

1 says to me is, somebody needs to ask the question, which I'm
2 sure he's asking.

3 DR. MILLER: I agree with you. I agree with both
4 of you. There's another point of view here that we're
5 really not designed to address here but it's the clinical
6 safety of heat processing these handpieces. I think there
7 is still clinical safety involved in heat processing these
8 handpieces. We don't want that to stop. So in the
9 meantime, as to when we can come up with a handpiece that
10 will stand or can be truly sterilized or develop a
11 sterilizer that will truly sterilize handpieces, we still
12 have to continue to heat process handpieces, I guess.

13 DR. ROBERTSON: I couldn't agree more, because
14 your data simply says we need to ask the question.

15 DR. KUEHNE: And that's what I'm getting at, is
16 that there is still validity in requiring the handpiece to
17 withstand the temperature involved in the autoclave process
18 because it is still, in effect, your control procedure, even
19 though it's not going to always achieve 100 percent
20 sterility.

21 DR. ROBERTSON: No, see, there you did bad.

22 [Laughter.]

23 DR. ROBERTSON: We were cooking right along. You
24 did bad right at the end.

1 MR. ULATOWSKI: Mr. Chairman, I think there is
2 room for argument and some historical perspective regarding
3 the challenge and the methodology that's been used to
4 establish whether or not a product is sterilized. For
5 example, one may have in the past simply used the spore
6 strips and macerated them and placed them in the head and
7 whatever and showed elimination and that was the threshold
8 for the test at the time for demonstration sterilization.

9 Dr. Miller's challenge is not excessive. I think
10 it's more real-world conditions as far as actual use
11 conditions, but it's something that raises questions, as
12 you've noted, on what are the appropriate procedures to use
13 for validating handpieces. Have we now moved towards a
14 higher threshold of expectations?

15 DR. PATTERS: I was also intrigued by the data
16 which show that when proteinaceous substances combined with
17 the organisms, it is much more difficult to sterilize the
18 handpiece. That seems to be a much more real-world
19 condition. Although it may not necessarily be sheep's
20 blood, there are certainly proteinaceous substances in
21 saliva. There is no doubt that they enter the turbine area
22 of the handpiece and that definitely makes them more
23 difficult to sterilize, based on Chris's data, anyway.

24 What I'd like to think is that this is really just

1 a matter of engineering and that handpieces have not to date
2 been designed with one of the major concerns, the ability to
3 completely sterilize the handpiece using the ordinary 121
4 degrees, one atmosphere of pressure steam autoclave. The
5 thrust of the engineering has been to design a precision
6 device which can maintain high speeds and last for a long
7 time.

8 I'm sure if this becomes a priority for
9 manufacturers, it won't take long until they change the
10 engineering such that it becomes much more easy--obviously,
11 they're not reaching the 121 degrees or the appropriate
12 pressure, and that's, to me, just a change in design that
13 will allow that to happen. What will be sacrificed as to
14 whether the life of handpieces will be shorter or not, I'm
15 not an engineer and I don't know.

16 But once this becomes a clear indication and
17 potential marketing means, that a new handpiece with a new
18 design can be shown to be sterilized under ordinary office
19 conditions almost 100 percent of the time, I think that will
20 change things.

21 DR. ROBERTSON: Yes?

22 DR. DRUMMOND: I guess I have a question about the
23 experiment. I don't want to criticize it, but we're all
24 assuming that the sterilization, it was the handpiece and

1 then it gets sterilized, but we really don't know if the
2 sterilizer had an even temperature zone, whether it had
3 zones in the sterilizer that did not get up to 121 degrees,
4 and before we base everything on one test, I think we had
5 better make sure that the sterilizer functioned completely
6 throughout the whole zone because a handpiece will cover a
7 complete zone and if you don't have thermocouples or
8 something in there to know the exact pressure and the
9 temperature throughout the sterilizer, I'm not sure I want
10 to believe everything that's presented.

11 DR. ROBERTSON: That was the whole point of the
12 data that suggests that there are questions that need to be
13 asked. I think there are a lot of reasons why the results
14 could be the way they are. But I was excited by it because
15 it says to me we need to ask some questions, which is
16 exactly what preliminary data is supposed to be.

17 Were there some dental students in there?

18 DR. MILLER: No, no, no, all lab tests.

19 DR. ROBERTSON: That's too bad.

20 [Laughter.]

21 DR. ROBERTSON: Good. Any more about the notion
22 of sterilization?

23 [No response.]

24 DR. ROBERTSON: The first question that FDA wanted

1 us to address was, is it necessary--and you'll interpret the
2 questions down there at the table for us, I assume, and tell
3 us what the questions really mean--is it necessary to
4 evaluate the susceptibility of handpieces to physical
5 damage, and (a) under that is, what type of damage would
6 compromise mechanical integrity or sterilizability?

7 One of the issues, interestingly enough, that came
8 up during the presentations was a concern about whether this
9 guidance document from FDA ought to be directed at the
10 health hazards rather than the kind of mechanical integrity,
11 with the exception of those issues of mechanical integrity
12 that are hazardous, like the heat of the end.

