what we call ILIF,
16 thoracic posterior fusion.

17 We're talking about today, correct?

18 Q. Correct.

19 A. I may have left one out.

20 Q. That's fine. When you talk about ALIF,
21 PLIF, TLIF, are you talking about minimally invasive
22 procedures or open procedures?

23 MR. MILLER: Objection; form.

24 THE WITNESS: I'm talking about those
25 procedures where the requirements are defined by the

1 approach.

2 BY MR. MILLER:

3 Q. Okay. So for ALIF, are there both minimally
4 invasive ALIF approaches as well as open ALIF
5 approaches?

6 MR. MILLER: Objection; form.

7 THE WITNESS: I'm not sure if minimally
8 invasive surgery has been well defined, and I would
9 especially state that in the -- in ALIF.

10 BY MR. MILLER:

11 Q. And how would you define it?

12 MR. MILLER: Objection; form, expert, scope.

13 THE WITNESS: I would -- I would define
14 minimally invasive surgery as the required aperture
15 to fulfill the surgical needs.

16 BY MR. MILLER:

17 Q. And what is that required aperture?

18 MR. MILLER: Objection; form, scope.

19 THE WITNESS: Depends upon what the surgery
20 is.

21 BY MR. MILLER:

22 Q. But there is a difference between open
23 procedures and minimally invasive procedures?

24 MR. MILLER: Objection; form, expert, scope.

25 THE WITNESS: I would tell you it becomes an

1 extraordinarily challenging description. If you can
2 tell me specifically what you mean.

3 BY MR. MILLER:

4 Q. Are there far ends of the spectrum from open
5 and minimally invasive?

6 MR. MILLER: Objection; form and scope.

7 THE WITNESS: I think -- I think a surgeon
8 who provides a larger exposure would tell you that
9 the requirements for that patient require a larger
10 exposure.

11 BY MR. MILLER:

12 Q. And a larger exposure is typically called an
13 open procedure?

14 MR. MILLER: Objection; form and scope.

15 THE WITNESS: Depending upon what the
16 requirements for surgery is.

17 BY MR. MILLER:

18 Q. Okay. And does NuVasive support surgeries
19 of larger apertures and smaller apertures?

20 MR. MILLER: Objection; form and scope.

21 THE WITNESS: We provide devices for
22 surgery. And, you know, based upon what the surgeon
23 deems is necessary to the patient in terms of what
24 the patient presents with.

25 BY MR. OLIVER:

1 Q. And are you aware that surgeons use those
2 for both larger opening apertures and smaller
3 apertures in surgery?

4 MR. MILLER: Objection; form and scope.

5 THE WITNESS: I've seen multiple different
6 apertures of exposure in multiple different types of
7 surgery.

8 BY MR. OLIVER:

9 Q. Using NuVasive products?

10 MR. MILLER: Objection; form --

11 THE WITNESS: Using everyone's products.

12 MR. MILLER: -- and scope.

13 THE WITNESS: I'm sorry.

14 BY MR. OLIVER:

15 Q. You previously worked for Medtronic; is that
16 correct?

17 A. Yes.

18 Q. And when was that?

19 A. Approximately '97 to 2000.

20 Q. 2000. And what was your role at Medtronic
21 during that time?

22 A. Marketing.

23 Q. Marketing. And while you were there, did
24 you work with a Dr. Foley?

25 A. I did.

1 Q. Did you work on any lateral transpsoas
2 techniques with Dr. Foley while you were at
3 Medtronic?

4 A. I did not.

5 Q. What was your work with Dr. Foley?

6 A. Dr. Foley was a codeveloper of a tube with
7 an endoscope in it for -- for para-median discectomy.

8 Q. And that wasn't being used, to your
9 knowledge, in a lateral transpsoas technique?

10 A. No.

11 Q. Do you know if Medtronic was using or
12 investigating a lateral transpsoas technique at that
13 time?

14 A. At no time when I was at Medtronic was I
15 aware of any discussion regarding any lateral
16 transpsoas techniques.

17 MR. OLIVER: Okay. Let's take a quick
18 five-minute break, if that's all right.

19 THE VIDEOGRAPHER: All agreed to go off the
20 record, we're off the record at 10:31 a.m.

21 (Recess held 10:31 a.m. to 10:40 a.m.)

22 THE VIDEOGRAPHER: We are back on the record
23 at 10:40 a.m.

24 BY MR. OLIVER:

25 Q. NuVasive has a product called NeuroVision;

1 is that correct?

2 A. At what time period?

3 Q. Why don't you tell me when -- was there a
4 NeuroVision product introduced by NuVasive?

5 A. At any time?

6 Q. Yes.

7 A. Yes.

8 Q. When was it first introduced?

9 A. To the best of my recollection, 2002.

10 Q. 2002. And is it still offered today?

11 A. We have a variant to that technology called
12 M5.

13 Q. M5. And have there been other variants
14 during -- since the 2002 launch of NeuroVision?

15 A. Yes.

16 Q. Okay. And what are the names of some of
17 those other ones?

18 A. There's software iterations which I could
19 attempt to go through but would not recall.

20 Q. Okay. And what is included -- in 2003 -- or
21 excuse me, you said it was launched in 2002?

22 A. That's correct.

23 Q. In 2002 when NeuroVision launched, what was
24 the -- what did the NeuroVision contain?

25 MR. MILLER: Objection; form.

1 THE WITNESS: Wires.

2 BY MR. OLIVER:

3 Q. Fair answer.

4 Does NeuroVision refer to a control system
5 for providing electrostimulation?

6 A. Can you restate the question, please.

7 Q. Does the NeuroVision -- is it a control
8 system that in -- among other features, provides
9 electrostimulation?

10 A. It's a computer that does that, yes.

11 Q. Okay. And to provide electrostimulation, do
12 you attach other instruments to the NeuroVision?

13 A. Depends upon what you're trying to do.

14 Q. Okay. What are some of the -- would you
15 attach dilators to the NeuroVision?

16 A. Yes.

17 Q. Okay. What are some other instruments that
18 you would attach to the NeuroVision?

19 A. A tap, a Jamshidi needle, a probe.

20 Q. Okay. And the NeuroVision system, whether
21 in 2003 or the, you said the M5 today, are those
22 systems -- well, let's start with one, the
23 NeuroVision. Was that system typically loaned to US
24 hospitals for use?

25 MR. MILLER: Objection; scope.

1 THE WITNESS: Yeah. I suspect 2002. I just
2 want to make sure I understand the timing of each of
3 the respective questions. So can you please restate.

4 BY MR. OLIVER:

5 Q. So in the 2002 to 2005 time frame, the
6 NeuroVision or other iterations thereof, were those
7 computers typically loaned to hospitals?

8 MR. MILLER: Objection; form and scope.

9 THE WITNESS: Speaking in generality, they
10 were loaned or consigned.

11 BY MR. OLIVER:

12 Q. Okay. And what about since 2005, were the
13 M5 or other iterations of NeuroVision, is the same
14 answer true?

15 MR. MILLER: I'm going to just -- objection;
16 scope.

17 Go ahead.

18 THE WITNESS: I just want to make sure I
19 understand your question. Did we loan or consign M5s
20 after 2005, if that's your question, yes.

21 BY MR. OLIVER:

22 Q. And was that the typical way they were
23 provided to hospitals?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: Yes.

1 BY MR. OLIVER:

2 Q. Okay. Prior to NeuroVision, did NuVasive
3 have a product called INS-1?

4 A. Yes.

5 Q. And what are the differences -- INS-1 was
6 also a computer that provided stimulation; is that
7 correct?

8 A. No.

9 Q. No, it did not?

10 A. Did not what?

11 Q. Was it -- was the answer it was not a
12 computer or it did not provide stimulation?

13 A. It's not a computer.

14 Q. What was it?

15 A. To the layperson's description, it was a --
16 it was a firmware box.

17 Q. As opposed to software?

18 A. Yes.

19 Q. Okay. So what are the differences -- or
20 what are some differences between the INS-1 and the
21 NeuroVision systems?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: I'd say applications.

24 BY MR. OLIVER:

25 Q. "Applications" meaning software applications

1 or the applications meaning how it was used?

2 A. How it was used.

3 Q. And how was it used different? How was the
4 NeuroVision used differently than the INS-1?

5 MR. MILLER: Objection; form, scope.

6 THE WITNESS: To the best of my
7 recollection, it was not used very much. But there
8 were applications on there that I would consider --
9 outside the norm.

10 BY MR. OLIVER:

11 Q. What applications were outside the norm?

12 A. Epi -- epidural electrode placement.

13 Q. Okay. Anything else?

14 A. General -- generally surrounding that area
15 of interest.

16 Q. Were there other nerve stimulation computers
17 available in 2002?

18 MR. MILLER: Objection; form, scope, expert.

19 THE WITNESS: If you're asking me if there
20 are other EMG devices, there were -- there were other
21 EMG devices.

22 BY MR. OLIVER:

23 Q. Did Cadwell offer an EMG device?

24 MR. MILLER: Objection; form and --
25 withdrawn.

1 Objection; scope.

2 THE WITNESS: I'm not familiar with regard
3 to the time that Cadwell started commercializing
4 their EMG device.

5 BY MR. OLIVER:

6 Q. Are you familiar with their device?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: Within -- within the current
9 time frame?

10 BY MR. OLIVER:

11 Q. Early 2000s.

12 A. I don't recall.

13 Q. Okay. Can you turn to Exhibit 1029. Do you
14 recognize this document?

15 A. Yes.

16 Q. And you referred earlier to the M5 computer;
17 is that correct?

18 A. Hold on a second. I did.

19 Q. And is this document directed to the M5?

20 A. It says M5 on the front.

21 Q. Okay. And this is a NuVasive publication?

22 A. It appears as such.

23 Q. Okay. Can you turn to page 4 of that
24 document. Underneath the bar graph there's a -- the
25 first sentence says (reading):

1 The NuVasive patented nonlinear
2 hunting algorithm enables the NVM5
3 system to arrive at and display
4 discrete EMG thresholds in realtime.
5 Is that correct?

6 A. Yes, that's what it says.

7 Q. Are you familiar with the nonlinear hunting
8 algorithm?

9 MR. MILLER: Objection; form.

10 THE WITNESS: Am I familiar with it in name,
11 is that what you're asking me?

12 BY MR. OLIVER:

13 Q. Yes.

14 A. I'm familiar with it in name, yes.

15 Q. Okay. Do you know what the -- how the
16 hunting algorithm operates?

17 MR. MILLER: Objection; form.

18 THE WITNESS: Yeah. I would -- I would
19 defer to my -- my product development software
20 writing colleagues.

21 BY MR. OLIVER:

22 Q. Do you know if that hunting algorithm -- how
23 that hunting algorithm enables discrete EMG
24 thresholds in realtime?

25 MR. MILLER: Objection; form, scope.

1 THE WITNESS: Yeah. I can speak to utility.
2 I can't speak to precisely how it works in terms of
3 the inside of a box and how it --

4 BY MR. OLIVER:

5 Q. And what's a utility then?

6 A. The utility's a nerve avoidance tool.

7 Q. And how does it avoid the nerves?

8 A. It --

9 MR. MILLER: Objection. Let me just object
10 to the form.

11 Go ahead.

12 THE WITNESS: It's used to assist in
13 determining distance and location.

14 BY MR. OLIVER:

15 Q. How would the hunting algorithm used in the
16 M5 be different than the way the INS-1 system
17 operated?

18 MR. MILLER: Objection; form and scope.

19 THE WITNESS: As it relates to the
20 generalities around the hunting algorithm, it's a
21 very dynamic environment. And so in terms of as you
22 approach the spine, you want speed and information.
23 And so if it's trying to determine a location and
24 distance, you want speed. And so foundationally, the
25 description or the hunting algorithm fulfills that

1 obligation.

2 BY MR. OLIVER:

3 Q. You mentioned the term "dynamic." What do
4 you mean by that term?

5 A. I mean that there's a lot going on in the
6 operating room, and there is a lot going on with
7 regard to the surgeon approaching the spine. It's a
8 very dynamic -- the environment's dynamic. The --
9 the approach, the approach on the spine is -- there's
10 a lot of movement which means dynamic.

11 Q. Movement of what?

12 A. Surgeon's hands, the patient -- making sure
13 the patient stays positioned properly, things of that
14 nature.

15 Q. So in your declaration you refer to dynamic
16 as being movement, that refers to movement of the
17 patient?

18 A. You're going to have to show me exactly what
19 the statement is. Just -- just -- and I don't care
20 if it's on the record or not. It's irritating for
21 you to -- to represent my declaration without
22 pointing to the specific parts. And it's bush
23 league, really.

24 Q. We'll get to them.

25 You mentioned speed as well. How does the

1 hunting algorithm choose speed?

2 MR. MILLER: Objection; form,
3 mischaracterizes.

4 Did you say -- I'm sorry, did you say
5 achieve or choose?

6 MR. OLIVER: Choose.

7 MR. MILLER: All right. I'm going to
8 withdraw the "mischaracterizes."

9 THE WITNESS: Please repeat the question.

10 BY MR. OLIVER:

11 Q. You mentioned the term "speed" as far as the
12 hunting algorithm. Does the hunting algorithm
13 achieve speed in the surgical procedure?

14 MR. MILLER: Objection; form.

15 THE WITNESS: If you're -- if you're asking
16 about the practical utility of the device, you want
17 information as quickly as possible when you're making
18 a small incision. And so if you can get that
19 information quickly, then speed is important because
20 of the dynamic nature of the environment.

21 BY MR. OLIVER:

22 Q. And how did the hunting algorithm achieve
23 that speed?

24 MR. MILLER: Objection; form, expert.

25 THE WITNESS: Yeah. I would ask that you

1 talk to -- in terms of the specifics of the hunting
2 algorithm, I would defer to my engineering
3 colleagues.

4 BY MR. OLIVER:

5 Q. Can you turn to Exhibit 1028.

6 A. Could we determine what that is?

7 MR. MILLER: Yeah. I'm getting a blank.

8 THE WITNESS: It's annoying.

9 MR. MILLER: I'm sorry. What are you --

10 THE WITNESS: Is that you?

11 MR. MILLER: Oh, the noise.

12 MS. LOTFOLLAHI: It's from outside.

13 MR. SCHAEFER. Yeah. Do we want to just go
14 off the record? I'll fix it.

15 MR. MILLER: Sorry. Maybe I'm not
16 navigating this binder right.

17 MR. OLIVER: No, you're right. There's -- I
18 didn't have them hole-punched. So here's 1028.

19 Q. If you could turn -- excuse me. Do you
20 recall giving a deposition in a patent infringement
21 litigation between Medtronic and NuVasive?

22 A. I've given multiple ones. I don't recall
23 any specific one.

24 Q. Do you recall giving one on November 22 of
25 2013?

1 A. I think I answered that. I don't recall any
2 specific one.

3 Q. Can you look at Exhibit 1028. Do you see
4 that says that is a -- if you look at page -- the
5 cover page, it says "In the matter of Warsaw
6 Orthopedic v. NuVasive."

7 A. That's what it says.

8 Q. And it has your name there; is that correct?

9 A. That is correct.

10 Q. Can you turn to page 192, and I'm referring
11 to the small page numbers at the top right-hand
12 corner of the panes of the document.

13 You refer there to how the hunting algorithm
14 works with respect to letters of the alphabet and the
15 phone book. Do you see that?

16 A. What line?

17 Q. Starting at line 14 through 20.

18 A. And the con -- the context of the
19 question -- please repeat the question.

20 Q. Do you recall explaining the hunting
21 algorithm in terms of a search that goes A-M as
22 opposed to A, B, C, D, E, F, G?

23 A. Within the context of the -- of the
24 deposition previously given, it appears as though
25 what someone's asking me is what's the difference

1 between the Cadwell system in November of 2013 and
2 what's meant by a hunting algorithm.

3 Q. Okay. And can you describe to me what you
4 meant by A-M versus A, B, C, D?

5 A. I can.

6 Q. Please do so.

7 A. The -- I believe it's somewhat
8 self-explanatory. As opposed to a -- a ramping of
9 a -- in essence, it -- it searches from A to M in a
10 phone book. Like if you -- software description
11 is -- is -- if there's a search element off of that,
12 it tries to narrow the location of, say, a name in a
13 phone book.

14 So if you say -- it doesn't go A, B, C, D,
15 E, because it could be between M and Z. So the
16 intent of that example was to provide a generalized
17 hunting algorithm description similar to that of a
18 phone book.

19 Q. Okay. And does performing that type of
20 search make the search quicker?

21 MR. MILLER: Objection; form, scope, expert.

22 THE WITNESS: Again, it depends upon a lot
23 of variables. The interest is -- from a pure
24 surgical perspective, your interest is getting
25 information fast.

1 BY MR. OLIVER:

2 Q. Can you look at lines 21 and 22 where you
3 were asked is it better than just ramping up, and you
4 said it's faster. Can you tell me what you mean by
5 it's faster?

6 A. It's the same description that I've given.
7 "Speed" and "faster," I would -- I would suggest, are
8 of similar ilk as it relates to one's interest in
9 information.

10 Q. And the hunting algorithm achieved that
11 speed?

12 A. Again --

13 MR. MILLER: Objection; form and scope.

14 THE WITNESS: Yeah. Depending upon -- you
15 know, if you want to talk about the specifics of a
16 specific patient where it was applied, and you want
17 experts in here to say was it faster compared to
18 what, happy to have -- have that done.

19 BY MR. OLIVER:

20 Q. Okay. Can you turn to your declaration,
21 paragraph 27, page 27.

22 MR. MILLER: Are we back to the declaration
23 in this case?

24 MR. OLIVER: Yes.

25 THE WITNESS: Is it this one?

1 MR. MILLER: This one. You want him to look
2 at -- ah, it's in this level binder.

3 THE WITNESS: You're going to have to repeat
4 what you want me to look at.

5 BY MR. OLIVER:

6 Q. Paragraph 27, page 27. You see the top
7 bullet point?

8 MR. MILLER: Are you there yet?

9 THE WITNESS: Uh-huh.

10 BY MR. OLIVER:

11 Q. There's a bolded section there that says
12 (reading):

13 With a proprietary enabling
14 technology in NeuroVision expanding
15 penetration of the company pioneer
16 XLIF procedure.

17 Then it goes on from there.

18 Do you see that?

19 A. I do see that, yes.

20 Q. What are you referring to as the
21 "proprietary enabling technology in NeuroVision"?

22 A. I think multiple elements.

23 Q. Would that include the hunting algorithm?

24 A. Yes, likely.

25 Q. What else would it include?

1 A. The dilators, the electrodes on the
2 dilators, the different applications of NeuroVision.

3 Q. And you say "the different applications of
4 NeuroVision," can you give me examples of the
5 different applications?

6 MR. MILLER: Objection; form.

7 THE WITNESS: The SSEP, somatosensory
8 monitoring, MEP, motor evoked potential monitoring.
9 There's a number of elements that make it, you know
10 proprietary. So that's what I was referring to.

