

1 DR. MARCHAND: So your total carbon assay
2 will show a signal. This means that when you have a
3 signal, this means that there is a probability of
4 having prions. But if you want to look in all the
5 little cranny little spots if there is a possibility
6 to have prion proteins, you would start with such an
7 assay before doing it with real prion, for instance.
8 And if there's no signal after the washing steps, you
9 would conclude that there's no need to look at it.

10 DR. TELLING: But isn't there an issue of
11 contact rather than transference?

12 DR. MARCHAND: Pardon me?

13 DR. TELLING: It's an issue of contact
14 rather than transference of material.

15 DR. MARCHAND: There are several ways to
16 do this assay, depending on what you want to measure,
17 the type of end-points you want to see. If you want
18 to see if some organic material has the capability to
19 be caught in some of the little cracks somewhere, you
20 can load with radioactive stuff, if you want. There
21 are several ways to do it.

22 CHAIRMAN EDMISTON: Dr. Priola, you have a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 comment?

2 DR. PRIOLA: No.

3 CHAIRMAN EDMISTON: No. Dr. Prusiner.

4 DR. PRUSINER: I'm not sure -- I would
5 like to disagree with this. I'm not sure how you do
6 this assay. I mean, if you just look for residual
7 material by mass spectrometry, for instance, you're
8 going to find carbon everywhere. We once thought --
9 it was Arthur Kornberg, whose name many of you know,
10 who said to me if you just prove the absence of
11 Adenosine you'll see there are no nucleic acids in
12 your preparation, because adenium is everywhere, it's
13 in the air. So I think the problem is to get rid of
14 the prion protein. And I discussed this earlier in
15 terms of infinite number of shapes of instruments that
16 there are, so this becomes a really difficult issue.
17 Whatever surface you're looking at, you want it in
18 contact with the brain. Doing a series of materials
19 is making different claims on different materials; of
20 course, you can do that. I mean, that's
21 straightforward. If you do stainless steel, you claim
22 it's for stainless steel. If you do some plastics, as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Dr. Burke will probably talk about in a second, you
2 can claim for these plastics. But I think the shape
3 issue is extremely hard to deal with, because you want
4 the buyer or whatever surface it is in contact with
5 the brain, and at the same time you don't want to
6 create a complex shape that doesn't touch the brain.
7 So it's an imperfect world. I've thought about this a
8 lot. Dr. Murphey and I have talked about this in the
9 past, and I'm not sure what the answer is.

10 CHAIRMAN EDMISTON: So what you're saying
11 is the nature of simulating the worst case scenario,
12 it would be very difficult to conceive of a device or
13 at least a simulated device that would be perfect in
14 every scenario.

15 DR. PRUSINER: Well, I think that's right.
16 I mean, let's take the writing, you serrate the
17 wiring, somebody manufactures these wires with all
18 these serrations in it, and we now put the wire into
19 the brain - what we would like, the prions
20 theoretically are going to survive in the trough of th
21 serration. That's where think the highest prion
22 levels might be, but that's the area that's going to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 touch the brain tissue the least when it goes in, so
2 I'm not sure how to make the perfect device.

3 DR. TELLING: So, Stan, your contention,
4 therefore, would be if the material is sequestered
5 from the cleaning agent, it would be sequestered from
6 contacting the available substrates in the brain.

7 DR. PRUSINER: I think there's a high
8 probability there. I want to make sure that it's --
9 this is a surface issue. This is not a shape issue.
10 I don't think we can speak to all these shapes. I
11 mean, the shapes are almost infinite.

12 CHAIRMAN EDMISTON: The only reason the
13 shape comes up is that for those of us that sort of
14 deal with this on a day-in/day-out basis, cleaning
15 endoscopes, cleaning a variety, we know that as that
16 debris field builds up in the cul-de-sac, it becomes
17 more and more difficult to effectively sterilize these
18 devices, so while attention is paid to that pre-
19 cleaning process, which we haven't said very much
20 about, but a lot of attention is paid to that --

21 DR. PRUSINER: Well, if you would allow me
22 15 seconds, I would like to say something about that,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 because I think one of the things -- John Contree
2 introduced me to all of the steps that go on. And one
3 thing that surprised me is that the workers who are
4 cleaning these instruments are exposed to everything
5 that comes down from the OR. They're sitting there
6 working with all this stuff, so I think we make a huge
7 dent in what they're exposed to by some procedure that
8 inactivates prions in advance of having these people
9 clean these instruments. And probably there are a lot
10 of instruments that can only be cleaned by hand, at
11 least to get a lot of the material out of there. And
12 then some kind of ultrasonic whatever it is with
13 additional liquids. But remember that every time you
14 create some ultrasonic device or you ask for that to
15 be done, you're creating aerosols. Every time you put
16 energy into any bath, you're creating aerosols for the
17 workers who have to clean all this stuff.

