

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

Volume II

Wednesday, August 9, 1995

8:45 a.m.

Marriott Hotel
Pooks Hill
Bethesda, Maryland

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JOHN KUEHNE, M.S., D.D.S., Guest

CHRIS H. MILLER, M.S., Ph.D., Guest Speaker

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1 P R O C E E D I N G S

2 DR. TYLEND: I would like to welcome everyone to
3 today's meeting of the Dental Products Panel. I'm Dr.
4 Carolyn Tylanda, Executive Secretary of the Panel.

5 We have a sign-up sheet out by the registration
6 desk. If anybody hasn't signed that sheet, we would
7 appreciate it if sometime during the morning you'd stop by
8 and sign.

9 I'd like to begin by introducing everyone at the
10 main table. Starting to my far left is Mr. Tim Ulatowski,
11 who is the Acting Director of the Pilot Division in the
12 Office of Device Evaluation, Center for Devices and
13 Radiological Health at FDA.

14 Next is Dr. Peggy O'Neill, who is the Vice Dean
15 Protom of the Dental Branch, University of Texas Health
16 Science Center at Houston.

17 Dr. Mark Patters, Professor and Chairperson,
18 Department of Periodontology, College of Dentistry,
19 University of Tennessee.

20 Dr. Bob Rosan, Professor, Department of
21 Microbiology, School of Dental Medicine, University of
22 Pennsylvania.

23 Dr. Jean Frazier, Philomath, Oregon. Dr. Frazier
24 is the consumer representative to the Panel.

1 On my right is Dr. Paul Robertson. Dr. Robertson
2 is the Chairperson for today's meeting. He is the Dean of
3 the School of Dentistry at the University of Washington.

4 Dr. Manville Duncanson, Jr., Professor and
5 Chairperson, Department of Dental Materials, College of
6 Dentistry, University of Oklahoma.

7 Dr. Deborah Greenspan, Clinical Professor of Oral
8 Medicine, Department of Stomatology, School of Dentistry,
9 University of California at San Francisco.

10 Dr. Willie Stephens, Associate Surgeon, Division
11 of Maxillofacial Surgery, Brigham & Women's Hospital,
12 Boston.

13 Dr. Otis Bouwsma, Senior Scientist, Health Care
14 Division, Procter & Gamble Company. Dr. Bouwsma is the
15 industry representative to the Panel.

16 Dr. James Drummond, Professor, Department of
17 Restorative Dentistry, College of Dentistry, University of
18 Illinois at Chicago.

19 Dr. Richard Norman, Professor, Department of
20 Restorative Dentistry, School of Dental Medicine, Southern
21 Illinois University.

22 Yesterday the Panel selected 1996 dates--these are
23 tentative dates--for next year's Panel meetings. These are:
24 February 27-29; May 7-9; September 10-12; and December 10-

1 12. I will remind everyone that the next meeting of this
2 panel will be tentatively set for December 5, 6, and 7.
3 There will definitely be a meeting. We don't know yet if it
4 will last all three days, but it will start on the 5th. On
5 that day, there will be an overlap meeting between the Panel
6 and the Dental Plaque Subcommittee.

7 There is a sheet outside giving you a phone number
8 for the Medical Device Advisory Committee, but in case you
9 didn't pick up that sheet, you can obtain up-to-date
10 information on Panel activities by calling 800-741-8138.
11 There is a code for each Panel at FDA. In order to avoid
12 having to listen to long messages and making choices, you
13 can punch in the Dental Products Panel code, which is 12518.
14 Sometimes there isn't much information on that line. That
15 means that we don't have any information. It's often only a
16 month before the meeting when we finally have a location for
17 the meeting. Any agenda items that we can publicize are
18 available on this message.

19 I will now read a letter from Dr. D. Bruce
20 Burlington, Director, Center for Devices and Radiological
21 Health, dated and signed August 7, 1995, appointment to
22 temporary voting status. Pursuant to the authority granted
23 under the Medical Devices Advisory Charter, dated October
24 27, 1990, and amended April 20, 1995, I appoint the

1 following persons as voting members of the Dental Products
2 Panel for the duration of this meeting on August 8-9, 1995:
3 Dr. Paul B. Robertson, Dr. Julianne Glowacki. Dr. Robertson
4 will serve as Chairperson for this meeting.

5 For the record, these people are special
6 Government employees and are either a consultant to this
7 Panel or a consultant or voting member of another panel
8 under the Medical Devices Advisory Committee. They have
9 undergone the customary conflict-of-interest review, and
10 they have reviewed the material to be considered at this
11 meeting.