11 BY MR. OLIVER:

12 Q. Can you explain somatosensory?

13 MR. MILLER: Objection; form, scope,
14 pertinent expert.

15 THE WITNESS: Generally. It becomes a -- a
16 cranial stimulation -- that defines the intact nature
17 of neural elements.

18 BY MR. OLIVER:

19 Q. And what types of surgeries would that be
20 used in?

21 MR. MILLER: Objection; form, scope and
22 expert.

23 THE WITNESS: Scoliosis surgery.

24 BY MR. OLIVER:

25 Q. Okay. In paragraph -- can you turn to

1 paragraph 16 of your declaration starting at page 11.

2 At the top of that page there's also a bolded
3 sentence that refers to realtime neuromonitoring.

4 What did you mean by realtime neuromonitoring?

5 A. Well, let me see. Let me read the context
6 of it.

7 (Document reviewed by witness.)

8 THE WITNESS: The intent was to describe the
9 speed by which I had previously communicated, which
10 is you're going at the spine, you want information
11 fast. And so the intent of that communication was
12 you want that information while you're doing it or as
13 close to it as you possibly can get.

14 BY MR. OLIVER:

15 Q. Okay. And the next bolded sentence refers
16 to dynamic discrete threshold EMG. In that context,
17 can you explain to me what "dynamic" means?

18 MR. MILLER: Mr. Miles, on all of these, if
19 you need to see the exhibit that was quoted you
20 should feel free to do so.

21 THE WITNESS: All right. 2053. Could you
22 repeat the question, please.

23 BY MR. OLIVER:

24 Q. What does the term "dynamic" mean in the
25 context of that bolded sentence that begins "Dynamic

1 discrete threshold EMG"?

2 MR. MILLER: Objection; form.

3 THE WITNESS: I'm speculating what the
4 authors specifically intended, but I took their paper
5 to mean speed. Information in as -- in as soon as
6 possible type of environment.

7 BY MR. OLIVER:

8 Q. And how is the speed achieved by
9 NeuroVision?

10 MR. MILLER: Objection; form.

11 THE WITNESS: The -- the speed is achieved
12 by NeuroVision based upon how the software interprets
13 the information.

14 BY MR. OLIVER:

15 Q. Okay. And what about "discrete threshold
16 EMG," what is meant by that in the context of that
17 same sentence?

18 MR. MILLER: Objection; form, expert.

19 THE WITNESS: Discrete threshold oftentimes
20 refers to a specific number.

21 BY MR. OLIVER:

22 Q. Okay. And what would be something that's
23 not a discrete threshold EMG?

24 MR. MILLER: Objection; form, expert.

25 THE WITNESS: Oftentimes a color can show up

1 which demonstrates a range, and then subsequently
2 find the specific number. So I think that the -- the
3 intent is when is there a discrete threshold and when
4 is there a range.

5 BY MR. OLIVER:

6 Q. And when you say a number, are you referring
7 to a number of an EMG response?

8 MR. MILLER: Objection; form, expert.

9 THE WITNESS: The discrete threshold EMG is
10 referring to an amplitude displayed on the
11 NeuroVision system.

12 BY MR. OLIVER:

13 Q. Okay. So when you say "a specific number,"
14 you're talking about an amplitude?

15 MR. MILLER: Objection; form and expert.

16 THE WITNESS: Yeah. You asked me what --
17 what I mean by number, and I told you that it means a
18 number that shows up on the display of NeuroVision.

19 BY MR. OLIVER:

20 Q. And what does that number represent?

21 MR. MILLER: Objection; form and expert.

22 THE WITNESS: It represents a -- an
23 amplitude. It says milliamps and it says a number.

24 BY MR. OLIVER:

25 Q. Okay. Can you turn to the previous page,

1 page 12, still within paragraph 16. There's a bolded
2 sentence at the top. Do you see that sentence?

3 A. I see a bolded sentence at the top of
4 page 12.

5 Q. And it says, it refers in that sentence to
6 automated neuromonitoring. Can you tell me in that
7 sentence what you meant by "automated"?

8 MR. MILLER: Objection; form,
9 mischaracterizes.

10 If you need to look at the reference
11 document, you should feel free.

12 (Document reviewed by witness.)

13 THE WITNESS: Could you repeat the question,
14 please.

15 BY MR. OLIVER:

16 Q. What is meant by the term "automated" in
17 that sentence?

18 A. Controlled.

19 Q. What do you mean by "controlled"?

20 A. It doesn't require an associated attendant.

21 Q. Okay. And what features of NeuroVision
22 allow it to not need an associated attendant?

23 MR. MILLER: Objection; form, expert.

24 THE WITNESS: Stimulation. Meaning the
25 initiation of the stimulation.

1 BY MR. OLIVER:

2 Q. Did attended machines also have stimulation?

3 A. Yes.

4 Q. So how is automated, then, different than
5 the attended?

6 MR. MILLER: Objection; form.

7 THE WITNESS: The surgeon has the capacity
8 to initiate stimulation with M5 where they previously
9 didn't. And again, you know, we should -- we should
10 clarify the years we're talking about. But in -- in
11 2003, when we launched NeuroVision, you were able to
12 initiate stimulation which would have created a level
13 of automation.

14 BY MR. OLIVER:

15 Q. And how does a surgeon initiate stimulation
16 using the NeuroVision?

17 A. He presses a button.

18 Q. And where is that button located?

19 A. In the operative field.

20 Q. Okay. And in the nonautomated systems, the
21 button was -- would the button have been in the
22 operating field?

23 MR. MILLER: Objection -- excuse me.

24 Objection; form, scope.

25 THE WITNESS: I can't speak of all of the

1 different systems.

2 BY MR. OLIVER:

3 Q. Okay. So we talked earlier about the
4 MaXcess retractor system. Is it true that the
5 MaXcess retractor has three blades?

6 A. Depends upon the context you're speaking of.

7 Q. Does it have the ability to use three blades
8 at once?

9 A. Yes.

10 Q. And you've stated -- is it correct that
11 you've stated in other proceedings that you're
12 responsible for the posterior blade, as far as its
13 design?

14 A. Please restate the question.

15 Q. Have you previously indicated that you were
16 responsible for the idea of using the third blade in
17 the MaXcess system, the --

18 MR. MILLER: Object --

19 BY MR. OLIVER:

20 Q. -- posterior blade?

21 MR. MILLER: Sorry.

22 Objection; form.

23 THE WITNESS: Again, I don't understand the
24 question. Have I previously testified that I have
25 done what?

1 BY MR. OLIVER:

2 Q. You came up with the idea of the third
3 blade?

4 MR. MILLER: Objection; form.

5 THE WITNESS: You have to be more specific
6 than that.

7 BY MR. OLIVER:

8 Q. What's unclear about that question?

9 A. One, you tell me which one's the third
10 blade.

11 Q. Posterior blade.

12 A. Did I come up with a posterior blade, no.

13 Q. Where did that idea come from?

14 MR. MILLER: Objection; form, scope.

15 THE WITNESS: Posterior blades or -- or --
16 the posterior blade is where you place it. If you'd
17 like to speak to specific requirements of the surgery
18 and -- and how you use the retractor, I'm happy to
19 describe that.

20 BY MR. OLIVER:

21 Q. Please describe that.

22 A. What application?

23 Q. For an interbody fusion procedure, XLIF
24 procedure.

25 A. Okay. You've got to give me more than that.

1 What level?

2 Q. You tell me. You can pick. Do a -- one
3 that's transpsoas. Pick a level that's transpsoas.

4 A. You want a description of the entire
5 surgery?

6 Q. No. Just the -- what the blade -- what the
7 blades do of the retractor system.

8 MR. MILLER: Objection; form.

9 THE WITNESS: The blades create exposure.

10 BY MR. OLIVER:

11 Q. Okay. And there are three blades used?

12 MR. MILLER: Objection; form.

13 THE WITNESS: Depends upon the surgery.

14 BY MR. OLIVER:

15 Q. Are there sometimes three blades used?

16 A. Yes, sometimes there's three blades used.

17 Q. And one of them is a posterior blade?

18 A. Depending upon the surgery.

19 Q. Okay. And what's the purpose of the
20 posterior blade?

21 MR. MILLER: Objection; form, expert.

22 THE WITNESS: To provide exposure.

23 BY MR. OLIVER:

24 Q. Do the other two blades provide exposure?

25 A. They do.

1 Q. What is different about the third blade?

2 MR. MILLER: Objection; form, scope.

3 THE WITNESS: It establishes a fixed
4 position.

5 BY MR. OLIVER:

6 Q. Okay. What makes the MaXcess retractor
7 system different from retractor systems that came
8 before it?

9 MR. MILLER: Objection; form, scope, expert.

10 THE WITNESS: I guess, what specifically are
11 you -- are you looking for? What made it different
12 than previous retractor systems before it?

13 BY MR. OLIVER:

14 Q. Yes.

15 MR. MILLER: Objection; form, scope and
16 expert.

17 THE WITNESS: I could -- I could speak to
18 the surgical elements that, in essence, made it
19 valuable in the utility of an XLIF procedure. I
20 can't speak to all of the retractors in time.

21 BY MR. OLIVER:

22 Q. Then -- then you can do that, in the context
23 of the XLIF procedure.

24 THE DEPOSITION OFFICER: I'm sorry. In
25 terms of the?

1 MR. MILLER: XLIF procedure.

2 THE WITNESS: At the time that MaXcess was
3 launched in 2003, and you would be approaching L4-5
4 in a transpoas manner, the retractor had multiple
5 unique elements that were designed specifically to
6 fulfill the obligations of that respective approach.
7 One of them was a fixed posterior blade.

8 BY MR. OLIVER:

9 Q. Okay. What were others?

10 A. Lighting elements, fixing the retractor in
11 the disk space. Ultimately, a -- a -- an electrode
12 to determine if a neural element sneaks under the
13 blade.

14 Q. Okay. Can you turn to paragraph 27 of your
15 declaration. I think it's around page 27. Starts on
16 26. The first sentence of paragraph 26 -- excuse me,
17 paragraph 27 on page 26, states (reading):

18 NuVasive's success has been
19 driven by our XLIF procedure and
20 instruments, namely, the nerve
21 monitoring enabled distractor and a
22 retractor.

23 How did the retractor derive success?

24 MR. MILLER: Objection; mischaracterizes,
25 form.

1 BY MR. OLIVER:

2 Q. Did the retractor derive success?

3 A. I think whenever you're trying to fulfill
4 the obligations of a surgery, and -- and you provide
5 the necessary tools to predictably fulfill the
6 obligation of surgery, those tools, in essence,
7 enable success. And that was the -- that was a
8 connotation of that description.

9 Q. Which features of the retractor were
10 important to the success?

11 MR. MILLER: Objection; form.

12 THE WITNESS: In what type of surgery?

13 BY MR. OLIVER:

14 Q. XLIF.

15 A. In -- in what levels? Like --

16 Q. Well, you tell me what you meant by
17 paragraph 27, the first sentence there that's -- the
18 retractor drove success.

19 MR. MILLER: Objection; mischaracterizes,
20 form.

21 THE WITNESS: Yeah. The -- the intended
22 communication was that multiple items have been core
23 to the fulfillment of a reproducible surgery, and
24 those included nerve monitoring and a retractor. And
25 so if you'd like to read into it more, you're welcome

1 to. That was the intent of this.

2 BY MR. OLIVER:

3 Q. Was there anything special about the
4 retractor that helped with the success?

5 MR. MILLER: Objection; form.

6 THE WITNESS: In certain applications
7 there -- there are certain benefits associated with
8 the retractor that we have hopefully designed in for
9 predictability sake.

10 BY MR. OLIVER:

11 Q. And what are those?

12 A. A fixed posterior blade.

13 Q. Okay.

14 MR. MILLER: You can give more --

15 THE WITNESS: Yeah. There's a multitude of
16 them that he's not interested in. But the --

17 BY MR. OLIVER:

18 Q. That's fine.

19 If you could turn to -- back to
20 Exhibit 2038.

21 MR. MILLER: 2020? Which one do you want?

22 MR. OLIVER: 2038.

23 MR. MILLER: 2038.

24 THE WITNESS: 10-K.

25 MR. MILLER: 10-K.

1 BY MR. OLIVER:

2 Q. At the bottom of page 4 of that document, in
3 the last paragraph there's a second sentence that
4 begins "The fundamental difference."

5 Do you see that sentence?

6 A. Let me get rid of it.

7 Do I see the sentence that says fundamental
8 difference? I do, yes.

9 Q. Yes. In that sentence, if you can read it,
10 it refers to allowing surgeons to continue to use
11 instruments -- instruments that are familiar to them.

12 A. Would you like me to read the sentence?

13 Q. I can read it or --

14 A. What are you asking me?

15 Q. My question is: What are the instruments
16 that are familiar to the surgeon that they continue
17 to use using the XLIF system?

18 MR. MILLER: Objection; form and scope and
19 expert.

20 THE WITNESS: This document that is
21 attendant upon a readership of potential investors.
22 What they gather is from the sentence (reading):

23 The fundamental difference
24 between our MAS platform and what was
25 previously called MIS, or minimally

1 invasive surgery, is the ability to
2 customize and reproduce -- customize
3 safe and reproducible access to the
4 spine while allowing surgeons to
5 continue to use instruments that are
6 familiar with them.

7 BY MR. OLIVER:

8 Q. Do you know --

9 MR. MILLER: Mr. Miles, when you read
10 things, you just need to read more slowly.

11 THE WITNESS: Thank you.

12 What were you saying?

13 BY MR. OLIVER:

14 Q. What are some examples of instruments that
15 are familiar to the surgeon that can still be used
16 in -- with the MaXcess system?

17 MR. MILLER: Objection; form, scope and
18 expert.

19 THE WITNESS: Instruments that are -- that
20 are -- that are familiar to them are manual
21 instruments. Meaning a pituitary, a curette. Those
22 are familiar instruments to surgeons.

23 BY MR. OLIVER:

24 Q. What are dilators?

25 A. Depends upon the surgeon.

1 Q. Depends upon the surgeon as to whether or
2 not dilators are familiar to them?

3 A. Yes.

4 Q. How long have dilators been known,
5 sequential dilators?

6 MR. MILLER: Objection; form, scope and
7 expert.

8 THE WITNESS: To what surgical specialty?
9 BY MR. OLIVER:

10 Q. Spine surgery.

11 MR. MILLER: Same objections.

12 THE WITNESS: I can't speculate as to the
13 derivation of timing associated with dilators in
14 spine surgery.

15 BY MR. OLIVER:

16 Q. You were working for spine surgery companies
17 in the 1990s; is that correct?

18 A. I was -- yes, I was. So -- so before 1993
19 there were dilators.

20 Q. Okay.

21 MR. OLIVER: We have to change the disk. So
22 we'll take a break here.

23 THE VIDEOGRAPHER: This concludes media
24 number 1 in the deposition of Patrick S. Miles.

25 We're off the record at 11:24 a.m.

1 (Recess held 11:24 a.m. to 11:38 a.m.)

2 THE VIDEOGRAPHER: This is the start of
3 media number 2 in the deposition of Patrick S. Miles.
4 We're back on the record at 11:38 a.m.

5 BY MR. OLIVER:

6 Q. Mr. Miles, you mentioned that dilators could
7 be used with the NeuroVision system; is that correct?

8 A. I don't know what the context was, but
9 dilators can be used with the NeuroVision system.

10 Q. And there are sequential dilators used in
11 the XLIF procedure; is that correct?

12 A. There are dilators of different sizes used
13 in the XLIF system.

14 Q. And do each one of those dilators have an
15 electrode?

16 A. The ones for the XLIF -- or for XLIF?

17 Q. For XLIF.

18 A. Yes.

19 Q. Okay. And are those dilators used in other
20 approaches?

21 A. What dilators?

22 Q. The XLIF dilators?

23 A. Not to my knowledge.

24 Q. And can you tell me the function that the
25 electrode serves on the dilators in the XLIF?

1 MR. MILLER: Objection; form, scope, expert.

2 THE WITNESS: The intended -- the intended
3 utility is to -- is to discern neural location
4 and -- and distance. Relative distance.

5 BY MR. OLIVER:

6 Q. Okay. And how does the design of the
7 dilator achieve that?

8 MR. MILLER: Objection; form, scope, expert.

9 THE WITNESS: Through the integration with a
10 computer.

11 BY MR. OLIVER:

12 Q. Okay. When were the XLIF dilators first
13 launched?

14 A. With the XLIF procedure.

15 Q. So around 2002?

16 A. No.

17 Q. 2003?

18 A. Yes.

19 Q. Okay. In the time frame between 2003 and
20 2005, were those XLIF dilators reusable?

21 A. Yes.

22 Q. And how were they -- did you typically loan
23 those XLIF dilators in that time frame, 2003, 2005,
24 to hospitals?

25 MR. MILLER: Objection; scope, form.

1 THE WITNESS: Just speaking in generalities,
2 they were within the instrument set. So we loaned
3 the instrument set which would include the dilators.

4 BY MR. OLIVER:

5 Q. Okay. And was that without charge?

6 MR. MILLER: Objection; scope.

7 THE WITNESS: I can't --

8 MR. MILLER: And form.

9 THE WITNESS: I can't speak to if we charged
10 a loaner fee or if we charged -- I wasn't associated
11 with the daily activity of how things were charged.

12 BY MR. OLIVER:

13 Q. Okay. So you're not sure whether or not
14 there was a fee associated with the loan?

15 MR. MILLER: Objection; form and scope.

16 THE WITNESS: If you want to determine --
17 you give me a hospital at a certain date and I'll
18 tell you if they were charged or not.

19 BY MR. OLIVER:

20 Q. Were the majority of those loaner sets in
21 2003 to 2005 loaned without charge?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: Yeah, I have no idea. Like --
24 again, if you want to -- if you're looking for an
25 answer, a real answer, then you give me a hospital

1 and you give me, you know, what was utilized, and
2 I'll look up and tell you if it was charged or not.

3 BY MR. OLIVER:

4 Q. What was -- you said sometimes there was a
5 loaner fee; is that correct?

6 A. I did say that, yes.

7 Q. And what would that -- what would be an
8 example of a loaner fee?

9 MR. MILLER: Objection; form and scope.

10 THE WITNESS: It is -- it is standard in our
11 industry that, at times, if I'm a -- if I'm a total
12 joint company or if I'm a spine company or if I'm a
13 cardiovascular company, there's times when you loan
14 something and charge a fee for the loaning of it. So
15 that's what I was --

16 BY MR. OLIVER:

17 Q. Was that a one time fee?

18 THE DEPOSITION OFFICER: I'm sorry. I
19 couldn't get the last part of the answer.

20 MR. OLIVER: Sorry.

21 THE DEPOSITION OFFICER: There's times when
22 you charge a loaner fee.

23 MR. MILLER: I think his concluding sentence
24 was, and that's what I referred to as a loaner fee.

25 ///

1 BY MR. OLIVER:

2 Q. What would be an example of loaner fee for
3 XLIF dilators in that 2003 to 2005 time frame?

4 A. I wasn't referring to a loaner fee for XLIF
5 dilators. I was referring to a loaner fee associated
6 with instrument sets that may have included a
7 dilator.

