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Other Bone Grafting Material for
Dental Bone Repair

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

MEETING OF THE
DENTAL PRODUCTS PANEL
OF THE MEDICAL DEVICES ADVISORY COMMITTEE

OPEN SESSION

Tuesday, August 8, 1995

2:09 p.m.

Marriott Hotel
Pooks Hill

Bethesda, Maryland

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P R O C E E D I N G S

[2:09 p.m.]

DR. TYLEND: Good afternoon. I would like to welcome everyone to today's open session of the Dental Products Panel. I'm Dr. Carolyn Tylanda, Executive Secretary of the panel.

If there's anyone in the audience who has not signed in, I would appreciate it if you would go to the registration some time during the meeting and sign the appropriate registration form. I'd also like to mention that while the hotel is able to provide some coffee for the panel members, unfortunately they weren't able to provide it for the audience, but there is a little restaurant down the hall called Allie's Place and they serve coffee. You'll be able to pick up a cup of coffee there.

Dr. Charles Bertolami, who chaired the last two panel meetings, is not here today. He has recently moved to the University of California at San Francisco, where he has accepted the position of dean of the dental school. He's very busy right now in his new position. I would like to thank Dr. Paul Robertson for graciously agreeing to serve as the chairperson for today's meeting. Dr. Bertolami will return to Chair future meetings of the panel.

I would now like to introduce the individuals who

1 are seated at the panel table. Beginning at my far left is
2 Mr. Tim Ulatowski, who is the Acting Director of the Pilot
3 Division in the Office of Device Evaluation, Center for
4 Devices and Radiological Health, at FDA. Next is Dr. Peggy
5 O'Neill, who is the Vice Dean Protem, Dental Branch,
6 University of Texas Health Science Center at Houston; Dr.
7 Mark Patters, Professor and Chairperson, Department of
8 Periodontology, College of Dentistry, University of
9 Tennessee; Dr. Burton Rosan, Professor, Department of
10 Microbiology, School of Dental Medicine, University of
11 Pennsylvania; Dr. Julianne Glowacki, Senior Investigator,
12 Department of Orthopedic Surgery, Brigham and Women's
13 Hospital, Boston. To my immediate left is Dr. Jean Frazier
14 from Philomath, Oregon, who is the consumer representative
15 to this panel.

16 On my right are Dr. Paul Robertson, Dean, School
17 of Dentistry, University of Washington; Dr. Manville
18 Duncanson, Professor and Chairperson, Department of Dental
19 Materials, College of Dentistry, University of Oklahoma; Dr.
20 Deborah Greenspan, Clinical Professor of Oral Medicine,
21 Department of Stomatology, School of Dentistry, University
22 of California at San Francisco; Dr. Willie Stephens,
23 Associate Surgeon, Division of Maxillofacial Surgery,
24 Brigham and Women's Hospital, Boston; Dr. Otis Bouwsma,

1 Senior Scientist, Health Care Division, Procter and Gamble
2 Company. Dr. Bouwsma is the industry representative to the
3 panel. Dr. James Drummond, Professor, Department of
4 Restorative Dentistry, College of Dentistry, University of
5 Illinois at Chicago; and Dr. Richard Norman, Professor,
6 Department of Restorative Dentistry, School of Dental
7 Medicine, Southern Illinois University.

8 Before we get into today's meeting, we have a task
9 to do, and that is to select the dates for next year's panel
10 meetings. We need to select four dates and I will need
11 input from Drs. O'Neill, Drummond, Rosan, Norman and
12 Stephens, all of whom will be voting members for 1995-96.
13 So if you will pull out your calendars, we can take a few
14 minutes and do that.

15 I will remind everyone that the next meeting of
16 the Dental Products Panel will be held on December 5th, 6th
17 and 7th of this year. As of right now, December 5th is
18 slated to be an overlap meeting between the Dental Products
19 Panel and the Dental Plaque Subcommittee.

20 I'm open to suggestion as to how we--which months
21 we select for these panel meetings. Everyone has meetings
22 they like to attend and we will try to work around that.
23 The IADR meeting is always around the 8th or the 14th or so
24 of March, so those dates, I know, we will need to avoid. We

1 could go February, May, August, December; February, June,
2 September, December.

3 Shall we start with February? Okay, February--
4 usually we pick Tuesday, Wednesday, Thursday. The 6th, 7th
5 and 8th of February? Call out if you have any problems with
6 those dates or if you're happy with those dates.

7 DR. ROSAN: I have to teach.

8 DR. TYLEND: Okay. How about 13th, 14th and
9 15th?

10 DR. ROSAN: I don't have my schedule. They don't
11 have it made yet. They don't have the dates on that yet,
12 but generally that whole month I lecture two times a week.

13 DR. TYLEND: Well, do you have a suggestion?
14 Would you like it in early March prior to the IADR meeting?

15 DR. ROSAN: That would be a little better.

16 DR. TYLEND: We could do the first week of March.
17 Dr. O'Neill, is that a good time for you, 5th, 6th and 7th
18 of March? I think that's immediately prior to the IADR
19 meeting.

20 DR. ROSAN: No. IADR is the 12th, 13th.

21 DR. TYLEND: Well, that's the week prior, but
22 that's okay with me if that's okay with all of you.

23 Dr. Drummond, do you like those dates?

24 DR. DRUMMOND: I prefer it earlier, but--

1 DR. TYLEND: Dr. Stephens, okay?

2 DR. STEPHENS: Yes.

3 DR. TYLEND: Okay, if Dr. Drummond is agreeable.
4 If not, we'll push it back into February and hope that Dr.
5 Rosan can come.

6 DR. ROSAN: Why don't we try--the end of February
7 should be all right. That should work out.

8 DR. TYLEND: Okay. That would be February 27th,
9 28th and 29th. Is everyone happy with those dates? Okay,
10 February 27th through the 29th, all right, and as always we
11 set aside three days. We won't know until we get closer to
12 the meeting date what items we have on the agenda, if any,
13 and if there's nothing to be discussed, then we will not
14 have the meeting. These are tentative dates so industry can
15 target their submissions and know when the next meeting will
16 be held.

17 We can have one in May if you like, May or June.
18 Anyone have any preference?

19 DR. O'NEILL: Early May.

20 DR. TYLEND: Early May, okay. How about 7, 8 and
21 9? Hearing no complaints, we'll put down tentatively the
22 7th through the 9th of May. That brings us to August, and
23 if August is better than September, we can go with August,
24 early in August. How about 6th, 7th and 8th, August 6th

1 through the 8th? Hearing no complaints--

2 DR. O'NEILL: I'm not going to be able to do it in
3 August at all.

4 DR. TYLEND: Well, how about early September?

5 DR. STEPHENS: No.

6 DR. TYLEND: Is September not a possibility for
7 you, Dr. Stephens, or you're just not sure?

8 DR. STEPHENS: Early.

9 DR. TYLEND: Early? Well, we could do it the
10 first week. I don't know when Labor Day is, but--

11 DR. ROSAN: The 2nd.

12 DR. TYLEND: Okay. How about the 3rd, 4th, 5th?
13 Is that good?

14 Dr. Frazier, I didn't mean to forget about you.

15 DR. FRAZIER: Do we travel on Labor Day?

16 DR. TYLEND: Is Labor Day the 2nd?

17 DR. ROSAN: Yes.

18 DR. TYLEND: Okay, then I'm sorry. I thought you
19 said the second week--I mean the second day. Would you like
20 it 4th, 5th and 6th, or would you like to go to the second
21 week? And Dr. Bouwsma should be giving input here, too.

22 DR. BOUWSMA: Any time is fine.

23 DR. TYLEND: Okay. Dr. Rosan and Dr. O'Neill,
24 what would you like?

1 DR. O'NEILL: I don't have any problem with either
2 of those.

3 DR. TYLEND: Okay. Dr. Frazier, do you have any-
4 -

5 DR. FRAZIER: No.

6 DR. TYLEND: So do you want to go Wednesday,
7 Thursday, Friday, the 4th through the 6th?

8 DR. STEPHENS: Can we go the second week?

9 DR. TYLEND: Second week? Certainly. How about
10 10, 11 and 12th? Do you like Tuesday, Wednesday, Thursday?

11 DR. STEPHENS: Yes.

12 DR. TYLEND: Okay. We'll go September 10 through
13 the 12th, and then into December. Just tell me what week
14 you like, first, second or third week. How about the second
15 week, the 10th through the 12th of December?

16 All right, let me just go through those again;
17 February 27th through the 29th, May 7 through 9, September
18 10 through 12, December 10 through 12.

19 DR. ROSAN: Any idea when the Jewish holidays fall
20 in September?

21 DR. ROBERTSON: What?

22 DR. ROSAN: Do the Jewish holidays fall on the
23 10th of September in '95? I don't have that.

24 DR. ROBERTSON: '96, you mean.

1 DR. TYLEND: Well, if it becomes a problem, if
2 you could tell us early, Dr. Rosan, we can make some phone
3 calls and adjust accordingly. All right.

4 Now, I will read a letter from Dr. D. Bruce
5 Burlington, who is the Director, Center for Devices and
6 Radiological Health at FDA. This is signed and dated August
7 7, 1995.

8 "Appointment to Temporary Voting Status: Pursuant
9 to the authority granted under the Medical Devices Advisory
10 Committee, dated October 27, 1990, and amended April 20,
11 1995, I appoint the following people as voting members of
12 the Dental Products Panel for the duration of this meeting
13 on August 8th and 9th, 1995: Paul B. Robertson, D.D.S.;
14 Julianne Glowacki, Ph.D. Dr. Paul Robertson will serve as
15 chairperson for this meeting."

16 For the record, these people are special
17 government employees and are either a consultant to this
18 panel or a consultant or voting member of another panel
19 under the Medical Devices Advisory Committee. They have
20 undergone the customary conflict of interest review and they
21 have reviewed the material to be considered at this meeting.
22 The voting members of today's panel are Drs. Drummond,
23 Glowacki, Norman, O'Neill, Robertson, Rosan, and Stephens.
24 Dr. Robertson, as chairperson, will cast a vote only in the

1 case of a tie.

2 I will now read a conflict of interest statement
3 for the record. The following announcement addresses
4 conflict of interest issues associated with this meeting and
5 is made part of the record to preclude even the appearance
6 of an impropriety. To determine if any conflict existed,
7 the agency reviewed the submitted agenda and all financial
8 interests reported by the committee participants. The
9 conflict of interest statutes prohibit special government
10 employees from participating in matters that could affect
11 their or their employers' financial interests. However, the
12 agency may determine that participation of certain
13 consultants and members, the need for whose services
14 outweighs the potential conflict of interest involved, is in
15 the best interests of government.

16 We would like to note for the record that the
17 agency took into consideration other matters regarding Drs.
18 Peggy O'Neill and Julianne Glowacki. Dr. O'Neill reported
19 that her school of dentistry has received aid from a
20 manufacturer of dental filling material. Dr. Glowacki
21 reported that a colleague at her department has a consulting
22 arrangement with the manufacturer of bone-filling and
23 augmentation materials. Since these matters are not
24 directly related to matters before the committee, the agency

1 has determined that Drs. O'Neill and Glowacki may
2 participate fully in committee deliberations.

3 We would like to note for the record that Dr.
4 Chris Miller, who is a guest speaker tomorrow, August 9th,
5 has acknowledged interest in and professional relationships
6 with several firms that manufacture dental handpieces.
7 These interests are in the form of research contracts. In
8 the event that the discussions involve any other products or
9 firms not already on the agenda for which an FDA participant
10 has a financial interest, the participant should exclude
11 themselves from such involvement, and their exclusion will
12 be noted for the record.

13 With respect to all participants, we ask, in the
14 interest of fairness, that all persons making statements or
15 presentations disclose any current or previous financial
16 involvement with any firm whose products they may wish to
17 comment upon.

18 There are three issues on the agenda for this two-
19 day meeting. Today, the panel will discuss the
20 classification of bone-filling and augmentation materials,
21 and will focus primarily on consolidating the definitions
22 for these devices that were developed at the June and
23 October 1994 meetings. We will end today no later than 6:00
24 p.m. and, if necessary, we will continue the discussion of

1 this issue tomorrow morning.

2 Tomorrow, the panel will address the issues of
3 dental device ingredient labeling and the guidance document
4 for dental handpieces. These latter two topics will not be
5 discussed today, regardless of what time the topic of the
6 bone-filling and augmentation devices is concluded.

7 Before I turn the meeting over to Dr. Robertson, I
8 would like to take a few minutes to go through with you what
9 you have in front of you. Some material was passed out
10 today and I know you didn't have time to look at it and I
11 would you to realize what is sitting on the table in front
12 of you.

13 You should all have received this green booklet
14 that was passed out to all members of the audience and you
15 have in your folder from early this morning. In this
16 booklet, you have the agenda for today's meeting, the
17 roster, and some materials that you will need for the
18 discussion of each of the topics.

19 For bone-filling and augmentation devices for oral
20 use, which is the topic for today, you have a background
21 statement on the topic, and you also have the bone grid that
22 you used at the October 1994 meeting. If you take a look at
23 it, you'll see that it has been completed with the
24 recommendations for each of the devices, the recommendations

1 that you made at that meeting. You also have some
2 consolidated definitions that you will be considering today.

3 The material in the green booklet contains a few
4 typographical errors, and in an effort to be accurate these
5 were corrected and we printed out a new version which you
6 have in that stack of material in front of you, and that's
7 what we will use today. We have a few other things not
8 related to today's topic. They're related to the handpiece
9 material and the guidance document, so we won't mention
10 those today.