13 So maybe you could tell us, elaborate on that
14 question for us a little bit so we can help you answer it.

15 DR. MENDELSON: We are primarily interested in
16 those aspects of physical damage that would have an effect
17 on safety, not necessarily the absolute RPM a handpiece
18 would achieve after it was dropped. I went through several
19 data bases available at our library before putting this
20 guidance document together and the kinds of reports that I
21 thought were sources of concern included reports of mainly
22 overheating of the heads of handpieces. The reasons weren't
23 always clear.

24 I was concerned about damage to the handpiece that

1 would allow it to come apart under the application of air
2 pressure after it was dropped, increased eccentricity which
3 could cause burs to break in use and fly off. Those are the
4 kinds of things I was looking at.

5 DR. NORMAN: Do you find, in the experimental
6 design or the papers that you have read, that the physical
7 damage to the handpiece was related to experimental design
8 or was it related to reported problems with handpieces that
9 had a survey sort of program, or how did you determine, or
10 what were the papers' content as it related to damage and
11 possible safety of the patient?

12 DR. MENDELSON: Unfortunately, I don't think you
13 could categorize these as papers. These were reports that
14 had been made from the field and it's very difficult to
15 interpret them. I wish it was easier to do it. There may
16 have even been cases where one incident was reported several
17 times as separate events, simply because it's difficult to
18 keep track of this. I understand that these data bases are
19 being consolidated. It's a long, slow process.

20 The only thing I found that was related to any
21 kind of failures that you might consider catastrophic, and
22 they're not really catastrophic but parts flying off while
23 handpieces were in use, was poor maintenance. Other than
24 that, there didn't seem to be any obvious causes.

1 DR. ROBERTSON: Are you saying that a review of
2 the available literature suggested to you that there were
3 not major problems, health hazards, with handpieces?

4 DR. MENDELSON: There were problems--some of the
5 problems were unrelated to the dropping of handpieces. This
6 is one of the questions we're asking. Overheating was the
7 most common cause. That may or may not have been as a
8 result of poor tolerances caused by a handpiece being
9 dropped. I don't know. But there are cases of handpiece
10 failures causing injury.

11 We don't have that much information about it, but
12 to put it bluntly, any clinician who has practiced for a
13 significant number of years knows that handpieces fail. I
14 have seen the end caps fall off. I have seen burs
15 disintegrate, and sometimes it occurred after there would
16 seem to be an increase in eccentricity in the head, in the
17 turbine. These things do occur. Admittedly, we can't find a
18 lot of scientific papers on these failures.

19 DR. ROSAN: But if this is due to poor
20 maintenance, let's say by the dentist, then beyond the
21 manufacturer giving directions of maintaining it, I don't
22 see--

23 DR. MENDELSON: In these reports, if the dentist
24 reporting an injury or a failure of a handpiece in the

1 patient's mouth is asked for any information that would
2 contribute to the investigation, I think the only
3 information that the dentist could offer is information
4 about the maintenance history of the handpiece. The dentist
5 can't offer any information about any other events that may
6 have occurred before the incident. The dentist didn't
7 design the handpiece.

8 DR. ROBERTSON: Is there presently a mechanism,
9 and maybe somebody from the manufacturers of handpieces in
10 the audience can help me, is there presently a mechanism to
11 allow a prevalence or an incidence study on the
12 mechanically-related health injuries with handpieces? Is
13 there a data base, and is there a way that that could be
14 reported? Remind me who you are?

15 MR. JIMENEZ: My name is Hector Jimenez and I am
16 from Midwest Division of Dentsply.

17 DR. ROBERTSON: Can you talk in the microphone for
18 us?

19 MR. JIMENEZ: There is a way, and it's through the
20 MDR reporting. Any failure of a handpiece or of any medical
21 device, for that instance, that can injure or harm a patient
22 or the user has to be reported.

23 DR. ROBERTSON: Is there data?

24 MR. JIMENEZ: And that data is available through

1 the FDA.

2 DR. ROBERTSON: Have we looked?

3 DR. MENDELSON: Yes, I did look.

4 DR. ROBERTSON: And?

5 DR. MENDELSON: Well, for example, in the MDR I
6 found 30 reports of burns to patients during use of
7 handpieces.

8 DR. ROBERTSON: During what period of time?

9 DR. MENDELSON: I don't have the time span
10 available now.

11 DR. ROBERTSON: Thank you.

12 MR. JIMENEZ: And there are also variables. Are
13 they all air driven, or they're electrical or nitrogen-
14 driven, because the heat ratio changes dramatically from air
15 to electrical-driven, so it's something to consider.

16 DR. MENDELSON: It may not even be able to
17 determine if they were all high-speed handpieces, but I
18 believe they were.

19 MR. HLAVINKA: Mr. Chairperson, one of the
20 problems with the MDR data base is a lot of people are
21 conservative about reporting. If it's not either a death or
22 a serious injury, then it does not get reported, so there
23 might be a lot of under-reporting in the MDR data base.