8 Q. Okay. Are there instances where the XLIF
9 dilators were loaned to hospitals without a charge?

10 MR. MILLER: Objection.

11 THE WITNESS: It's history --

12 MR. MILLER: Let me just -- objection;
13 scope.

14 Go ahead.

15 THE WITNESS: It's history we could look up.

16 BY MR. OLIVER:

17 Q. I'm asking if you know.

18 A. I don't -- I don't specifically recollect,
19 you know, what hospitals were charged something and
20 which hospitals weren't.

21 Q. I'm not asking which hospitals. I'm asking
22 whether you recollect in 2003 to 2005 whether any of
23 the dilator sets were loaned without a fee?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: That was not my role in the

1 company. So I didn't pay much attention to that
2 effort.

3 BY MR. OLIVER:

4 Q. So you don't know?

5 A. I don't know specifically.

6 Q. Okay. Can you turn back to Exhibit 2038,
7 please, and can you look at page 6 of that document.

8 You see there are bullet points towards the
9 bottom of page 6. If you can look at the third
10 bullet point. Do you see that the first full
11 sentence there says (reading):

12 We believe that having a sales
13 force dedicated to selling only our
14 products is critical to achieving
15 continued growth across our various
16 product lines deriving greater market
17 penetration and increasing our
18 revenues.

19 A. I do.

20 Q. And do you believe NuVasive was speaking
21 truthfully when it stated that?

22 MR. MILLER: Objection; form, scope.

23 THE WITNESS: In a -- in an SEC document,
24 under the auspices of our strategy, I think it's --
25 it's generally correct that our intent was to -- in

1 the year of 2000 -- was this 2013? -- that we were
2 trying to dedicate our selling efforts? I think --
3 taken in context, I think it's correct.

4 BY MR. OLIVER:

5 Q. And why was having a dedicated sales force
6 important to achieving continued growth?

7 MR. MILLER: Objection; form.

8 THE WITNESS: I think it's -- it's -- it's
9 commonplace across the industry to have a sales force
10 that is familiar with the products that they're
11 trying to sell.

12 BY MR. OLIVER:

13 Q. And how did you go about getting a dedicated
14 sales force?

15 MR. MILLER: Objection; form, scope.

16 THE WITNESS: We hired people to represent
17 NuVasive products.

18 BY MR. OLIVER:

19 Q. Were there existing salespeople that you
20 hired who had been -- are there existing salespeople
21 that you hired from the industry?

22 MR. MILLER: Objection; form, scope.

23 THE WITNESS: If you're asking me if we have
24 hired individuals with sales experience, the answer
25 would be yes.

1 BY MR. OLIVER:

2 Q. And how did you go about getting them to
3 become dedicated to selling only your products?

4 MR. MILLER: Objection; form and scope.

5 THE WITNESS: We compelled them.

6 BY MR. OLIVER:

7 Q. Okay. Can you look at your declaration,
8 paragraph 14. It's on page 9. And the first
9 paragraph -- page -- excuse me, paragraph 14 states
10 that (reading):

11 During those early years,
12 NuVasive put substantial resources
13 into educating the spinal community
14 to overcome that skepticism and show
15 that XLIF was indeed a safe and
16 effective solution for spinal fusion.
17 Do you see that sentence?

18 A. I see that sentence.

19 Q. And what were the substantial resources
20 NuVasive put into the education of the spine
21 community?

22 A. It's a multitude of -- of efforts from
23 cadaveric training to communication to post-market
24 collection of clinical data. So if you're looking
25 for something specific, I'm happy to speak to it,

1 but...

2 Q. What about marketing? Was there a marketing
3 budget?

4 MR. MILLER: Objection; form.

5 THE WITNESS: Do we have a marketing budget,
6 is that what you're asking?

7 BY MR. OLIVER:

8 Q. Yeah.

9 A. In what year, this year?

10 Q. It says during those early years. What were
11 you referring to as "those early years"?

12 A. The context of the -- of during those early
13 years was meant to communicate that if something's
14 not done, you -- you have to attempt to educate
15 someone as to what you're doing.

16 Q. And which years were you referring to in
17 paragraph 14?

18 A. The previous paragraphs under The Initial
19 Skepticism, Roman numeral V, talks about what the --
20 kind of the original acceptance from a marketplace
21 was, and there was -- and it was that of skepticism.
22 So the intent in speaking of the early years was as a
23 response to the initial skepticism.

24 Q. And the early years, are you referring to
25 years around 2001, 2002?

1 A. The -- we're speaking about post launch of
2 XLIF in 2003 in paragraph 12, and again in paragraph
3 13. And so based upon the sequence of these
4 communications, my expectation was that we were
5 speaking from the 2003 to 2008. I'm speculating. I
6 was trying to utilize a term that was reflective of a
7 time requisite to the initial skepticism.

8 Q. Do you know how much was spent on marketing
9 during those years?

10 A. I don't recall.

11 Q. Was it millions of dollars?

12 A. If you'd like me to --

13 MR. MILLER: Objection to form.

14 THE WITNESS: If you'd like me to gather the
15 information, I'm happy to gather it. I don't know
16 how much was spent.

17 BY MR. OLIVER:

18 Q. I'm not asking for an exact number. Do you
19 know a ballpark?

20 A. I don't.

21 Q. Do you know if it was more than a million?

22 MR. MILLER: Objection to form.

23 THE WITNESS: Over what period of time?

24 BY MR. OLIVER:

25 Q. 2003 to 2005.

1 A. What do you consider a marketing expense?

2 Q. Well, what do you consider marketing?

3 MR. MILLER: Objection; form.

4 THE WITNESS: I consider marketing making
5 people aware of something.

6 BY MR. OLIVER:

7 Q. Okay. And what did NuVasive do to make
8 people aware of it, of XLIF?

9 MR. MILLER: Objection; form.

10 THE WITNESS: We participated in trade
11 shows.

12 BY MR. OLIVER:

13 Q. Did you have other marketing efforts?

14 A. Yes.

15 Q. What other marketing efforts did NuVasive
16 have for the XLIF?

17 MR. MILLER: Objection; form.

18 THE WITNESS: We had all kinds of
19 different -- we had a brochure that would communicate
20 the features and benefits of a procedure. We had
21 different communication tools.

22 Depending upon one's definition of
23 marketing, we also had educational forums at trade
24 shows where surgeons can interact in a peer
25 environment.

1 You know, it depends upon how you define
2 marketing. It dictates, you know, whether that's
3 quote-unquote marketing.

4 BY MR. OLIVER:

5 Q. Did you pay any doctors to act as advisors
6 or consultants for NuVasive during that period?

7 MR. MILLER: Objection; form, scope.

8 THE WITNESS: Yes. It's industry
9 commonplace to do that.

10 BY MR. OLIVER:

11 Q. Okay. And who are some of the doctors that
12 were paid advisors or consultants for NuVasive during
13 the 2000s?

14 MR. MILLER: Objection; scope.

15 THE WITNESS: Luiz Pimenta.

16 BY MR. OLIVER:

17 Q. Can you give me examples of others?

18 MR. MILLER: Same objection.

19 THE WITNESS: William Taylor.

20 BY MR. OLIVER:

21 Q. Any others?

22 A. Let's see. In what time frame?

23 Q. In the 2000s.

24 MR. MILLER: So between 2000 and 2010?

25 MR. OLIVER: Yes.

1 THE WITNESS: We had -- we had multiples.

2 MR. MILLER: Let me just --

3 THE WITNESS: Yeah.

4 MR. MILLER: -- interpose. Objection; form
5 and scope.

6 Go ahead.

7 THE WITNESS: We relied heavily upon
8 surgeons to interject their perspectives on what
9 we're talking about. If you want to specifically
10 narrow the scope of a specific area, I'm happy to --

11 BY MR. OLIVER:

12 Q. Did Dr. Frank Phillip serve as a paid
13 consultant or advisor?

14 MR. MILLER: Objection; form.

15 THE WITNESS: At what period of time?

16 BY MR. OLIVER:

17 Q. Any time in the 2000s?

18 A. Yes.

19 Q. And you're familiar with a Dr. Yusuf?

20 A. Yes. Dr. Phillips had -- I think what's
21 important is that you define, you know, the field or
22 the area of their consultation. Like, to ask if
23 they're consultants is --

24 Q. I'm just asking whether they were paid by
25 NuVasive as a consultant.

1 A. Yeah. Dr. Phillips was also paid by
2 Medtronic as a consultant. So...

3 Q. What about Dr. Yusuf, was he paid by
4 NuVasive?

5 MR. MILLER: Objection; form.
6 In the same period?

7 MR. OLIVER: Yes.

8 THE WITNESS: In the 2000s?

9 BY MR. OLIVER:

10 Q. Uh-huh.

11 A. Is that you're asking?

12 Yes. He was a paid consultant for us as
13 well as for multiple other companies, based upon the
14 importance of his capacity to communicate technical
15 information that assisted in the design and
16 development of goods.

17 Q. Okay. Was -- did Dr. Blake Rodgers serve as
18 a paid consultant for NuVasive?

19 MR. MILLER: Objection; form.

20 THE WITNESS: At what period of time?

21 BY MR. OLIVER:

22 Q. During the 2000s.

23 A. To the best of my recollection, he was an
24 education consultant whereby he -- he provided
25 services to -- to assist in peer-to-peer education

1 associated with the safe and reproducible exchange of
2 information that would drive safe and reproducible
3 experience with a procedure.

4 So if that's what you're asking, yes, that's
5 what he -- that's what he was doing.

6 Q. And he was compensated for that?

7 A. Significantly less than what he would have
8 been compensated for if he stayed in his own town and
9 worked.

10 Q. And this is Dr. Blake Rodgers?

11 A. Yeah. This is Blake Rodgers. This is Frank
12 Phillips. This is Jim Yusuf. These guys lose money
13 when they come and do education for companies.

14 Q. Are you aware of a CBS news report that
15 reported that Dr. Blake Rodgers received \$600,000 in
16 consulting and teaching fees from NuVasive in 2011?

17 A. I'm aware of it. I didn't read it.

18 Q. Do you know if it's true?

19 A. I don't know if it's true or not.

20 Q. Is that a -- a number that would -- that an
21 expert from NuVasive has been paid in a year?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: Repeat the question. I want
24 to make sure I understand.

25 ///

1 BY MR. OLIVER:

2 Q. Have you paid doctors \$600,000 in a single
3 year to serve as consultants?

4 A. No.

5 Q. NuVasive hasn't done that. So the CBS
6 report is not accurate?

7 MR. MILLER: Objection; form, scope.

8 THE WITNESS: You want to consider me an
9 expert on the CBS report, I'm not.

10 BY MR. OLIVER:

11 Q. I'm asking about what you know from --

12 A. You're asking about the CBS report and for
13 me to provide context with regard to CBS. I'm not
14 going to do that.

15 Q. I'm asking whether NuVasive has ever paid a
16 surgeon as a consultant more than \$600,000 a year.

17 A. And I answered no.

18 Q. Okay. Has Dr. Mark Peterson served as a
19 paid consultant for NuVasive?

20 MR. MILLER: Objection; form.

21 THE WITNESS: Yes.

22 BY MR. OLIVER:

23 Q. How about Dr. Juan Uribe?

24 A. How about Dr. Juan Uribe what?

25 Q. Did he serve as a paid consultant for

1 NuVasive?

2 A. He has with us, with Orthofix and
3 potentially Medtronic.

4 Q. Are you familiar with the acronym SOLAS,
5 S-O-L-A-S?

6 A. Yes.

7 Q. And what does that stand for?

8 A. Society of Lateral Access Surgeons.

9 Q. And did NuVasive fund the formation of that
10 society?

11 MR. MILLER: Objection; scope, form.

12 THE WITNESS: Can you repeat the question,
13 please.

14 BY MR. OLIVER:

15 Q. Did NuVasive fund the formation of SOLAS?

16 MR. MILLER: Same objection.

17 THE WITNESS: We are the sole underwriters
18 of SOLAS, if that's your question.

19 BY MR. OLIVER:

20 Q. It is.

21 How did NuVasive train surgeons -- did
22 NuVasive train surgeons in cadaver labs to perform
23 the XLIF procedure?

24 MR. MILLER: Objection; form. Just
25 objections, form.

1 Go ahead.

2 THE WITNESS: Did NuVasive train surgeons in
3 cadaver. So the question was did NuVasive train
4 surgeons in cadaver labs?

5 BY MR. OLIVER:

6 Q. Correct. To perform the XLIF procedure.

7 A. I would say surgeons -- surgeons trained
8 surgeons in the cadaver labs to perform XLIF surgery.

9 Q. And does that take place at NuVasive
10 facilities?

11 A. Yes.

12 Q. And the surgeons that perform the training,
13 do you compensate them for teaching the XLIF
14 procedure?

15 MR. MILLER: Objection; form.

16 THE WITNESS: Yes. And as stated, they make
17 substantially less money in training their peers in
18 hopes to create reproducibility than what they would
19 have made if had they stayed home.

20 So if the inference is some -- if they're
21 enthusiastic about doing it, their enthusiasm is
22 associated with creating reproducibility in a peer.

23 BY MR. OLIVER:

24 Q. Okay. And the surgeons that come to
25 NuVasive facilities to learn the XLIF procedure, who

1 pay for their travel there?

2 MR. MILLER: Objection; form and scope.

3 THE WITNESS: It's industry standard that
4 corporations over the years have paid for it, for the
5 surgeon's travel.

6 BY MR. OLIVER:

7 Q. So NuVasive pays for the surgeons to fly to
8 receive training in the XLIF?

9 A. Much like Medtronic, Johnson & Johnson,
10 NuVasive. Now J&J Synthes. It is common practice,
11 the orthopedic companies of Zimmer, Biomet, Smith &
12 Nephew, yes, all of us do.

13 Q. And do you pay for their hotel stays while
14 they're training to learn the XLIF procedure?

15 MR. MILLER: Objection; form, scope.

16 THE WITNESS: Yes, we pay for their hotel.

17 BY MR. OLIVER:

18 Q. And their meals while they're there, do you
19 pay for those while they're there?

20 MR. MILLER: Objection; form and scope.

21 THE WITNESS: I can't speculate as to who
22 paid for what meals over the ten years of the -- of
23 the surgeon education we've put on.

24 BY MR. OLIVER:

25 Q. And do you charge surgeons to learn the XLIF

1 procedure?

2 MR. MILLER: Objection; form, scope.

3 THE WITNESS: Traditionally we have not, no.

4 BY MR. OLIVER:

5 Q. So NuVasive does not charge to learn the
6 XLIF method?

7 A. No, we don't.

8 MR. MILLER: Objection; form and scope.

9 BY MR. OLIVER:

10 Q. Does NuVasive charge surgeons to perform the
11 XLIF procedure on patients?

12 MR. MILLER: Objection; form, scope.

13 THE WITNESS: Does XLIF -- does NuVasive
14 charge surgeons to perform the XLIF pay -- the XLIF
15 on patients, is that your question?

16 BY MR. OLIVER:

17 Q. Correct. Separate and apart from what you
18 may charge for implants or disposables.

19 MR. MILLER: Let me just -- objection; form
20 and scope.

21 Go ahead.

22 THE WITNESS: I'm happy -- I'm happy to
23 answer the question. But my desire is for, you know,
24 direct questions and I'll give you direct answers.

25 And does NuVasive charge surgeons to provide a

1 service to a patient is a nonsensical question. And
2 so if you would answer that no, we don't charge
3 surgeons to provide a service to a patient who's
4 desperate. So no.

5 BY MR. OLIVER:

6 Q. Okay. If you could turn to your
7 declaration, Exhibit 2024, paragraph 10.

8 A. Can you -- what page did you say? 24?

9 Q. It's exhibit -- it's your declaration,
10 page 7, paragraph 10. In the -- are you there?

11 A. I am now.

12 Q. Okay. The second sentence of paragraph 10
13 states that you estimate that NuVasive spent between
14 20 and \$30 million on the initial development of
15 NuVasive's XLIF solution from the middle of 2001 to
16 the fall of 2004. Is that true?

17 A. That's what it says.

18 Q. What was that 20 to 30 million spent on?

19 MR. MILLER: Objection; form.

20 THE WITNESS: The -- the estimate was based
21 upon what our spend was as a private company at that
22 time. So the intent of that dollar volume was about
23 the money spent to form a company and to -- and to --
24 and to move the company into a commercial position.

25 ///

1 BY MR. OLIVER:

2 Q. So would that have included the costs
3 associated with the training of surgeons on the XLIF
4 procedure?

5 MR. MILLER: Objection; form.

6 THE WITNESS: At what period of time?

7 BY MR. OLIVER:

8 Q. Well, you say in the sentence 2001 to 2004.

9 A. If you're asking me was there surgeon
10 training between the launch in 2003 and -- and 2004
11 as it relates to the ultimate reflection of XLIF 90,
12 the answer is yes.

13 Q. I'm asking that 20 to \$30 million figure,
14 did that include --

15 A. That's not what you asked me.

16 Q. Okay.

17 MR. MILLER: Well, let him just ask a new
18 question.

19 BY MR. OLIVER:

20 Q. That 20 to \$30 million figure between 2001
21 and 2004, did that include surgeon training of the
22 XLIF?

23 MR. MILLER: Objection; form.

24 THE WITNESS: The 20 to 30 million included
25 a lot of different things. And I would presume it

1 also included some of the fees associated with
2 surgeon education.

3 BY MR. OLIVER:

4 Q. Would it have included fees paid to
5 consultants who are also surgeons?

6 MR. MILLER: Objection; form.

7 THE WITNESS: Not to my recollection.

8 BY MR. OLIVER:

9 Q. No, it wouldn't have included that?

10 A. Back in -- back from 2001 to 2004 in terms
11 of the exact expenditure and how we did surgeon
12 education is not something that I recollect.

13 Q. Okay. What else can you tell me that was
14 included in the 20 to \$30 million amount there?

15 MR. MILLER: Objection; form.

16 THE WITNESS: It was really -- in general,
17 the beginning of building a company. And so as -- as
18 the context of the sentence (reading):

19 NuVasive expended substantial
20 capital in human resources in
21 developing innovations and in the
22 commercialization of XLIF. I
23 estimate that NuVasive spent between
24 20 and 30 million on the initial
25 development of NuVasive's XLIF

1 solution.

2 So the -- that was, foundationally, our
3 company. And so, you know, what we were doing is
4 spending money on building the infrastructure of a
5 company. So that would include a multitude of
6 different things. I don't specifically recall how
7 the money was disbursed, but it includes a lot in
8 terms of the creation of a commercialization entity.

9 MR. OLIVER: Okay. I think that's probably
10 a good time to break for lunch.

11 THE VIDEOGRAPHER: We are going off the
12 record at 12:06 p.m.

13 (At 12:06 P.M., the deposition of PATRICK S. MILES
14 was adjourned for luncheon recess.)

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1 SAN DIEGO, CALIFORNIA, THURSDAY, SEPTEMBER 4, 2014

2 1:34 P.M.

3
4 THE VIDEOGRAPHER: We're back on the record
5 at 1:34 p.m.