11 Now, in addition, on the table you have some other
12 materials. You have a couple of sheets that show examples
13 of device definitions from the Code of Federal Regulations.
14 We wanted to give you an idea of how device definitions are
15 stated in the Federal Register so you can compare this with
16 the way the device definitions for the bone-filling and
17 augmentation materials were developed.

18 You also have a two-page time line that will help
19 you understand where the process of classification that
20 begins here will lead. You also have copies of the
21 completed worksheets from the October 1994 meeting as
22 reference material in case you should wish to check up on--
23 refresh your memory on what was discussed at that meeting
24 and what the final decisions were, the final

1 recommendations.

2 You have some material from W.L. Gore and
3 Associates, Incorporated, on the bone-filling definition
4 issue, and you have some materials from Bioplant,
5 Incorporated, another manufacturer of bone-filling and
6 augmentation devices. There's some other material there
7 that relates to tomorrow's topics, and so I won't go through
8 those today. You might take a few minutes during the break
9 to have a little closer look at the materials that were
10 provided to you for this meeting.

11 With that, I'll turn the meeting over to Dr.
12 Robertson.

13 DR. ROBERTSON: Thank you, and I welcome everybody
14 here today on this cool Washington day. I noted earlier
15 this morning that in my absence, during my retirement,
16 actually, the Public Health Service saw fit to reward Dr.
17 Tylanda with the rank of Captain, and I was actually
18 thrilled to hear that because I think Dr. Tylanda has
19 brought great credit to the FDA and to the Public Health
20 Service and to the profession of dentistry. I convey my
21 sincere congratulations.

22 DR. TYLEND: Thank you.

23 DR. ROBERTSON: Our task today, as Carolyn noted,
24 was to finalize our recommendations for bone-filling and

1 augmentation devices, but that's a commencement to begin a
2 series of actions once we have reached consensus on those
3 recommendations, and to give us some information about that
4 process, I recognize Tim Ulatowski.

5 MR. ULATOWSKI: Thank you, Dr. Robertson. Before
6 we begin deliberations today, I'd like to make a brief
7 statement for the record regarding the classification of
8 devices and the panel's role in the process. This panel has
9 been involved with a number of these actions in the past few
10 years and from the questions we've received as a result of
11 these deliberations, I believe it would be helpful to
12 clarify the process to all concerned.

13 The classification process is defined by federal
14 law and regulations. Section 513 of the Federal Food, Drug
15 and Cosmetic Act provides a legal foundation for the
16 classification of medical devices. In turn, FDA regulations
17 under Part 860 provide the means to implement the statute.

18 The FD&C Act tasked FDA to classify all devices on
19 the market prior to the May 1976 enactment of the medical
20 device amendments to the Act. In order to assist FDA, the
21 Act provided for classification panels which would provide a
22 recommendation to FDA on the class into which a type of
23 device should be placed.

24 As with the proceedings today, the panel has the

1 opportunity to review the scientific evidence on a medical
2 device subject to classification. Upon completion of the
3 panel's review of the evidence on the device referred to it,
4 the panel provides FDA its formal recommendation. The
5 recommendation includes a summary of the reasons for
6 classification, a summary of the data supporting the
7 assigned class, and an identification of risks to health.
8 For devices recommended for Class I, the panel also a
9 provides a recommendation on exemptions from pre-market
10 notification, good manufacturing practices, and records and
11 reports.

12 Now, I emphasize the word "recommendation" because
13 many believe the panel's vote is binding on the agency. It
14 is not. The panel's review and recommendation to FDA is
15 only one step of the due process afforded to the public
16 during official rulemaking. After FDA receives the
17 recommendation, it considers the recommendation and the data
18 upon which the recommendation is based, and renders its own
19 tentative decision based upon this public record. FDA may
20 agree or disagree with the panel.

21 FDA publishes a notice of the proposed class in
22 the Federal Register and the reasons for the proposed class.
23 This notice provides the opportunity for any interested
24 parties to comment on any aspect of the classification of

1 the subject device. That includes the general public,
2 industry, members of the clinical community, virtually
3 anyone else.

4 After the period stated in the notice to allow for
5 any comments, FDA assembles the comments and formulates
6 changes or amendments to the classification or other
7 appropriate responses. After full consideration of all
8 information related to the classification, including the
9 public comment, FDA classifies the device by announcing the
10 final classification in the Federal Register. In the
11 Federal Register, a response to each and every comment is
12 provided.

13 I want to reemphasize the fact that the panel's
14 recommendation is very important to FDA, but it is only one
15 step in the process. I also want to assure the public and
16 others that all concerns brought to the attention of the
17 agency, all concerns, at any time during the process will be
18 addressed during the course of the classification.

19 As a last note, let me say that while the
20 classification process is open, or at any time, a petition,
21 technically called a citizen's petition, may be submitted to
22 the FDA asking that we consider a particular classification
23 or reclassification for any device that is in the
24 marketplace. Details about the procedure and the

1 information that is necessary to support such a petition is
2 available through the Division of Small Manufacturers,
3 Assistance, and CDRH.

4 Thank you.

5 DR. ROBERTSON: Thank you, Tim.

6 Are there any questions from the panel?

7 [No response.]

8 DR. ROBERTSON: Good. Thank you again.

9 We'll move now to the open public hearing on bone-
10 filling and augmentation devices, and to follow up on what
11 Tim says, we're here to facilitate as much information to
12 FDA as possible so they have the whole story.

13 We have two speakers listed who will present some
14 information to us, but if there are others who wish to
15 address the panel, we'll give you an opportunity after the
16 two speakers. I'll remind the speakers that I'm older since
17 I last chaired this panel, but no less grumpy, and so I'd
18 ask you to stay within the time limit so we can get our
19 business conducted.

20 The first speaker is Ms. Jackie Kalbach from W.L.
21 Gore. Welcome, Jackie.

22 MS. KALBACH: Thank you. Don't worry. This isn't
23 the speech. Here are copies.

24 Dr. Robertson, members of the Dental Products

1 Advisory Panel, and Dr. Tylanda, my name is Jacqueline
2 Kalbach and I am a regulatory affairs associate for W.L.
3 Gore and Associates. First, I would like to thank you for
4 this opportunity to speak on behalf of Gore and its
5 products. As you are aware, Gore manufactures both non-
6 resorbable and resorbable barrier membranes, and these
7 devices fall within the initial classifications that you're
8 recommending for dental bone-filling and augmentation
9 devices.

10 Gore recognizes that the panel has had a difficult
11 task in formulating a workable recommendation because of the
12 broad spectrum of devices encompassed by the term "dental
13 bone-filling and augmentation devices." We understand that
14 you have been asked to streamline the table that you used at
15 the October 1994 meeting to recommend initial
16 classifications for these devices. We recently provided FDA
17 with a document that we hope you were able to review prior
18 to this panel meeting. The document set out points that
19 Gore believes are important for the panel to consider in
20 developing its recommendations concerning the classification
21 of dental bone-filling and augmentation devices.

22 Rather than repeat the information that has been
23 provided to you in writing, Gore would like to propose this
24 matrix for non-resorbable and resorbable barrier membranes,

1 and there's an overhead in the front of the room. We
2 believe that this matrix accurately reflects products
3 currently in use, the manner in which they are used, and
4 correctly classifies them according to their safety and
5 efficacy. We would like to emphasize that our comments and
6 revisions pertain only to the section of the table
7 concerning barrier membranes.

8 You'll notice on the table that we've asked the
9 panel--we have two types of membranes, the non-resorbable
10 and resorbable. However, we believe that the two indication
11 statements that are supported by valid scientific evidence
12 are the filling of periodontal defects, and this could
13 include periapical defects and defects associated with
14 apicoectomy, and also localized osseous defects with or
15 without endosseous implants; for example, extraction,
16 dehiscence or fenestration defects, and localized ridge
17 augmentation.

18 Gore believes that there is ample valid scientific
19 evidence to support these indications in a Class II
20 designation. Contrary to specific indications on the table
21 used by the panel at the October 1994 meeting, barrier
22 membranes are not, to our knowledge, used for genioplasty,
23 filling of osteotomy sites, LeFort I, II and III procedures,
24 or for correction of congenital acquired temporomandibular

1 joint abnormalities.

2 In fact, the instructions for use that accompany
3 GORE-TEX Regenerative Material state clearly in a
4 contraindication statement that the material is, quote, "not
5 intended for use in load-bearing, articulating situations
6 such as temporal mandibular joint reconstruction."

7 Perhaps most importantly, our proposed indications
8 and recommended classifications echo the recommendations
9 made by you at the December 1993 panel meeting. Your
10 recommendations followed your review of documentation from
11 manufacturers and hearing testimony from many manufacturers
12 and clinical and research experts. They all recommended
13 Class II for these barrier membranes based on the valid
14 scientific evidence and the opinion that non-resorbable and
15 resorbable barrier membranes do not pose a substantial risk
16 to patients. At the conclusion of the December 1993
17 meeting, you voted in favor of a bone defect indication for
18 non-resorbable barrier membranes that is broader and more
19 appropriate to actual conditions of use than the
20 recommendations made by you in October 1994.

21 Despite the December 1993 panel recommendations,
22 the October 1994 meeting was focused on a totally new
23 classification matrix developed with no opportunity for
24 public input. Additionally, the matrix that was used to

1 focus and facilitate your discussions at the October 1994
2 meeting was incorrectly based on a perceived need of the
3 panel to deal with the issue of a predicate device.

4 We would like to emphasize that at the December
5 1993 meeting, FDA staff told the panel not to be concerned
6 about a predicate device. I quote, ". . . You are dealing
7 with a predicate device here. You don't have to worry about
8 these membranes being equivalent to a predicate device. If
9 you're classifying, you're saying they are the predicate
10 device."

11 Since Gore submitted its written documentation to
12 the panel in 1993, there have been additional supportive
13 scientific publications and there was an international
14 symposium concerning evidence-based outcomes with
15 regenerative therapy. The international symposium was the
16 result of an independent process that involved both the
17 research and clinical communities. The goal of these
18 experts was to perform a large-scale, independent, evidence-
19 based evaluation of the literature that has been generated
20 over the last decade and that supported the appropriate and
21 predictable use of barrier membranes.

22 Separate task forces were formed to focus on
23 predictability and periodontal defects and bone defects
24 associated with and without endosseous implants. The work

1 by these task forces was parallel to the efforts of the
2 panel. The task forces reviewed the scientific literature
3 to determine outcomes supported by the evidence.
4 Essentially, these clinical and research experts determined
5 with a reasonable assurance where barrier membranes can be
6 used safely and effectively. The conclusions reached by
7 these clinical and research experts who participated in the
8 symposium also support the matrix proposed by Gore.

9 Gore believes that based on the published
10 literature and the independent, evidence-based outcomes
11 process, there is ample valid scientific evidence to support
12 a Class II designation for non-resorbable and resorbable
13 barrier membranes for the indications listed in the matrix
14 presented today. The devices are neither life-sustaining
15 nor life-supporting. Their use is not of substantial
16 importance in preventing impairment of human health, and
17 they do not present potential unreasonable risk of illness
18 or injury to patients. The special controls applicable to
19 Class II devices will provide a reasonable assurance that
20 non-resorbable and resorbable barrier membranes are safe and
21 effective.

22 Gore appreciates your consideration, and thank
23 you.

24 DR. ROBERTSON: Thank you very much, Jackie.

1 Are there questions from the panel for Jackie?

2 [No response.]

3 MS. KALBACH: Thank you, Dr. Robertson.

4 DR. GLOWACKI: Dr. Robertson?

5 DR. ROBERTSON: Yes?

6 Jackie?

7 DR. GLOWACKI: Ms. Kalbach, I found that a very
8 useful presentation. One of the concerns as a panelist in
9 voting for a recommendation for Class II is to be able to
10 answer the follow-up question on what the special controls
11 are, and I appreciate the precision of the language in the
12 top right-hand column of your table, but wondered if you
13 could be even more specific with regard to the size of the
14 defects, what you mean by "localized" with regard to the
15 defects, and ridge augmentation.

16 MS. KALBACH: I'm not a scientist or a clinician,
17 but I believe that Dr. Mellonig, who's here on behalf of the
18 AAP--perhaps in his presentation, he would be better
19 equipped to answer that because he has been involved in this
20 symposium and has reviewed the literature and would have a
21 better idea of, you know, the size of the defects where
22 these membranes are used.

23 DR. ROBERTSON: Thank you. We'll save the
24 question for Dr. Mellonig.

1 MS. KALBACH: Okay.

2 DR. ROBERTSON: Dr. Greenspan?

3 DR. GREENSPAN: I wonder if I could ask the
4 response of the symposium and where it was held and what
5 information arising during that symposium has been
6 published.

7 MS. KALBACH: It has been published.

8 DR. GREENSPAN: Oh, I asked the right question.

9 MS. KALBACH: Here are copies of the journal in
10 which the symposium results were published. If you'd like
11 more copies, I can get them to the panel. The international
12 symposium, I believe, was held last August in Toronto.

13 DR. GREENSPAN: And sponsored by?

14 MS. KALBACH: It was sponsored by a number of
15 manufacturers and I believe--I wasn't involved with the
16 process, but I believe Dr. Mellonig, once again, can answer
17 more of those questions for you.