24 DR. NORMAN: Dr. Mendelson, how many total

1 handpiece injuries do you have available? You say 30 that
2 are related to burns? Don't count them, but are we talking
3 about 100? Are we talking about 300? What's the round
4 number of the reports that you've gone through?

5 DR. MENDELSON: I don't think I could give you a
6 number. I suppose 100 would be fair. By the way, these
7 reports covered a period of several years. This was not the
8 total history of the reporting system.

9 DR. ROBERTSON: Dr. Greenspan?

10 DR. GREENSPAN: Yes. It may have been mentioned
11 earlier, and I apologize I'm asking you to tell me again,
12 but how much of this is addressed in the 510(k), or is this
13 something that is going to be added in a guidance document?

14 MR. ULATOWSKI: This guidance document establishes
15 additional information that would be requested, for the most
16 part. In some 510(k)s there is more information than in
17 others. I'm trying to normalize the documents.

18 DR. GREENSPAN: But at the moment, is this
19 question addressed in the current 510(k) for handpieces at
20 all?

21 MR. ULATOWSKI: For current 510(k)s, not
22 consistently, no.

23 DR. ROSAN: I have a question. I remember when I
24 was in practice, if I had a problem with a handpiece that

1 was relatively new, I sent it back to the manufacturer. I
2 am wondering, this may be a way of evaluating how many
3 problems you have. They always sent me a new one. I'm just
4 wondering, because I think that would be true. If you have
5 a problem develop, if it were relatively new or what you
6 thought was within a reasonable period of time, you do call
7 up the manufacturer. I'm wondering if they see that or have
8 any data on that.

9 DR. MENDELSON: Do I have data--

10 DR. ROSAN: No, no, I'm not asking you. It would
11 be the manufacturers. I don't expect you would, but that
12 would be a way. I think that would be a more likely choice
13 when you have a problem, that you contact the manufacturer.

14 DR. ROBERTSON: I don't hear the panel having
15 great expertise in answering your question, that first
16 question, but it seems to me it would be important for me to
17 know the extent of the problem. My excitement would
18 increase, as it did with Dr. Miller's search, my excitement
19 would increase if I thought that there was a severe problem
20 versus no severe problem.

21 I'm not sure what--in terms of the bacterial side
22 and the sterilization side, I think the answer to that
23 question is clearly yes and we have established that we
24 desperately need to sort that out. On the mechanical side,

1 I guess I don't know the answer to your question.

2 DR. KUEHNE: There's only one condition that I
3 know of that the susceptibility of the handpiece to physical
4 damage could shed light on its safety and that's what was
5 referred to earlier in some of the comments from the
6 manufacturers, the drop test, whether it applies to all the
7 handpieces or disposable handpieces. In the document, the
8 way it's written, it just applies to handpieces because all
9 of them are going to be subject to the same one.

10 The point is that with a metal reusable handpiece,
11 the drop test is not going to mean anything. You can drop
12 it from three feet; it works. It's only going to apply to
13 the disposable handpieces, because disposable handpieces are
14 made of plastic. They're molded in two mirror-image forms
15 and then glued or fused together by some mechanism.

16 If that handpiece is dropped and that drop weakens
17 the seal of those two sides, then it's possible that it
18 would not withstand the air pressure that it's subjected to.
19 The head of it could come apart or something like that.
20 That's the only thing that I know of, and I don't know that
21 that's ever happened, but it's possible.

22 DR. ROBERTSON: Ms. Johnson made, I thought, a
23 very interesting point, and that was if you drop that
24 disposable handpiece, it was moot because it was now

1 contaminated and you wouldn't use it again anyway.

2 DR. KUEHNE: That's not necessarily true. First
3 of all, they come in a package, so it's not necessarily true
4 that just because you drop it, the handpiece would be
5 contaminated if you opened up the package. It could be
6 sealed.

7 Secondly, just because you drop it doesn't mean
8 that that dentist isn't going to use it. As soon as he
9 begins to use it, it could cause damage to himself or
10 someone in the area. That's assuming a lot, that because
11 someone is going to drop it, just because they drop it,
12 they're going to throw it away.

13 DR. ROBERTSON: I'm more likely to accept the
14 former than the latter, and your point about dropping it in
15 the case or dropping multiple packages of it where it's
16 still protected is a good one.

17 Dr. Patters?

18 DR. STEPHENS: A handpiece could be dropped on
19 your sterile working surface, which is metal.

20 DR. ROBERTSON: Onto a sterile surface, you mean?

21 DR. PATTERS: I'm not sure that the panel has the
22 expertise to help the staff with item number one. I'd like
23 to maybe ask the chair if we might want to move on.

24 DR. ROBERTSON: Yes, good. I'm so glad you did

1 that.

2 DR. PATTERS: There's some degree of engineering
3 knowledge here as to force and momentum and deformation of
4 pieces which we're just not trained in. Dr. Drummond, I
5 know, is trained in that.