6
7 EXAMINATION

8 BY MR. OLIVER:

9 Q. Mr. Miles, I'm going to hand you a document
10 here I've just labeled as Exhibit 1053.

11 (The document referred to was marked
12 by the CSR as Deposition Exhibit 1053
13 (507) for identification and attached
14 to the deposition transcript hereto.)

15 BY MR. OLIVER:

16 Q. Look at that document.

17 MR. MILLER: Justin, could I have a copy of
18 that?

19 MR. OLIVER: Yeah.

20 MR. MILLER: Thank you.

21 BY MR. OLIVER:

22 Q. Do you recognize that document?

23 A. Not really.

24 Q. Do you see that it says NuVasive on the top
25 left corner?

1 A. I do.

2 Q. Does it appear to be a NuVasive press
3 release?

4 A. It looks like a -- a screen capture of the
5 website.

6 Q. Of NuVasive?

7 A. It says www.nuvasive.com below, so I
8 presume.

9 Q. Okay. Can you look on the second page of
10 that document. The end of the second line there's a
11 reference to a Triad, NuVasive's Triad.

12 Do you see the Triad?

13 A. The word "Triad," I see that, yes.

14 Q. Do you know what the Triad is?

15 A. Back in 2001 we had a -- a machined
16 allograft product line named Triad.

17 Q. And was that an intervertebral implant, the
18 Triad?

19 A. Yes. There were multiple intervertebral
20 implants.

21 Q. Okay. And were they inserted in the XLIF
22 procedure?

23 A. We had them for PLIF, for TLIF. And we had
24 them for A, C, D, F. And we had them for XLIF.

25 Q. Okay. And do you recall what the shape of

1 that implant was?

2 A. It was a C-shaped implant based upon the --
3 the bone structure of the femur.

4 Q. Okay. So it's C-shaped in that the C was
5 around the axis of the spine when it was implanted?

6 A. No.

7 Q. How was it C-shaped then?

8 A. It was C-shaped based upon the inner
9 medullary canal of the fume.

10 Q. Okay. And it was an intervertebral implant?

11 MR. MILLER: I'm just going to object to
12 form and scope.

13 THE WITNESS: What's the question again?

14 BY MR. OLIVER:

15 Q. It was an intervertebral implant?

16 MR. MILLER: Same objections.

17 THE WITNESS: No.

18 BY MR. OLIVER:

19 Q. It wasn't an intervertebral implant?

20 A. Do you mean inner body implant? Was it used
21 in the inner body space?

22 Q. Yes.

23 A. Yes.

24 Q. Okay. Do you know approximately how long it
25 was?

1 MR. MILLER: Objection; scope, form.

2 THE WITNESS: How long what was?

3 BY MR. OLIVER:

4 Q. How long the Triad implant was?

5 A. There were multiple --

6 MR. MILLER: Objection to form.

7 THE WITNESS: Sorry.

8 MR. MILLER: Go ahead.

9 THE WITNESS: There were multiple Triad
10 implants.

11 BY MR. OLIVER:

12 Q. And what did their lengths range from?

13 MR. MILLER: Objection; scope.

14 THE WITNESS: To the best of my
15 recollection, from 6 millimeters in length to 30 to
16 35 millimeters in length.

17 BY MR. OLIVER:

18 Q. Okay. And they were inserted laterally in
19 the XLIF procedure?

20 A. They were inserted in A, C, D, F. They were
21 inserted in PLIF. They were inserted in TLIF. They
22 were inserted in XLIF.

23 Q. And the XLIF is a lateral procedure; is that
24 correct?

25 A. Yes. There's XLIF 60 and XLIF 90, and so

1 there's a postero-lateral procedure and a lateral
2 procedure.

3 Q. Okay. I'm going to hand you an exhibit
4 already marked Exhibit 1055.

5 (The document referred to was marked
6 by the CSR as Deposition Exhibit 1055
7 (507) for identification and attached
8 to the deposition transcript hereto.)

9 BY MR. OLIVER:

10 Q. Do you recognize this document?

11 MR. MILLER: Justin, what is this an exhibit
12 to?

13 MR. OLIVER: What is this an exhibit to?

14 MR. MILLER: Yes. Where was it marked? Oh,
15 what proceeding is this?

16 MR. OLIVER: 507 proceeding.

17 MR. SCHAEFER: This is clearly out of scope.
18 The 507 proceeding --

19 MR. OLIVER: Excuse me. Who is defending
20 this deposition?

21 MR. SCHAEFER: I am speaking. I'm the lead
22 attorney.

23 MR. OLIVER: To me, he is defending this
24 deposition. There should be only one person
25 objecting.

1 MR. MILLER: Well, Mr. Schaefer has
2 knowledge of the other proceedings, other IPR
3 proceedings of which this pertains. I am defending
4 the deposition of this proceeding in which this
5 exhibit does not pertain because this is not an
6 exhibit to Mr. Miles's declaration. So I'm assuming
7 that you're going to use this to attempt to impeach
8 something that Mr. Miles said in his declaration. If
9 not, then it's completely out of the scope of the
10 declaration.

11 MR. OLIVER: So your objection is to scope?

12 MR. MILLER: My objection is to scope.

13 MR. OLIVER: Okay. Mr. Miles.

14 MR. SCHAEFER: And, to be clear, I am lead
15 counsel in the proceeding to which this Exhibit 1055
16 pertains, which is IPR 2013-00507, which was not
17 designated in the question, and I just want to make
18 sure that the record is clear as to what proceeding
19 this exhibit number relates to.

20 MR. OLIVER: This -- this MSD 1055 is an
21 exhibit from the IPR2013-00507.

22 Q. Now, Mr. Miles, do you recognize this
23 document?

24 A. I'm familiar with a NuVasive reimbursement
25 guide, and I'm not overtly familiar with this

1 document per se.

2 Q. But it appears to be a NuVasive document?

3 A. It has the name NuVasive on there, yes.

4 Q. And are you familiar with the NuVasive's
5 reimbursement guide and what it's used for?

6 MR. MILLER: Objection; form.

7 THE WITNESS: I'm familiar with NuVasive
8 publishing a reimbursement guide.

9 BY MR. OLIVER:

10 Q. And does this appear to be that guide?

11 A. It appears as such.

12 Q. I'm going to hand you a document now marked
13 MSD Exhibit 1041, also in the 0507 proceeding.

14 (The document referred to was marked
15 by the CSR as Deposition Exhibit 1041
16 (507) for identification and attached
17 to the deposition transcript hereto.)

18 BY MR. OLIVER:

19 Q. Are you familiar with what a 510-K is?

20 MR. MILLER: Just a moment. I need to see
21 the document.

22 Objection; scope.

23 Go ahead.

24 THE WITNESS: Generally, yes.

25 ///

1 BY MR. OLIVER:

2 Q. Okay. And do you recognize this to be a
3 NuVasive 510-K filing?

4 Are you reading the entire document,
5 Mr. Miles?

6 A. If you're asking me what it is, I figure I
7 should read it. Is that not the case?

8 Q. I'm wondering if you could recognize from
9 the cover page that it is a NuVasive 510-K filing?

10 A. If you're going to hand me something, I'm
11 going to read it. And so if you'll excuse me.

12 Q. Let me ask a different question.

13 Can you look at the cover page, please?

14 Does it say NuVasive Incorporated on the top
15 left-hand corner? Doesn't it say NuVasive on the top
16 left-hand corner?

17 A. If you're going to hand me a stack of
18 documents, I need to review the documents. I have no
19 idea how these are assembled, and you're providing me
20 a stack of documents.

21 Q. I'm just asking you --

22 A. I'm going to read the documents to make sure
23 they reflect what you suggest they do.

24 Q. Mr. Miles --

25 MR. MILLER: Mr. Miles, you should feel free

1 to do so, especially since this is not an exhibit to
2 your declaration in any of the IPRs.

3 BY MR. OLIVER:

4 Q. I had a simple question. Can you turn to
5 the cover page.

6 A. I'm interested in understanding what you
7 handed me so I can answer it in a proper context.

8 Q. If I -- you're more than welcome to take
9 time. If I ask you --

10 A. I'm going to take as much time as I need.
11 So sit tight. And I'll review what the document
12 says. You hand me a document, I'm going to read the
13 document.

14 Q. I have a specific question.

15 A. I'm not interested. I've --

16 Q. You're not interested in my question?

17 A. I'm not interested in answering a question
18 that I've not understood the context because you've
19 handed me a stack of documents. That's what I'm not
20 interested in.

21 Q. Can you turn to --

22 A. Ask me whatever you want to, and I'm going
23 to review the document.

24 Q. I'd like you go the cover page, please?

25 A. Again, are you going to allow me the

1 opportunity to look a document that you're asking my
2 opinion about? Is that yes or no?

3 Q. I'm not asking your opinion on the document.
4 I'm asking what --

5 A. You're asking me to verify something I have
6 no idea about.

7 MR. MILLER: Let me see if I can simplify.
8 Justin, are you going to ask him any
9 question about this document other than the fact that
10 NuVasive is on the first page?

11 MR. OLIVER: Are you willing to authenticate
12 that this is an NuVasive document?

13 MR. MILLER: This document is not part of
14 this proceeding.

15 MR. OLIVER: Hat's not what I'm asking him.

16 THE WITNESS: I'm not going to authenticate
17 anything until I have the opportunity to read it.

18 MR. OLIVER: I'm --

19 MR. MILLER: He should read the document.
20 If you are going to ask him anything that speaks to
21 authenticate this document, then he should read it.

22 MR. OLIVER: I'm asking him questions only
23 about the cover page.

24 MR. MILLER: He --

25 MR. SCHAEFER: We have to shut this down.

1 This is ridiculous.

2 MR. MILLER: Well, Steve -- let's go off the
3 record for a moment.

4 THE VIDEOGRAPHER: All agreed to go off the
5 record, we're off the record at 1:48 p.m.

6 (Recess held 1:48 p.m. to 1:53 p.m.)

7 THE VIDEOGRAPHER: We're back on the record
8 at 1:53 p.m.

9 BY MR. OLIVER:

10 Q. Mr. Miles, the cover page of the document
11 1041 from the 507 IPR that I handed to you states
12 "NuVasive, Inc." on the top left-hand corner.

13 (Document reviewed by witness.)

14 THE WITNESS: Would you repeat the question?

15 BY MR. OLIVER:

16 Q. The cover page of that document, does it
17 indicate on the top left corner NuVasive
18 Incorporated?

19 A. I'm not sure. It's a cover page. There's a
20 document, and the initial page has NuVasive in the
21 upper left-hand corner.

22 Q. Okay. Does this appear to be a NuVasive
23 510-K filing?

24 MR. MILLER: Objection; form and scope and
25 lack of foundation.

1 THE WITNESS: I usually don't see the
2 submission, so I'm not familiar that this is a
3 submission.

4 BY MR. OLIVER:

5 Q. But you're familiar with 510-K submissions;
6 is that correct?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: I told you, I'm generally
9 familiar with what a 510-K is.

10 BY MR. OLIVER:

11 Q. And can you explain to me what a 510-K is?

12 MR. MILLER: Objection; form, scope, expert.

13 THE WITNESS: I can.

14 BY MR. OLIVER:

15 Q. And what do you understand to be a 510-K
16 submission to the Food and Drug Administration?

17 A. In -- in layman's terms, it is a -- a
18 registration to -- to sell that's required to sell
19 devices in the United States.

20 Q. And then is it correct that you have to get
21 approval from the Food and Drug Administration to
22 sell medical implants?

23 MR. MILLER: Objection; form, scope, expert.

24 THE WITNESS: No.

25 ///

1 BY MR. OLIVER:

2 Q. Is that no?

3 A. No.

4 Q. And so what do you need approval for?

5 MR. MILLER: Objection; form, scope, expert.

6 THE WITNESS: Class 3 devices.

7 BY MR. OLIVER:

8 Q. Okay. And is it normal for NuVasive to file
9 510-Ks such as these to get approval on its class 3
10 devices that it sells?

11 MR. MILLER: Objection; form and scope.

12 THE WITNESS: Can you repeat the question,
13 please.

14 BY MR. OLIVER:

15 Q. Is it normal business for NuVasive to file
16 510-Ks to receive FDA approval for its -- what did
17 you call them, class 3 devices that it sells?

18 MR. MILLER: Objection; form and scope, also
19 mischaracterizes.

20 THE WITNESS: Can you repeat the question
21 one more time.

22 BY MR. OLIVER:

23 Q. Is it your understanding that NuVasive
24 commonly files 510-K submissions to receive Food and
25 Drug Administration approval for some of the implants

1 that it sells?

2 MR. MILLER: Objection; form, scope,
3 mischaracterizes.

4 THE WITNESS: Approval applies toward
5 class 3 devices that require a clinical trial. And
6 so if you're asking me about approvals, ask me about
7 devices that require approval. This device does not
8 require an approval.

9 BY MR. OLIVER:

10 Q. Which device doesn't require approval?

11 A. The device defined in the document that you
12 handed me that you suggest is a cover sheet to a -- a
13 510-K pre-market notification.

14 Q. Are you referring to the CoRoent device?

15 A. The CoRoent device did not require an IDE
16 study for approval. I'm trying to help you with
17 regard to the nomenclature that you don't know.

18 Q. Well, isn't it correct that a 510-K filing
19 is for approval based on --

20 A. It's not.

21 Q. So what would you say it's for then?

22 MR. MILLER: Objection; form, scope, expert.

23 BY MR. OLIVER:

24 Q. Is it used to establish equivalency to a
25 predicate device?

1 MR. MILLER: Objection; form, scope and
2 expert.

3 THE WITNESS: Are you asking me is a 510-K
4 required to provide equivalency to a previously
5 marketed device?

6 BY MR. OLIVER:

7 Q. Correct.

8 A. Yes.

9 Q. Okay. And is it normal for NuVasive to file
10 510-Ks for products that require it?

11 MR. MILLER: Objection; form and scope.

12 THE WITNESS: It is typical for any company
13 to market any class 1 or 2 device, mostly class 2
14 devices, to petition for a pre-market notification
15 510-K.

16 BY MR. OLIVER:

17 Q. Okay. And the document I handed you
18 previously, MSD 1050, the reimbursement guide, does
19 NuVasive typically provide reimbursement guides to
20 doctors and hospitals?

21 A. This is --

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: This is MSD 1055.

24 BY MR. OLIVER:

25 Q. Yes.

1 A. Yeah, which I've already testified appears
2 as though it's a reimbursement guide. So now, what's
3 the question?

4 Q. I'm asking does NuVasive typically, in any
5 given year, provide reimbursement guides as part of
6 their normal business to hospitals and doctors?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: We do our best to provide
9 information that hospitals or doctors request. In
10 this case, it's reflected in a reimbursement form.

11 BY MR. OLIVER:

12 Q. And did you provide a reimbursement form in
13 2013 to hospitals?

14 MR. MILLER: Objection; form and scope.

15 THE WITNESS: I don't recall.

16 BY MR. OLIVER:

17 Q. Was it common to -- for NuVasive to provide
18 reimbursement guides to hospitals?

19 A. It's common --

20 MR. MILLER: Objection --

21 THE WITNESS: Sorry.

22 MR. MILLER: -- form and scope.

23 THE WITNESS: It's common industrywide.

24 BY MR. OLIVER:

25 Q. Okay. If we can turn back to your

1 declaration, Exhibit 2024. 2024. If you look at
2 paragraph 16 on page 12. It refers in the top there,
3 top line, which is bolded (reading):

4 It is safe and reproducible with
5 few complications due to the use of
6 automated neuromonitoring.

7 And if you can look on a previous page,
8 page 11, in the darkened bold point, first, the XLIF
9 technique. Is the "it" you're referring to the XLIF
10 technique?

11 MR. MILLER: Objection; form.

12 THE WITNESS: I don't understand the
13 question.

14 MR. MILLER: Go ahead.

15 BY MR. OLIVER:

16 Q. If you look at page -- the top of page 12,
17 you say it is safe and reproducible with a few
18 complications. What is the "it" you're referring to?

19 MR. MILLER: Mr. Miles, if you need to look
20 at the referenced --

21 MR. OLIVER: Excuse me. Objections with a
22 single word would be fine.

23 MR. MILLER: Okay. Mr. Miles, if you need
24 to look at the referenced exhibit to answer the
25 question and derive context, you should feel free to

1 do so. And I'm sure counsel would like you to do
2 that.

3 MR. OLIVER: There is no reference to
4 exhibit on the bullet point I'm referring to.

5 MR. MILLER: It's all the same block quote
6 from the same exhibit, 2043.

7 THE WITNESS: I guess I read the context as
8 being clear (reading):

9 Following our quotes from some of
10 the plethora of statements and
11 publications that spine surgeons have
12 made regarding XLIF.

13 And under the bullet point (reading):

14 Since the introduction of the XL
15 technique to North America in late
16 2003, a host of advantages of our
17 patients have become apparent.

18 And so the "it" within the context of
19 statements in publications by spine surgeons, yes, it
20 refers to XLIF.

21 BY MR. OLIVER:

22 Q. Okay. And is safety and reproducibility an
23 advantage of the XLIF procedure?

24 MR. MILLER: Objection; form.

25 THE WITNESS: Safety and reproducibility is

1 a foundation for any medical procedure.

2 BY MR. OLIVER:

3 Q. Including the XLIF procedure?

4 A. Yes, you'd hope.

5 Q. In that quote it also indicates one of the
6 advantages is the large load-bearing interbody
7 construction. On the second bullet point on the top
8 of page 12. And that refers to the implant as we
9 discussed before; is that correct?

10 MR. MILLER: Objection; asked and
11 answered -- I'm sorry. Objection; form.

12 THE WITNESS: (Reading):

13 The following -- within the
14 context of the following are quotes
15 from some of the plethora of
16 statement -- statements in
17 publications that spine surgeons have
18 made regarding XLIF.

19 The second bullet point that says (reading):

20 The large load-bearing interbody
21 construction provides displaced
22 distraction, indirect decompression,
23 sagittal alignment correction and
24 stability.

25 I'm representing the words of -- of the

1 plethora of surgeons as identified in the previous
2 precursor to these bullet points.

3 BY MR. OLIVER:

4 Q. Do you agree with the quote, that one of the
5 advantages of the XLIF procedure is the large
6 load-bearing interbody construction?

7 A. I believe what the surgeons have -- have
8 communicated, which is, the large load-bearing
9 interbody construction provides displaced
10 distraction, indirect decompression, sagittal
11 alignment correction and stability.

12 Q. And is that one of the -- do you agree with
13 the quote then, that that is an advantage of the XLIF
14 procedure?

15 A. It'd be difficult for me to disagree with
16 the quotes of a plethora of statements in
17 publications that spine surgeons have made.

18 Q. Okay. Is the NeuroVision system important
19 to the XLIF procedure?

20 MR. MILLER: Objection; form.

21 THE WITNESS: I'd say based upon the
22 publications and the plethora of statements in the
23 publications that the spine surgeons have made, I
24 would -- I would suggest that it is.