18 DR. ROBERTSON: Other questions? Other questions
19 for Ms. Kalbach?

20 [No response.]

21 DR. ROBERTSON: Thank you.

22 MS. KALBACH: Thank you.

23 DR. ROBERTSON: Dr. Jim Mellonig from the American
24 Academy of Periodontology, who has a box of slides.

1 DR. MELLONIG: Dr. Robertson and members of the
2 panel, it's a pleasure for me to be here today to address
3 you. My name is Jim Mellonig. I am a Professor and
4 Director of the Advanced Education Program at the University
5 of Texas Health Science Center at San Antonio, but I am here
6 today as president-elect representing the American Academy
7 of Periodontology. I have no interest in any of the
8 products, financial or otherwise, which I will discuss.

9 It is the opinion, again, of the American Academy
10 of Periodontology that the products used for guided tissue
11 regeneration are safe and effective. I would like to go
12 over some of the basic biological principles relatively
13 briefly and then show you some cases to help everybody
14 understand exactly what we mean about the efficacy and
15 safety record of these products.

16 As most of you know, guided tissue regeneration
17 involves the placement of a physical barrier, as you can see
18 here, separating the gingival epithelium or gingival
19 connective tissue from the tooth surface, thereby creating a
20 space allowing cells to emanate both from the periodontal
21 ligament cells and from the bone to migrate into this area
22 and to repopulate that area. Hopefully, then, we will get
23 back new bone, new cementum, and a new periodontal ligament.

24 Some of the critical features, then, that the

1 barrier membrane does is that, one, it provides a space. So
2 space creation is extremely important. And, number two, it
3 provides a certain stability for the underlying blood clot
4 so that it can undergo reorganization, and therefore new
5 connective tissue attachment to the tooth surface can occur.

6 These are examples of the some of the types of
7 defects that are treated routinely in periodontal therapy
8 which no longer than ten years ago were felt to be
9 impossible to treat. And as you can see, this is a Class II
10 forcation defect in a molar tooth in which bone has been
11 lost deep into the forcation, so this is a Class II type of
12 forcation.

13 Because some of these defects, then, are
14 relatively large and non-space-making, augmentation
15 materials--and this happens to be decalcified freeze-dried
16 bonalograft--is placed into the defect, and that's simply to
17 hold the space. Otherwise, the membrane, because of its
18 stiffness and the largeness of the defect, might collapse,
19 actually, into the defect. The membrane is therefore
20 placed, and subsequently a year later, after the membrane
21 has been removed, you can see that this defect, then, is
22 entirely filled with new bone formation.

23 Other defects such as interproximal defects which
24 you see here may or may not require supplemental type of

1 materials. In this particular case, the defect is of such a
2 dimension that the membrane can be easily placed without
3 additional supportive type of materials. When the membrane
4 is removed, we have this rather gelatinous connective type
5 of tissue type of attachment. The membrane is removed at
6 about six weeks, and subsequently then that area can be
7 reentered and you can see new bone formation into that
8 defect.

9 This is another indication where both
10 technologies. In the past, if we were to place a bone graft
11 material into that area, micro movement of the flap across
12 these particular particles would have caused this material,
13 then--this is bone graft material--to go into fibrogenesis
14 rather than into osteogenesis, and by placing a membrane
15 over the top, then, a number of features are accomplished,
16 number one of which we have created stabilization over the
17 bone graft material. The bone graft material has provided
18 space.

19 Then we have the ability to block the epithelium,
20 block the overlying competition with connective tissue. As
21 you can see, when reentered with this particular type of
22 defect--this dehiscence type of defect, that is--new bone
23 formation has occurred over that. The development, then, of
24 a reinforced membrane has allowed the necessary stiffness in

1 non-space-making defects, so that this membrane then can be
2 applied without the use of additional supportive material.

3 Again, a dehiscence type of defect. You can see
4 calculus on the root surface. The calculus has been root-
5 planed off. The membrane is implanted and shaped so that it
6 maintains the space underneath the membrane; again, the
7 suturing to completely cover that membrane, and again the
8 reentry over in here. This is approximately six weeks
9 later--a little bit longer than that, rather, and a new
10 relatively dense type of tissue has formed conforming to the
11 shape of the membrane, as you can see.

12 Another type of membrane, bio-resorbable type of
13 membrane, also is used extensively. Again, you can see a
14 Class II forcation type of defect. Again, this one is
15 without filling materials because of the judgment of the
16 clinician again. It is sutured into place. Again, this is
17 a reentry. This is a one-year type of reentry, looking and
18 seeing a considerable amount of fill, and this time with a
19 hard tissue-like substance into the forcation.

20 Again, here is a preoperative probing depth and a
21 post-operative probing depth, indicating that significant
22 fill of this Class II forcation defect has occurred. And I
23 want to emphasize again to the panel that this technology
24 has really provided us in the field with really a valuable

1 method to treat these Class II forcation defects. And as I
2 said before, not more than ten years ago a lot of these
3 teeth would have been extracted and today we can maintain
4 them in health, comfort, function and aesthetics.

5 Out of that consensus development conference based
6 on the literature and outcomes assessment, various decision
7 trees were formulated based on patient factors and a number
8 of other factors that we will go into relatively briefly.
9 So if all these factors could be controlled--for example,
10 behavioral factors or smoking or susceptibility to stress,
11 compliance--the decision is made by the clinician either to
12 treat with guided tissue regeneration or the decision is not
13 made to treat. If they are felt to be controllable, yes,
14 then the decision is to go ahead and treat, and based on the
15 defect--again, based on the number of walls and the size of
16 the defects, and this happens to be just with inter-bony
17 type of defects--then a number of treatments can be done--
18 the membrane alone; a bone graft material such as the
19 calcified freeze-dried bonalograft, plus guided tissue
20 regeneration; or the bone graft material alone.

21 And, again, there are a number of factors that go
22 into those decisionmaking trees--surgical considerations, of
23 course, or plague control and infection control. And,
24 again, in surgery the same number of factors occur, and the

1 incision, again, and the root debridement, and then the
2 choice of materials that one does and how one goes ahead and
3 places that, and again post-operative treatment. Again, the
4 purpose of showing you that was that a lot of work has
5 already gone into that for the

6 clinicians in how to properly use these particular
7 types of materials.

8 This is a fenestration type of defect and another
9 type of defect in which the membrane technology has also
10 been used and guided tissue type regeneration. Again, you
11 can see the membrane over in here is placed over the top of
12 that, and I'm going to have to go back because I notice I
13 put this slide out of place. But over in here, you can see
14 the fill of the dehiscence type defect that has occurred
15 once that membrane has been removed.

16 This is another type of defect which I think
17 exemplifies what we mean by ridge augmentation. This
18 particular defect could be caused by a number of different
19 problems; for example, a large periapical area that maybe
20 the tooth happened to be extracted, or multiple types of
21 tooth extraction, or implants that were failing, that are
22 fractured, which will leave relatively extensive type of
23 ridge deformities.

24 This type of deformity, you can see here, is

1 actually approximately maybe 20 millimeters or so, 15 to 20
2 millimeters; again, maybe 15 to 20 millimeters in depth, so
3 it's a relatively extensive type of defect. And I think you
4 can see again here it has been shown to be restored with
5 decalcified--this is freeze-dried bonalograft--excuse me--in
6 here. A membrane is placed. Here is, again, a picture of
7 that defect prior to the placement of the graft material
8 over the top.

9 Again, a membrane is in place, and then once that
10 membrane is removed, again here we see a relatively dense
11 tissue. This is not particularly bone, but if this was
12 covered up, then, with the soft tissue and we allow that to
13 mature for approximately six to eight months and take a
14 biopsy of that, we can see new bone formation occurring
15 around the particles over in here of the freeze-dried
16 bonalograft, and that's relatively a dense cortical type of
17 bone.

18 Again, here is this ridge. It can be left alone.
19 It could have implants, but it can be restored for a
20 prosthesis, such as the removal of a partial denture. In
21 this particular case, the clinician decided to place
22 implants into that newly restored ridge.

23 So, again, there are a number of patient factors
24 again that go into the decisionmaking tree whether to

1 restore ridges or to restore defects associated with implant
2 placement; again, the same types of conditions and the
3 clinician makes the decision, yes, that these conditions are
4 controllable or, no, they're not controllable. If no, then
5 no treatment or guided tissue regeneration is done. If, in
6 fact, they are, the decision tree goes into the type of
7 defect anatomy.

8 If the defect is extremely small or a non-space-
9 making defect or space-making defect--in other words, the
10 membrane is not going to collapse into the defect, the
11 membrane has enough stiffness of itself--then the membrane
12 alone can be used. If, in fact, the defect is of such a
13 dimension, sometimes augmentation materials, such as bone
14 graft materials, are needed, then, to help hold the space.
15 And pre-surgical conditions are always important, such as
16 infection control and your prosthetic plan and your plaque
17 control type of procedure. And then the surgical procedure,
18 again, must be done with precision in order for this
19 particular treatment to be effective, and again we have the
20 various post-operative type of conditions.

21 So, again, in closing, I'd like to emphasize again
22 that it is the opinion of the American Academy of
23 Periodontology that these particular materials, both
24 resorbable and non-resorbable, are effective for a wide

1 variety of intraoral type of osseous type of defects, some
2 of which I have presented to you today. I want to thank you
3 again for your time and your consideration.

4 DR. ROBERTSON: Dr. Glowacki?

5 DR. GLOWACKI: Thank you very much, Dr. Mellonig.
6 Could I have a sense from you whether you feel that there
7 are very specific numbers that can be put on the sizes of
8 the defects, the osseous defects and the ridge defects, that
9 can be managed with the membranes?

10 DR. MELLONIG: I will tell you this, that I have
11 seen the entire examples of the entire maxilla being handled
12 with multiple barriers and having a successful procedure.
13 As far as we are concerned from the American Academy of
14 Periodontology, I don't think that's within our purview as
15 periodontists treating those extensive defects. So we tend
16 to treat relatively defects maybe of two or three teeth in
17 dimension such as I showed you here on that screen before.
18 But I will also say that I have also seen relatively large,
19 extensive defects for these materials.

20 DR. GLOWACKI: And if I learned from your
21 presentation accurately, then the size would determine
22 whether or not to use a filling material?

23 DR. MELLONIG: It depends upon--the indications
24 for a filling material are based, again, on space creation.

1 If the defect is of such a dimension that the material
2 itself does not have enough stiffness or support in itself
3 that when you place a flap back against it, it would
4 collapse into the defect, that obviates one of the
5 biological principles of space creation. So, therefore, in
6 the judgment of the clinician, if that would occur, then a
7 filling material is used, a bone graft material.

8 DR. GLOWACKI: And I got the impression from your
9 slides that it was primarily freeze-dried banked bone that
10 you use.

11 DR. MELLONIG: Those are mine and I happen to use
12 a lot of that. That's personal, okay. A lot of clinicians
13 have used a lot of variety of materials, including
14 autogenous material, allogeneic material, and alloplastic
15 material or synthetic graft materials.

16 DR. GLOWACKI: Yes, and do you think that there is
17 enough objective information out there on which
18 supplementary materials are more or less effective, combined
19 with the membranes, or does it matter?

20 DR. MELLONIG: There is enough information out
21 there on all three of those types of materials, on the
22 allogeneic and the autogenous materials and the alloplastic.
23 The evidence-based conference that was held last August--and
24 based on the evidence, a wide variety of materials were

1 recommended. Mainly, they were autogenous because there was
2 an abundance of evidence for that--excuse me--mainly, the
3 allogeneic materials because most of the evidence and the
4 articles that have been published have been done with either
5 decalcified or freeze-dried bonalograf, and secondarily
6 with the autogenous materials.

7 DR. GLOWACKI: And then if I remember correctly,
8 at a previous presentation by a representative of the AAP, I
9 understood that there was no position paper on the
10 resorbable membranes at that time.

11 DR. MELLONIG: That's correct.

12 DR. GLOWACKI: Are you telling me now there is a
13 position paper?

14 DR. MELLONIG: There is not a position paper, but
15 I'm saying that it is the position as we stand here today
16 that both resorbable and non-resorbable membranes are safe
17 and effective.

18 DR. GLOWACKI: Just two more questions. Under
19 what circumstances would you select the resorbable versus
20 the non-resorbable?

21 DR. MELLONIG: I would select--first of all, let's
22 go into the non-resorbable. If I had a situation where I
23 felt that there might be a soft tissue dehiscence and where,
24 in my judgment, I felt that the defect was of such a nature

1 and the tissue was of such a nature that once I
2 reconstructed that ridge that the tissue might open up
3 prematurely, then, in fact, I would use the non-resorbable
4 membrane because that's easier to control. In a situation
5 where I felt that that soft tissue coverage could be
6 maintained intact for the entire length of time that I
7 needed it to be intact, then I would use a bio-absorbable or
8 resorbable type of membrane.

9 DR. GLOWACKI: And, finally, what features of the
10 resorbable membranes do you feel are important for success?
11 I'm specifically interested in what the rate of resorption
12 should be for efficacy without getting into problems with
13 interfering with the healing process, for example.

14 DR. MELLONIG: I would hate to comment on that
15 because I'm not an expert, but I'll make an opinion as long
16 as you understand that that's a personal opinion. And I
17 would say that, to my best knowledge, biologically the
18 wound-healing process takes place within the first month or
19 so, and so therefore you would like to have a membrane that
20 would stay for at least, let's say, 21 to 28, 30 days. And
21 after that, then, how it degrades, I think, would be a
22 matter of the material itself. Certainly, you wouldn't want
23 something that would stay on forever and ever and ever, but
24 you would like something within a reasonable period of time

1 to be replaced by host tissue.