6 DR. ROBERTSON: I do think, however, it is
7 important to address perhaps some of these questions to know
8 if there is a problem and the nature of the problem, and if
9 there is not an existent data base, then one of the
10 recommendations might very well be to get one. I mean, it
11 may be that we don't have any expertise around the table
12 because of who we are, but maybe there is no expertise and
13 at the moment we simply don't have data.

14 The second is, what performance characteristics,
15 if any, are needed to ascertain the ability of handpieces to
16 withstand repeated use and reprocessing? We've had a lot of
17 discussion about that, actually, quite excellent discussion,
18 I thought, from the manufacturers. I think they provided
19 some very good information having to do with the
20 relationship between reprocessing defined as decontamination
21 and sterilization and how that relates to the performance of
22 the handpiece.

23 I'm not sure there's more expertise on the panel
24 than you got from those presentations. Is there any

1 specific issue here that we can help you with that hasn't
2 been dealt with?

3 DR. MENDELSON: I don't believe so.

4 DR. ROBERTSON: Please discuss the effect of the
5 actual bioburden that is accumulated during clinical use.
6 Does this bioburden impair the sterilizability of the more
7 inaccessible areas of the handpiece?

8 Well, that's the question that Dr. Miller is
9 beginning to address, I think, and one of the interesting
10 things he said at the beginning of this presentation was, in
11 a review of the literature, he was only able to find one
12 paper or perhaps one series of papers existent, probably on
13 modern handpieces, that addresses that question, and so
14 that's what started him out doing those studies. So I think
15 the answer is, we have a lot of research to do.

16 DR. GREENSPAN: If one were to extrapolate from
17 other situations of bioburden and instruments and load and
18 recommendations for cleaning instruments before sterilizing
19 and sterilizing cycles being based on bioburden--

20 DR. ROBERTSON: The answer would be yes.

21 DR. GREENSPAN: --the answer would be yes. Now,
22 what that means and how it affects what we do, I don't think
23 that is part of that question.

24 DR. ROBERTSON: The answer would be yes, but what

1 this preliminary study does is ask whether sterilizability,
2 as presently defined, is sufficient no matter what the
3 bioburden is.

4 DR. MILLER: But it might be important to come to
5 a definition of what that is at this point in time or soon
6 afterwards, because some of the sterilization systems,
7 either chemical or heat, would require serum versus what we
8 had used as blood, versus should it be adult bovine serum or
9 fetal calf serum or et cetera, et cetera, bovine serum
10 albumin. That may be helpful.

11 DR. ROBERTSON: I think that point is that we need
12 to encourage that research, because in the absence of that,
13 any discussion we are having is moot.

14 DR. GREENSPAN: And one other thing that concerns
15 me a little in studies that are done, although I think the
16 use of the chemclave is very valuable, there are many, many
17 dental offices that do not have chemclaves, and also, even
18 in many hospital centers they are being phased out because
19 of the difficulty with venting and all the other things. So
20 I think that although it's important to look at that, too, I
21 would caution against putting a lot of effort into only
22 using a chemclave in some of these studies.

23 DR. ROBERTSON: Are there any areas of handpieces
24 that are consistently difficult to sterilize? Can you

1 recommend particular locations where the inoculum should be
2 placed? And again, the answer, based on what we have heard
3 this afternoon, is maybe and we need to look.

4 Is it appropriate that handpieces be required to
5 endure a minimum number of reprocessing cycles, for example,
6 250 cycles as required by ISO 7785? Is it more appropriate
7 to provide labeling stating the number of cycles, and there
8 were some additions here, a particular model can withstand
9 subject to forces such as the price of manufacturer, willing
10 to pay.

11 DR. GREENSPAN: Consumers.

12 DR. MENDELSON: Would you like me to read it
13 again?

14 DR. ROBERTSON: Yes.

15 DR. MENDELSON: Is it more appropriate to provide
16 labeling stating the number of cycles a particular model can
17 withstand, subject to forces such as price consumers are
18 willing to pay and the maintenance steps they're willing to
19 perform?

20 DR. ROBERTSON: Dr. Patters?

21 DR. PATTERS: I have a concern here, and I think
22 it's similar to the concern expressed by a number of
23 individuals from industry who spoke. Unless the guidance
24 document clearly defines what a reprocessing is, this is

1 just going to be an advertising mechanism that ours will do
2 1200, but 1200 what? I think if you want it labeled, if you
3 want it on the label, then you're going to have to define it
4 very, very precisely so that everybody's reprocessing cycle
5 means the very same thing.

6 I know one of the manufacturers wanted to ask FDA
7 a question, and maybe they weren't able to, but since I'm
8 sitting up here, I will. Where did the ten percent decrease
9 in performance come from? Is that some artificial standard
10 that sounded good, or is there some data? It's the top of
11 page nine.