12 Dr. Glowacki was present for yesterday's portion
13 of the meeting, but she will not be able to be here today.

14 The voting members for today's meeting are: Drs.
15 Drummond, Norman, O'Neill, Robertson, Rosan, and Stephens.
16 Dr. Robertson as Chairperson will vote only in the case of a
17 tie.

18 I now have a conflict-of-interest statement to
19 read.

20 Conflict-of-interest statement for the Dental
21 Products Panel, August 8-9, 1995. The following
22 announcement addresses conflict-of-interest issues
23 associated with this meeting and is made part of the record
24 to preclude even the appearance of an impropriety. To

1 determine if any conflict existed, the agency reviewed the
2 submitted agenda and all financial interests reported by the
3 committee participants. The conflict-of-interest statues
4 prohibit special Government employees from participating in
5 matters that could affect their or their employer's
6 financial interests. However, the agency may determine that
7 participation of certain consultants and members, the need
8 for whose services outweighs the potential conflict of
9 interest involved, is in the best interest of the
10 Government.

11 We would like to note for the record that the
12 agency took into consideration matters regarding Drs. Peggy
13 O'Neill and Julianne Glowacki. Dr. O'Neill reported that
14 her School of Dentistry has received aid from a manufacturer
15 of dental filling material. Dr. Glowacki reported that a
16 colleague in her department has a consulting arrangement
17 with the manufacturer of bone-filling and augmentation
18 materials. Since these matters are not directly related to
19 matters before the committee, the agency has determined that
20 Drs. O'Neill and Glowacki may participate fully in committee
21 deliberations.

22 We would like to note for the record that Dr.
23 Chris Miller, who is a guest speaker with us today, has
24 acknowledged interest in and professional relationships with

1 several firms that manufacture dental handpieces. These
2 interests are in the form of research contracts.

3 In the event that the discussions involve any
4 other products or firms not already on the agenda for which
5 an FDA participant has a financial interest, the
6 participants should exclude themselves from such
7 involvement, and their exclusion will be noted for the
8 record.

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

14 As everyone knows by now, there are three items on
15 the agenda for this two-day meeting. Yesterday the Panel
16 began finalizing the definitions related to the
17 classification of bone-filling and augmentation materials
18 for oral use. This topic will be completed this morning,
19 and so we will begin the other two topics following
20 completion of this issue.

21 There are a few handouts out on the table, if
22 anyone in the audience would like them and hasn't picked one
23 up. These are the definitions--the working definitions that
24 the Panel developed yesterday. If you have a copy, you'll

1 be able to follow along as the Panel goes through these and
2 comments and votes.

3 The other two issues will be addressed in the
4 following order: first, the Dental Device Ingredient
5 Labeling, and next the Guidance Document for Dental
6 Handpieces.

7 I would like to take just a couple minutes to
8 alert the Panel to the material that's in their file folders
9 related to the latter two topics. You have in your packets
10 in front of you related to Dental Device Ingredient Labeling
11 in the booklet, the green booklet, a background statement on
12 the topic, and you have a list of the devices, this list you
13 developed at the October 1994 meeting, list of items to be
14 recommended for ingredient labeling, along with the
15 recommended priority. You have another list that includes
16 the items that you are not interested in recommending for
17 ingredient labeling at this time.

18 In that same booklet, on the topic of handpieces,
19 you have a background statement, and you have a list of
20 questions and topics to help guide you in today's
21 discussions.

22 You have, not in the booklet but in the packet in
23 front of you, a number of items, and I'll just go through
24 them in case you want to look them over a little later or

1 follow along during the presentations. You have a letter
2 and statement from the Dental Manufacturers of America,
3 Dental Device Ingredient Labeling. You have the text of Dr.
4 McKenzie's presentation that he will be giving during the
5 open public hearing portion of the meeting on the same
6 topic, ingredient labeling.

7 You have a statement on ingredient labeling by the
8 American Dental Trade Association. This is the presentation
9 by Mr. Fise. On dental handpieces, you have a copy of the
10 guidance document; a letter from Laros Research, a
11 manufacturer of dental handpieces, stating their concerns; a
12 letter from Den-Tal-Ez, another manufacturer of dental
13 handpieces; a letter from Dr. Pedrazzi, a practitioner from
14 California; and the text of the presentation by Mr. Steve
15 Jefferies from Dentsply, who will be speaking this morning
16 during the open public hearing portion of the meeting.