25 ///

1 BY MR. OLIVER:

2 Q. Okay. And if you can turn to page 15 of
3 your declaration. The first bullet point there,
4 there's a bolded section. The first full sentence of
5 which begins "The small incision."

6 A. I'm sorry. What -- what page did you say
7 again?

8 Q. Page 15.

9 A. 15. And you said the first bullet point?

10 Q. First full bullet point. There's a bolded
11 section and there's a sentence that's bolded there
12 that begins "The small incision."

13 A. I'm not tracking you.

14 MR. MILLER: I'm not tracking where you're
15 at either.

16 THE WITNESS: You're using the big number or
17 the small number?

18 BY MR. OLIVER:

19 Q. The small numbers. All the bottom small
20 numbers.

21 A. Right. On page 15, the first full bullet
22 point says (reading):

23 The XLIF surgery is performed
24 with the patient laying on his or her
25 side.

1 Q. Yes. And if you go down to the next
2 sentence, it begins "The small incision."

3 A. Okay.

4 Q. It says -- the statement there says
5 (reading):

6 The small incision are made to
7 help guide the nerve monitoring
8 system which is what allows the
9 procedure to have a quicker recovery
10 time.

11 Do you agree with that statement?

12 A. Yeah. I think it's -- the context of it
13 is -- is from a communication by Dr. Blake Rodgers
14 that has extensive experience in this field. That,
15 in essence, says the small incisions are to help
16 guide the neuromonitoring which allows the procedure
17 a quicker recovery. I presume that's been his
18 experience and that's what he's communicated in the
19 referenced ad.

20 Q. Is it your understanding that small
21 incisions used in the XLIF procedure allow for
22 quicker recovery times?

23 A. I would -- I would tell you that --

24 MR. MILLER: Let me just interpose an
25 objection, Mr. Miles. I'm sorry.

1 Form and scope.

2 Go ahead.

3 THE WITNESS: This is -- this is a
4 reflection of Dr. Rodgers' experience. So he's had
5 that experience. So my representation of his
6 experience is inherent to what it is.

7 BY MR. OLIVER:

8 Q. Do you believe it to be true?

9 A. Why would I not?

10 Q. Okay. How important is the dilator
11 design -- XLIF dilator design to the XLIF procedure?

12 MR. MILLER: Objection; form and scope.

13 THE WITNESS: Are you referring to any
14 context or just in general?

15 BY MR. OLIVER:

16 Q. In general.

17 A. It's important.

18 Q. Okay. What about directional neural
19 monitoring, is that important to the XLIF procedure?

20 MR. MILLER: Objection; form and scope.

21 THE WITNESS: I would say it's the opinion
22 of the peer-reviewed literature that it is.

23 BY MR. OLIVER:

24 Q. And do you believe that's accurate?

25 A. You're asking if I -- sorry.

1 MR. MILLER: Objection; form and scope.

2 THE WITNESS: Are you asking me if I believe
3 the peer-reviewed literature?

4 BY MR. OLIVER:

5 Q. Yes.

6 A. Yes.

7 Q. Okay. Do you believe the MaXcess retractor
8 system is important to the XLIF procedure?

9 MR. MILLER: Objection; form and scope.

10 THE WITNESS: I would answer it the same
11 way. It's been communicated in peer-reviewed
12 literature that the MaXcess retractor is important in
13 the XLIF procedure.

14 BY MR. OLIVER:

15 Q. Okay. And do you believe it's important to
16 use the extreme lateral approach for the XLIF
17 procedure?

18 MR. MILLER: Objection; form and scope.

19 THE WITNESS: Can you repeat the question,
20 please.

21 BY MR. OLIVER:

22 Q. Let me restate. Is the transpsoas approach
23 important to the XLIF procedure?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: It sounds like, you know, word

1 trickery. Do you go through the psoas with an XLIF
2 procedure, you do.

3 BY MR. OLIVER:

4 Q. Okay. Is it important that you go through
5 the psoas for the XLIF procedure?

6 MR. MILLER: Objection; form and scope.

7 THE WITNESS: It's important that you
8 penetrate the skin to do an XLIF procedure.

9 BY MR. OLIVER:

10 Q. What about the psoas muscle?

11 MR. MILLER: Objection; form.

12 THE WITNESS: Subsequent to the skin would
13 be the muscle and then the retro perineum. You're
14 asking me questions that -- that don't make a lot of
15 sense. And so if you're -- if you want to play word
16 games, you know, I'm not following what you're really
17 wanting.

18 BY MR. OLIVER:

19 Q. It's a simple question. I'm just
20 asking if --

21 A. It's not a simple question.

22 Q. Okay. Let me go down a different line here.
23 You've testified -- or do you believe that the XLIF
24 was a commercial success?

25 A. In my opinion as an executive in the medical

1 device field, I believe it to be an objective truth
2 that XLIF has been a commercial success.

3 Q. And is safety and reproducibility one factor
4 that led to it being a commercial success?

5 A. There's no such thing as commercial success
6 without safety and reproducibility.

7 Q. Okay.

8 A. In any medical device. So it's not unique
9 to -- to XLIF.

10 Q. Okay. Was the design of the CoRoent XL
11 implant important to the success of the XLIF
12 procedure?

13 MR. MILLER: Objection; form, scope, expert.

14 THE WITNESS: Which CoRoent implant?

15 BY MR. OLIVER:

16 Q. Any of the XLs.

17 MR. MILLER: Same objections.

18 THE WITNESS: The assembly of the technology
19 was core to the success of the XLIF procedure.

20 BY MR. OLIVER:

21 Q. What do you mean by "assembly of the
22 technology"?

23 A. The assembly of a retractor. The assembly
24 of automated neurophysiology. The assembly of an
25 implant. The fulfillment of the requirements

1 associated with a specific need a patient has creates
2 the likelihood for success of a procedure.

3 Q. You said "assembly of the implant." Do you
4 mean the design of the implant?

5 A. I didn't say that. I said the assembly of
6 the -- of the goods.

7 Q. You said assembly of an implant. Could
8 you -- are you talking about the design of the
9 implant?

10 A. No. My -- my intended communication was
11 that it is not in any one component. It is in the
12 assembly of all of those goods that creates an
13 environment for safety and reproducibility that
14 ultimately reflects commercial success.

15 Q. And what are all of those goods?

16 A. The foundation goods for XLIF is a -- is a
17 retractor called MaXcess, an automated
18 neurophysiology system referred to as M5 and an
19 interbody implant.

20 Q. And what's the interbody implant referred to
21 as?

22 A. We refer to it as CoRoent XL. And it comes
23 in a variety of sizes, shapes, forms, for all kinds
24 of different things.

25 Q. Is there anything else that's important to

1 the success of the XLIF?

2 A. Yes.

3 Q. Can you tell me what some of those things
4 are?

5 A. The bed.

6 Q. The bed. What do you mean by "the bed"?

7 A. The bed needs to accommodate fluoroscopy.

8 Q. Are you talking about the OR table?

9 A. If you'd like to refer to it as the OR
10 table, yes. The OR table.

11 Q. The -- so the bed is -- the bed is what the
12 patient lies on during surgery?

13 A. Yes. My point is, is there are multiple
14 factors that create success for the procedure.

15 Q. Okay. What's important about the bed?

16 A. That you can fit a CR underneath it, that
17 it's radiolucent, that it provides for the ability to
18 angle a patient. There's -- there's multiple -- can
19 you tape the patient to the bed? Does the patient
20 move on the bed? Is there an arm board so the
21 patient's arm can get out of the way?

22 Let me know if you'd like me to continue
23 down the road of a bed.

24 Q. I've heard people say that strict adherence
25 to the XLIF surgical technique is also important. Is

1 that true?

2 MR. MILLER: Let me just -- objection; form.

3 THE WITNESS: Any time that you define
4 success in a procedure and you request adherence to
5 that procedure, the likelihood for success
6 accelerates, and so if that's the context you're
7 asking me, yes.

8 BY MR. OLIVER:

9 Q. So you've mentioned the MaXcess retractor,
10 automated nerve monitoring, the CoRoent implant, the
11 bed.

12 Out of those, is any one more important than
13 the others to the commercial success of XLIF?

14 MR. MILLER: Objection; form and scope.

15 THE WITNESS: There's a multitude of things
16 that I haven't mentioned, and so I'm providing you an
17 example of several things. And if you want to sit
18 and talk XLIF, I'm happy to describe all of them for
19 you.

20 BY MR. OLIVER:

21 Q. Okay. What are the important features of
22 the MaXcess retractor that led to the commercial
23 success of XLIF?

24 MR. MILLER: Objection; form.

25 THE WITNESS: The customized exposure.

1 BY MR. OLIVER:

2 Q. I'm sorry. What was that?

3 A. The customized exposure.

4 Q. What's the customized exposure?

5 A. It's the ability to customize the aperture
6 of the exposure.

7 Q. Okay. And how does the posterior --

8 A. It's the --

9 Q. I'm sorry?

10 A. It's the light. It's the integrated shim,
11 it's the fourth blade, it's the removable handles
12 it's the density of the body, the retractor body.
13 Let's see. It's the -- it's the different length
14 blades.

15 Q. Is any one of those more important than
16 another to the success of the XLIF procedure?

17 MR. MILLER: Objection; form.

18 THE WITNESS: It's a -- I'm not sure I can
19 answer the question. So if I had -- if a patient
20 needs 90-millimeter length blade and I only have
21 180-millimeter length blades, you're asking me what's
22 more important if functionally it doesn't work based
23 upon our inability.

24 So you're saying -- so I would tell you,
25 gosh, it's the length of the blade, depending upon

1 what the patient's size is, is -- is a meaningful
2 feature. Which one's more important? If you can't
3 customize it to the patient's habitus, then some of
4 the other features aren't that valuable.

5 BY MR. OLIVER:

6 Q. Okay. There is -- you have offered in your
7 declaration that there's been praise of the XLIF
8 procedure; is that correct?

9 A. I think it's -- it's well documented in some
10 of the references that we provide.

11 Q. I asked you several questions concerning
12 what led to the commercial success of the XLIF.
13 Would those be the same answers for what would be the
14 praise of the XLIF procedure?

15 MR. MILLER: Objection; form.

16 THE WITNESS: I guess I don't understand the
17 question.

18 BY MR. OLIVER:

19 Q. I'm just trying to avoid us going through
20 all those again. We were talking about what was --
21 what made the XLIF procedure commercially successful.
22 You gave me several answers.

23 Would you have any different answers if I
24 asked you what led to the praise of the XLIF
25 procedure?

1 MR. MILLER: Objection; form.

2 THE WITNESS: I would -- I guess I would
3 answer it, and my desire is to -- is to -- is to
4 answer it as directly as possible. The commercial
5 success is based upon the -- the -- the clinical
6 acceptance by a wide surgeon base, which means --
7 which ultimately affirms its success.

8 Does that help you?

9 BY MR. OLIVER:

10 Q. So you believe there's been praise of the
11 XLIF procedure; is that correct?

12 A. I have -- I have personally had people
13 praise the XLIF procedure to me. It is well
14 documented that people have praised the XLIF
15 procedure. So if you're asking me if there's been
16 praise, I would say yes, there has.

17 Q. And is any of that praise due to the MaXcess
18 retractor?

19 MR. MILLER: Objection; form.

20 THE WITNESS: I think the most authentic
21 praise is by the people who utilize the assembly of
22 the tools, which would include the MaXcess retractor,
23 and understand the value that these tools provide
24 them in their desire to help a patient.

25 ///

1 BY MR. OLIVER:

2 Q. So with respect to the praise that the XLIF
3 procedure has obtained, is that due to the MaXcess
4 retractor system in part?

5 MR. MILLER: Go ahead.

6 THE WITNESS: It's -- it's foundationally
7 due to NuVasive's capacity to assemble products in a
8 way that creates surgical elegance, and so when
9 someone, in essence, experiences surgical elegance
10 and they say, gosh, all these things work well
11 together, and I have been able to fulfill my surgical
12 plan for some desperate person in need of my
13 services, oftentimes, that elicits enthusiasm by a
14 surgeon who will oftentimes come to me and say,
15 Congratulations, this is a great procedure. You
16 saved me time today.

17 BY MR. OLIVER:

18 Q. And would part of that elegance of the
19 procedure be due to the use of NeuroVision?

20 A. It would be -- it would be due to a
21 multitude of things. It would be due to a lateral
22 plate. It would be due to a pedicle screw. It would
23 be due to, you know, you know, the surgeon's interest
24 in creating a procedure to fulfill what the -- what
25 the patient's needs are.

1 Q. Okay. And the plate and screw referred to
2 are used in XLIF procedures?

3 A. Yes.

4 MR. MILLER: Object --

5 BY MR. OLIVER:

6 Q. The NeuroVision system uses a discrete
7 threshold EMG; is that correct?

8 MR. MILLER: Objection; form.

9 THE WITNESS: The -- the -- it provides a
10 discrete threshold on the screen when one's
11 identified.

12 BY MR. OLIVER:

13 Q. Okay. And it's also an automated system; is
14 that correct?

15 A. It's what we refer to as automated.

16 Q. Okay. And you had stated before that it's
17 surgeon driven in that the surgeon actually operates
18 the stimulation?

19 MR. MILLER: Objection; form.

20 THE WITNESS: Yes. Our belief is -- is that
21 if the surgeon is most knowledgeable about where he
22 is in space, then it would make sense that he would
23 initiate the utility of the stimulation.

24 BY MR. OLIVER:

25 Q. Okay. And you also indicated that

1 NeuroVision provides dynamic EMG monitoring; is that
2 correct?

3 MR. MILLER: Objection; form.

4 THE WITNESS: I don't remember specifically.

5 BY MR. OLIVER:

6 Q. Does it provide dynamic EMG monitoring?

7 MR. MILLER: Objection; form.

8 THE WITNESS: Yeah, it depends on what you
9 mean by "dynamic."

10 BY MR. OLIVER:

11 Q. Can you look at page 13 of your declaration,
12 the first full bullet point. In there, there's a
13 bolded section that starts with "dynamic." Can you
14 tell me what "dynamic" means?

15 MR. MILLER: Objection; form.

16 THE WITNESS: It appears like a
17 representation from a paper entitled "Dynamically
18 Evoked, Discrete-Threshold Electromyography in the
19 Extreme Interbody Fusion Procedure," a clinical
20 article by Antoine Tohmeh, William Blake Rodgers, and
21 Mark Peterson.

22 BY MR. OLIVER:

23 Q. So what do you understand "dynamic" to mean?

24 MR. MILLER: Objection; form. Asked and
25 answered -- objection; form.

1 THE WITNESS: I understood this to mean
2 because, in essence, I'm interpreting what Dr.
3 Tohmeh, Rodgers and Peterson have written, is that
4 exactly what the entire bullet point says, which is
5 realtime monitoring using -- utilizing -- using the
6 NeuroVision does help minimize --

7 MR. MILLER: Slow down.

8 THE WITNESS: Okay -- does help minimize the
9 risk of injury by providing reliable realtime
10 information. And so I interpret that to mean
11 realtime information.

12 BY MR. OLIVER:

13 Q. Okay. Out of NeuroVision being surgeon
14 driven, using discrete thresholds, being automated,
15 being dynamic, being realtime, and having the hunting
16 algorithm discussed, are any one of those more
17 important than others to the commercial success of
18 the XLIF procedure?

19 MR. MILLER: Objection; form.

20 THE WITNESS: It's a lot of features.

21 BY MR. OLIVER:

22 Q. I can repeat them if you need it.

23 A. Yeah, please.

24 Q. Surgeon driven, discrete threshold,
25 automated, dynamic, realtime, hunting algorithm.

1 MR. MILLER: Objection; form.

2 THE WITNESS: I would equate it to your car
3 has tires, you know, seats, a steering wheel. Which
4 one's most important? Would it be the tires or the
5 steering wheel? Okay.

6 They're assembled to fulfill the
7 requirements of a specific surgery, and so for me to
8 say, gosh, this one is not valuable, I don't think we
9 would have developed it if we didn't believe it to be
10 to be a valuable part of the procedure.

11 BY MR. OLIVER:

12 Q. So they're all valuable? Is that what
13 you're trying to say?

14 MR. MILLER: Objection; form.

15 THE WITNESS: Because, you know, you named
16 the ones that you -- you had most -- are most
17 concerned with, which is surgeon directed. I think
18 it's valuable for the surgeon to determine if they
19 should initiate the -- so I think it's important. Is
20 it more important than determining what the threshold
21 of the EMG is? That's a tough one to answer. And
22 I'm not sure that I'm qualified to answer the stim --
23 initiating the stimulation is more important than
24 determining what the threshold is.

25 ///

1 BY MR. OLIVER:

2 Q. Okay. Are there any other features of the
3 NeuroVision system that are important to the
4 operation of that system in an XLIF procedure?

5 MR. MILLER: Objection; form.

6 THE WITNESS: Can you speak within a
7 specific time frame?

8 BY MR. OLIVER:

9 Q. 2003 to 2005.

10 MR. MILLER: Same objection.

11 THE WITNESS: I would say you left out
12 free-run EMG. Off the top of my head, I can't --

13 BY MR. OLIVER:

14 Q. That's fine. How important was surgeon
15 education to the -- to what you believed to be the
16 commercial success of the XLIF procedure?

17 MR. MILLER: Objection; form.

18 THE WITNESS: If you're asking me how
19 important was it to teach surgeons to apply the
20 procedure, they wouldn't have been able to apply the
21 procedure without learning it. So I would tell you
22 that that's probably commercially important.

23 MR. OLIVER: Okay.

24 MR. MILLER: Is this a good time for a
25 break?

1 MR. OLIVER: One more question, then it will
2 be a good time.

3 Q. There's a reference to NuVasive having
4 100 percent of the lateral market in the 2003-2004
5 time frame.

6 Do you know what's -- what's being
7 referred -- actually, let's look at your declaration,
8 paragraph 24.

9 At the bottom of the page, the last two
10 lines, there's reference to 100 percent of the
11 lateral market. Do you understand that to be a
12 reference to lateral fusion market?

13 A. So you're at page 24?

14 Q. Excuse me, 23, paragraph 24.

15 A. Paragraph 24.

16 MR. OLIVER: Declaration.

17 MR. MILLER: I don't know if your binder is
18 complete and has 2001 in it or not mine doesn't.

19 MR. OLIVER: We're looking at his
20 declaration.

21 MR. MILLER: Right, and it references
22 documents. So I don't know if you have a complete
23 set of them.

24 MR. OLIVER: I don't have a complete set of
25 documents, no.

1 MR. MILLER: Do you have Exhibit 2001 that
2 you could provide to Mr. Miles?

3 MR. OLIVER: 2001?

4 MR. MILLER: Yeah. Actually, there's a
5 picture of it. And 2003.

6 THE WITNESS: So your question is -- is the
7 reference with regard to the 100 percent market share
8 and what does it refer to or what?

9 BY MR. OLIVER:

10 Q. Yeah. When you state "lateral market
11 share," are you referring to lateral interbody fusion
12 or are you referring to some other market share?