12 DR. MENDELSON: It doesn't sound good, but the
13 reason ten percent was picked is we were interested more in
14 a particular percentage reduction in performance that could
15 be applied to all handpieces. Since we didn't specify that
16 a handpiece withstand a particular number of cycles, what
17 matters is the number of cycles a particular handpiece can
18 withstand, and the question is, how do you define that
19 number.

20 DR. PATTERS: So it's an arbitrary end point?

21 DR. MENDELSON: Well, yes, it has to be. I didn't
22 pick it because it sounded good. It is arbitrary.

23 DR. PATTERS: And that's the end point? Once you
24 lose ten percent, that's the end point?

1 DR. MENDELSON: It could be 20, it could be 50
2 percent.

3 DR. PATTERS: I don't have any problem with that,
4 but things like application of appropriate loading, I think
5 FDA's going to have to define appropriate loading because
6 each manufacturer will choose a different definition which
7 will give a very different result.

8 DR. MENDELSON: That's true, and they have picked
9 different loading schemes.

10 DR. PATTERS: But if you want it on the label, I'm
11 concerned. I think I've expressed it.

12 DR. ROBERTSON: Does any of the rest of the panel
13 have concerns about a number which reflects in some way the
14 number of cycles that a handpiece can withstand?

15 DR. DRUMMOND: I don't see how you can define a
16 number if you don't tell me how you're going to test it.

17 DR. TYLEND: Perhaps the panel could make some
18 suggestions on how they should be tested, what kind of a
19 load should be applied and how it should be applied, or if
20 there should be a load applied between the cycles.

21 DR. DRUMMOND: I think you should run a test that
22 mimics how the handpiece is going to be used clinically, but
23 that's still not--I mean, that, at best, is going to be a
24 guess. As has been asked here, how is a dentist going to

1 measure ten percent decrease?

2 DR. O'NEILL: But if we don't even know what
3 standards we're going to require, what's going to be
4 required for sterilization, for example, what temperature,
5 what length of time, what conditions, then I think we can't
6 say that we're going to require a certain number of cycles
7 of anything. That's what Mark said a while ago. We have to
8 define the parameters first before you can require a certain
9 number of cycles, and that's the question that I think we've
10 been addressing today, is that we don't know what those
11 parameters are at this point.

12 DR. PATTERS: This really sounds like a Federal
13 Trade Commission rather than the Food and Drug
14 Administration.

15 DR. ROBERTSON: I think you're right. I
16 appreciate, actually, Peggy, your point, but one of the
17 things that struck me was that there seems to be some
18 independence between the number of cycles of sterilization
19 and the in-fact failure of the handpiece.

20 In her very elegant discussion this afternoon, Ms.
21 Johnson suggested that the primary variables associated with
22 handpiece failure, of which there were a number, did not
23 include sterilization cycles. I don't actually know whether
24 that's true or not, but it was an interesting concept for

1 me. There were a lot of other things that caused the
2 handpiece to fail other than sterilization.

3 So if sterilization is my primary concern in terms
4 of safety of this handpiece, then picking out a number of
5 miles per hour that this handpiece will last is more a kind
6 of a sales and marketing venture than it is of importance to
7 me for my primary issue, which is the biohazard of this
8 handpiece.

9 I think that's the kind of advice--you can take
10 it, actually, or leave it; that's the nice thing about
11 advisory panels--that's the kind of advice we can give FDA.
12 I'm not sure, Carolyn, that we can tell you exactly what the
13 standards are under which this handpiece needs to be tested.
14 I think we can just give you general guidelines.

15 I think your point is right, that if you must come
16 up with a number that's written on that handpiece, then the
17 conditions have to be shared among all manufacturers, but
18 the expertise is probably not around this table to define
19 them.

20 DR. GREENSPAN: But I think that, at least what I
21 understand to be behind this question, is that our handpiece
22 is required to endure a minimum number, whatever that may be
23 and however we define reprocessing, or is it sufficient that
24 adequate labeling is provided indicating what the number of

1 cycles are, so that if somebody chooses to produce a
2 handpiece that will only withstand X-number of cycles, then
3 that should be very clearly stated. It's up to the
4 purchaser, then, to decide whether they want to buy
5 handpiece A, that does 20 cycles, or handpiece B, that does
6 250 cycles.

7 My feeling is that it's the labeling and the
8 information that's important and that it probably would be
9 more appropriate to have both types of handpieces available
10 and it's the information on the labeling that's important.
11 Exactly what constitutes reprocessing, I agree, is a problem
12 and will have to be carefully worked out.

13 DR. PATTERS: The definition of cycle has to be
14 very clear.

15 DR. GREENSPAN: Well, yes. I mean, all of those
16 kinds of things precisely defined. But having defined the
17 cycle, let us take the position that we know what we mean by
18 cycle and reprocessing, that handpieces can be produced that
19 have different cycles, different numbers of cycles that can
20 be expected of them before they need to be thrown away or
21 serviced or what have you, but that that should be clearly
22 stated and there shouldn't just be one standard.

23 DR. PATTERS: I could agree completely, but I
24 still see that as a consumer issue and not as a health and

1 safety issue.