17 With that, I'll turn the meeting over to Dr.
18 Robertson.

19 CHAIRMAN ROBERTSON: Well, good morning. It's
20 another pretty morning in Washington, D.C.

21 The first thing we need to do this morning is
22 complete our recommendations to FDA for bone-filling and
23 augmentation devices, their definitions and the recommended
24 classifications. I have reviewed Dr. Bertolami's, the Chair

1 of this committee, previous work, and I will try to review
2 all of that quickly, hear a motion for approval of those
3 recommendations to FDA.

4 DR. NORMAN: So moved.

5 CHAIRMAN ROBERTSON: I'll entertain some
6 discussion and then we will do the vote.

7 The first classification is ceramic, polymeric, or
8 composite bone-filling devices that do not include
9 tricalcium phosphate for use in the filling of periodontal
10 defects. That's our Classification 1A, defined as a
11 ceramic, polymeric, or composite bone-filling device for use
12 in the filling of periodontal defects, a device that is to
13 be used to aid in the filling and repair of periodontal
14 defects. The device may be resorbable or nonresorbable, a
15 material that is naturally or synthetically derived or
16 composed of a single polymer, copolymers, or composites of
17 two or more materials of a different type or phase. Devices
18 may be in granular, mesh, or solid form.

19 The Panel has decided that the device is not life
20 sustaining or supporting. It is important in human health.
21 It does not present an unreasonable risk of illness or
22 injury, and the Panel decided that there was sufficient
23 information to establish special controls to provide
24 reasonable assurance of safety and effectiveness, those

1 controls to include voluntary standards, guidance documents,
2 and training.

3 The device is an implant, and any risks to health
4 are associated with those post-operative complications that
5 occur with oral flap procedures. There may be specific
6 immune reactions or material fragmentation.

7 Those conclusions were based on testimony before
8 the Panel, review of the literature, and the judgment of
9 Panel members, and the Panel concluded that the materials in
10 this category should be restricted to use by licensed
11 professionals with appropriate training in the use of the
12 device.

13 May I have a motion for approval of the
14 recommendation of ceramic, polymeric, or composite bone-
15 filling devices for use in the filling of periodontal
16 defects with the recommended class of Class II?

17 DR. ROSAN: So moved.

18 CHAIRMAN ROBERTSON: And a second?

19 DR. O'NEILL: Second.

20 CHAIRMAN ROBERTSON: Any discussion, additions,
21 corrections to that overview?

22 MR. ULATOWSKI: Mr. Chairman?

23 CHAIRMAN ROBERTSON: Yes?

24 MR. ULATOWSKI: Mr. Hlavinka has brought to my

1 attention that under the previous grid construction that we
2 had for polymers, clinical studies were indicated as a
3 special control. I don't know if the Panel wants to
4 reconsider that to include that provision or whatever.

5 CHAIRMAN ROBERTSON: We have used clinical studies
6 here to indicate new materials that may be like the--in that
7 context?

8 MR. HLAVINKA: Well, for the ceramic and the
9 composite, clinical studies weren't a part of the special
10 controls, only for the polymeric device was clinical studies
11 listed in the special controls. So it seemed to be an
12 anomaly. With the new grid, clinical studies are not
13 mentioned.

14 CHAIRMAN ROBERTSON: Any comment? Can we carry
15 over, Lou, the special control for polymeric materials?

16 MR. ULATOWSKI: I think you could make that
17 specific in regard to the polymers for your recommendation
18 purpose.

19 MR. HLAVINKA: On special controls, you could just
20 add clinical studies for the polymeric device.

21 CHAIRMAN ROBERTSON: Does any member of the Panel
22 have a problem with that?

23 [No response.]

24 CHAIRMAN ROBERTSON: So we will add clinical

1 studies for polymeric devices under special controls.

2 Any further discussion, problems?

3 [No response.]

4 CHAIRMAN ROBERTSON: Then all in favor of the
5 voting members, Drs. O'Neill, Rosan--I have a motion on the
6 floor--Norman, Drummond, Stephens, Rosan O'Neill. So we
7 have a motion, which has been seconded, to recommend our
8 grouping 1A, ceramic, polymeric, or composite bone-filling
9 devices in the filling of periodontal defects with the
10 recommended class of Class II with special controls,
11 voluntary standards, guidance documents, training, and
12 clinical studies for the polymeric devices. All in favor of
13 the motion, please raise your hand.

14 [A show of hands.]