13 A. I'm referring to the commentary on
14 Exhibit 2003 and Exhibit 2001 as defined by
15 Medtronic. I was representing their assessment of
16 what's entitled the "Lateral Interbody Market Share
17 Model."

18 MR. OLIVER: Okay.

19 MR. MILLER: Break?

20 MR. OLIVER: Sure.

21 THE VIDEOGRAPHER: And all agreed to go off
22 the record, we're off the record at 2:36 p.m.

23 (Recess held 2:36 p.m. to 2:50 p.m.)

24 THE VIDEOGRAPHER: We're back on record at
25 2:50 p.m.

1 BY MR. OLIVER:

2 Q. Mr. Miles, could you tell me what the cost
3 of the CoRoent implant is?

4 MR. MILLER: Objection; form and scope.

5 THE WITNESS: Which implant specifically?

6 BY MR. OLIVER:

7 Q. What are the range of prices for any CoRoent
8 implant?

9 MR. MILLER: Objection; form and scope.

10 THE WITNESS: I would be speculating, but
11 the range of price is from 700 to -- to \$5,500.

12 BY MR. OLIVER:

13 Q. Okay. What's the average price for a
14 CoRoent implant?

15 MR. MILLER: Objection; form and scope.

16 THE WITNESS: I don't know that stuff off
17 the top of my head.

18 BY MR. OLIVER:

19 Q. Okay. When an XLIF procedure is performed
20 where a CoRoent implant is put in, what other charges
21 are there from NuVasive?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: Could you be more specific
24 with regard to what kind of surgery?

25 ///

1 BY MR. OLIVER:

2 Q. A XLIF L4-L5.

3 MR. MILLER: Same objection.

4 THE WITNESS: Single XLIF L4-5.

5 BY MR. OLIVER:

6 Q. Uh-huh.

7 A. Any other details?

8 Q. No.

9 A. Is there instability? The -- the question
10 is -- I'm trying to get a feel for exactly what
11 you're asking.

12 Q. Okay. If there is instability, what other
13 NuVasive devices would be used?

14 A. Potentially this is all dependent upon the
15 surgeon's assessment of how much instability. But
16 there is the potential for utility of pedicle screws.

17 Q. And what do you typically -- what does
18 NuVasive typically charge for pedicle screws?

19 MR. MILLER: Objection; form and scope.

20 BY MR. OLIVER:

21 Q. Just a range.

22 A. The same --

23 MR. MILLER: The same objection.

24 THE WITNESS: Yeah, the same thing that
25 Medtronic does. Between 800 and \$1,200 per screw.

1 BY MR. OLIVER:

2 Q. Okay. And how many screws would be used in
3 a single level procedure?

4 MR. MILLER: Objection; form and scope.

5 THE WITNESS: Typically four.

6 BY MR. OLIVER:

7 Q. Okay. And are there any other implants that
8 are put in when there's instability in an XLIF
9 procedure single level?

10 MR. MILLER: Objection; scope.

11 THE WITNESS: Potentially an interbody
12 device.

13 BY MR. OLIVER:

14 Q. Other than the CoRoent?

15 A. No. CoRoent XL. Potentially some biologic
16 extender. Like there's all kinds of different
17 potential --

18 Q. And what would the -- what is a range of
19 charges for a biological extender?

20 MR. MILLER: Objection; form and scope.

21 THE WITNESS: If they use BMP, Medtronic's
22 BMP, it could be \$4,000.

23 BY MR. OLIVER:

24 Q. Are there any NuVasive biologic extenders
25 that would be used in an XLIF procedure?

1 MR. MILLER: Objection --

2 THE WITNESS: Yes.

3 MR. MILLER: -- scope.

4 BY MR. OLIVER:

5 Q. And what would the charge be for the
6 NuVasive biologics used in an XLIF procedure?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: It depends. We're talking in
9 broad generalizations. So --

10 BY MR. OLIVER:

11 Q. Sure.

12 A. -- \$2,500.

13 Q. Okay. And you said this is for one level.
14 How often -- is it common for there to be more than
15 one level performed in a single surgery?

16 MR. MILLER: Objection; form, scope.

17 THE WITNESS: The number of levels is often
18 dictated by the volume of pathology. So without a
19 specific description of a type of pathology it's
20 difficult to speculate as to how many levels one
21 would do.

22 BY MR. OLIVER:

23 Q. But sometimes surgeons will perform surgery
24 on multiple levels in the same procedure?

25 MR. MILLER: Objection -- actually,

1 withdrawn.

2 THE WITNESS: Surgeons have the right to
3 treat as many levels or do whatever they want to.

4 BY MR. OLIVER:

5 Q. And you mentioned screws. What are the
6 screws used to -- to screw in?

7 A. You want to restate the question?

8 Q. You mentioned --

9 A. Screws in.

10 Q. You mentioned sometimes four screws are used
11 when there's instability. Are those screws used to
12 put in plates?

13 A. They could. Again, we're talking about kind
14 of a broad scenario. They could be screws for the
15 pedicle. They could be screws like pars screws they
16 could be screws for the lateral body. There could be
17 screws for all kinds of different things.

18 Q. And are screws sometimes used to secure
19 plates in an XLIF procedure?

20 A. They're intended to provide stability. I'm
21 not sure if they are intended to purely secure a
22 plate.

23 Q. Are plates sometimes used in connection with
24 XLIF procedures?

25 A. Yes.

1 Q. And what does NuVasive charge for its
2 plates, a range again?

3 MR. MILLER: Objection; form and scope.

4 THE WITNESS: A range. Typically industry
5 standard stuff between 15 and \$2,500 something to
6 that effect.

7 BY MR. OLIVER:

8 Q. Other than what we've just discussed are
9 there other NuVasive products that are sold in
10 connection with an XLIF procedure?

11 MR. MILLER: Objection; form.

12 THE WITNESS: Oftentimes the product
13 utilized are less to do with the approach and more to
14 do with the requirements of the patient. And so it
15 becomes very difficult to say what products are sold
16 in an XLIF procedure because oftentimes it's dictated
17 by what the patient requirements are.

18 BY MR. OLIVER:

19 Q. Are the products we've talked about NuVasive
20 products we talked about the primary products sold in
21 connection when a surgeon performs an XLIF procedure?

22 MR. MILLER: Objection; form.

23 THE WITNESS: For the most part screws and
24 plates and things those are often sold if that's your
25 question.

1 BY MR. OLIVER:

2 Q. Yes. Okay. Anything else you can think of
3 as far as NuVasive products sold for use in an XLIF
4 procedure?

5 MR. MILLER: Objection; form.

6 THE WITNESS: There's -- there's -- we're
7 speculating on such a broad -- you know, it becomes
8 difficult for me to answer that question because
9 you're not providing me what, you know, what someone
10 would be trying to treat and what typical surgical
11 tools would be with regard to a specific pathology
12 associated with a specific number of levels.

13 If you want to speak in generalities, are
14 screws used? Yeah. Are interbody devices used?
15 Yes. Are plates used? Yep. And so --

16 BY MR. OLIVER:

17 Q. I want to direct your attention to
18 Exhibit 2030 that was referenced in your declaration.
19 Are you familiar with this document?

20 A. I am.

21 Q. And can you see on the cover of page 1,
22 bottom right, it refers to -- it's a supplement to
23 the December 15, 2010, issue; is that correct?

24 A. That's what it states, supplement to
25 December 15, 2010.

1 Q. And do you understand that to mean that this
2 was a supplement to the Spine Journal.

3 THE WITNESS: Yes.

4 BY MR. OLIVER:

5 Q. Can you turn to page 2? There's an
6 acknowledgment to NuVasive there. Underneath that,
7 it says (reading):

8 NuVasive has provided support for
9 publication of this supplemental
10 focus issue on minimally invasive
11 techniques of spine surgery.

12 Is that correct?

13 A. It is.

14 Q. Do you know what support NuVasive provided
15 for the publication of this supplement?

16 A. I believe the same support that Medtronic
17 provided in their supplement.

18 Q. And what, for NuVasive, what would that be
19 financial support?

20 A. Yeah. It's the same standard support
21 requirement for all companies.

22 Q. Okay. So correct me if I'm wrong, NuVasive
23 provided financial support for the publication of
24 this supplement?

25 A. That's what is required when you do

1 supplements, so...

2 Q. Okay.

3 A. Yes, Medtronic, NuVasive, J&J have all
4 provided financial support for supplements to the
5 Spine Journal.

6 Q. Okay. Can you turn to page 5, please. On
7 the top left, there's a summary statement, and then
8 there's a title "Minimally Invasive Spine Surgery,"
9 and below it is a list of authors, is that correct,
10 or contributors?

11 A. It appears as such.

12 Q. One of the listed names is William D. Smith.
13 Do you see that?

14 A. Not yet.

15 Q. Fifth line down.

16 A. Yep. Yes, I do.

17 Q. Do you know William Smith?

18 A. I do.

19 Q. Has he ever served as a paid consultant or
20 advisor for NuVasive?

21 A. He has.

22 Q. Okay. And the name listed next to him we've
23 discussed earlier, Juan Uribe. You also indicated
24 that he served as a paid consultant?

25 A. It's Juan Uribe.

1 Q. Uribe. Excuse me.

2 A. Yes. Dr. Smith has been a paid consultant
3 for Medtronic and NuVasive. Uribe has been a paid
4 consultant for Orthofix and NuVasive. So the
5 answer's yes.

6 Q. And the next line down, William Blake
7 Rodgers, is that the William Blake Rodgers you
8 indicated earlier had served as a paid consultant for
9 NuVasive?

10 A. Yes.

11 Q. And on the bottom right, there's an entry
12 for minimally invasive surgery. It lists
13 contributors down there, the first of which is Jim A.
14 Youssef. Do you see that?

15 A. Yes, I do.

16 Q. And is Jim A. Youssef -- has Jim A. Youssef
17 served as a paid NuVasive advisor?

18 A. Yes, as I stated before, for us and for
19 others.

20 Q. Okay. Can you turn to Exhibit 2031. This
21 is a document entitled "SOLAS News"; is that correct?

22 A. It appears as such.

23 Q. And SOLAS is the entity we discussed earlier
24 that was originally funded by NuVasive; is that
25 correct?

1 A. It is the -- the society that we spoke of
2 before, yes.

3 Q. And was that society funded by NuVasive?

4 MR. MILLER: Objection; form.

5 THE WITNESS: The meetings have been
6 underwritten by NuVasive.

7 BY MR. OLIVER:

8 Q. Underwritten meaning they provided
9 financial -- NuVasive provided financial support?

10 A. Yes.

11 Q. Okay. Can you turn to Exhibit 2032. One of
12 the listed authors is Burak Ozgur. Is that who you
13 referred to before as being a paid consultant for
14 NuVasive?

15 A. I've never referred to Burak Ozgur in our
16 discussion.

17 Q. Forgive me if I'm misremembering. Do you
18 know who Burak Ozgur is?

19 A. I do.

20 Q. Has he ever been a paid consultant of
21 NuVasive?

22 A. Not to my knowledge.

23 Q. Has he served in any teaching or advisory
24 roles for NuVasive?

25 A. Not to my recollection.

1 Q. Do you know of any involvement he's had with
2 NuVasive?

3 A. Other than a personal relationship, I don't.

4 Q. Okay. Luis Pimenta is also listed as an
5 author; is that correct?

6 A. Yes, Henry, Orion, Ozgur, Pimenta, Taylor.

7 Q. And Pimenta has been a paid consultant for
8 NuVasive; correct?

9 A. He has.

10 Q. And has he received any stock in NuVasive?

11 A. I can't recollect.

12 Q. Do you know if he received any stock options
13 for NuVasive before it went public?

14 A. I don't recollect.

15 Q. Do you know if NuVasive pays Dr. Pimenta any
16 royalties?

17 A. Yes.

18 Q. Okay. Do you know how much those royalties
19 run a year?

20 MR. MILLER: Objection; form.

21 THE WITNESS: Do I know the amount of money
22 the royalty is? Is that the question?

23 BY MR. OLIVER:

24 Q. Yes.

25 A. Yes, I do.

1 Q. How much is that?

2 A. About a 60th of Kevin Foley's, which would
3 be about \$400,000 a quarter. It's more than that.
4 Probably \$700,000 a quarter.

5 Q. \$700,000 a quarter, four quarters of a year?

6 A. Yes, correct.

7 Q. And how long has that been going on?

8 A. It hasn't been \$700,000 a quarter. I'm
9 speaking of the last quarters.

10 Q. Okay.

11 A. Back -- back when it initiated, it was zero.

12 Q. And when did it first initiate?

13 A. Probably in the 2003 range when we
14 launched --

15 Q. Okay.

16 A. -- the procedure.

17 Q. And when did the first actual payment take
18 place?

19 A. Tough to tell. I don't -- like, I don't
20 recall the kind of the sequence of when the payment
21 started and --

22 Q. Would it have been before 2006?

23 A. I believe so.

24 Q. Okay. Can you turn to -- with respect to
25 Dr. Ozgur we mentioned, do you know his background?

1 A. With regard to?

2 Q. Spine surgery.

3 A. I know he's a neurosurgeon. I know where he
4 trained.

5 THE DEPOSITION OFFICER: I'm sorry?

6 THE WITNESS: A neurosurgeon. I know where
7 he took his training.

8 BY MR. OLIVER:

9 Q. Anything else?

10 A. I know his ethnic background.

11 Q. Can you turn to Exhibit 2034, please? Are
12 you familiar with a Dr. William Smith?

13 A. I am.

14 Q. And has he been a paid NuVasive consultant?

15 MR. MILLER: Objection; form.

16 THE WITNESS: Yes. We've been through that.

17 MR. MILLER: Three times.

18 BY MR. OLIVER:

19 Q. Can you turn to Exhibit 2047. On the top
20 right-hand corner, it discusses Thomas Weisel
21 Partners. Are you familiar with that company?

22 A. I am.

23 Q. Have they worked with NuVasive before?

24 MR. MILLER: Objection; form.

25 THE WITNESS: What do you mean by worked

1 with us?

2 BY MR. OLIVER:

3 Q. Did Thomas Weisel Partners work on
4 NuVasive's initial public offering?

5 A. I believe they are a minority participant.

6 Q. Okay. Do you know if Thomas Weisel Partners
7 was compensated for that work?

8 A. I had zero interaction with that.

9 Q. You don't know.

10 Can you turn to Exhibit 2052. If you can
11 turn to page 6 of that document, there's an
12 acknowledgment. There's an acknowledgment that
13 states (reading):

14 We appreciate NuVasive for
15 providing the cadavers for this
16 study.

17 You see that?

18 A. I do.

19 Q. Do you know if NuVasive provided any other
20 funding for the study discussed in this document?

21 A. I need to refresh my memory with regard to
22 what this study is.

23 (Document reviewed by witness.)

24 THE WITNESS: Not to my recollection.

25 ///

1 BY MR. OLIVER:

2 Q. So other than providing cadavers, you're not
3 sure whether any other funding was provided?

4 A. I don't believe so.

5 Q. You don't recall or you don't believe so?

6 A. I don't believe so.

7 Q. Okay. Can you turn to Exhibit 2065.

8 There's a Paul McAfee listed as an author. Do you
9 see that?

10 A. Yes. Paul McAfee.

11 Q. McAfee. Is that the same Dr. McAfee you
12 referred to earlier?

13 A. It is.

14 Q. And has Dr. McAfee served as a paid
15 consultant or advisor for NuVasive?

16 A. He has been a paid consultant of virtually
17 every company in the spine industry.

18 Q. Does that include NuVasive?

19 A. It includes Medtronic, NuVasive, J&J,
20 Synthes, Orthofix, Transoral, P -- Link. So yes, it
21 includes a lot of them.

22 Q. Have you ever been named as an inventor in a
23 US patent?

24 A. Yes.

25 Q. So you're aware of the patent process?

1 MR. MILLER: Objection; form.

2 THE WITNESS: Generally.

3 BY MR. OLIVER:

4 Q. Are you aware that general inventors have to
5 sign an oath as part of filing a patent application?

6 A. Yes.

7 Q. Do you believe that NuVasive or one of its
8 inventors would ever put something in a patent
9 application that was intentionally unsafe for use?

10 MR. MILLER: I need that one back.

11 (The record was read as follows:

12 Q Do you believe that NuVasive or
13 one of its inventors would ever put
14 something in a patent application that
15 was potentially unsafe for use?)

16 MR. MILLER: Objection; form.

17 MR. OLIVER: "Intentionally" rather than
18 "potentially."

19 THE WITNESS: I see the exercise as two
20 completely independent exercises, I guess.

21 BY MR. OLIVER:

22 Q. What two exercises?

23 A. The determination of a safe and reproducible
24 experience in the operating room far exceeds any
25 other, you know, requirement, and you're asking me if

1 a -- if a patent describes something unsafe. I
2 guess, I don't begin to understand how to answer that
3 question.

4 Q. I'm not asking if the patent describes
5 something unsafe. I'm asking whether NuVasive would
6 intentionally put something in the patent application
7 that was intentionally unsafe.

8 MR. MILLER: Objection; form.

9 BY MR. OLIVER:

10 Q. You're still thinking?

11 A. No. It's an offensive question. I can't --
12 I can't even believe you'd ask it, honestly.

13 Q. Could you answer it, please?

14 A. Repeat the question.

15 Q. Would NuVasive or one of its inventors put
16 something in a patent application that was
17 intentionally unsafe for use?

18 MR. MILLER: Objection; form.

19 THE WITNESS: It's an offensive question.
20 Really. Is this really how you want to spend your
21 time?

22 BY MR. OLIVER:

23 Q. I'm just asking for an answer to the
24 question.

25 A. I'm not going to answer that question. That

1 is complete silliness, really.

2 Q. I understand.

3 A. You're wasting my time. That's what you're
4 doing.

5 Q. The more time it takes here, the longer it's
6 going to take.

7 A. Okay. Well, get comfortable. It's an
8 absurd question, and if this is the direction that
9 you're going to spend your day --

10 MR. MILLER: Mr. Miles, just say that
11 question can't be answered. If it can't be answered,
12 then let's move on.

13 THE WITNESS: It can't be answered.

14 BY MR. OLIVER:

15 Q. Why can't it be answered?

16 MR. MILLER: Objection.

17 THE WITNESS: I'm done with that question.
18 Really. Complete silliness. Shameful, really.

19 BY MR. OLIVER:

20 Q. Why can't you answer the question?

21 MR. MILLER: Objection; form.

22 THE WITNESS: It's an absurd question. If
23 you want to sit and argue, I'm happy to argue with
24 you.

25 ///

1 BY MR. OLIVER:

2 Q. I'm not trying to be argumentative.

3 A. You're trying not to be argumentative
4 really? You're asking me if we intentionally put
5 something in a patent we knowingly believed to hurt
6 someone? Is that what you're asking me?

7 Q. Yes.

8 A. It's an -- it's an absurd question, and it's
9 an offensive question.

10 Q. Why is it offensive?

11 A. You should be ashamed of yourself. Because
12 the inference that a company would do that is -- is
13 unbelievable to me, and the fact that you could sit
14 across here with a straight face and ask it to me is
15 absurd.