2 DR. GREENSPAN: But that's what the question asks,
3 in a way. I mean, we're asking--I mean, the health and
4 safety issue is, will the handpiece perform? And if it
5 performs, how many times will it perform? In other words,
6 it has to be sterilizable, it has to be able to go through a
7 cycle, and if it doesn't go through a cycle, it's
8 disposable, but it still has to perform.

9 What the question, I think, is asking is, is it
10 sufficient that provided the handpiece can withstand a
11 certain number of cycles, should all handpieces have to have
12 a minimum number or would it be appropriate to be able to
13 label handpieces that can be used for different periods of
14 time, or different numbers of cycles, I beg your pardon.

15 DR. ROBERTSON: Yes. If, in fact, the
16 sterilization cycle is not the major variable in handpiece
17 failures, then--

18 DR. GREENSPAN: Well, even if you add a mechanical
19 failure, that having established that standard of what
20 constitutes the reprocessing, is that the handpiece should
21 then be labeled saying how many times it can be used and
22 then sterilized.

23 DR. ROBERTSON: I mean, I guess my preference
24 would be to have some minimum number of cycles through which

1 a handpiece would go without anything else being done and
2 not used, not dropped, not put in saliva, not any of those
3 things, just some minimum number, so that you knew that at
4 that, it would survive.

5 DR. GREENSPAN: But do we select the number?

6 DR. ROBERTSON: It would have nothing to do with a
7 number written on a handpiece because it would be unrelated
8 to the actual failure of the handpiece.

9 DR. GREENSPAN: You have a disposable handpiece
10 which is designed to be used once, and then you might buy a
11 handpiece which is stated that can be used 30 times, and
12 that--

13 DR. ROBERTSON: No, that can be sterilized 30
14 times.

15 DR. GREENSPAN: Well, yes. Once we've defined
16 what constitutes reprocessing--

17 DR. ROBERTSON: It might only last once, but it
18 could be sterilized 30 times.

19 DR. GREENSPAN: But we are wrangling with the
20 problems of dealing with sterilizing and reprocessing and
21 what the handpiece goes through, through its use. But
22 nevertheless, once that has been defined, can we then--is it
23 appropriate, then, for handpieces to be developed for use at
24 different times, and I think it was Ms. Johnson who said it

1 very nicely. Is it all right to produce a handpiece that
2 can be used 30 times as opposed to a handpiece that can be--
3 and costs \$50, as well as having a handpiece which costs
4 \$500 and which reprocesses--forgive the use of the term--but
5 can be used 600 times? Should we allow that flexibility?

6 Yes, but, I mean, that's the question that I think
7 is being asked here. That's the question you're asking.

8 DR. TYLEND: I don't think that's really the
9 question we are asking. We have in this guidance document
10 that we would like a handpiece to be--if a handpiece meets
11 ISO standards, that's acceptable to us. My perception is
12 that industry would like us to move more towards acceptance
13 of standards. It makes their life easier and it makes our
14 life easier. If we look at a standard and we feel that's a
15 set of minimum criteria and we are happy with that, then it
16 seemed to us industry would be happy to accept, then we'd
17 have to accept that. So this guidance is based upon the ISO
18 standard.

19 It also says somewhere in there that if there are
20 parts of the ISO standard that the handpiece does not meet,
21 the manufacturer should state that and give an explanation,
22 and if the explanation is reasonable, the ISO standard may
23 state that it should be able to be reprocessed 250 times.
24 If they're making one that can only withstand reprocessing

1 30 times and they say, we're going to sell it at a low price
2 and we're going to put that in the labeling, that's
3 certainly acceptable.

4 A separate issue is whether we should require them
5 to label handpieces, to place in the labeling the number
6 that the manufacturer will stand behind.

7 DR. ROBERTSON: The number of what?

8 DR. TYLEND: Reprocessing cycles with the
9 handpiece still being useful after each reprocessing cycle.

10 DR. ROBERTSON: Right. That was my point.

11 DR. TYLEND: That's a separate issue from a
12 minimum.

13 DR. ROBERTSON: Yes.

14 DR. TYLEND: What I'm hearing is it's felt that
15 that is more a consumer issue and not an FDA issue, if I
16 interpret the panel's comments correctly. And secondly, if
17 we do feel that we need that information, we have to better
18 define the method, the testing method that should be used by
19 all manufacturers. The number has to derive from the data
20 that is collected, using the same method by all
21 manufacturers.

22 DR. MENDELSON: Excuse me. Maybe I'm not
23 interpreting these comments properly. This guidance
24 document does not ask for any minimum number of cycles, any

1 arbitrary number. Based on this guidance document, a
2 company can market a handpiece that can be autoclaved no
3 times or ten times or 1,000 times. It's up to the company.