18 CHAIRMAN EDMISTON: Thank you. Dr. Burke,
19 I believe you had a comment you wanted to make.

20 DR. BURKE: Yes, I agree with Dr.
21 Prusiner. I think it would be impractical. If you
22 take an endoscope, for instance, you go back to the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 alpha studies, it's very clear that you will never
2 achieve zero carbon level, as Dr. Prusiner was saying.

3 In our laboratory, we know this is true. On other
4 complex devices, that it also going to be true.

5 However, that's not to say that there is a
6 micro organism or a prion present because there is a
7 carbon atom present at that same time. So I think
8 that to try to put that bar up that level, I think it
9 would be absolutely impractical. Testing a variety of
10 materials, plastic, et cetera, as Dr. Prusiner said, I
11 think would be very acceptable.

12 CHAIRMAN EDMISTON: Dr. Haines.

13 DR. HAINES: I just have to disagree with
14 that completely. The fact that we can't do it
15 perfectly doesn't mean we shouldn't do it at all. I
16 mean, to fail to test these against some model of
17 complexity is a complete failure to try to deal with
18 the safety issue.

19 CHAIRMAN EDMISTON: Dr. Priola.

20 DR. PRIOLA: In a way, I agree with that,
21 because if you take a non-serrated wire and a serrated
22 wire, you can still do the experiment and see if you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 get any difference, or if you get the same result.
2 And I think you have to try it, just to see what would
3 happen. You could do that with multiple materials.
4 Serrate the wire, make nicks in it, whatever, put it
5 in there and see what happens. And that will give you
6 some indication how well the stuff survives deep down
7 in the hinges of things, whatever. If you think it's
8 not a difficult thing to try, and it may not work, or
9 it may work, but I think it should be considered in
10 terms of deciding about how to do these validation
11 studies. It doesn't have to be a perfect reproduction
12 of the instrument, just something with surfaces,
13 variable surfaces.

14 CHAIRMAN EDMISTON: In other words, a
15 scored surface of some type for comparison purposes.

16 Do I have a consensus in this panel about that
17 comment, that the use of a non-scored surgical needle
18 compared to a scored surgical needle is, at least, a
19 starting point to compare the efficacy of these
20 inactivation components? Yes, Dr. Schonberger.

21 DR. SCHONBERGER: I don't want to jump too
22 far ahead, but later on we're going to talk about the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 degree of claim, whether there's complete elimination
2 or not complete elimination. And I think what we're
3 talking about is a lot of the difficulties we're going
4 to have to say that everything is just complete
5 elimination because of these little crannies and so
6 on. So we could adjust our claim, as well as go ahead
7 and proceed as you're talking about, trying additional
8 types of tests.

9 CHAIRMAN EDMISTON: Any other comments?

10 The material that was provided to myself and others, I
11 don't see anything in there which allows us to choose
12 any alternative devices or models in these studies.
13 However, I would encourage, encourage the FDA to
14 consider looking at some modification of that wire
15 device, be it serration or some other scoring, at
16 least to look at that. Now whether you write that
17 into your requirements for the vendors, I don't know.

18 That's going to be your decision, but I think it is
19 enough of an issue for those of us that sort of deal
20 with this on a day-in/day-out basis. We do always
21 worry about those interstices that we can't seem to
22 reach, and whether or not they're relevant. It may

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 very well be they're not relevant, and additional
2 testing may prove they're not relevant. But I would
3 encourage the FDA to consider this. Yes, Dr. Gordon.

4 DR. GORDON: I was just thinking that with
5 the complex materials, those are the -- or the complex
6 devices, that's the real heart of a lot of this,
7 because a lot of the simple things we can just discard
8 anyway, and that's where a lot of the value is, and a
9 lot of the millions of dollars that are getting thrown
10 out. But maybe there's some of in vitro study that
11 can be done, not necessarily into a mouse's head or
12 anything, but that can be seen how much prion there is
13 that's available, like a bio assay or something like
14 that. And then if we know that they get rid of it on
15 the steel, then that would be the correlation with the
16 in vivo, you know what I mean? Because otherwise, the
17 value of it is going to be so supremely limited,
18 they're going to say okay, fine, that's great for
19 straight things that don't have serrations, but we
20 can't make any comments about kind of other protection
21 that we're going to provide for these patients.