16 Q. So the inference is unbelievable?

17 A. It's unbelievable that you'd ask me the
18 question the fact that I help you through your lack
19 of knowledge on the regulatory front of not even
20 knowing the words and you sit across a table and ask
21 me something of that magnitude, it's absurd.

22 MR. MILLER: There's no question pending.
23 Let's take a break. Let's take a break.

24 THE WITNESS: You know --

25 THE VIDEOGRAPHER: I'll change the tape.

1 This concludes media number 2 in the
2 deposition of Patrick S. Miles. We're off the record
3 at 3:17 p.m.

4 (Recess held 3:17 p.m. to 3:30 p.m.)

5 THE VIDEOGRAPHER: This is the start of
6 medium number 3 in the deposition of Patrick S.
7 Miles. We're back on the record at 3:30 p.m.

8 BY MR. OLIVER:

9 Q. Mr. Miles, can you turn to Exhibit 2089,
10 please. This one of the documents relied in your
11 declaration. Do you recognize the gentleman in the
12 picture on the first page of the document?

13 A. I do.

14 Q. And is that Dr. Antoine Tohmey?

15 A. It is.

16 Q. And Dr. Tohmey also served as a paid
17 consultant for NuVasive?

18 A. Yes.

19 Q. And do you understand that Dr. Tohmey was
20 interviewed in connection with this article?

21 A. Based upon the quotes I would -- I would
22 guess as much.

23 Q. Okay. I'm going to hand you a document
24 numbered Exhibit 1043 in the 507 IPR.

25 (The document referred to was marked

1 by the CSR as Deposition Exhibit 1043
2 (507) for identification and attached
3 to the deposition transcript hereto.)

4 BY MR. OLIVER:

5 Q. Can you tell me what document is?
6 (Document reviewed by witness.)

7 MR. MILLER: Justin, while Mr. Miles is
8 reviewing this document I'll simply note our
9 objection based on scope as we previously discussed
10 because this document is not part of Mr. Miles'
11 declaration in this case or these cases.

12 THE WITNESS: Would you repeat the question,
13 please.

14 BY MR. OLIVER:

15 Q. Do you recognize the document?

16 A. I don't specifically recognize the document.

17 Q. Is it a NuVasive publication?

18 A. It appears as such.

19 Q. Okay. And it's a fact sheet for the extreme
20 lateral interbody fusion procedure; is that correct?

21 MR. MILLER: Objection; form, scope.

22 THE WITNESS: It appears like a patient
23 related communique.

24 BY MR. OLIVER:

25 Q. And did NuVasive provide these type of

1 communicates to patients?

2 MR. MILLER: Objection; form, scope.

3 BY MR. OLIVER:

4 Q. Did NuVasive typically provide these types
5 of communiques to patients?

6 A. I would say indirectly. We made information
7 available to patients to help with informing them.

8 Q. I'm going to hand you one other document,
9 MSD 1040 from the 507 IPR.

10 (The document referred to was marked
11 by the CSR as Deposition Exhibit 1040
12 (507) for identification and attached
13 to the deposition transcript hereto.)

14 BY MR. OLIVER:

15 Q. Do you recognize this document?

16 A. Are you done with this?

17 Q. Yes.

18 MR. MILLER: Again this is exhibit --

19 MR. OLIVER: 1040.

20 MR. MILLER: -- 1040 from the 507 IPR and
21 because it is not referenced by Mr. Mr. Miles'
22 declaration we object to it and questions about it on
23 scope grounds.

24 (Document reviewed by witness.)

25 ///

1 BY MR. OLIVER:

2 Q. Is it correct this NuVasive document -- is
3 it correct that document compares -- scratch that.

4 Is it correct that NuVasive compares in this
5 document the CoRoent XL 60-millimeter implant to a
6 stretch Hummer?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: I wouldn't read the document
9 to infer a comparison with a stretch Hummer. I would
10 suggest that the -- that the author of the document
11 was -- was trying to be funny. So he -- he put a
12 table, which is apparent in the document, of -- of
13 elements associated with the implant and next to it
14 put a Hummer. I don't think he intended to compare
15 the implant to the Hummer.

16 BY MR. OLIVER:

17 Q. And what then are the check boxes below with
18 respect to "impressively long market leading strength
19 and support"?

20 A. Exceptionally good looking. Again, is this
21 really -- I think both of them are fantastic looking,
22 if that's part of the question.

23 Q. It wasn't.

24 A. Well, it's as relevant as what you're asking
25 me. So...

1 Q. So you don't think these check boxes are a
2 comparison of the two --

3 A. I don't.

4 Q. -- even if humorous?

5 A. Impressive, exceptionally good looking, I
6 never thought of any implant as exceptionally good
7 looking, and so do I think that that's an appropriate
8 comparison or one that has any rhyme or reason, I
9 don't.

10 Q. But it is a comparison, correct?

11 A. Substantively, it's not.

12 Q. What do you mean by "substantively, it's
13 not"?

14 A. Anyone who's serious about either of the
15 elements would never compare a stretch Hummer to an
16 implant.

17 Q. This is a NuVasive published document
18 though; correct?

19 MR. MILLER: Objection; form, scope.

20 THE WITNESS: It's a document that
21 communicates to the sales field in a way that is
22 attempting to draw humor.

23 BY MR. OLIVER:

24 Q. Okay. A communication from NuVasive to its
25 sales force?

1 MR. MILLER: Objection; form and scope.

2 THE WITNESS: Based upon the fact that it's
3 a field announcement, I would -- I would expect that
4 it was a sales-related communique.

5 BY MR. OLIVER:

6 Q. From NuVasive?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: It says NuVasive on there. It
9 has a date. So I would -- I would suggest you're
10 right.

11 MR. OLIVER: Okay. I'd like to take another
12 break just to see what else I have.

13 THE VIDEOGRAPHER: All agreed to go off the
14 record, we're off the record at 3:41 p.m.

15 (Recess held 3:41 p.m. to 3:59 p.m.)

16 THE VIDEOGRAPHER: We're back on the record
17 at 3:59 p.m.

18 BY MR. OLIVER:

19 Q. Mr. Miles, can you turn to Exhibit 1033.
20 It's this binder here. And if you'd turn to page 2
21 of -- the second page of that document. And we have
22 talked about 10-Ks before, have we not?

23 A. We've looked at a couple of 10-Ks, yes.

24 Q. And this is another 10-K; is that correct?

25 MR. MILLER: I don't know what this one is.

1 Justin, are you representing that this is an
2 exhibit in these IPR proceedings?

3 MR. OLIVER: It has been marked in this
4 IPR -- it will be marked in this IPR proceeding, yes.

5 MR. MILLER: It has not -- it is not part of
6 any filing that Medtronic has made, right?

7 MR. OLIVER: Not yet.

8 MR. MILLER: Okay. Then I'll object to it
9 on scope grounds. It is not part of Mr. Miles'
10 declaration. It's not referenced in that
11 declaration.

12 BY MR. OLIVER:

13 Q. And this is a --

14 MR. MILLER: Yeah, it's here.

15 I'll also note for the record that it
16 appears to be about 400 pages long.

17 MR. OLIVER: I have a very specific question
18 and then I'll be moving on. So it won't take time.

19 THE WITNESS: I'm happy to review it.

20 BY MR. OLIVER:

21 Q. I'm sure you are.

22 This is another NuVasive 10-K filing; is
23 that correct?

24 A. I don't know without reviewing it.

25 Q. On page 2, do you see that it says NuVasive,

1 Inc.?

2 A. I see that it says NuVasive, Inc.

3 Q. And at the top it says it's a 10-K.

4 A. I do.

5 Q. Okay. Can you turn to what is the fourth
6 page. It's labeled page 1.

7 Do you see that?

8 A. I do.

9 Q. At the bottom it lists a few NuVasive
10 products including the NeuroVision.

11 Do you see that?

12 A. I do.

13 Q. And it states that NuVasive is a proprietary
14 software driven nerve avoidance system.

15 A. You want me to testify that that's what it
16 states?

17 Q. Yes.

18 A. Yes.

19 Q. And is that a true statement?

20 MR. MILLER: Objection; form and scope.

21 THE WITNESS: Within the context of a 10-K
22 to an investment community under the auspices of an
23 overview, it -- it is an appropriately written
24 sentence.

25 ///

1 BY MR. OLIVER:

2 Q. Okay. Do you know what it means to be a
3 proprietary software?

4 MR. MILLER: Objection; form and scope.

5 THE WITNESS: Are you asking me
6 independently?

7 BY MR. OLIVER:

8 Q. Yes.

9 A. It's not what that states.

10 Q. I'm just asking you independently.

11 A. Do I know what proprietary software is?

12 Q. In the context of the NeuroVision system.

13 A. The way I read this is, it says a
14 proprietary software driven. So it means that the
15 box operates via software.

16 Q. And is the specific software that the
17 NeuroVision system uses important to its commercial
18 success that you believe it has?

19 MR. MILLER: Objection; form.

20 THE WITNESS: I don't even -- can you
21 restate the question.

22 BY MR. OLIVER:

23 Q. The software that's used in the NeuroVision
24 system, is that important to what you believe to be
25 the commercial success of the XLIF procedure?

1 MR. MILLER: Objection; form.

2 THE WITNESS: I would suggest it wouldn't
3 work without software.

4 BY MR. OLIVER:

5 Q. Any software or is there something special
6 about NuVasive software?

7 MR. MILLER: Objection; form, scope.

8 THE WITNESS: Restate the question, please.

9 BY MR. OLIVER:

10 Q. Is the software that's specifically used in
11 NeuroVision important to what you believe to be the
12 commercial success of the XLIF procedure?

13 MR. MILLER: Objection; form.

14 THE WITNESS: I believe that the NeuroVision
15 operates pursuant to the direction of the software
16 that was written by us and defined by NuVasive.

17 BY MR. OLIVER:

18 Q. And what features does the software achieve
19 in connection with the NeuroVision system?

20 MR. MILLER: Objection; form, scope.

21 THE WITNESS: It ultimately reflects the
22 features of the system.

23 BY MR. OLIVER:

24 Q. Is the hunting algorithm executed by the
25 software of the NeuroVision system?

1 MR. MILLER: Objection; form.

2 THE WITNESS: It's -- it's driven by
3 software.

4 BY MR. OLIVER:

5 Q. The hunting algorithm?

6 A. To the best of my knowledge.

7 Q. Okay.

8 A. I would defer to the software engineers.

9 Q. Okay. Do you know a Dr. Hansen Yuan?

10 A. I do.

11 Q. And has Dr. Yuan been a paid consultant of
12 NuVasive?

13 A. Not to my knowledge.

14 Q. Has Dr. Yuan received any payments from
15 NuVasive in connection with work he may have done?

16 A. I believe he has.

17 Q. Do you know if he's received any stock or
18 stock options?

19 A. I don't specifically know the -- the
20 resolution of his compensation.

21 Q. But he has had compensation?

22 A. Yeah. He's a board member of ours.

23 Q. Okay. Do you know whether he's been
24 compensated, since NuVasive went public, over a
25 million dollars?

1 A. What I can testify to is that he's been
2 compensated as a board member for NuVasive.
3 Beyond -- beyond that, I don't have any clarity with
4 regard to accessing the amount of money that Dr. Yuan
5 has been paid.

6 Q. Do you believe it's more than a million
7 dollars?

8 MR. MILLER: Objection; form, scope.

9 THE WITNESS: I would be extraordinarily
10 doubtful that it even approached that.

11 BY MR. OLIVER:

12 Q. For all the compensation he's received from
13 NuVasive?

14 MR. MILLER: Objection; form and scope.

15 THE WITNESS: Viewing -- viewing what board
16 compensation looks like, that's what I'm judging it
17 by. It would be of surprise to me that a board
18 member of our, based upon the knowledge of what our
19 board members get paid, that it would broach the
20 numbers that you're describing.

21 BY MR. OLIVER:

22 Q. Are you including stock and stock options in
23 that?

24 MR. MILLER: Objection; form and scope.

25 THE WITNESS: Yeah. Again, I can't -- I

1 can't speak to what the board compensation is. As a
2 matter of fact, I think it's publicly -- it's a
3 public document. So -- or publicly available. But I
4 don't know what it is.

5 BY MR. OLIVER:

6 Q. Do you if he received stock options?

7 MR. MILLER: Objection; form and scope.

8 THE WITNESS: Again, I can't -- I can't
9 recall the resolution of our board compensation.

10 BY MR. OLIVER:

11 Q. NuVasive's CEO is Alex Lukianov; is that
12 correct?

13 A. No.

14 Q. What is -- who is the CEO?

15 A. Alex Lukianov.

16 Q. Lukianov. And is Alex Lukianov friends with
17 Dr. Yuan?

18 MR. MILLER: Objection; form.

19 THE WITNESS: How do you define "friend"?

20 BY MR. OLIVER:

21 Q. Are they friendly?

22 MR. MILLER: Objection; form.

23 You don't know Alex.

24 THE WITNESS: Are they friendly? That's a
25 hell of a hard question to answer. Pardon me. But

1 are they friendly, do you mean do they exchange
2 hellos? They do.

3 BY MR. OLIVER:

4 Q. Do they keep in touch via e-mail or phone
5 calls?

6 MR. MILLER: Objection; form.

7 THE WITNESS: If that's a definition of
8 friend, then we have a monstrous number of friends.
9 Is that your definition of a friend?

10 BY MR. OLIVER:

11 Q. That's a separate question. I'm just asking
12 if they keep in touch.

13 A. You'd have to ask Alex.

14 Q. Have you ever referred to Dr. Yuan as Alex's
15 guy?

16 MR. MILLER: Objection; form.

17 THE WITNESS: Have I referred to Dr. Yuan as
18 Alex's guy?

19 BY MR. OLIVER:

20 Q. Yes.

21 A. I referred to a lot of people as Alex's guy.
22 I don't specifically recall Dr. Yuan as Alex's guy.

23 Q. You don't recall referring to him that way?

24 A. I may have.

25 Q. Okay. Are you familiar with the hemi-arc

1 instrument as used in the XLIF 60 procedure?

2 MR. MILLER: Objection; form and scope.

3 THE WITNESS: Am I familiar to what we call
4 the hemi-arc, yes.

5 BY MR. OLIVER:

6 Q. Okay. And was that used in XLIF 60
7 procedures?

8 MR. MILLER: Objection; scope.

9 THE WITNESS: It was utilized as an
10 evaluation tool within a narrow group of XLIF 60
11 surgeries.

12 BY MR. OLIVER:

13 Q. And who performed those surgeries?

14 MR. MILLER: Objection; scope.

15 THE WITNESS: Mark Malberg, Frank Phillips,
16 Mark Peterson, Bill Taylor. Trying to think who
17 else. Probably a handful of guys.

18 BY MR. OLIVER:

19 Q. Okay. I have one more document to ask you
20 about and then we can wrap up, if that sounds good to
21 you. I'm going to hand you MSD 1030 in the 507 IPR.

22 (The document referred to was marked
23 by the CSR as Deposition Exhibit 1030
24 (507) for identification and attached
25 to the deposition transcript hereto.)

1 MR. MILLER: For the same reasons we
2 previously stated, NuVasive objects to this document
3 and questions about it on scope grounds.

4 (Document reviewed by witness.)

5 BY MR. OLIVER:

6 Q. Do you recognize this document?

7 A. I believe so.

8 Q. Is it a NuVasive marketing brochure?

9 A. What do you mean by "marketing"?

10 Q. Is it a NuVasive publication?

11 A. Yes.

12 Q. Okay. And what was the purpose of this
13 document?

14 A. To assist in the facilitation of patient
15 communication.

16 Q. This document would have been provided to
17 patients?

18 A. Potentially.

19 Q. And was it normal for NuVasive to put
20 together publications explaining its techniques for
21 patients to review?

22 MR. MILLER: Objection; form and scope.

23 THE WITNESS: It's customary for device
24 companies to assist the surgeons in the communication
25 with their patients.

1 MR. OLIVER: Okay. Let's go off the record
2 for just a minute. I think I have nothing left, but
3 I'll check.

4 THE VIDEOGRAPHER: Okay. All agreed to go
5 off the record, we're off the record at 4:14 p.m.

6 (Recess from 4:14 p.m. to 4:16 p.m.)

7 THE VIDEOGRAPHER: We're back on the record
8 at 4:16 p.m.

9 MR. OLIVER: I have no further questions for
10 the witness.

11 MR. MILLER: NuVasive will have some
12 questions on redirect, but before we do so, we'll
13 take a break.

14 THE VIDEOGRAPHER: Okay. All agreed to go
15 off the record, we're off the record at 4:16 p.m.

16 (Recess held 4:16 p.m. to 4:38 p.m.)

17 THE VIDEOGRAPHER: We're back on the record
18 at 4:38 p.m.

19
20 EXAMINATION

21 BY MR. MILLER:

22 Q. Good afternoon, Mr. Miles. I just have a
23 few questions to follow up on those that you were
24 asked earlier today.

25 I believe that you testified earlier today

1 that you worked at Medtronic from about 1997 to 2000.

2 Is that about right?

3 A. It's about right. Maybe '96 to 2000, but in
4 that general area.

5 Q. Great.

6 Now, in that time frame, was nerve
7 monitoring known?

8 A. Yes.

9 Q. In that time frame, was stimulated EMG
10 known?

11 MR. OLIVER: Objection; leading.

12 THE WITNESS: Stimulating EMG was known and
13 most commonly used in pedicle screw testing.

14 BY MR. MILLER:

15 Q. During that time frame, were medical
16 retractors known?

17 MR. OLIVER: Objection; leading.

18 THE WITNESS: Yes.

19 BY MR. MILLER:

20 Q. In that time frame, were sequential dilators
21 known?

22 A. Yes.

23 MR. OLIVER: Objection; leading.

24 BY MR. MILLER:

25 Q. During that time frame, were there surgical

1 consultants -- withdrawn.

2 During that time frame, were there surgeon
3 consultants who worked with the Medtronic Spine
4 Group?

5 A. Yes, hundreds.

6 Q. Could you identify some of those that you
7 recall working for the Medtronic Spine Group?

8 A. Volker Sonntag, Reg Hague (phonetics), Ken
9 Burkus, Kevin Foley, Maurice Smith. Let's see. Who
10 else?

11 Q. Was Dr. Obenchain one of those consultants?

12 A. I don't specifically recall Obenchain when I
13 was there.

14 Q. Dr. McAfee?

15 A. Yes.

16 Q. Dr. Phillips?

17 A. Yes.

18 Q. Do you recall any others?

19 A. Off the top of my head -- there's -- it's
20 a -- there's a public document outlining all of them.
21 I don't recall all hundred, but there's a lot of
22 them.

23 Q. All right. During the time that you worked
24 at Medtronic, were these surgeon consultants paid by
25 Medtronic for their consulting work?

1 A. Yes.

2 MR. OLIVER: Objection; leading.

3 BY MR. MILLER:

4 Q. Can you quantify how much, what the range
5 was that these surgeons were paid to consult for
6 Medtronic during the time that you worked at the
7 company?