4 DR. ROBERTSON: So how is the question that you're
5 asking related to what you just said?

6 DR. MENDELSON: I'd like to know your opinion on
7 that.

8 DR. PATTERS: My opinion is this is like buying
9 tires. There are a lot of different tires that will fit
10 your car and some of them will cost \$90 and some of them
11 will cost \$30, but there's a number on the side as to how
12 long it's likely to last under--I assume that all
13 manufacturers derive the number from the same test, and
14 that's important for me to know as a consumer, but I don't
15 see what this has to do with FDA. Pardon me, but I don't.

16 DR. ROBERTSON: With the exception that you would
17 have difficulty from a health perspective with a handpiece
18 that could not be sterilized.

19 DR. PATTERS: Oh, absolutely.

20 DR. ROBERTSON: So maybe the only answer we can
21 give is that we would have difficulty with a handpiece that
22 could not be sterilized.

23 DR. PATTERS: Yes, absolutely. The other comment
24 I would make is that I appreciate, was it Ms. Johnson from

1 Midwest saying that autoclaving was not a significant factor
2 in handpiece failure, but I'm not sure that there is data
3 that establishes that. If you ask any practicing dentist
4 who began to autoclave handpieces who didn't used to, they
5 will tell you that handpieces have a shorter life, yet they
6 claim to do the same maintenance. So I think it is a
7 factor, whether it is--

8 DR. ROBERTSON: Ms. Johnson, we have said nice
9 things about you. Now we have a chance to be mean to you.

10 DR. PATTERS: Anyway, it is my opinion that it is
11 a factor. Whether it is a major factor, I don't know.

12 MS. JOHNSON: Excuse me. I want to clarify,
13 because you had mentioned the same thing. I said that it
14 was not a safety factor but it was clearly a life factor.
15 What sterilization has done is that it has accelerated how
16 quickly a handpiece fails but it has not changed the failure
17 from basically a safe failure mode to an unsafe failure
18 mode. So yes, it's had impact. It's economic, not safety
19 related.

20 DR. ROBERTSON: That was my point.

21 DR. PATTERS: While she's here, could I ask
22 another question?

23 DR. ROBERTSON: Yes.

24 DR. PATTERS: If it turned out that to sterilize

1 handpieces we had to use 134 degrees instead of 121, do you
2 believe, based upon your knowledge of the engineering and
3 mechanics of handpieces, that that would even have a greater
4 impact on the life of a handpiece?

5 MS. JOHNSON: I believe most handpiece
6 manufacturers and sterilizer manufacturers are recommending
7 134 and have been over the years, so any testing we have
8 done has been at those degrees. And really, I think most
9 doctors would be operating at that temperature. It's 275
10 degrees Fahrenheit, which is pretty standard.

11 DR. PATTERS: Gosh, I hope you're right.

12 MS. JOHNSON: I think I am.

13 DR. KUEHNE: If I could just follow up on that,
14 there was some evidence of Dr. Miller's that suggested that
15 maybe even 134 would not be satisfactory in all conditions
16 and maybe we ought to even be thinking in the future about a
17 higher temperature. There would be, if you went from 134 to
18 137 degrees, there probably would be manufacturers that
19 would be not very happy with that temperature.

20 DR. ROBERTSON: It was suggested that should that
21 be the case, there would probably be some redesign.

22 DR. KUEHNE: Right.

23 DR. ROBERTSON: To make sure that the temperature-
24 -I mean, 134 degrees is sufficient. It just needs to get

1 there.

2 DR. KUEHNE: Right.

3 DR. ROBERTSON: To make sure that the temperature
4 in all areas, in fact, reached that point. I'm sure, as was
5 suggested somewhere, there would be some redesigning before
6 there would be a major increase.

7 DR. KUEHNE: A hundred-and-thirty-four has been
8 the temperature so far and that's what people have been
9 designing to.

10 DR. GREENSPAN: And that's what the manufacturers
11 will produce data on to show the effectiveness of the
12 handpiece.

13 DR. ROBERTSON: Is there a potential hazard posed
14 to the patients and staff by the debris and microorganisms--
15 luckily, we have a microbiologist with us--by the debris and
16 microorganisms blown from the turbine of a high-speed
17 handpiece through the exhaust line? Is this a concern that
18 should be addressed in the future? This is clearly a
19 question for Dr. O'Neill.

20 DR. ROSAN: The answer is yes.

21 DR. O'NEILL: Yes, I agree with Dr. Rosan.

22 DR. PATTERS: I would say no.

23 DR. ROBERTSON: Oh, good, good. And can you say
24 why?

1 DR. PATTERS: Yes. The word "potential" is a big
2 word, but I guess I'll have to ask, where are the bodies?
3 Stuff has been coming out of handpieces for a very long
4 time. Everybody in the operatory is today using universal
5 precautions. There are a lot of other ways that they're
6 going to get contaminated besides what's coming out of the
7 back end of a handpiece. I don't think that there's strong
8 evidence that this is a significant problem, safety and
9 health problem, in the dental operatory. There are many
10 other problems that are far worse than what's coming out of
11 the back of a handpiece.