2 DR. GLOWACKI: Could you specify a little more
3 what you mean by "forever and forever." I mean, if it
4 stayed longer than four weeks, six weeks--

5 DR. MELLONIG: Well, let's say I reentered that
6 area. You know, obviously, we know that when we place
7 certain graft materials in the defect that those particles
8 are there and incorporated with host bone and those
9 particles remain non-viable with no osteocides for up to
10 several years and still be functioning. The part can still
11 function.

12 On the other hand, with these other type of
13 materials, as long as they are inert and not causing any
14 problem, I certainly--I would feel more comfortable if it
15 was under a year, if you want a number.

16 DR. GLOWACKI: Thank you very much.

17 DR. MELLONIG: Okay, thank you.

18 DR. ROBERTSON: Dr. Greenspan, you wanted to ask
19 about the conference?

20 DR. GREENSPAN: No.

21 DR. ROBERTSON: Okay, so you're happy?

22 DR. GREENSPAN: Yes.

23 DR. ROBERTSON: Dr. Stephens?

24 DR. STEPHENS: Can you tell me what kind of

1 problems you've seen with early dehiscence on the resorbable
2 membrane and how you've handled them?

3 DR. MELLONIG: If you have early dehiscence on the
4 non-resorbable membranes, which occasionally might be a
5 problem, that's part of the technology. That's like any
6 type of surgical procedure; you're going to have occasional
7 problems. When those problems do arise in the membranes of
8 a non-resorbable variety, that patient can easily be watched
9 very carefully.

10 Number one, we monitor the patient carefully.
11 Number two, we treat that area with an anti-bacterial type
12 of substance such as chlorhexadene. And, number three, if
13 we do perceive a problem, the patient is placed on a wide
14 variety of antibiotics depending upon the discretion of the
15 clinician.

16 DR. STEPHENS: Are the problems any different with
17 the resorbable membranes?

18 DR. MELLONIG: If the membrane is bio-absorbable,
19 usually we don't use the chlorhexadene, but we do treat the
20 patient with an antibiotic at that particular time. And to
21 be quite honest with you, with the membranes, when they're
22 bio-absorbable, they do become exposed. There sometimes
23 might be a little problem with flaking. We have to watch
24 that patient just a little bit more carefully, but still it

1 can be managed and still the procedure is successful.

2 DR. STEPHENS: With the reinforced membrane, do
3 you have any idea of the critical size defect that you can
4 use the membrane without a space maintainer underneath it or
5 without a graft?

6 DR. MELLONIG: I don't know if I want to judge an
7 opinion on that. I have seen relatively extensive defects
8 of areas of up to three to four implants that have been done
9 that I have seen personally.

10 DR. STEPHENS: Without a graft?

11 DR. MELLONIG: Without a graft underneath it with
12 the membrane alone. I'll give you my opinion personally.
13 In large, extensive defects, I as a clinician, not talking
14 from the AAP or anybody else, I always use a bone graft
15 material.

16 DR. ROBERTSON: Dr. Patters?

17 DR. PATTERS: Jim, with regard to the non-
18 periodontal localized osseous defects which you'd like to
19 augment, are you as comfortable with the evidence of safety
20 and efficacy of resorbable membranes as I'm sure you are
21 with the non-resorbable?

22 DR. MELLONIG: Yes. We have--I didn't bring any
23 examples--maybe I should have--of large periapical defects,
24 and I mean large, the size of quarter, so to speak, a

1 centimeter-and-a-half, maybe, that would not be--I don't
2 think it could be corrected. In fact, these were
3 longstanding, chronic type of defects that were corrected
4 with the use of graft and the resorbable membrane.

5 DR. PATTERS: How about for use with implants?

6 DR. MELLONIG: The same.

7 DR. PATTERS: You're equally comfortable with the
8 non-resorbable as the resorbable?

9 DR. MELLONIG: Equally comfortable with that,
10 depending upon the conditions, again. I mean, there are
11 indications when both are applicable and there are
12 indications when one or the other is applicable.

13 DR. PATTERS: And do you agree with the proposed
14 classification of lumping periapical defects and periodontal
15 defects with regard to membranes?

16 DR. MELLONIG: Yes, I'm comfortable with that.

17 DR. PATTERS: Thank you.

18 DR. ROBERTSON: Dr. Glowacki?

19 DR. GLOWACKI: Just a follow-up question based on
20 those last three questions of Dr. Patters.

21 DR. MELLONIG: Sure.

22 DR. GLOWACKI: On what basis is your level of
23 comfort in terms of numbers of patients that you have
24 experience with?

1 DR. MELLONIG: You mean how many patients have I
2 treated--

3 DR. GLOWACKI: Each of those categories, each of
4 those categories, the periapical--

5 DR. MELLONIG: I don't understand. Dr. Glowacki,
6 I don't understand. How many patients would I like to see
7 treated this way?

8 DR. GLOWACKI: No, no. Have you treated with the
9 resorbable membranes for the periapical defects, for the
10 defects with implants, et cetera?

11 DR. MELLONIG: Yes. We've been involved in large-
12 scale clinical trials for over three years with a large
13 number of patients. So what I would say--personal
14 experience with the bio-absorbable membrane, it's well--I've
15 personally treated well over 50 patients with those.

16 DR. GLOWACKI: Thank you.

17 DR. ROBERTSON: Dr. Greenspan?

18 DR. GREENSPAN: One of the things that the panel
19 often has to wrestle with is this concern about special
20 control, and the information you present us with--and,
21 obviously, in your very skilled hands and those of some of
22 the papers that have been published and are summarized in
23 this journal--are done by clinicians who have been involved
24 in some of the research trials and are experienced

1 clinicians.

2 One of the things that I have trouble with is the
3 special control. So much of the success seems to be based
4 on judgment and experience. It is true with many things
5 that that's the case, but I'm wondering, particularly with
6 the use of these non-resorbable versus resorbable versus
7 alveolar defects, et cetera, what type of advice you can
8 give us as a panel as to how to use these materials, because
9 I keep hearing, well, you take all these things into
10 consideration.

11 DR. MELLONIG: I know.

12 DR. GREENSPAN: Is there any way that it can be
13 simplified that one can suggest special control or some sort
14 of recommendations?

15 DR. MELLONIG: Let me give you an answer
16 relatively generic to that. I would hope that any clinician
17 who wanted to use these materials, A, would have the
18 foresight to take advance training so that he felt
19 comfortable in the outcomes that he was going to achieve
20 with the use of these materials; and, B, if he was not able
21 to take advance training or take enough continuing education
22 where he felt comfortable, that he would refer the patient.

23 DR. GREENSPAN: So would I.

24 DR. ROBERTSON: Are there any more questions for

1 Dr. Mellonig?

2 [No response.]

3 DR. ROBERTSON: Jim, thank you very much.

4 DR. MELLONIG: Thank you, Mr. Chairman.

5 DR. ROBERTSON: Are there any others in the
6 audience who would like to address the panel, and if so
7 would you stand?

8 I have one person who wishes to address the panel.
9 Are there any others in the audience who wish to address the
10 panel?

11 [No response.]

12 DR. ROBERTSON: Thank you. Then would you please
13 introduce yourself and tell us who you represent?

14 MS. WATSON: I'm Barbara Watson. I'm with Ceramed
15 Corporation. Ceramed manufactures bone-grafting materials,
16 both synthetic and naturally-derived. I have a couple of
17 remarks, and obviously they would apply only to the
18 specialty of Ceramed, which is hydroxyapatite materials.

19 First of all, I'm sure that the panel is aware of
20 this, but I'd like to once again bring up the fact that
21 there is a standard set forth by the American Society for
22 Testing and Materials which describes the composition of
23 ceramic hydroxyl apatite for surgical implants. This is a
24 well-accepted standard. It has been around since 1988 and

1 it has sufficed for the entire time from 1988 to assure the
2 quality of this hydroxyapatite bone-grafting material.
3 Also, recently, the ASTM approved a standard for the
4 composition of anorganic bone for surgical implants.

5 My general observation--and this is brief, but I
6 think it should be brought up. Yes, there is a lack of
7 thorough and well-controlled studies for most of the
8 indications that the panel has discussed for bone-grafting
9 materials. However, decades of clinical use have shown that
10 the worst risks associated with these materials include
11 pain, thermal sensitivity, and loss of the implant material.
12 These are not life-threatening risks. Yet, we are looking
13 at a Class III assignment for most indications, requiring
14 vast commitments of time and money for scientific and
15 clinical trials. What will this accomplish to improve the
16 standards for safety and efficacy of these materials above
17 the standards that have already been established? I urge
18 the panel and the FDA to consider a greater emphasis on the
19 use of existing standards to assure the safety and efficacy
20 of grafting materials.

21 Thank you.

22 DR. ROBERTSON: Thank you. Are there questions?
23 Dr. Glowacki?

24 DR. GLOWACKI: Ms. Watson, there are some who

1 argue that the ASTM standard for hydroxyapatite implants is,
2 in fact, not very specific with regard to the composition
3 and the physical characteristics of that, and I believe that
4 the ASTM is trying to refine and improve those standards
5 because they are not well accepted. Do you know anything
6 about that, or does anyone else in the audience know
7 anything about that?

8 MS. WATSON: I don't know anything specific about
9 exactly what's being changed on the hydroxyapatite standard,
10 but part of the ASTM's mission is to constantly review their
11 standards and improve whenever something presents itself.

12 John Kay knows a lot more than I do about that
13 particular standard.

14 DR. GLOWACKI: Could Dr. Kay answer that question,
15 Mr. Chairman?

16 DR. ROBERTSON: Certainly.

17 DR. KAY: Good afternoon. My name is John Kay.
18 I'm here representing both BioInterfaces and CalciTech,
19 Incorporated. With regard to the ASTM standards, I was one
20 of the principals in drafting the original standards for HA.
21 One of the problems, if anyone has ever been on an ASTM
22 committee, is that it is very much like yourselves. You
23 have a group of data from many different people with many
24 different interests, materials, et cetera, et cetera, and

1 that standard is a broad standard. So it really doesn't in
2 most cases pin down very specifically many specific
3 criteria.

4 For the specific example of hydroxyl apatite, it
5 really is almost like the equivalent of an FDA guidance
6 document. It tells you what to look for, in some cases how
7 to test generically, but specific guidelines and numbers
8 probably don't appear, and probably in the revision, which
9 is up, by the way, for HA, probably won't appear again. So
10 the standards act as guidelines, maybe, to guide the quality
11 departments of various manufacturers of what to look for,
12 maybe density, x-ray pattern, et cetera, et cetera.

13 DR. GLOWACKI: But isn't the issue of quality
14 control and testing of various batches and different--let's
15 say we're talking about a bulk material. Where you do the
16 testing, how frequently you do it, and how much variability--
17 -isn't that of concern to the engineering community, and why
18 isn't that being incorporated into the standard?

19 DR. KAY: Again, I think the HA standard when it
20 was developed had to cover, if I could be specific, not only
21 physical forms that ranged from the smallest particulates
22 which were 250 nominal microns in dimensions, all the way up
23 to small bulk ceramic articles that were indicated for
24 orthognathic surgery at the time. So we're talking about

1 something from 250 microns in nominal dimension all the way
2 up to something that is probably in the largest dimension at
3 the time--I don't know--two centimeters. So, that's the
4 physical range.

5 Chemically, it involved materials that were
6 derived from sea coral, with all the physiological
7 impurities that--when you transform sea coral to an immature
8 form of hydroxyl apatite, a lot of those impurities go along
9 with the process--to very pure synthetic materials
10 rigorously prepared from the purest chemicals on earth, to
11 at that time analogs of naturally-derived materials which
12 have subsequently been split out on a new standard, to
13 materials that were high-fired ceramics, to materials that
14 were relatively low-temperature materials.

15 Now, we know a lot more today in terms of the
16 biological response of that complete three-dimensional
17 spectrum, but certainly at the time what that standard chose
18 to do, because, again, the members of the committee were
19 from the various corporate entities, is to list the
20 specifics of what to look for and, again, x-ray IR density,
21 things like that.

22 DR. GLOWACKI: So do you agree, though, that the
23 panel should not have the impression that those standards
24 relate specific characteristics to clinical efficacy?

1 DR. KAY: Well, I think the references--the ASTM
2 standards are organized in such a fashion that references
3 are included at the end, and I think Barbara is right in
4 that the long-term clinical indications that are represented
5 in the peer-reviewed literature are pretty much equivalent
6 for the perio usage and, for example, the ridge augmentation
7 because the materials are the same and their history is
8 approximately 15 years old in the clinical environment.

9 In terms of the quality, I don't think you can--I
10 think the onus of responsibility there is on the
11 manufacturer to put in proper quality assurance steps to
12 make sure that the product they put out is uniform. Whether
13 that translates to safety and efficacy, per se--probably
14 not. I think the--

15 DR. ROBERTSON: Good. I think I finally found the
16 answer to Dr. Glowacki's question.

17 DR. KAY: Okay.

18 DR. ROBERTSON: I was drifting through that.

19 DR. KAY: Okay.

20 DR. ROBERTSON: The answer was no. Is that right?

21 DR. KAY: Well, I don't think a material quality
22 standard can ever translate to clinical safety and efficacy
23 under any circumstances.