8 A. It's public record. But you're talking
9 about -- you know, the highest paid ones are in the
10 15 million range to 18 million. All the way down to,
11 I presume, in the thousands.

12 Q. And are those annual payments or cumulative
13 payments?

14 A. They'd be annual payments.

15 Q. So 15 to \$18 million per year?

16 A. Yes. Tom Zdeblick and Kevin Foley are in
17 the range of 15 million.

18 Q. Now, while you worked at Medtronic, were you
19 involved in any discussions about combining
20 stimulated EMG, sequential dilators and retractors to
21 perform a lateral transpsoas approach for interbody
22 fusion?

23 MR. OLIVER: Objection; leading.

24 THE WITNESS: No.

25 ///

1 BY MR. MILLER:

2 Q. While you worked at Medtronic, did you ever
3 hear any discussions about combining stimulated EMG,
4 sequential dilators and retractors to perform a
5 lateral transpsoas approach for interbody fusion?

6 A. No.

7 Q. While you worked at Medtronic, did you
8 hear -- ever hear anyone, regardless of who they
9 worked for, advocating for a lateral transpsoas
10 approach to the lumbar spine for a fusion procedure?

11 MR. OLIVER: Objection; leading.

12 THE WITNESS: No.

13 BY MR. MILLER:

14 Q. Do you have an understanding as to why that
15 was the case?

16 A. It was -- a lateral transpsoas approach
17 would have been, and prior to NuVasive, it was deemed
18 unsafe.

19 Q. And I believe you testified about Drs. Regan
20 and McAfee earlier today. Do you recall generally
21 talking about them?

22 A. I do.

23 Q. Now, are you familiar with a paper that they
24 wrote about a lateral approach to the spine in the
25 1990 time frame?

1 A. I am.

2 Q. Do you -- and you know both of these
3 gentlemen?

4 A. I know both Drs. Regan and McAfee.

5 Q. And I believe you testified earlier that
6 Dr. Regan was on NuVasive's board in the early days?

7 A. Yes, that's correct.

8 Q. And was Dr. McAfee on NuVasive's board at
9 any time?

10 A. No.

11 Q. But he did consult for NuVasive?

12 A. Yes.

13 Q. Is Dr. Regan still on NuVasive's board?

14 A. No.

15 Q. When did -- when approximately did Dr. Regan
16 stop being on NuVasive's board?

17 A. I believe around 2003.

18 Q. Now, as to the lateral approach that
19 Drs. Regan and McAfee described in the 1990s, was
20 that ever commercialized?

21 A. I believe it was.

22 Q. And did that lateral approach that Dr. Regan
23 and McAfee described, did it become commercially
24 successful?

25 A. It did not.

1 Q. And do you know why that was?

2 A. Yes.

3 Q. Why?

4 A. Their -- their description was a endoscopic
5 approach that traversed the retroperineal space with
6 an endoscope dilator, which was difficult to use and
7 it was challenging for the -- for the untrained. But
8 more importantly, they went anterior to the psoas and
9 tried to peel the psoas back and retract it because
10 they wouldn't -- it wouldn't go transpsoas.

11 Q. Now, while Dr. Regan was on NuVasive's
12 board, was that in the time when the XLIF 60 was
13 being discussed?

14 A. Yes. It was -- it was during the XLIF 60
15 and then the initiation of XLIF 90.

16 Q. Did Dr. Regan recommend exploring the
17 lateral approach to the --

18 MR. OLIVER: Objection; leading.

19 THE WITNESS: He -- he suggested that we get
20 an optical trocar and replicate the very thing that
21 he described previously, which would be anterior to
22 the psoas, utilizing an optical trocar to get from
23 skin to psoas.

24 BY MR. MILLER:

25 Q. Now, was Dr. Regan on NuVasive's board when

1 the concept of XLIF 90 was first discussed?

2 A. Yes.

3 Q. And do you recall what Dr. Regan's response
4 was to that proposed approach and procedure?

5 A. Yes. He was very critical, believing that
6 it would be a commercial failure and one that would
7 be dangerous.

8 Q. Did he say why he thought it would be
9 dangerous?

10 A. He was very skeptical of the -- of the
11 ability to avoid the neural elements in the psoas.

12 Q. You were asked some questions earlier today
13 about whether NuVasive loaned such things as
14 retractors and dilators and nerve monitoring
15 equipment.

16 Do you generally remember those questions?

17 A. I do.

18 Q. Now, I believe it was your testimony also
19 that NuVasive charges for its CoRoent XL implants and
20 other single use items like screws, plates and
21 biologics.

22 Do you recall that testimony?

23 A. Yes, and disposables.

24 Q. Why is it that NuVasive charges for
25 disposables and doesn't charge for things that are

1 not disposables?

2 A. It's -- it's as much of an industry
3 standard, you know, leaving -- leaving implants
4 behind and leaving -- they're single use items. And
5 so they requires a charge for most single use items.

6 Q. Does the fact that NuVasive charges for
7 single use items suggest anything about their
8 relative value to items that are not single use?

9 MR. OLIVER: Objection; form, speculation.

10 THE WITNESS: No. It's -- it's -- I
11 would -- I would suggest that the currency of our
12 industry has been defined by the implant. But it
13 has -- it's inconsistent with regard to the value
14 that each element plays in the role of surgery.

15 BY MR. MILLER:

16 Q. Based on your experience, what would the
17 value of the CoRoent XL implant be if it could not be
18 delivered safely and reproducibly through a lateral
19 transpsoas approach to the spine by surgeons of all
20 skill levels?

21 MR. OLIVER: Objection; form.

22 THE WITNESS: It would be worth nothing.
23 The inability to safely and reproducibly deliver an
24 implant -- if you can't do it safely and
25 reproducibly, there's no business there and so it

1 would be worth nothing.

2 BY MR. MILLER:

3 Q. Now, you were asked some questions earlier
4 today about Triad.

5 Do you remember that?

6 A. I do.

7 Q. And was the Triad femoral allograft implant,
8 was that used in the XLIF procedure, XLIF 90
9 procedure, before the CoRoent XL was introduced?

10 A. Yes, it was.

11 Q. And could you just -- let me just ask you
12 this way: Is femoral allograft, is that bone from a
13 donor, a deceased person?

14 A. Yes.

15 Q. Earlier today you were asked about
16 Exhibit 2030. I'll find that for you. And this was
17 the supplement to the Spine Journal.

18 A. Yes.

19 Q. Do you recall that?

20 A. I do.

21 Q. Now, I think you were asked about whether
22 NuVasive compensated or paid some fee associated with
23 this supplement.

24 Do you recall that?

25 A. Yes. I communicated it's typical to

1 compensate or pay for a supplement to -- to the Spine
2 Journal.

3 Q. Does -- does the fact that this is a
4 supplement, and that NuVasive paid for it to be
5 published, does that mean that it was not peer
6 reviewed by the editorial board of Spine?

7 MR. OLIVER: Objection; leading.

8 THE WITNESS: No, it was peer reviewed and
9 it exists in the peer-reviewed literature.

10 BY MR. MILLER:

11 Q. Do you know who peer reviewed that
12 supplement, Exhibit 2 -- 2030?

13 A. Yeah. There were multiple -- multiple
14 surgeons on both the -- that are deputy editors and
15 associate editors.

16 Q. Do you know whether any of those editors and
17 associate editors are -- are or have been consultants
18 for Medtronic?

19 A. I do.

20 Q. And what is the answer?

21 A. Who are they, is that the question?

22 Q. Sure.

23 A. Steve Garfin, Curtis Dickman, Scott Boden,
24 Alex Vaccaro, Paul Anderson, Jean Dubousset, Frank
25 Eismont, John Heller, Harry Herkowitz, Larry Lenke,

1 Paul McAfee, Frank Schwab, Volker Sonntag, Vince
2 Traynelis, Tom Zdeblick. Those are the only ones
3 that I recognize as consultants.

4 Q. Great. I'm going to shift gears a little
5 bit.

6 You were asked some questions about SOLAS
7 earlier today.

8 A. Yes.

9 Q. Now, is SOLAS still an ongoing organization?

10 A. It is.

11 Q. And do surgeons attend meetings of SOLAS?

12 A. They do.

13 Q. When was the last meeting of SOLAS?

14 A. The last meeting was prior to ISASS, which,
15 I believe it was in the April time frame of this
16 year.

17 Q. And do you know approximately how many
18 surgeons attended SOLAS?

19 A. Close to 200.

20 Q. Does NuVasive pay the surgeons to attend the
21 SOLAS meetings?

22 A. No.

23 Q. I'm going to show you what has previously
24 been marked as NuVasive Exhibit 2063. And before you
25 panic, I am not going to ask you to read the patent.

1 I'm simply going to ask you to look at Figures 3 and
2 4 of it.

3 MR. MILLER: And for the record, this is
4 Michelson US Patent 5,860,973. I'll let you orient
5 yourself to those two figures.

6 Q. Now, during your career in the spine field,
7 did any commercial implant look like and have the
8 size of what is shown in Figure 4?

9 MR. OLIVER: Objection; leading, form.

10 THE WITNESS: No. I think if you were to
11 take a look at the anatomic distance between what
12 would be considered most posterior and most anterior
13 in the lumbar spine, you're looking at approximately
14 30 millimeters. And there is not an implant,
15 especially one placed from lateral approach, that
16 would not provide or not create some type of an
17 injury delivered in this fashion.

18 BY MR. MILLER:

19 Q. You somewhat anticipated my next question.
20 If the implant of Figure 4 was cleared by whatever
21 regulatory agencies are necessary and introduced into
22 the spine market for a lateral solution, based on
23 your experience, would it be commercially successful?

24 MR. OLIVER: Objection; leading, scope,
25 speculation.

1 THE WITNESS: I don't believe it would be
2 successful.

3 BY MR. MILLER:

4 Q. Why did do you say that?

5 A. Without the assembly of a -- a retractor, a
6 neurophysiologic solution that is specifically
7 designed for the utility of an approach that would
8 accommodate the neural elements, then the ability to
9 reproducibly and safely get this placed would be very
10 improbable, if not impossible.

11 Q. Is the construction shown in Figure 3 safe?

12 MR. OLIVER: Objection; form, speculation.

13 THE WITNESS: It's not one that would
14 suggest a predictable experience. There are a number
15 of variables that would suggest that this is not a
16 construct that would succeed over time.

17 BY MR. MILLER:

18 Q. I believe you said that it would be
19 challenging, or something to this effect, to place
20 this implant that's shown in Figure 4?

21 A. That's correct.

22 Q. Why is that?

23 A. Based upon the location of --

24 MR. OLIVER: Objection; speculation.

25 BY MR. MILLER:

1 Q. Go ahead.

2 A. Based upon the location of the neural
3 elements in the plexus.

4 Q. What do you mean by that?

5 A. As you were -- if you were to try to go
6 transpsoas with this implant, it would be very
7 difficult to place based upon how you would have to,
8 in essence, go through the psoas and impinge upon the
9 nerve elements.

10 And so, again, I think it would -- it would
11 undermine the propensity to be safe and reproducible,
12 which foundation becomes a litmus test for creating
13 commercial success.

14 Q. In lay terms, if I understand what you're
15 saying -- well, are you saying that attempting to
16 insert an implant like that shown in Figure 4 through
17 a lateral transpsoas approach would cause nerve
18 injury to the patient?

19 MR. OLIVER: Objection; leading.

20 THE WITNESS: Likely yes.

21 BY MR. MILLER:

22 Q. We're in the home stretch here.

23 Because a highly skilled and well-respected
24 surgeon is paid to teach or consult for a spine
25 company, in your view, do you believe they would

1 recommend or speak well of a surgical procedure that
2 they did not believe to be safe and effective?

3 MR. OLIVER: Objection; leading,
4 speculation.

5 THE WITNESS: Absolutely not.

6 BY MR. MILLER:

7 Q. What do you think about the inference that
8 surgeons would speak highly and recommend a surgical
9 procedure that they did not believe to be safe and
10 effective simply because they were paid to be a
11 consultant?

12 MR. OLIVER: Objection; leading.

13 THE WITNESS: I think it's egregious.

14 BY MR. MILLER:

15 Q. What do you mean by that?

16 A. I think it's foolhardy to suggest that a
17 surgeon whose reputation is -- is based upon his
18 capacity to provide sound patient care would lie
19 about what they believe to be safe and reproducible.

20 MR. MILLER: Thank you. I need to consult,
21 and I think that may be my last question for now.

22 THE VIDEOGRAPHER: Go off?

23 MR. OLIVER: Are you directing him to go off
24 or stay on?

25 MR. MILLER: We can stay on record. And

1 Mr. Schaefer needs to make a statement about the
2 proceeding, the IPR proceedings, in which he is
3 counsel of record.

4 MR. SCHAEFER: So I'm lead counsel in three
5 IPR matters.

6 MR. OLIVER: Hold on. This is questions for
7 the witness.

8 MR. MILLER: He is making a statement.

9 MR. OLIVER: This is not the time to make a
10 statement.

11 MR. MILLER: Well, he's making one.

12 MR. SCHAEFER: We're reserving rights.

13 MR. OLIVER: Who is defending the witness
14 here?

15 MR. MILLER: Mr. Schaefer is making a
16 statement about --

17 MR. OLIVER: Who's defending the witness?

18 MR. MILLER: I am defending the witness.

19 Mr. Schaefer is making a statement about other
20 proceedings in which he is lead counsel that are not
21 these proceedings.

22 MR. OLIVER: Okay. I object as leading.

23 MR. SCHAEFER: I'm lead counsel in
24 IPR2013-00507, 00508, 00506. Numerous out-of-scope
25 questions today we feel have been directed to these

1 IPR matters and are irrelevant to the IPRs for which
2 this deposition has been noticed.

3 The deposition -- the IPR matters for which
4 this deposition was noticed are those six IPR matters
5 that Mr. Cavanaugh listed at the beginning of these
6 proceedings. We objected to those questions as out
7 of scope for these proceedings and object to the use
8 of this deposition in connection with those
9 proceedings.

10 Medtronic had the opportunity and chose not
11 to depose Mr. Miles in connection with those
12 proceedings on the direct testimony he provided in
13 those proceedings.

14 As we stated on numerous occasions today,
15 including during breaks, this is an improper use of
16 IPR deposition procedure. Importantly, we are not
17 taking redirect top -- redirect on topics related to
18 these three IPR proceedings, namely, the 507, 508 and
19 506 IPR proceedings. And we reserve the right to do
20 so should Medtronic improperly attempt to use any
21 testimony here today in those proceedings.

22 MR. MILLER: And with that, we have no
23 further questions at this time on redirect.

24
25 EXAMINATION

1 BY MR. OLIVER:

2 Q. Just have a few quick questions on recross.
3 Between the end of my questioning on
4 cross-examination and the beginning of Mr. Miller's
5 questioning on redirect, did you have any discussions
6 with counsel in this room?

7 A. I did.

8 Q. And what were those discussions?

9 A. He described to me that he has an
10 opportunity to -- to ask me questions.

11 Q. And did he discuss any of those questions
12 with you?

13 A. Not specifically.

14 Q. Were there any other discussions concerning
15 the substance of your testimony either on cross or
16 redirect?

17 A. No.

18 Q. Okay. Can you turn to Exhibit 2030, please.
19 You read several names that you believe to
20 be consultants for Medtronic. Was that from the
21 section of page 3 titled "Associate Editorial Board"?

22 A. It is from the deputy editors as well as the
23 editorial board.

24 Q. Okay. And do you know if all of those
25 individuals reviewed the article specifically in this

1 supplement?

2 A. I think I testified that I did not know --

3 Q. Okay.

4 A. -- which ones did.

5 Q. You went through and listed the people you
6 believe to be Medtronic consultants; is that correct?

7 A. Yes, it is.

8 Q. Can you do the same and identify any people
9 listed in both under the deputy editors and the
10 associate editorial board that were NuVasive
11 consultants at any time?

12 A. Sure. Alex Vaccaro, Ed Benzel, Paul McAfee,
13 Dan Resnick, Frank Schwab. That's it.

14 MR. OLIVER: Okay. Thank you.

15 I have no further questions.

16 MR. MILLER: I have no further questions.

17 THE VIDEOGRAPHER: This concludes media
18 number 3 of 3 in the deposition of Patrick S. Miles
19 we're off the record at 5:05 p.m.

20 (Deposition concluded at 5:05 p.m.)

21 * * *

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23

24

25

DECLARATION UNDER PENALTY OF PERJURY

I, PATRICK S. MILES, do hereby certify under penalty of perjury that I have read the foregoing transcript of my deposition taken September 4, 2014; that I have made such corrections as appear noted herein, in ink, initialed by me; that my testimony as contained herein, as corrected, is true and correct.

DATED this _____ day of _____, 2014, at _____, California.

PATRICK S. MILES

1 STATE OF CALIFORNIA)
) ss.
2 COUNTY OF LOS ANGELES)
3

4 I, NIKKI ROY, Certified Shorthand Reporter,
5 certificate number 3052, for the State of California,
6 hereby certify:

7 The foregoing proceedings were taken before me
8 at the time and place therein set forth, at which
9 time the deponent was placed under oath by me;

10 The testimony of the deponent and all objections
11 at the time of the examination were recorded
12 stenographically by me and were thereafter
13 transcribed;

14 The foregoing transcript is a true and correct
15 transcript of my shorthand notes so taken;

16 I further certify that I am neither counsel for
17 nor related to any party to said action nor in any
18 way interested in the outcome thereof.

19 In witness whereof I have hereunto subscribed my
20 name this 4th day of September, 2014.

21
22
23
24
25

NIKKI ROY

CERTIFICATE OF OFFICER

I certify that:

- (1) the witness, Mr. Patrick Miles, was duly sworn by me before
commencement of testimony by the witness;
 - (2) the attached transcript is a true record of the testimony given by the
witness;
 - (3) the testimony was recorded in my presence;
 - (4) the following opponents were present:
 - a. on behalf of Medtronic, Inc.
Justin Oliver, and
Sharre Lotfollahi
 - b. on behalf of NuVasive, Inc.
Stephen Schaefer,
James Garrett, and
Jonathan Spangler;
 - (5) the deposition was taken at the following place:
3111 Camino Del Rio North, Suite 4000
San Diego, CA
- beginning at the following date and time:
September 4, 2014 at 9:12 a.m.

CERTIFICATE OF OFFICER

ending at the following date and time:

September 4, 2014 at 5:05 p.m.;

(6) I am an officer authorized by law to take depositions to be used in the courts of the United States, or of the State where I reside; and

(7) I have no disqualifying interest, personal or financial, in a party.



SIGNATURE OF OFFICER

9/29/14

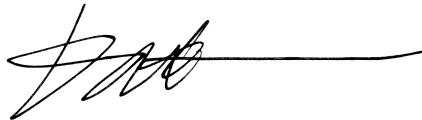
DATE

Nikki Roy

NAME OF OFFICER

SEAL OF OFFICER

sworn before me
on this 29th day of September 2014



KATE KLAUSNER
Notary Public, State of New York
No. 01196183941
Qualified in Westchester County