22 CHAIRMAN EDMISTON: I think one of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 problems that we have is that we're dealing with the
2 here and now, and we don't have any device available
3 that can be simulated to achieve those goals. I think
4 that's the issue.

5 DR. ARDUINO: I think, too, it's
6 methodologic. If you had a bronchoscope, if the only
7 way you can test for a prion is to do a bio -- I mean,
8 an in vivo assay by taking -- what do you, dissect the
9 scope and take it and implant is in the head? We need
10 another assay, so we're going to need to develop tools
11 to do some of this other -- other tools.

12 CHAIRMAN EDMISTON: I think if Dr. Giles'
13 data is correct and we're down at that minus one log
14 issue, that this issue will be revisited. But I think
15 with the current information that we have, more than
16 likely the data that will be coming in based on
17 testing, using that needle, that five millimeter
18 needle, which does not appear to be sufficient when
19 you look at it, but appears to be the best methodology
20 we currently have to-date, is probably going to hold
21 up for a while. Am I off base on this, or do you
22 think --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealgross.com

1 DR. ARDUINO: No, but I would use that as
2 a modified carrier test, and not only use stainless
3 steel, but use other materials that you could actually
4 make into a needle, as well. And for that matter, we
5 could even use needles that have been used so they're
6 pitted or damaged, or whatever.

7 CHAIRMAN EDMISTON: The serrated needle,
8 or the -- yes. Yes, sir.

9 DR. LIN: If I may make a comment from
10 what I heard here, you are discussing, you are
11 indicating very much is saying that all agree that
12 stainless steel - the needle, or whether it's
13 stainless steel, or plastic, or whatever, that will be
14 sufficient to try, FDA to approve a product that could
15 be used clinically. Is that what you are saying?

16 CHAIRMAN EDMISTON: I think what we're
17 saying, and everybody jump in and correct me, is that
18 the current methodology which evolves around the use
19 of a needle appears to be the best methodology, or
20 best device simulation that we have, with the
21 exception, the caveat, it would be nice if we could
22 take that device and score it, or in some way etch

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealgross.com

1 that surface so that you have now a device that may
2 more simulate devices that are being used over, and
3 over, and over again, because if you look at medical
4 devices that are reprocessed over and over again, the
5 structural nature of that surface always changes, if
6 you look at it by SEM. And actually, some of these
7 devices become significantly scored with time,
8 especially some of the biopsy needles, if they're
9 still using reusable biopsy needles. Dr. Haines.

10 DR. HAINES: I think we may be softening
11 this a little too much. The needle is a great way of
12 producing the infection, but is not very realistic in
13 terms of presenting an obstacle to eliminating it.
14 And it is the obstacles to eliminating the infective
15 material that we're having to deal with.

16 CHAIRMAN EDMISTON: What would you
17 suggest?

18 DR. HAINES: Well, I think even more
19 complex than just serrating it, I think you have to
20 deal with issues of lumens, of bends where the
21 material comes very close to itself. And, obviously,
22 not get carried away with this, but simply, it's got

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealgross.com

1 to -- I think it needs to be tested against devices,
2 small testing devices that are significantly more
3 complex than just a straight piece of steel, even if
4 it's irregular.

5 CHAIRMAN EDMISTON: What data is out there
6 on lumens, luminal inactivation, or luminal log
7 reduction? Is there any data out there at all, on
8 hollow board?

9 DR. PRUSINER: There's one paper from Paul
10 Brown where they were using a needle. They were
11 sticking the needle in the -- there was no log
12 reduction in there. It was just the absence of
13 infectivity, and so we're not talking about needles
14 with these little wires.

15 CHAIRMAN EDMISTON: Right.

16 DR. PRUSINER: They're not hollow. The
17 wire is very narrow. We're just talking about a
18 surface. That's what Charles Weissmann started doing
19 with these studies.