24 DR. ROBERTSON: Thank you.

1 Are you--

2 DR. GLOWACKI: Thank you.

3 DR. ROBERTSON: Thank you very much.

4 Any other presentations from the floor?

5 [No response.]

6 DR. ROBERTSON: Well, thank you.

7 We'll move, then, to an open committee discussion,
8 and we will have some brief presentations by Dr. Glowacki
9 and then Dr. Patters and then Pam Scott to bring us up to
10 date on where we are, and then we'll take a break and we'll
11 begin the discussion.

12 So, Dr. Glowacki, the floor is yours.

13 DR. GLOWACKI: Thank you. I thought it would be
14 useful to kind of review very briefly the activities of the
15 panel with regard to the task we were given to make
16 recommendations on classification of the bone-filling and
17 augmentation materials.

18 I think it was back in the winter of 1992-93 that
19 the panelists received, was it six cartons of information
20 from the FDA that was solicited from the industry to aid the
21 panel in this classification process. It was, to say the
22 least, a formidable task. There was a lot of very
23 interesting material included in that delivery, but there
24 was also a lot of material that really didn't relate to the

1 topic at hand. I remember some veterinary uses, orthopedic
2 uses, and it was very difficult to sift through it all with
3 regard to the task of recommending the dental application.

4 So the charge was to determine which products and
5 which indications could be recommended into the three
6 possible classifications--Class I, II, and III--and it
7 wasn't considered very prudent to deal with each product and
8 each indication separately. So in order to organize this
9 overwhelming amount of information, the panel needed to make
10 some decisions about lumping and splitting into meaningful
11 working definitions--hopefully, just temporary definitions.

12 So although, in my opinion, the real-world use of
13 these materials is certainly most importantly tied to the
14 clinician's judgment and skill rather than to relative
15 effectiveness of these materials, that wasn't an option for
16 the panel to recommend that all presently marketed devices
17 be classified as Class II, with the clinician determining
18 the indications, although that may be what has been
19 happening in the past. So we couldn't do that.

20 Further, the panel was looking for very practical
21 advice about simplifying and generalizing the clinical
22 experiences with these devices with regard to special
23 controls if a Class II recommendation was made, and we
24 needed to be able to justify and document those special

1 controls.

2 So at open meetings, then, manufacturers,
3 representatives from professional associations, and other
4 commentators recommended classification to the panel, but in
5 my opinion, all of these people could have provided us with
6 more specific help in making general definitions rather than
7 responding to our queries with very, very specific
8 information about their product, because the panel needs
9 precise information to define the special controls that
10 include the indications, the directions, labeling, et
11 cetera.

12 In this context, then, the panelists reviewed the
13 entire field, taking into account the documents provided,
14 the published literature, oral and hand-out materials
15 collected at open meetings, presentations by experts, and
16 common experiences and practices by clinicians. For some of
17 these issues, it may have seemed to have been an artifice to
18 distinguishable, for example, resorbable and permanent when,
19 in fact, it is a matter of the rate of resorption of all of
20 these materials. But at the initial approach, it was felt
21 prudent to separate them to see if there were any specific
22 documentation or experiences that would strengthen one group
23 versus the other group.

24 It was also for a period of time useful to

1 separate natural and synthetic ceramics during the analysis
2 in order to come up with a level of comfort on whether
3 special controls would allow us to lump these two together.
4 For some issues, the panelists asked for further specific
5 information, but learned it just wasn't available, and I
6 want to take this opportunity once again to commend the FDA
7 staff for the intelligent, objective, and very thorough
8 assistance given to the panel over these years.

9 The product of all of these reviews was a draft
10 grid designed to expedite the panel's consideration of the
11 definitions, leading to recommendations for classification
12 of bone-filling materials. Fully recognizing that there is
13 an arbitrariness and artificial aspect in defining the
14 groups of materials, it was suggested that the panel
15 consider the draft grid. Previous to that, we had worked on
16 outlines, but somehow this grid seemed a little more
17 helpful, although certainly imperfect.

18 So, armed with the grid, the panelists could
19 return to those boxes of documents offered by the
20 manufacturers and try to assess them in a more methodical
21 manner. Driven by the goal to consolidate and simplify the
22 definition, the panel discovered in some certain instances
23 that there was little information for some of the grids,
24 sometimes because there was apparently little use of certain

1 materials for a certain application. This exercise led to
2 the removal of certain categories and to further
3 consolidation of others, sometimes. Because of actual or
4 theoretical differences in materials, for the time being the
5 ceramics and the polymers, the latter having little real
6 risk for an immune reaction, it was useful to separate those
7 as a subset.

8 After energetic participation of the panelists and
9 the experts, then, we used the grid to organize our voting
10 on the classification of bone-filling devices. In general,
11 I think that the panel voted for Class II when it was
12 believed that there was sufficient evidence of efficacy and
13 safety, and sufficient information available to define
14 special controls.

15 After voting for the classification last time, it
16 now appears to me unnecessary to retain some of these
17 separate groups. Today, we will reconsider the definition
18 of these groups, and I hope we will produce more simplified,
19 clearer, and meaningful terms to aid the FDA and the
20 industry in marketing effective and safe bone-filling
21 devices.

22 Thank you.

23 DR. ROBERTSON: Thank you.

24 Questions from the panel for Dr. Glowacki to make

1 sure that we're all up to speed?

2 [No response.]

3 DR. ROBERTSON: Thank you.

4 Dr. Patters?

5 DR. PATTERS: Well, included in bone-filling
6 materials, of course, are augmentation devices, primarily
7 membranes, and as this grid was developed, barrier
8 membranes, both of the resorbable and non-resorbable types,
9 were classed separately and were placed in with the
10 indications for the ceramics and synthetic materials
11 regarding bone-filling.

12 In some ways, that's unfortunate because, as I
13 think I've previously stated, many of the indications for
14 some of the bone-filling materials do not really directly
15 apply to the barrier membranes, and thus there was little or
16 no information on the efficacy and safety of barrier
17 membranes in situations which they had not been specifically
18 designed for, but bone-filling materials had been designed
19 for.

20 So with regard to resorbable membranes, there were
21 no indications for numbers 2, 3 and 5 either recommended by
22 the manufacturer or available in the literature. With
23 regard to the non-resorbable membranes that have been
24 available to the practicing clinicians for a considerably

1 longer period of time, there had been some indications, but
2 those indications were lacking in well-controlled clinical
3 trials.

4 Quite clearly, both the non-resorbable and
5 resorbable membranes--there are well-documented studies on
6 their use in filling of periodontal defects and, in my
7 opinion, although it was not necessarily shared by the
8 panel, there was sufficient data to ascribe special controls
9 for the filling of intraosseous gaps, voids and clefts with
10 non-resorbable membranes.

11 Since we've considered this, additional evidence
12 has become available now with regard to resorbable membranes
13 in the same area of the filling of non-periodontal gaps and
14 voids. So I think, you know, as this process matures,
15 consolidation of the grid, I think, maybe a reasonable
16 approach and I'll suggest that the panel discuss that as our
17 deliberations continue.

18 DR. ROBERTSON: Thank you.

19 Questions from the panel for Dr. Patters? Dr.
20 Greenspan?

21 DR. GREENSPAN: Thank you. Just to ask you about
22 the last sentence, did I understand you to mean that these
23 barriers, whether non-resorbable or resorbable, would be
24 used alone or in conjunction with other filling materials?

1 DR. PATTERS: I didn't say.

2 DR. GREENSPAN: No, you didn't say that, but I was
3 trying to ask you whether you felt that this would be an
4 indication if used alone or in combination, or either. So
5 much of the data that we heard just now and I've heard in
6 the past has been with these membranes used with other
7 filling materials that it's very hard for me to separate
8 these out when it comes to how we should write the
9 indications. In other words, would you recommend this as a
10 Class II, but with the special controls that it may need to
11 be used with something else? I don't know.

12 DR. PATTERS: I think that's difficult to say
13 because it is a problem to separate the space-creating
14 effect of the filling material and any possible physiologic
15 or healing effects that the material may have. I mean, a
16 totally inert material may suffice to create the barrier. I
17 think that present a dilemma, and also I would suggest we
18 discuss that further.

19 DR. ROBERTSON: Other questions?

20 [No response.]

21 DR. ROBERTSON: Good. We'll now hear from Ms. Pam
22 Scott. Somebody actually needs to say that this was an
23 extraordinarily difficult piece of work, and the panel owes
24 great thanks to Pam Scott for helping us through a most

1 difficult process. Thank you.

2 MS. SCOTT: You're welcome, and thank you. Again,
3 my name is Pamela Scott. I'm a reviewer in the Dental
4 Branch of the Office of Device Evaluation. Good afternoon
5 to the Chair and the Dental Products Panel members.

6 I would like to ask the panel members if they
7 would take out the hand-out on bone-filling and augmentation
8 device definitions and recommended classifications, and also
9 I believe most of the panel members have the bone table also
10 in front of them. In addition, you received a hand-out
11 that's entitled "Examples of Device Definitions" from the
12 Code of Federal Regulations, Title 21.

13 As has been nicely summarized by Dr. Glowacki and
14 Dr. Patters, the panel has taken a number of meetings to
15 deliberate the issue regarding the classification of bone-
16 filling and augmentation devices. As you know, a table was
17 developed to categorize the devices according to material
18 type and intended use, and each material type and intended
19 use represented a device group.

20 During the last panel meeting, the panel
21 recommended classifications for each device group and
22 outlined risks and identified special controls for devices
23 recommended for Class II. The panel also recommended device
24 groups that could be combined. The recommendations for the

1 combination of devices were as follows. It was recommended
2 that devices that were in the bone grid box 2A, 2B and 2D be
3 combined. Also, 3A, 3B and 3D were also recommended to be
4 combined. It was also recommended that boxes 5A, 5B, C, D
5 and 5E also be combined. The suggested group combinations
6 were based on similarities in recommended classification,
7 health risks and intended use.

8 Presently, the panel recommendations for
9 classification, health risks and special controls were
10 incorporated into the table, and based on the panel's
11 recommendations, we have now consolidated some of the
12 devices into new groups with corresponding definitions and
13 the classification recommended by the panel.

14 The devices were consolidated based on material
15 type, intended use, recommended class, health risks, and
16 special controls. In this outline and consolidation of
17 devices, the first level of organization in the outline is
18 by material or device type. For example, if you notice in
19 your outline entitled "Bone Filling and Augmentation Device
20 Definitions and Recommended Classifications," the first
21 group is the ceramic bone-filling device. The second level
22 of organization in the outline is by intended use, and the
23 third level of organization is by the recommended class.

24 The format that was used in this outline to

1 consolidate the devices was patterned after other devices in
2 which there are different classes for different intended
3 uses of the device. Examples of these types of devices are
4 provided in this slide. They include the shortwave
5 diathermy device, the cardiovascular permanent or temporary
6 pacemaker electrode, and the rigid gas permeable contact
7 lens.

8 As defined in the Code of Federal Regulations,
9 Title 21, 890.5290, the shortwave diathermy device is
10 classified in Class II for use as a device that applies to
11 specific areas of the body electromagnetic energy in the
12 radio frequency band as stated in the CFR and is intended to
13 generate deep heat within body tissues for the treatment of
14 selected medical conditions. For this intended use, the
15 device is Class II. It also states that the device is Class
16 III for all other uses, except for the treatment of
17 malignancies, when the device is intended for treatment of
18 medical conditions other than the generation of deep heat
19 within body tissue.

20 The cardiovascular temporary pacemaker electrode
21 and the permanent pacemaker electrode are given in CFR
22 870.3680. The device is Class II for the temporary
23 pacemaker electrode and it is Class III for the permanent
24 pacemaker electrode. Another example is the rigid gas

1 permeable contact lens, which is defined in 21 CFR 886.5916.
2 The device is Class II if it is intended for daily wear use
3 only. It is Class III if it is intended for extended wear
4 use.

5 These devices are provided just to give the panel
6 an example of devices with different classifications for
7 different intended uses and how the devices are identified
8 in the regulations.

9 We request that the panel discuss these device
10 definitions provided in the outline and provide suggested
11 changes. The panel should then vote on the device
12 definitions, incorporating any proposed changes that the
13 panel may have.

14 Before the panel begins their discussion, I would
15 like to review the outlined device groups and definitions,
16 and you may refer to your hand-out, which is the corrected
17 version of the outline.

18 The first device group is the ceramic bone-filling
19 device. Please note that this category does not include
20 tricalcium phosphate granules. The first device in this
21 group is the ceramic bone-filling device for use in filling
22 periodontal defects. This device represents a combination
23 of bone grid boxes 1A and 1B.

24 The device is defined as a resorbable or non-

1 resorbable device that is naturally or synthetically derived
2 and is to be used to aid in the filling and repair of
3 periodontal defects. These devices may be in granular or
4 mesh form. The recommended class is Class II, and the
5 recommended controls are voluntary standards, guidance
6 documents, and training.

7 The second device is the ceramic bone-filling
8 device for bone defects in the non-load-bearing oral and
9 maxillofacial region. This is a combination of bone grid
10 boxes 2A and 2B. This device, again, is a resorbable or
11 non-resorbable device that is naturally or synthetically
12 derived and is to be used to aid in the filling and repair
13 of oral and maxillofacial intraosseous gaps, voids and
14 clefts in non-load-bearing regions where the bony cavity is
15 defined. Again, these devices may be in granular, mesh or
16 solid form. The device was recommended for Class III.