12 DR. GREENSPAN: And the problem is that I think
13 you have to consider that the work that's been done on
14 looking what can be collected from aerosols and the studies
15 that have been done on aerosolization, both trying to sort
16 of spin hepatitis B around, and I think a lot of people are
17 familiar with those studies, and there's very little data
18 showing that aerosolization from use of something like a
19 laser or from a high-speed handpiece on what you're trying
20 to collect actually is a true health hazard.

21 But unfortunately, you have here the word
22 "potential", and I think you can't possibly say there is no
23 potential hazard.

24 DR. PATTERS: No, I couldn't.

1 DR. GREENSPAN: It's a very difficult question. I
2 mean, is there a reasonable risk? I agree with Mark,
3 probably not. But I think if you're going to have that
4 question written in that way--

5 DR. PATTERS: I guess I read the next line, which
6 is, is this a concern? I was not that concerned, but maybe
7 others are. I have many worse things that I dream about at
8 night than what's coming out of the back of a handpiece.

9 DR. ROBERTSON: Dr. Miller?

10 DR. MILLER: Could I make a comment on that? I
11 think to fully understand that there is potential concern
12 here, you have to look at what the source of the microbe is.
13 The source of a microbe coming out of the back of a
14 handpiece is the air line, right? Am I understanding what
15 you're asking here? It's not generating aerosols from the
16 mouth but it's the air coming into the handpiece.

17 DR. PATTERS: It's the exhaust line.

18 DR. MILLER: Well, the air has to come from a
19 compressor first, flip the turbine around, and go out the
20 exhaust line.

21 DR. PATTERS: Right.

22 DR. MILLER: So the source of the microbe is in
23 the compressor, is that not correct?

24 DR. PATTERS: And anything sucked into the

1 turbine.

2 DR. MILLER: And anything that comes in from the
3 patient's mouth itself, okay.

4 DR. MENDELSON: In writing that question, I was
5 concerned about suck-back when the turbine decelerates,
6 which is, I understood, the biggest problem with infection
7 control in handpieces. Those organisms are in the turbine
8 and it's probably more likely that they're going to be blown
9 through the exhaust than expelled through leaks in the front
10 of the turbine.

11 DR. MILLER: So we have a combination of
12 organisms, then, inside the handpiece that comes from the
13 compressor as well as being retracted back into the turbine
14 chamber. We need tremendous amounts of research done on air
15 compressors, because I can guarantee you there will be
16 pseudomonas in there. You are taking unfiltered air and
17 compressing it, and of course there's moisture in air, and
18 then you're forming water in the bottom of these compressor
19 tanks. Bob knows this. This is just a common environmental
20 situation that we're dealing with here. So it's not just
21 the aerosolization of organisms but it's the environmental
22 organisms, to say nothing of the water lines.

23 DR. GREENSPAN: Yes.

24 DR. ROSAN: And what actually I'm thinking of is

1 the fact that these aerosols, if you look at what you get in
2 terms of dental personnel, hepatitis and these kinds of
3 things from patients, in other words, there's very little
4 evidence, as we know it, of the dentists transferring it,
5 but the dentists do get ill from patient contamination. One
6 assumes that this might be a mechanism that it occurs.

7 DR. PATTERS: I understand the concern about
8 aerosols, but there's a far greater aerosol produced into
9 the environment by the rotating bur and the water hitting
10 the bur to cool it than is ever coming out of the back of
11 the handpiece and that's coming out two inches from your
12 eyes.

13 DR. GREENSPAN: And that's what's been looked at.

14 DR. ROBERTSON: Lastly, are the recommendations
15 for sterilization validation in this guidance adequate? I
16 think so, but I don't know. Hopefully, people are
17 scampering to compete with Dr. Miller to do good research in
18 this area.

19 I actually think you got a disappointing level of
20 help from the panel, but I think you got a phenomenal level
21 of help from industry. I think their presentations were
22 superb and I think some of the issues that Dr. Miller
23 raised, which apply directly to this document, are also very
24 important.

1 It sounds to me like the kinds of help you need
2 and the kinds of advice you need needs to come from a group
3 who have particular expertise in the problems you want to
4 solve, and you need to put such a group together to help you
5 do that.

6 Is there anything else the panel can help you
7 with?

8 DR. MENDELSON: I can't think of anything right
9 now.

10 DR. ROBERTSON: Carolyn?

11 DR. TYLEND: No. I think the panel did a
12 wonderful job over these two days. They've been a long two
13 days. We're really pleased that we finished the "Bone
14 Filling and Augmentation Devices for Oral Use". I want to
15 thank everyone for all of their input and I wish you all a
16 safe trip home.

17 DR. ROBERTSON: I will entertain a motion for
18 adjournment.

19 DR. NORMAN: So moved.

20 DR. ROBERTSON: Second?

21 DR. PATTERS: Second.

22 DR. ROBERTSON: All in favor, say aye.

23 [Chorus of ayes.]

24 DR. ROBERTSON: Opposed?

1 [No response.]
2 DR. ROBERTSON: Adjourned.
3 [Whereupon, at 5:13 p.m., the meeting was
4 adjourned.]
5 - - -