20 DR. BURKE: Yes, I think that's true, and
21 when you talk about lumens, such that are in an
22 endoscope, there's a lot of data that -- it doesn't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 talk about prions at all, but about cleaning of those,
2 and the level that is still residual in the lumen, and
3 there's a lot of literature in that area. And I
4 think one of the authors was quoted today, and that's
5 Michele Ather, so I would suggest the panel look at
6 those documents, because there is always residual in
7 endoscopes, and so, therefore, the challenge is
8 getting it as clean as possible in pre-cleaning, and
9 then in your final stages to render it free of
10 organisms, and in this case the prion.

11 CHAIRMAN EDMISTON: So you gentlemen
12 believe that surface is important, shape is not
13 important. Correct?

14 DR. GILES: It's not shape is unimportant.
15 We're unable to test it with the current
16 methodologies, because we're limited to bio assay in a
17 brain, so the only other option would be to use
18 something with a larger brain, which a non-human
19 primate. It's not reasonable to start doing bio
20 assays in non-human primates because that's the only
21 way to assay a more complex shape.

22 CHAIRMAN EDMISTON: My take on this, and

1 this has always been, regardless of what the FDA is
2 looking at, this is always a moving target. And as
3 more data comes in, there is an effort to refine the
4 methodology, and even place greater burden upon the
5 vendor to achieve higher levels. So I think, Dr.
6 Haines, from your perspective, is that since we have
7 this moving target perspective, that I'm not aware of
8 anything, and I think the experts are ahead of us
9 here, I'm not aware of anything that we could
10 supplement that would give us -- if a device were to
11 come into the FDA on January 1st, and they were to
12 make a recommendation, I'm not sure that there would
13 be sufficient validation studies out there, looking at
14 new types of simulated devices to test against
15 whatever they may be submitting.

16 Now that doesn't preclude the possibility
17 of sort of moving us forward with time. But I think
18 within the here and now, I don't see any alternative
19 to continuing with the devices that we're using.

20 DR. HAINES: Well, I don't see how
21 difficult it is to take the wire and twist it, and see
22 if that can be effectively disinfected, or to use a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 very small needle with a lumen, clean it, and see if
2 that is as effectively disinfected. I mean, we don't
3 need to build a five millimeter endoscope to do this.

4 CHAIRMAN EDMISTON: Dr. Coffey.

5 DR. COFFEY: Yes. One can find on any
6 hospital shelf a 25 gauge spinal needle, for example,
7 that has a stylet in it. And one worst case scenario
8 that one could envision would be to infect the hollow
9 needle and the stylet to "infect" it, try and
10 sterilize it or disinfect it in the assembling stage,
11 and then perhaps implant each component into an
12 animal. I mean, a little bit of ingenuity could go a
13 long way into sorting out some of these things.

14 CHAIRMAN EDMISTON: Let me get a consensus
15 from the panel. Let me just kind of go through. How
16 many on the panel, and this is not official vote, but
17 how many on the panel feel that in the testing
18 criteria that may be required in the future, and the
19 future could be as soon as next year or whatever, that
20 there needs to be an effort to test more than one type
21 of device based on some structural change or
22 confirmation? I think there's pretty much a consensus

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 here that the panel recommends that in developing
2 criteria, and I suspect we're supposed to be
3 developing these criteria but I don't think we can,
4 developing criteria for the FDA that there is a need
5 to test more than just that five millimeter needle.
6 There needs to be an effort to test other simulated or
7 surrogate devices. And of different materials.

8 Okay. Let's move on to question five.
9 "How close should the experimental treatment
10 conditions for a product, process claiming to reduce
11 TSE infectivity replicate the actual conditions under
12 which the proposed product, process would actually be
13 used? Should such issues as instrument cleaning,
14 conditions which might fix protein to instrument,
15 possible interactions between the new product process
16 and standard cleansing agents, sterilizer cycles, et
17 cetera, be considered? I think the answer is, of
18 course, but to what degree?

19 I think there should be an effort, from my
20 perspective, that we should simulate the clinical
21 condition as closely as possible, which involves, of
22 course, drying. While we don't like to do that on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 neurosurgical instruments. I keep them moist prior to
2 cleaning, or other comments relative from the panel.
3 What's your take on this component of the question?
4 Dr. Lurie.

5 DR. LURIE: It seems to me that the
6 compatibility issues are driven by market forces, that
7 if one devises a process that's incompatible with the
8 present systems, it's not going to be marketable. So
9 I think, obviously, we like to mimic the situations
10 where they're actually being used, and I think the
11 second half would be driven by market --

12 DR. EDMISTON: And all these devices are
13 going to be steam sterilized at some point. At some
14 point in the cycle, they're all going to be steam
15 sterilized, so it's a front end issue, so I think it
16 really is important that they do mimic the clinical
17 situation. Yes, Dr. Schonberger.