17 The third device in this group is the ceramic
18 bone-filling device for use in the augmentation of the
19 alveolar ridge. This is part of bone grid boxes 3A and 3B
20 combined. The device is defined as a resorbable or non-
21 resorbable device that is naturally or synthetically derived
22 and is to be used for the augmentation of the alveolar
23 ridge. The device was recommended for Class III.

24 The next device in this group is a non-resorbable

1 bone-filling device for use in the repair of bone defects in
2 load-bearing regions and for onlay augmentation. This
3 device is defined as a non-resorbable device that is
4 naturally or synthetically derived and is to be used to aid
5 in the filling and repair of intraosseous defects that are
6 in load-bearing regions and for functional and/or cosmetic
7 correction in other maxillofacial load-bearing and non-load-
8 bearing onlay applications. These devices are generally in
9 solid form. The recommended class is Class III.

10 The last device in this group is the ceramic bone-
11 filling device for filling tooth extraction sites. This is
12 a combination of bone grid boxes 5A and 5B. This device is
13 a resorbable or non-resorbable device that is naturally or
14 synthetically derived and is to be used to fill and aid in
15 the repair of tooth extraction sites. These devices may be
16 in granular, mesh, or solid form. The recommended class is
17 Class III.

18 The next device group is the polymer or composite
19 bone-filling device. The first device in this group is the
20 polymer or composite bone-filling device for use in filling
21 periodontal defects. This is represented in bone grid box
22 1D. This is a device that is composed of a single polymer,
23 copolymers, or composites of two or more materials of a
24 different type or phase that is to be used to aid in the

1 filling and repair of periodontal defects. These devices
2 may be in granular or mesh form. The recommended class is
3 Class II, and the special controls include voluntary
4 standards, guidance documents, and training.

5 The next device is the polymer or composite bone-
6 filling device for filling bone defects in the non-load-
7 bearing oral and maxillofacial region, and this is a device
8 intended to be used to aid in the filling and repair of oral
9 and maxillofacial intraosseous gaps, voids and clefts in
10 non-load-bearing regions where the bony cavity is defined.
11 These devices are generally in granular or solid form. The
12 recommended class is Class III.

13 Device 2(c) is the polymer or composite bone-
14 filling device for use in the augmentation of the alveolar
15 ridge. This is part of bone grid box 3D, and this is a
16 device that is composed of a polymer, copolymers, or
17 composite material that is intended to be used for the
18 augmentation of the alveolar ridge. The recommended class
19 is Class III.

20 Device 2(d) is the polymer or composite bone-
21 filling device for use in filling tooth extraction sites.
22 This is bone grid box 5D, and the definition for this device
23 is that it is a device to be used to fill and aid in the
24 repair of tooth extraction sites. The recommended class is

1 Class III.

2 The third device group is the non-resorbable
3 barriers and membranes. The non-resorbable barrier or
4 membrane for use in filling periodontal defects is
5 represented by bone grid box 1E, and it is defined as a
6 device that is naturally or synthetically and is intended to
7 function as a barrier that allows selective tissue in-growth
8 to aid in the filling and repair of periodontal defects.
9 These devices are intended to be removed. The recommended
10 class is Class II, and the special controls identified by
11 the panel include guidance documents, labeling to indicate
12 the time point for removal of the device post-insertion,
13 training, and clinical studies for the introduction of new
14 materials.

15 The second device is the non-resorbable barrier or
16 membrane for use in the repair of bone defects in the non-
17 load-bearing oral region. This is bone grid box 2E. This
18 device is intended to function as a barrier that allows
19 selective tissue in-growth to aid in the filling and repair
20 of oral intraosseous gaps, voids and clefts in the non-load-
21 bearing region where the bony cavity is defined. These
22 devices are intended to be removed, and the recommended
23 class is Class III.

24 Device 3(c) is the non-resorbable barrier or

1 membrane for augmentation of the alveolar ridge. This is
2 part of bone grid box 3E, and this device is intended to
3 function as a barrier to allow selective tissue in-growth
4 for the augmentation of the alveolar ridge. The recommended
5 class is Class III.

6 The last device in this group is the non-
7 resorbable barrier or membrane for use in the filling of
8 tooth extraction sites and it is to aid in the filling or
9 repair of tooth extraction sites. The recommended class is
10 Class III.

11 The last device group is the resorbable barrier or
12 membrane. Device 4(a) is the resorbable barrier or membrane
13 for use in the filling of periodontal defects, represented
14 by bone grid box 1F. This device is defined as a device
15 that is naturally or synthetically derived and is intended
16 to function as a barrier that allows tissue in-growth to aid
17 in the filling and repair of periodontal defects. It was
18 recommended for Class II, and the special controls include
19 guidance documents, animal studies, clinical studies, and
20 training.

21 To review, the major device groups given in the
22 outline are the ceramic bone-filling device, the polymer or
23 composite bone-filling device, the non-resorbable barrier or
24 membrane, and the resorbable barrier or membrane.

1 At this time, we would like the panel to provide
2 comments and suggested changes to the device groups and
3 definitions as presented, and also it is the prerogative of
4 the panel to reconsider any of their recommendations.

5 Thank you.

6 DR. ROBERTSON: Thank you. Are there questions
7 from the panel for Pam for our charge?

8 Dr. Glowacki?

9 DR. GLOWACKI: Yes. I'm really inspired by the
10 examples you've given us from the Federal regulations, on
11 the compactness of those, and hope that we can do the same
12 thing. And in that direction, I think many of the reasons
13 that we separated the different indications were to take a
14 careful independent look at the specific risks that were
15 associated with them.

16 Is it necessary to keep those separate for that
17 reason or for any other reason? I'm really leaning toward
18 lumping all of those together and don't see any scientific
19 or clinical reason to keep them separate.

20 MS. SCOTT: If there is information such that the
21 particular devices can be combined, particularly if many of
22 the risks are the same or are similar for the different
23 devices or for the same device with different indications,
24 then there's no reason why we should not be able to combine

1 those devices into one device. I believe that that is a
2 great possibility to be able to combine the devices as
3 appropriate, and that is the type of recommendation and type
4 of suggestion that we would like from the panel.

5 DR. GLOWACKI: Just in terms of the history again
6 with regard to the ceramics versus the synthetic polymeric
7 materials, I know that a lot of the information on the
8 polymeric materials came to us much later and now there is
9 even a more recent hand-out here that we haven't had a
10 chance to look at. Can you kind of remind us about how that
11 fit into the whole system?

12 MS. SCOTT: I believe that we wanted--in terms of
13 separating the ceramics from the polymers, I believe that we
14 wanted to make sure that we did not combine them and lump
15 them together possibly when they needed to be separated
16 because of differences possibly in risk or in particular
17 special controls. But if there are similarities between the
18 devices, then they can be combined.

19 Also, we wanted to make sure that, for example, if
20 one device had sufficient data for the panel such that the
21 panel recommended Class II for one device, but did not feel
22 there was data for another type of device, then that would
23 not be lumped together and confused.

24 DR. GLOWACKI: So because they ended up in the

1 same Class II, we could lump all three of those groups
2 together?

3 MS. SCOTT: That would be possible to do that.

4 DR. ROBERTSON: Good. Well, we will break now,
5 but before--I'm sorry.

6 DR. STEPHENS: Can you tell me if barrier
7 membranes have been cleared for use with any other materials
8 or bone grafts, or whether the original clearance is for use
9 alone?

10 MS. SCOTT: From the submissions and the labeling
11 that I have seen submitted, I believe that the barrier
12 membranes are indicated for use alone.

13 DR. ROBERTSON: We will take a break now, but
14 before Dr. Patters and Dr. Glowacki get to feel they could
15 spend the whole time breaking, given the discussion we have
16 had and the presentations that have been given to us, since
17 you are going to lead us through these four groups, you
18 might be thinking about ways in which we might amend them
19 and combine them even further.

20 Thank you. So we'll meet back at--Captain, my
21 Captain?

22 DR. TYLEND: 4:15, 4:10?

23 DR. ROBERTSON: 4:10.

24 [Recess.]

1 DR. ROBERTSON: Well, we'll start the technical
2 part and see if we can't move our way through this. First,
3 I think, on the list is that we have before us a
4 recommendation of four general groups for bone-filling and
5 augmentation device definitions, and those are ceramic bone-
6 filling devices, polymer or composite bone-filling devices,
7 non-resorbable barriers, and resorbable barriers.

8 Dr. Glowacki, do you have any sense that you'd
9 like to revise those four into more or less?

10 DR. GLOWACKI: Yes. I think after looking at all
11 of them separately, we looked at particulate and bulks
12 forms. We looked at the resorbable and non-resorbable
13 ceramics and the polymers, also, as granular and bulk forms.
14 I think the time has come that I'm very comfortable putting
15 them back together and calling these devices as ceramic or
16 polymeric bone-filling devices--polymeric and composite--
17 ceramic, polymeric and composite bone-filling devices.
18 Bring them back together.

19 DR. ROBERTSON: All right. Mark, the resorbable
20 and non-resorbable, however, have a problem in that one has
21 to be removed. So based on that, what would you like to do
22 with those two categories?

23 DR. PATTERS: Although the indications are
24 generally same, since the non-resorbable has to be removed

1 and the manufacturer has to specify when is the appropriate
2 time for removal, I feel it's appropriate to keep them in
3 separate categories.

4 DR. ROBERTSON: Fine. So may I then have a motion
5 for the recommended groups to be three, as I understand it--
6 one, ceramic, polymer or composite bone-filling device? Is
7 that right, Julie?

8 DR. GLOWACKI: Maybe I would just--I guess I say
9 it polymeric, just to make them all adjectives. I would so
10 move.

11 DR. ROBERTSON: Fine. Ceramic, polymeric, or
12 composite?

13 DR. GLOWACKI: And composite.

14 DR. ROBERTSON: And composite bone-filling device.
15 So for the record, then, may I have a motion to revise these
16 categories into, one, ceramic, polymeric and composite bone-
17 filling device; two, non-resorbable barrier or membrane;
18 and, three, resorbable barrier or membrane?

19 DR. GLOWACKI: So moved.

20 DR. ROBERTSON: May I have a second?

21 DR. O'NEILL: Second.

22 DR. ROBERTSON: Good. Moved and seconded that we
23 collapse these into three groups. Now, we have discussion.
24 Any concerns with that? Yes?

1 DR. ROSAN: Well, it seems to me the reason we had
2 separated these out was a concern that these will become
3 predicate devices for other things down the line and that we
4 wanted to--and because of differences in components, I
5 think, was the reason we tried to separate them out; in
6 other words, the distinct differences in their chemistry.
7 And I'm wondering if we just should look at that
8 consideration because I think that was the reason we
9 separated them out in the first place because many of the
10 indications were identical, but their compositions could be
11 quite different, and anything coming down the line with the
12 same indications with quite a different chemical character
13 could then be classified in the same manner. And so maybe
14 we need some controls or special considerations so that if a
15 new substance with the same indications would come into
16 being, it would not necessarily fall into the categories.

17 DR. ROBERTSON: Dr. Glowacki?

18 DR. GLOWACKI: I would think that the special
19 controls could be defined to be very precise and avoid any
20 ambiguity.

21 DR. ROBERTSON: Under each of these three, we
22 still have subgroups, A, B, C, D, E, each of which might
23 have its own special control, and so on.

24 Can FDA--where's Pam?

1 DR. GLOWACKI: They're all there.

2 DR. ROBERTSON: There you all are. Help, advice,
3 concerns?

4 MR. HLAVINKA: Well, for a new material, the
5 special controls could define, you know, the existing
6 materials and then we could evaluate any new material by
7 whatever data might be required--characterization in
8 clinical trials, et cetera.

9 DR. ROBERTSON: Pamela?

10 MS. SCOTT: Any new material that could
11 potentially fall outside of the definition when it came into
12 the agency--if it came in as a pre-market notification, it
13 would have to be assessed based on the data as to whether
14 it's substantially equivalent or not substantially
15 equivalent to the classified device.

16 DR. ROBERTSON: So that, in fact, simply lumping 1
17 and 2 together does not preclude you from doing that?

18 MS. SCOTT: Right, right. If there is information
19 and data to show that a new device or a new type of material
20 with the same intended use is substantially equivalent to
21 the classified device, then it can be found substantially
22 equivalent.

23 DR. ROBERTSON: Any further discussion? You're
24 now comfortable?

1 DR. GLOWACKI: Yes.

2 DR. ROBERTSON: Good. Of the voting members, Dr.
3 O'Neill, Dr. Rosan, Dr. Glowacki, Dr. Stephens, Dr. Drummond
4 and Dr. Norman, all in favor of the motion, please raise
5 your hand.

6 [Six hands were raised.]

7 DR. ROBERTSON: All opposed?

8 [No response.]

9 DR. ROBERTSON: Let the record show that the vote
10 was unanimous in favor of establishing a grouping with three
11 categories--ceramic, polymeric and composite bone-filling
12 materials; non-resorbable barriers; and resorbable barriers.
13 Good.

14 So we'll now start with the first category and our
15 intent here now is to go through this first category and
16 discuss and amend any of the material, and then at the end
17 we'll vote for recommending the definitions, the recommended
18 class, and the special controls to FDA.

19 So, Dr. Glowacki, maybe you can lead us, then,
20 through what is now 1 and 2 to see whether there are any
21 amendments or combinations that you want to do for these
22 categories, and we're working then from the revised document
23 entitled "Bone Filling and Augmentation Device Definitions
24 and Recommended Classifications."