15 CHAIRMAN ROBERTSON: And all opposed?

16 Let the record show that the voting members
17 unanimously supported the motion.

18 The second group is Group 1B, ceramic, polymeric,
19 or composite bone-filling devices for use alone--for use
20 alone--in filling bone defects and/or augmentation of the
21 alveolar ridge in the nonload-bearing oral and maxillofacial
22 region defined as a ceramic, polymeric, or composite bone-
23 filling device for use alone in filling bone defects and/or
24 augmenting the alveolar ridge in the nonload-bearing oral

1 and maxillofacial region, a device that is to be used to aid
2 in the filling and repair of intraosseous gaps, voids, and
3 clefts and/or for augmentation of the alveolar ridge in
4 nonload-bearing oral and maxillofacial regions. The device
5 may be resorbable or nonresorbable materials that are
6 naturally or synthetically derived or composed of a single
7 polymer, copolymers, or composites of two or more materials
8 of a different type or phase. These devices may be in
9 granular, mesh, or solid form.

10 Previous discussions of the Panel concluded that
11 the device was not life sustaining or life supporting, was
12 of importance in human health, did not present a potential
13 unreasonable risk of illness or injury, but the Panel felt
14 that there was not sufficient information to establish
15 special controls to provide reasonable assurance of safety
16 and effectiveness.

17 The risks of health were not the major issues.
18 Those risks included post-operative complications which
19 might be associated with any oral flap procedure, and there
20 were the same specific hazards, immune reactions and
21 fragmentation, as before. But the Panel felt that evidence
22 for the efficacy of the material used alone was not
23 sufficient to provide special controls and, therefore,
24 recommended Class III. In addition, the Panel recommended

1 restriction of use to licensed professionals who have
2 appropriate training in the use of the device.

3 So for purposes of discussion, may I have a motion
4 to approve the Panel's recommendation of Group 1B, ceramic,
5 polymeric, or composite bone-filling devices, for use alone
6 in filling bone defects or augmenting the alveolar ridge for
7 the recommended class of Class III?

8 DR. O'NEILL: So moved.

9 CHAIRMAN ROBERTSON: And a second?

10 DR. STEPHENS: Second.

11 CHAIRMAN ROBERTSON: And discussion?

12 [No response.]

13 CHAIRMAN ROBERTSON: Because the Panel was
14 confident about the data thus far in terms of safety and the
15 questions for these materials had to do with efficacy and
16 that there simply wasn't sufficient evidence to provide
17 special controls, the Panel previously recommended a
18 priority for the Class III of low. Is that consistent with
19 your present view?

20 [No response.]

21 CHAIRMAN ROBERTSON: Any further discussion?

22 [No response.]

23 CHAIRMAN ROBERTSON: All in favor of approving our
24 Class 1B, ceramic, polymeric, or composite bone-filling

1 devices for use alone in filling bone defects and/or
2 augmentation of the alveolar ridge in the nonload-bearing
3 oral and maxillofacial region with a recommended class of
4 III, priority low, please raise your hand.

5 [A show of hands.]

6 CHAIRMAN ROBERTSON: Three, four, five. Let the
7 record show that the voting members were unanimous, and the
8 motion carries.

9 The next grouping is Group 1C, ceramic, polymeric,
10 or composite bone-filling devices for use alone in the
11 repair of bone defects and/or augmentation of the alveolar
12 ridge in load-bearing sites of the oral and maxillofacial
13 region, defined as ceramic, polymeric, or composite bone-
14 filling devices for use alone in the repair of bone defects
15 and/or augmentation of the alveolar ridge in load-bearing
16 sites in the oral and maxillofacial region, a device that is
17 to be used to aid in the filling and repair of intraosseous
18 defects and/or for the augmentation of the alveolar ridge in
19 load-bearing oral and maxillofacial regions. The device may
20 be a resorbable or nonresorbable material that is naturally
21 or synthetically derived or composed of a single polymer,
22 copolymer, or composites of two or more materials of a
23 different type or phase. These devices may be in granular,
24 mesh, or solid form, and for exactly the same reasons as we

1 just discussed for the nonload-bearing areas, the Panel
2 concluded that there was not sufficient information to
3 establish special controls to provide reasonable assurance
4 of safety and effectiveness. The Panel recommended
5 classification as III, with a low priority, with the same
6 health risks, specific hazards to health, and restriction to
7 use by licensed professionals with appropriate training in
8 the use of the device.