18 DR. SCHONBERGER: But you also want to
19 incorporate if there should be an error, such as
20 drying, and you didn't intend it to be dried, but --

21 DR. EDMISTON: Yes.

22 DR. SCHONBERGER: That would, as Suzette

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 was talking about, the rougher, the tougher
2 conditions.

3 CHAIRMAN EDMISTON: Mr. Evans.

4 MR. EVANS: Yes. And I just wanted to
5 add, to look at the complexity of the process as close
6 to the real-world situation as possible. When you
7 look at a central material supply in a major hospital
8 where all these instruments are coming through, and
9 these different processes and different procedures for
10 different instruments, the rate of error in which step
11 came first, whether they're being washed, exposed to a
12 chemical agent, whatever, that we look at that
13 process, too. Any validated training tools that need
14 to go along with that.

15 CHAIRMAN EDMISTON: Dr. Jarvis.

16 DR. JARVIS: I agree that it should be as
17 close to the clinical situation as possible. There
18 are several areas, for instance, in the risk
19 assessment, like how much protein is on a
20 neurosurgical instrument, that I'm kind of surprised
21 that we have to make a guess at what that would be.
22 It seems like in neurosurgical procedures, it would be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 easy enough for researchers to get equipment that's
2 used and calculate exactly how much protein is there.

3 And I guess the other thing is we'd like the worst
4 case scenario, but for instance, inoculating an
5 instrument with ten to the ninth organisms, when in
6 fact we find clinically it's always ten to the fifth,
7 there should be some clinical correlation between the
8 two.

9 CHAIRMAN EDMISTON: Ms. Howe.

10 MS. HOWE: I'm just wondering about the
11 implication to the patient and where they're being
12 treated, if it's a large medical center, if this
13 product has some kind of a certification process
14 that's only accessible to a large center, where maybe
15 a community hospital might need to send out their
16 instruments, and if that would be available to them,
17 so there's some consistency in service to the patient.

18 DR. MANGAIYARKARASI: That's a good point.

19 That's a good point, but the transportation process
20 would be a little more difficult in that case, so we
21 have to think about the transportation, how we are
22 going to transport the instruments to the other

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 hospitals because of the infective thing.

2 CHAIRMAN EDMISTON: These instruments
3 typically after a neurosurgical case, will require
4 sometimes extensive cleaning. There may be some bone
5 fragments on these devices. There may be pieces of
6 brain matter on some of these devices, up to 50
7 milligrams in some cases, and all of these have to be
8 cleaned. So I think any request to the FDA really
9 requires that these devices mimic, the procedure
10 mimics as closely as possible the clinical scenario of
11 large bio burden contamination. In some cases there
12 may be blood on these devices that have to be removed,
13 tissue proteins, all which makes it very, very
14 difficult to clean these devices, which the effort is
15 always made to pre-clean them prior to the
16 sterilization process. So I think yes. The answer to
17 that is yes, there has to be an effort to simulate the
18 clinical situation. And as good example is that
19 looking at these devices, both wet and dry, because
20 we'll see them come to us in both conditions, both wet
21 and dry. And the devices that are dry require much
22 more effort in terms of cleaning, than the instruments

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that are wet. Okay. Let's move on to-- is that
2 sufficient?

3 Move on to number six - "Considering the
4 current state of the science and existing
5 investigative methods for estimating the potential for
6 TSE transmission, can a claim of complete elimination
7 of TSE infectivity be validated?" Now I would have
8 thought that prior to Dr. Prusiner's presentation and
9 his colleagues, the answer would be no, but it appears
10 as though there may be some data out there suggesting
11 that this could be the case. And I think what's
12 important is that we need to continue to address this
13 data.

14 I'm not convinced the risk is ever going
15 to be zero. That's my own personal feeling about
16 this, but I think that there obviously -- this is part
17 of that moving target scenario, that as methodologies
18 improve, and if we're talking about total
19 inactivation, as opposed to just log reduction, we may
20 actually achieve that. Do we have any comments from
21 the panel on that? Dr. Schonberger.