1 DR. GLOWACKI: Actually, for what I'm going to
2 suggest, it may be simpler to look at the old grid because
3 I'm going to propose a simplification by grouping six--it
4 will amount to six groups together. That's 2A, 2B, 3A, 3B,
5 5A, 5B. What that amounts to is the non-periodontal defects
6 that are either load-bearing or non-load-bearing. I don't
7 think there's any particular reason for lifting the
8 intraosseous gaps, the void, the clefts, the augmentation of
9 the alveolar ridge, other load-bearing deficiencies, onlay
10 augmentation, or fresh extraction sites into three separate
11 groups, but I feel that they're all osseous either voids or
12 augmentations. And since there were no functional
13 consequences in terms of the classification, it would be
14 more streamlined to group them all together as indications.

15 So the language of that would become, for example,
16 on the first page of the outline, 1(b), 1(c), 1(d) and 1(e)
17 indications combined. Is that clear? That would amount to
18 on the outline grouping all of the indications currently
19 under 1(b), 1(c), 1(d), 1(e). And then, of course, we've
20 already grouped the polymers together, so that would be
21 2(b), 2(c), 2(d), and then I guess all others, and there is
22 a formal definition.

23 DR. ROBERTSON: Yes, Mark?

24 DR. PATTERS: A question for Dr. Glowacki. Some

1 of these materials, particularly the non-resorbable
2 materials, have been shown to be very effective in non-load-
3 bearing areas where one would use them, for instance, for
4 some aesthetic, but when placed under load have fractured or
5 are not so successful. Are you comfortable, then, inputting
6 load and non-load-bearing areas together in a single group?

7 DR. GLOWACKI: Well, since they're all under Class
8 III, I don't see that there's a reason to be worried about
9 that.

10 DR. PATTERS: Doesn't that remain to be
11 determined, what they're going to be under?

12 DR. ROBERTSON: Yes.

13 DR. PATTERS: Isn't that an assumption that maybe
14 we shouldn't make yet? I mean, if someone meets one of
15 those indications, such as for augmenting for non-load-
16 bearing areas, does that mean you have to meet them all?

17 DR. GLOWACKI: Well, as a matter of fact, I was
18 going to make a recommendation for a reclassification for
19 certain indications that we've already defined, so maybe
20 we're putting the cart before the horse and we ought to
21 reassess the classification. Would that be more efficient?

22 DR. ROBERTSON: Well, if you're going to do that,
23 what I think we probably ought to do is, where we can, going
24 back to this outline, use the grid to rewrite the

1 definition.

2 DR. GLOWACKI: Okay. Then maybe I--

3 DR. ROBERTSON: But you have to rewrite the
4 definition such that the class that you recommend and the
5 special controls that you recommend are consistent with that
6 definition, and I think that's what Mark is trying to get us
7 to do.

8 DR. PATTERS: Well, the filling of periodontal
9 defects or intraosseous gaps--these are indications, are
10 they not? Those are indications for use?

11 DR. ROBERTSON: That's correct.

12 DR. PATTERS: So I think one would have to feel
13 comfortable in combining indications that they indeed are
14 combinable.

15 DR. ROBERTSON: Right.

16 DR. PATTERS: And I'm a little uncomfortable with
17 combining them all at this point.

18 DR. ROBERTSON: So that maybe we can start out
19 with rewriting the definition of those that you're
20 comfortable with in terms of classification.

21 DR. GLOWACKI: Well, this isn't particularly with
22 regard to Dr. Patters' comments, but maybe I could just try
23 to get this out of the way for discussion because it's a
24 little bit simpler. I was going to recommend that under

1 definition 1(a), it would be the ceramic and polymeric and
2 composite bone-filling devices for use in filling
3 periodontal defects or as extenders of fresh autogenous bone
4 grafts in filling other non-load-bearing intraosseous
5 defects.

6 And the reason for this is that those were the
7 very earliest indications for using these materials in oral
8 applications, and the literature on that is very compelling
9 in terms of effectiveness and safety. And the dental
10 community has added on over the years other uses without the
11 fresh autogenous bone, but rather mixing with blood or
12 saliva for filling in those large defects, and for those
13 uses I don't feel that there's very solid evidence for
14 effectiveness. But rather than throwing the baby out with
15 the bath water, given the consequences in terms of
16 classification, that would be a tidy definition for 1(a).

17 DR. ROBERTSON: Well, yes, and maybe we can go
18 1(a) and 2(a), which is what you're trying to combine.

19 DR. GLOWACKI: Yes.

20 DR. ROBERTSON: So that if we all look at--let's
21 start at the top and if we all look at 1(a) and 2(a), we
22 then have a ceramic, polymeric, or composite bone-filling
23 device for use in filling periodontal defects--.

24 DR. GLOWACKI: Can I restate my recommendation for

1 the next words?

2 DR. ROBERTSON: Yes.

3 DR. GLOWACKI: "or as an extender of fresh
4 autogenous bone graft in filling bone defects in the non-
5 load-bearing oral and maxillofacial region," with a
6 recommendation.

7 DR. ROBERTSON: We can do that, but suppose we
8 kept it separate from that? I mean, based on your
9 indications, we're just trying to get periodontal defects
10 done.

11 DR. GLOWACKI: Yes.

12 DR. ROBERTSON: We may be able to lump even
13 further, but maybe we'll work our way down a little bit at a
14 time.

15 So if we do 1(a) and 2(a), help me with how it
16 reads. Does it read, then, "A ceramic, polymeric, or
17 composite bone-filling device for use in the filling of
18 periodontal defects?" And then where do I go, then, with
19 defining what kind of device it is? What do I do with
20 resorbable and non-resorbable device versus a device that is
21 composed of a single polymer, copolymers, or composites of
22 two or more materials of a different type? Are we together
23 here?

24 DR. GLOWACKI: You're into the definition?

1 DR. ROBERTSON: Yes. I mean, you want to combine
2 those two and I'm trying to help you do it.

3 DR. GLOWACKI: "Either a resorbable or non-
4 resorbable device that is naturally or synthetically
5 derived," and then I think the next part of it is redundant.
6 Go ahead. You're ahead of me on that. Go ahead.

7 DR. ROSAN: "Or composed of a single polymer,
8 copolymers, or composites of two or more materials." I
9 think that would stop--

10 DR. GLOWACKI: Yes.

11 DR. ROSAN: It just drafts in all of the
12 materials.

13 DR. ROBERTSON: Okay, and what do you do with
14 "these devices may be in granular or mesh form?" Common for
15 both of them?

16 DR. GLOWACKI: Yes, and then we have to leave in
17 this category "does not include tricalcium phosphate
18 granules." So we've just merged two sentences two times.

19 DR. ROBERTSON: Right. Pam, are you with us?

20 MS. SCOTT: Yes.

21 DR. ROBERTSON: No. I meant in terms of what we
22 just did.

23 MS. SCOTT: Yes.

24 DR. ROBERTSON: I mean, we probably ought to chop

1 this up into short sentences instead of one long, flowing
2 thing, and the sentence probably ought to be one--I mean,
3 the first sentence ought to be, "A ceramic, polymeric, or
4 composite bone-filling device for use in filling periodontal
5 defects." And then the second sentence is, "The device is a
6 resorbable or non-resorbable device that is naturally or
7 synthetically derived, or is composed of a single polymer,
8 copolymers or composites of two or more materials of a
9 different type or phase." And then the third sentence is,
10 "These devices may be in granular or mesh form."

11 Did I do good there?

12 DR. GLOWACKI: Yes. I think that's okay.

13 DR. ROBERTSON: Okay. So that is, then, the
14 proposed--that would be the proposed definition of 1(a)
15 under--that's 1(a) for the moment, and that's periodontal
16 defects.

17 Okay. If we can go, then, to 1(b) and 2(b), so
18 this is non-load-bearing oral and maxillofacial region.

19 DR. PATTERS: There is no more (b), is there?

20 DR. GLOWACKI: We haven't added (b) yet. We
21 haven't merged (b) yet.

22 DR. PATTERS: I'm sorry, okay.

23 DR. ROBERTSON: Okay?

24 DR. PATTERS: It's little a, little b.

1 DR. ROBERTSON: Yes. I'm sorry; little b, 1(b)
2 and 2(b).

3 Okay. So if I follow your pattern here, it is "A
4 ceramic, polymeric, or composite bone-filling device for use
5 in filling bone defects in the non-load-bearing oral and
6 maxillofacial region." The second sentence: "The device is
7 a resorbable or non-resorbable device that is naturally or
8 synthetically derived"--

9 DR. GLOWACKI: "Or."

10 DR. ROBERTSON: --"or is composed of a single
11 polymer, copolymers, or composites of two or more materials
12 of a different type or phase." "The devices are to be used
13 to aid in the filling and repair of oral and maxillofacial
14 intraosseous gaps, voids and clefts in non-load-bearing
15 regions where the bony cavity is defined. These devices are
16 generally in granular, mesh or solid form."

17 Did I do okay?

18 DR. GLOWACKI: Well, except in anticipation of my
19 coming back to the first definition, I would recommend in
20 the very beginning to say, "A ceramic, polymer or composite
21 bone-filling device used alone for filling . . ."

22 DR. ROBERTSON: Okay, good. And then the
23 recommended class for 1(b), which in general I'll call non-
24 load-bearing and oral maxillofacial, is III.

1 DR. PATTERS: You need to determine that.

2 DR. ROBERTSON: I'm sorry. Both of them were
3 recommended before as III. I'm sorry. You're right, Mark.
4 Okay, so then can we try to make a 1(c) out of the old 1(c)
5 and 2(c), one for the augmentation of the alveolar ridge--
6 augmentation of the alveolar ridge?

7 "A ceramic, polymeric or bone-filling device for
8 use in the augmentation of the alveolar ridge. The device
9 is a resorbable or non-resorbable device that is naturally
10 or synthetically derived or that is composed of a single
11 polymers, copolymers or composites of two or more materials
12 of a different type or phase. The device is to be used for
13 the augmentation of the alveolar ridge. These devices may
14 be in granular, mesh or solid form."

15 DR. GLOWACKI: I would wonder if the repair of
16 bone defects in load-bearing regions could be combined with
17 the alveolar ridge augmentation.

18 Dr. Patters is shaking his head, yes. That works.

19 DR. PATTERS: That works for me.

20 DR. ROBERTSON: Willie?

21 DR. STEPHENS: Those are basically the same, yes.

22 DR. ROBERTSON: Okay.

23 MS. SCOTT: Dr. Robertson, if I can just clarify
24 the reason why those two indications were separate, the

1 reason being that there are devices in which the device is
2 cleared for use in augmentation of the alveolar ridge, but
3 it's not cleared for other load-bearing indications, and so
4 that's why they were separated. So, that is something for
5 you to consider in this process.

6 DR. ROBERTSON: Why is it important for me to do
7 that?

8 DR. TYLEND: You mean not cleared for load-
9 bearing; cleared for alveolar ridge augmentation, but not
10 for load-bearing.

11 MS. SCOTT: Not for load-bearing. I'm sorry. If
12 I said non-load-bearing, forgive me. That was a
13 misstatement. Right. There are devices that have been
14 cleared for alveolar ridge augmentation in their indication
15 statement, but it did not include other load-bearing--I'm
16 sorry--other load-bearing--

17 DR. TYLEND: Load-bearing.

18 DR. STEPHENS: Other load-bearing, such as--

19 DR. TYLEND: I think you mean that did not
20 include load-bearing.

21 MS. SCOTT: Yes, the wording of part (d).

22 DR. PATTERS: I would be more comfortable with (c)
23 reflecting non-load-bearing areas and (d) reflecting load-
24 bearing areas, and leave alveolar ridge out of the equation.

1 Julie?

2 DR. GLOWACKI: So Keeping them separate--

3 DR. PATTERS: No.

4 DR. GLOWACKI: --as three separate--I didn't
5 follow that.

6 DR. ROBERTSON: (c) now is augmentation of the
7 alveolar ridge.

8 DR. GLOWACKI: So (b) was non-load--

9 DR. ROBERTSON: (b) was non-load-bearing.

10 DR. STEPHENS: Paul, could you read (c) again?

11 DR. ROBERTSON: (c) is presently augmentation of
12 the alveolar ridge, augmentation of the alveolar ridge.

13 DR. STEPHENS: Period?

14 DR. ROBERTSON: That's right, period, at the
15 moment. And Julie was suggesting adding--

16 DR. GLOWACKI: (d), load-bearing.

17 DR. ROBERTSON: --(d), load-bearing regions.

18 That's right, combine (c) and (d), and I guess you have to
19 remind me what augmentation of the--what's the difference
20 between augmentation of the alveolar ridge and repair of
21 bone defects in load-bearing regions.

22 DR. PATTERS: It's possible to augment the
23 alveolar ridge in a non-load-bearing area.

24 DR. DRUMMOND: Can you explain that to me? I'm

1 getting lost here.

2 DR. PATTERS: Who said that?

3 DR. DRUMMOND: I did. I'm having trouble with the
4 definition of load-bearing and--

5 DR. PATTERS: Sure. If someone has had some
6 trauma where they've lost a large part of the alveoli, say,
7 in the maxillary anterior, and you place material in order
8 to bring the alveolar ridge out in a more labile direction,
9 that area would likely not be load-bearing. Only the
10 occlusal direction would be load-bearing.