9 May I have a motion to recommend approval of this
10 classification, with a recommended Class III of 1C, ceramic,
11 polymeric, or composite bone-filling devices for use alone
12 in the repair of bone defects and/or augmentation of the
13 alveolar ridge in load-bearing sites in the oral and
14 maxillofacial region.

15 DR. O'NEILL: So moved.

16 CHAIRMAN ROBERTSON: And a second?

17 DR. NORMAN: Second.

18 CHAIRMAN ROBERTSON: Any discussion?

19 MR. ULATOWSKI: Mr. Chairman, before we get too
20 far along, and Carolyn, I was trying to recall how we had
21 dealt with fresh extraction sites, how that was accommodated
22 under this consolidation.

23 CHAIRMAN ROBERTSON: Well, we used the term bone
24 defects in its broadest context and felt--

1 MR. ULATOWSKI: To generalize--

2 CHAIRMAN ROBERTSON: And chose not to include all
3 of the particular nomenclature for particular bone defects,
4 and thought, like other defects, we didn't have sufficient
5 information to establish controls for extraction sites or
6 any other similar osseous defect.

7 MR. HLAVINKA: So that's now captured in the
8 repair of bone defects?

9 CHAIRMAN ROBERTSON: That's correct.

10 MR. ULATOWSKI: That's fine.

11 CHAIRMAN ROBERTSON: Further questions or
12 discussion?

13 [No response.]

14 CHAIRMAN ROBERTSON: Then all in favor of
15 recommending the grouping 1C, ceramic, polymeric, or
16 composite bone-filling devices for use alone in the repair
17 of bone defects and/or augmentation of the alveolar ridge in
18 load-bearing sites in the oral and maxillofacial region,
19 with a recommended Class III, please raise your hand.

20 [A show of hands.]

21 CHAIRMAN ROBERTSON: Let the record show that the
22 voting members were unanimous, and the motion passes.

23 The fourth category is 1D, and 1D is ceramic,
24 polymeric, or composite bone-filling devices for use as an

1 extender of fresh autogenous bone grafts, defined as a
2 ceramic, polymeric, or composite bone-filling device for the
3 use as an extender of fresh autogenous bone grafts, a device
4 that is intended to be used for filling nonperiodontal
5 osseous defects in the oral and maxillofacial region. The
6 device may be a resorbable or nonresorbable material that is
7 naturally or synthetically derived or composed of a single
8 polymer, copolymers, or composites of two or more materials
9 of a different type or phase. Devices may be in granular,
10 mesh, or solid form.

11 The Panel recommended a classification of II. The
12 Panel determined the device was not life sustaining or life
13 supporting, was of importance for human health, did not
14 present an unreasonable risk of illness or injury; but
15 because there was considerable information about both the
16 safety and the efficacy of the use of these materials to
17 expand the volume of fresh autogenous bone, the Panel
18 thought that there was sufficient information to establish
19 special controls, those special controls to include
20 voluntary standards, guidance documents, and training.

21 The identification of risks to health were those
22 associated with oral flap procedures. The specific hazards
23 to health, again, included immune reactions and
24 fragmentation of the material. The information that the

1 Panel used was based on testimony before the Panel and
2 reviews of existing literature, and identification of needed
3 restrictions was the same as before, restriction to use by
4 licensed professionals with appropriate training in the use
5 of the device.

6 To facilitate discussion, may I have a motion to
7 recommend to the FDA this grouping 1D, ceramic, polymeric,
8 or composite bone-filling devices for use as extenders of
9 fresh autogenous bone grafts, with a recommended class of
10 II.

11 DR. ROSAN: So moved.

12 CHAIRMAN ROBERTSON: And a second?

13 DR. DRUMMOND: Second.

14 CHAIRMAN ROBERTSON: Discussion?

15 MR. ULATOWSKI: Yes, Mr. Chairman. Unlike the
16 other groupings, which were somewhat consolidations of
17 previous portions of the grid and the classification sheets
18 were taken from past discussions, as well as discussions
19 yesterday, 1D is somewhat unique, and that is, it's a new
20 construct. And I wanted the Panel to recognize that the
21 discussion regarding the classification that the Chairman
22 spoke of is fresh information. And so make sure that
23 everyone agrees regarding the ingredients on that sheet.

24 DR. TYLEND: Tim, are you referring to the

1 supplemental data sheet?

2 MR. ULATOWSKI: Yes, that's correct.

3 MS. JEFFRIES: Yes, the Panel should please fill
4 out the general device questionnaire and the supplemental
5 data sheet for this device.