22 DR. SCHONBERGER: I agree with what you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 said.

2 CHAIRMAN EDMISTON: Dr. Haines.

3 DR. HAINES: I think there are two issues
4 that it brings up, and one is sort of hanging over the
5 whole discussion, is the concern that a false sense of
6 effectiveness could lead to unintended changes in the
7 way instruments are processed and handled, that could
8 have very negative effects. And that because of the
9 potential for very long incubation periods, and
10 because the overall risks are very low right now, that
11 I think there's a burden for post-market surveillance
12 that really is very important, and should be part of
13 an approval process.

14 CHAIRMAN EDMISTON: That's an excellent
15 consideration because post-market surveillance has
16 become an important part of the FDA review process.
17 The structure of that is not our purview, but I think
18 you bring up a very, very good point. Any other
19 comments? Yes, Dr. Coffey.

20 DR. COFFEY: The problem with that, and I
21 agree with Dr. Haines, and I think we're both sort of
22 echoing the slides that Dr. Murphey presented at the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 beginning of the morning regarding risks associated
2 with these devices, or reduced vigilance, reduced
3 diagnostic acumen, lowering our guard, is that post-
4 market surveillance would have to be for the lifetime
5 of every patient who undergoes almost any invasive
6 endoscopic or surgical procedure, even including
7 something like a tonsillectomy.

8 CHAIRMAN EDMISTON: What's the lifetime
9 surveillance for a biomedical implant? Is that
10 lifetime?

11 DR. LIN: Not necessarily, depending on
12 what kind of implanted device --

13 DR. EDMISTON: Breast implant.

14 DR. LIN: Well, breast implant could be --

15 DR. EDMISTON: Special case.

16 DR. LIN: But heart implant could be
17 sometimes six, seven years, and then you have to take
18 out, and implant it again.

19 DR. HAINES: It actually requires special
20 action to require more than two years, at present.

21 CHAIRMAN EDMISTON: Let me ask the panel
22 this question. Based on everything that we've heard

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 today, can a claim of complete elimination of TSE
2 infectivity be validated to-date? I think the answer
3 to that question is no, so the answer to number six is
4 no, with the current information we have to-date.

5 Are there any other points or questions
6 that the panel might like to bring up at this time?
7 Any final comments? If there are no final comments,
8 first of all, I want to thank -- yes, Dr. Lin.

9 DR. LIN: Well, maybe --

10 DR. EDMISTON: I almost got passed you,
11 but go ahead.

12 DR. LIN: Well, I don't know, do you have
13 -- maybe before you adjourn, I want to say something.

14 CHAIRMAN EDMISTON: Oh, you want to say
15 something before I actually leave the room, or before
16 we all leave the room? Do you want to say something
17 now?

18 First of all, I really want to thank the
19 FDA for the time and effort they put into this. This
20 is it for me, and so I really want to thank them for
21 Zall the time and effort they put into this particular
22 meeting. The CDs that were provided by Scott, and the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 support that we've had today was extraordinary. I
2 want to thank the members of the public who devoted
3 their time to come here and present in many non-
4 proprietary perspective on some of these issues. And,
5 of course, I want to thank the various members of the
6 panel for their time and commitment, and it's been a
7 pleasure serving you all. Thank you very much.

8 And with that I'd like to adjourn this
9 meeting, but Dr. Lin wants to say a few words.

10 DR. LIN: I just wanted to announce that
11 Dr. Edmiston, this will be his last panel meeting as
12 the Chairman, so on behalf of the FDA, I wanted to
13 sincerely thank Dr. Edmiston for great contribution to
14 FDA's mission and your efforts is greatly appreciated.

15 And let's give him applause.

16 CHAIRMAN EDMISTON: Thank you very much.
17 We're adjourned.

18 (Whereupon, the proceedings went off the
19 record at 4:24 p.m.)
20
21
22

CERTIFICATE

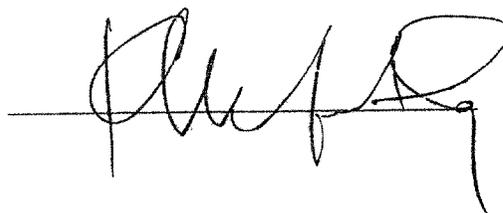
This is to certify that the foregoing transcript in the
matter of: General Hospital and Personal Use
 Devices Panel Meeting

Before: DHHS/PHS/FDA/CDRH

Date: September 27, 2005

Place: Gaithersburg, MD

represents the full and complete proceedings of the
aforementioned matter, as reported and reduced to
typewriting.

A handwritten signature in black ink, appearing to be "R. J. [unclear]", written over a horizontal line.