11 DR. DRUMMOND: I mean, but you forget lip muscle
12 pressure on there. It comes--

13 DR. PATTERS: I don't think that's the kind of
14 load we're talking about.

15 DR. DRUMMOND: Well, that's my question. What's
16 your definition of a load, because if you have an alveolar
17 ridge and you put a denture on it, to me, that's load-
18 bearing.

19 DR. PATTERS: It absolutely is; that is load-
20 bearing.

21 DR. DRUMMOND: So I'm confused.

22 DR. ROBERTSON: Maybe another example is I'm
23 putting in a three-unit bridge over an extraction site where
24 I've lost much of the bone and I want to plump up that ridge

1 for aesthetic reasons where the ponc will be. The area
2 will bear essentially no load. I'm doing it for aesthetic
3 reasons only.

4 DR. PATTERS: Load refers to occlusal load, does
5 it not, Paul?

6 DR. DRUMMOND: I mean, your case is maybe a
7 vertical load, but I'm going to argue there's a horizontal
8 load if you're doing that.

9 DR. ROBERTSON: That would be fine with me. I
10 don't have any problem with it.

11 DR. DRUMMOND: I'm unfortunately trained as an
12 engineer, and you have a load. You're arguing over
13 direction of the load.

14 DR. PATTERS: No. It's more than direction. It's
15 also the intensity of the load.

16 DR. DRUMMOND: Okay, but you have load or no load.

17 DR. PATTERS: It's well-known that some of these
18 materials in a minimal load--I won't call it no-load any
19 longer, Dr. Drummond.

20 DR. DRUMMOND: Okay.

21 DR. PATTERS: --in a minimal load, will do just
22 fine, but place them under occlusal load and they will
23 fracture.

24 DR. DRUMMOND: I'm not arguing that. I'm getting

1 confused on your definition of a load.

2 DR. PATTERS: Occlusal load.

3 DR. DRUMMOND: Okay, but that's not what this
4 says.

5 DR. PATTERS: Well, there are loads and there are
6 loads.

7 DR. DRUMMOND: Yes, I know.

8 DR. GLOWACKI: Can we ask Pam what has been
9 cleared in this category, because that is what brought the
10 whole thing up? Could you help us? Mr. Hlavinka, what has
11 been cleared?

12 MS. SCOTT: For some of the indications that we've
13 seen in the labeling, we've seen--and I'm going to
14 paraphrase the type of indication we've seen. For filling
15 of non-load-bearing oral bone defects and for alveolar ridge
16 augmentation, this device should not be used for load-
17 bearing indications or load-bearing applications.

18 DR. GLOWACKI: So nothing has been cleared for
19 load-bearing bone-filling material?

20 MS. SCOTT: Yes, there have been some non-
21 resorbable ceramics cleared for non-load-bearing and load-
22 bearing indications. We have not identified any resorbable
23 ceramics that were cleared for load-bearing indications, nor
24 have we been able to identify any of the polymeric or

1 composite materials for load-bearing indications.

2 DR. GLOWACKI: Is it our purpose, then, to only
3 have terminology in these definitions that refer to cleared
4 indications?

5 MS. SCOTT: I will respond to this and then I
6 would like to ask either Ms. Jeffries or Mr. Hlavinka or Mr.
7 Ulatowski to also provide some explanation. The
8 classifications should classify the pre-amendments device if
9 it's not a pre--or a device that we have found substantially
10 equivalent to the pre-amendments device. So when I say it
11 hasn't been cleared, then it had not been found
12 substantially equivalent to a pre-amendments device.

13 DR. ROBERTSON: It probably doesn't hurt us,
14 actually, to stay with, you should forgive me, non-load-
15 bearing separate from--and I still think we could have an
16 (a), (b), (c), and leave the ridge augmentation as a
17 separate category and it doesn't hurt anything.

18 DR. PATTERS: I would just argue to try to make
19 Dr. Drummond's problems worse and have (b) be filling of
20 defects in non-load-bearing areas and (c) filling of defects
21 in load-bearing areas, and leave augmentation of alveolar
22 ridges out of the issue entirely, because I then become
23 confused if you left that as a separate item and I'm trying
24 to decide, well, is that load-bearing or not load-bearing.

1 DR. GLOWACKI: When you say out of the issue, you
2 mean a separate definition?

3 DR. PATTERS: No. You don't need a definition at
4 all. There are just load-bearing areas and non-load-bearing
5 areas.

6 DR. ROBERTSON: Well, I think augmentation of the
7 alveolar ridge was quite a specific indication for which a
8 number of devices were offered to FDA, and therefore the
9 classification appears here because it so often appears as
10 an indication for these devices; indeed, among the very
11 earlier indications of these devices.

12 DR. PATTERS: That's fine, but you'll have to then
13 separate that into intended to be load-bearing and not
14 intended to be load-bearing, will you not?

15 DR. ROBERTSON: Yes.

16 DR. GLOWACKI: We don't have to. If it's cleared
17 without those specifications, then we don't have to raise
18 that issue, do we?

19 DR. PATTERS: See, I would say that you could say
20 for (b) "for use in filling bone defects or augmenting the
21 alveolar ridge in non-load-bearing areas." And then I feel
22 that for (c) you could say "for augmentation of the alveolar
23 ridge and repair of bone defects in load-bearing areas," and
24 that would make me happy.

1 DR. ROBERTSON: Okay. That's a nice solution,
2 actually. So we have augmentation of the alveolar ridge in
3 both (b) and (c).

4 DR. PATTERS: And load-bearing and non-load-
5 bearing differentiates them and it gets rid of a category,
6 which is always helpful.

7 DR. ROBERTSON: Fine, so let's make sure we all
8 agree on how (b) reads. (b) reads, "A ceramic, polymeric or
9 composite bone-filling device used alone for filling bone
10 defects and augmenting"--

11 DR. PATTERS: "And/or."

12 DR. ROBERTSON: --"and/or augmenting the alveolar
13 ridge in the non-load-bearing oral and maxillofacial
14 region."

15 DR. PATTERS: I love it.

16 DR. GREENSPAN: I think this reads beautifully,
17 but I'm wondering if you would consider the area which in
18 this sentence is called a non-load-bearing alveolar ridge a
19 bone defect. In other words, do you actually need to even
20 mention that?

21 DR. ROBERTSON: Filling--

22 DR. ROSAN: It says "bone-filling defect and/or."

23 DR. ROBERTSON: Yes. It's--

24 DR. GREENSPAN: But I'm wondering if you need the

1 augmentation of the alveolar ridge in non-load-bearing areas
2 at all. Is that not a bone defect?

3 DR. GLOWACKI: No.

4 DR. PATTERS: I tried that.

5 DR. GREENSPAN: All right.

6 DR. GLOWACKI: Yes, we tried that before. It
7 doesn't work.

8 DR. PATTERS: I tried that line. The Chairman
9 didn't go for it.

10 DR. GREENSPAN: He didn't go for it, okay. I
11 understand. I apologize.

12 DR. ROBERTSON: I'm trying to think of examples.
13 I mean, plumping out would be--I would accept the notion of
14 plumping out as being augmentation of the ridge. I was just
15 trying to be clear, since augmentation of the ridge appeared
16 so often. I mean, of all the indications we had to look at,
17 it was number one. I was just trying to keep it in there,
18 and I didn't know that keeping it in hurt anything.

19 DR. PATTERS: I agree.

20 DR. GREENSPAN: Agreed.

21 DR. DRUMMOND: Can I come back to--can we then put
22 in non-occlusal? As I understand your definition, load-
23 bearing means occlusal. Can we put that in there somewhere?
24 I mean, if that's the generally accepted definition, fine,

1 but--

2 DR. ROBERTSON: I think people would understand.

3 DR. PATTERS: Yes. I don't think they think about
4 the passage of air molecules in and out of the oral cavity
5 as putting a load on the tissue. I think they think
6 occlusion. I don't think they think about the lips or the
7 tongue. I'm pretty comfortable with it.

8 DR. STEPHENS: That's the principal load that
9 we're concerned about.

10 DR. ROBERTSON: So now we go back to 1(c). Let me
11 make sure I have this. "Ceramic . . . bone-filling device
12 used alone for filling bone defects and augmenting the
13 alveolar ridge in the non-load-bearing oral and
14 maxillofacial region." Good. So, that's non-load-bearing,
15 and now in 1(c) we're going to have load-bearing, is that
16 correct? And it is going to read, "A ceramic"--okay, Julie,
17 help me here. We're going to try to combine what is
18 presently (c) and (d), is that correct?

19 DR. GREENSPAN: No.

20 DR. O'NEILL: No. You don't need (c)--

21 DR. PATTERS: Yes, we do need--you're correct.

22 DR. ROBERTSON: Yes, I think so. We need to
23 combine old--

24 DR. PATTERS: Augmentation is going in both the

1 new (b) and the new (c).

2 DR. ROBERTSON: Right.

3 DR. GLOWACKI: For the load-bearing, right.

4 DR. ROBERTSON: So we're trying to combine 1(c)
5 and (d) and 2(c) and (d) into one statement.

6 DR. GLOWACKI: That will be "A ceramic, polymeric
7 or composite device for use in the repair of bone defects
8 and/or augmentation of the alveolar ridge in load-bearing
9 regions." That's the parallel sentence.

10 DR. ROBERTSON: Good, and the distinction in the
11 old 1(c) and (d) between ceramic bone-filling device and
12 non-resorbable bone-filling device doesn't bother you? You
13 don't care whether these are resorbable or non-resorbable?

14 DR. GLOWACKI: Well, I don't care, but maybe there
15 was some reason it was done.

16 DR. ROBERTSON: It is not so much true with the
17 old 2(c) and (d). You see, that was--

18 DR. GLOWACKI: There may not be any resorbable--

19 DR. ROBERTSON: So are there non-resorbable bone-
20 filling devices, Pam?

21 DR. GLOWACKI: Are there resorbable, you mean.
22 The question is are there resorbables in load-bearing--

23 DR. ROBERTSON: Right. There's a non-resorbable--
24 the word "non-resorbable" in 1(b), which is the first time

1 "non-resorbable" appears. Why is that?

2 MS. SCOTT: We were unable to identify any
3 resorbable ceramic devices that were indicated for load-
4 bearing applications other than a general statement of
5 augmentation of the alveolar ridge.

6 DR. GLOWACKI: So we should keep "non-resorbable"
7 in.

8 DR. ROBERTSON: But does that mean that there's a
9 resorbable--

10 MS. SCOTT: But there are resorbable devices for
11 augmentation of the alveolar ridge.

12 DR. PATTERS: In non-load-bearing--

13 DR. GLOWACKI: In non-load-bearing--that's covered
14 in--

15 MS. SCOTT: In some of the indications, the
16 statement for augmentation of the alveolar ridge wasn't
17 necessarily specified load-bearing or non-load-bearing. It
18 was a general statement of augmentation of the alveolar
19 ridge.

20 DR. ROBERTSON: But it doesn't fit with (c), which
21 has non--we have 1(c), which is a ceramic bone-filling
22 device for use in the augmentation of the alveolar ridge is
23 a resorbable or non-resorbable device, and then when we get
24 down to (d), it's non-resorbable. So you couldn't find a

1 resorbable, but there might be one?

2 MS. SCOTT: Yes. We couldn't identify resorbable.

3 DR. ROBERTSON: Right, but there might be one?

4 MS. SCOTT: Right. There could be one.

5 DR. ROBERTSON: So is that--

6 DR. GLOWACKI: Unlikely.

7 DR. ROBERTSON: Yes, I would say. But I mean do
8 we have to have the language say--can they both start out
9 saying "A ceramic bone-filling device for use in the repair
10 of bone defects and/or augmentation of the alveolar ridge in
11 load-bearing regions and for onlay augmentation?"

12 DR. PATTERS: You've raised my confusion. Have we
13 not combined into a single group the resorbable and non-
14 resorbable ceramics, as well as the polymeric, and
15 therefore every definition we're writing encompasses all
16 three of those groups?

17 DR. ROBERTSON: Yes.

18 DR. PATTERS: Okay.

19 DR. ROBERTSON: I'm just trying to deal with the
20 resorbable versus non-resorbable.

21 DR. PATTERS: Is that necessary that we do that?

22 DR. ROBERTSON: That's what I'm asking.

23 MS. SCOTT: Dr. Robertson, I think Ms. Jeffries
24 had a statement that may clarify things.

1 MS. JEFFRIES: Okay. I don't think resorbable or
2 non-resorbable is an issue because if you have a general
3 category of ceramic, polymeric and composite bone-filling
4 devices, the 510(k) process will take care of getting the
5 appropriate data for a resorbable device because there won't
6 be, you know, anything to find it equivalent to without
7 getting performance data. So you don't have to specify
8 resorbable and non-resorbable. That can be accommodated in
9 the process of finding a device substantially equivalent.

10 DR. ROBERTSON: Good.

11 DR. GLOWACKI: That would hold for all
12 definitions?

13 MS. JEFFRIES: That would hold for all
14 definitions, yes.

15 DR. GLOWACKI: It should for all.

16 MS. JEFFRIES: Right, right.

17 DR. ROBERTSON: Good. All right, then, can we go
18 back? Now that we have the three put together, while we're
19 having our discussion on the barriers, Dr. Glowacki is going
20 to write these out for us, these three things, from start to
21 end.

22 Can we go back to those three now? The first, the
23 periodontal defects, and we have a recommended Class II for
24 both of them, and I'm opening the question as to whether