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1 exclude individuals that they may personally think
2 should not be performing those procedures, true?
3 A. Also correct.
4 Q. As matter of fact, NASS doesn't even
5 put a disclaimer in their classes which says, hey,
6 look, by the way if you learn from us, and you are
7 this specialty, that should not be your
8 sub-specialty, does it?
9 A. I don't believe such a disclaimer
10 exists.
11 Q. So they know, when I mean they, you
12 as the president understands that NASS understands
13 also that other physicians are coming there to
14 practice, and those physicians are not board
15 certified; isn't that true?
16 A. That is true.
17 Q. And they are not even neurosurgeons
18 or orthopedists, but they still take their money and
19 teach them; isn't that true?
20 A. That is true.
21 Q. Now, Ms. Hafner asked you about these
22 articles, treatises, these guidelines. We went
23 through it. I'm satisfied with your answers as far
24 as I'm concerned except with regard to one follow-up
25 is that when she asked you if they were current

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1 today, your first answer was that they were
2 contemporaneous with regard to many of the eleven
3 patients treated by Dr. Kaul, true?
4 A. Yes.
5 Q. Which of the many are we talking
6 about, was it contemporaneous for, and which was it
7 not?
8 Many doesn't mean all.
9 A. Agreed. I would say that since
10 guidelines are typically updated sometime between
11 five and ten years after they are first published,
12 so it would be contemporaneous for at least 2005 to
13 2010 and then potentially up to 2015 theoretically
14 depending on when the next update is published.
15 Q. So if a procedure took place prior to
16 2005, it's fair for me to say that those guidelines,
17 that P-92 is not applicable to them; isn't that
18 true?
19 A. It is somewhat true, meaning that the
20 process of developing that body of literature as a
21 combination wouldn't have existed to be referenced,
22 but some of the articles, studies that made the
23 basis for those guidelines would have been out there
24 whenever they happened to have been published.
25 So some of the information would have

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1 been there but not compiled in a guideline manner.
2 Q. Exactly. So there would have been
3 articles but not guidelines, true, prior to 2005?
4 A. That is correct.
5 Q. And as a matter of fact, they really
6 wouldn't have even close to the relevance or
7 significance until 2005 because how would a
8 physician have noticed that would be a potential
9 component of a guideline in 2005, true?
10 A. I would say that is mostly true. The
11 exception that I would place is there was a
12 prospective randomized study among articles
13 published before 2005. We already know as
14 physicians those are unusual studies, typically
15 having some of the highest levels of evidence.
16 So you would put some weight on that,
17 and you would expect that to show up if a guideline
18 were ever published.
19 Q. The types of diagnoses, the
20 discography and the other types of diagnoses of back
21 pain, some of those are mentioned in P-92 as
22 guidelines, true?
23 A. Yes.
24 Q. And some of them are mentioned as
25 options, true?

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1 A. Yes.
2 Q. But we all know now, after your
3 testimony earlier this morning, that there is a
4 plethora of methods in which individuals diagnosed
5 conditions related to the spine, true?
6 A. Yes.
7 Q. And all of those, because of the
8 level of uncertainty which is significant, isn't it
9 true that all of those methods of evaluation that
10 are put into P-92, all of them are accepted in the
11 industry; isn't that true?
12 A. Yes.
13 Q. You were shown the labeling for
14 OptiMesh and read the specific component, which
15 really that component makes it off label, true?
16 That is the clear definition of off
17 label, isn't it?
18 A. Yes.
19 Q. And when you refer to Dr. Kaul
20 utilizing medical devices, specifically in this case
21 pedicle screws, OptiMesh, the method in which they
22 are utilized in the context in which you reviewed
23 them were -- OptiMesh was always off label, true?
24 A. Yes.
25 Q. Pedicle screw placement at some point

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1 and in some cases for some patients was off label
2 also, true?

3 A. Yes.

4 Q. We have already gone through that is,
5 already accepted in the industry. You would agree
6 with that, true?

7 A. Yes.

8 Q. So the last piece is that your
9 testimony before, very insightful and accurate, that
10 the FDA doesn't regulate physicians. That is why,
11 they allow off label use, true?

12 A. Yes.

13 Q. And that is why it's a doctor's,
14 decision, not the little piece of paper that
15 Ms. Hafner gave you; isn't that true?

16 A. Yes.

17 MR. SHAW: Thank you, Judge.

18 JUDGE SOLOMON: Okay.

19 Ms. Hafner.

20 Thank you, Doctor, again for your
21 testimony.

22 THE WITNESS: You are welcome.

23 JUDGE SOLOMON: You can return to
24 your seat and leave, in fact, if you would like.

25 THE WITNESS: Thank you.

1 (Whereupon, the witness was excused.)

2 JUDGE SOLOMON: Ms. Hafner, any
3 witnesses for today?

4 MS. HAFNER: No, Your Honor.

5 JUDGE SOLOMON: All right. Your next
6 witness is Friday?

7 MS. HAFNER: That's correct, at
8 2:00 o'clock, Your Honor.

9 JUDGE SOLOMON: If you will note, the
10 office for Friday at 2:00 o'clock.

11 Any housekeeping before I close the
12 record?

13 MR. SHAW: I have none, Judge.

14 MS. HAFNER: I don't have anything,
15 Your Honor.

16 JUDGE SOLOMON: All right.

17 We will see everybody Friday at
18 2:00 p.m.

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20 (Whereupon proceeding adjourned.)

21 Time noted: 11:41 a.m.)

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CERTIFICATE

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I, GERALDINE ADINOLFI, a Notary Public and
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