6 CHAIRMAN ROBERTSON: I have filled out--I thought
7 it was better to do it afresh. So everything I have read to
8 you is a newly filled out both check sheet and descriptive
9 sheet.

10 DR. TYLEND: Would you like Dr. Robertson to go
11 through, read off all of the numbers and what he has checked
12 out for the Panel? Is that what you're asking, Tim?

13 CHAIRMAN ROBERTSON: I just did, but I'll do it
14 again.

15 MS. JEFFRIES: I guess if they accept it--

16 CHAIRMAN ROBERTSON: I think we understand that.

17 MS. JEFFRIES: Yes, I think it's all right. I
18 just wanted to make sure you had one made out.

19 MR. ULATOWSKI: That's fine, as long as everyone
20 understands that that's a fresh sheet and not a
21 consolidation of past sheets and discussions of hazards and
22 risks and what-not.

23 CHAIRMAN ROBERTSON: Yes, it was discussed
24 throughout, at least the sessions--

1 MR. ULATOWSKI: Yesterday, and before.

2 CHAIRMAN ROBERTSON: And before.

3 MR. ULATOWSKI: Right.

4 CHAIRMAN ROBERTSON: And Dr. Glowacki made the
5 point, I think, in previous meetings that I attended, as
6 well as yesterday, that there was considerable information,
7 particularly in the orthopedic literature, in the use of
8 these materials to expand the volume of fresh autogenous
9 bone. And it was the one area in which she and her
10 colleagues were comfortable that special controls were
11 sufficient.

12 MR. ULATOWSKI: Any procedural issues here?

13 MS. JEFFRIES: No. As long as the Panel agrees,
14 you know, has a consensus agreement with what Dr. Robertson
15 has written down, that's fine. It's just that we have to
16 have those pieces of paper.

17 MR. ULATOWSKI: Okay.

18 CHAIRMAN ROBERTSON: All in favor of the motion to
19 recommend this grouping 1D, ceramic, polymeric, or composite
20 bone-filling devices for use as an extender of fresh
21 autogenous bone grafts, with a recommended class of II, with
22 special controls of voluntary standards, guidance documents,
23 and training, please raise your hand.

24 [A show of hands.]

1 CHAIRMAN ROBERTSON: The vote is unanimous among
2 the voting members, and the motion carries.

3 The next grouping is 2A, nonresorbable barrier or
4 membrane for use in filling periodontal defects, defined as
5 a nonresorbable barrier membrane for use in filling
6 periodontal defects, a device that is naturally or
7 synthetically derived and is intended to function as a
8 barrier that allows selective tissue ingrowth to aid in the
9 filling and repair of periodontal defects. These devices
10 are intended to be removed.

11 The Panel concluded that these devices were not
12 life sustaining or supporting, were of importance in human
13 health, did not present a potential unreasonable risk of
14 illness or injury, and that there was sufficient information
15 to establish special controls to provide reasonable
16 assurance of safety and effectiveness, recommended that they
17 be classified as II, with the voluntary standards to
18 include--with the special controls to include voluntary
19 standards, guidances, training, labeling to indicate time of
20 removal, and clinical studies for the introduction of new
21 materials.

22 The device was an implant, and risks included
23 those post-operative complications associated with
24 periodontal flap procedures, including pain and thermal

1 sensitivity and infection, with specific hazards of
2 sloughing of the flap because of the potential to impede
3 blood supply and infection, with microbial colonization of
4 the membrane.

5 The information upon which the classification was
6 based was testimony before the Panel and review of the
7 literature, and the Panel recommended restriction to use by
8 licensed professionals with appropriate training in the use
9 of the device.

10 May I have a motion to recommend to the FDA this
11 grouping 2A, nonresorbable barrier or membranes for use in
12 filling defects with a recommended class of II, with special
13 controls of guidance documents, labeling to indicate the
14 time point for removal of device post-insertion, training,
15 and clinical studies for the introduction of new materials?

16 DR. O'NEILL: So moved.

17 CHAIRMAN ROBERTSON: And a second?

18 DR. ROSAN: Second.

19 CHAIRMAN ROBERTSON: And discussion?

20 [No response.]

21 CHAIRMAN ROBERTSON: Hearing no discussion, then
22 all those in favor of the motion to approve nonresorbable
23 barrier or membrane for use in filling periodontal defects
24 with a recommended Class II and those associated special

1 controls, please raise your hand.

2 [A show of hands.]

3 CHAIRMAN ROBERTSON: Let the record show that the
4 voting members are unanimous in support of the motion, and
5 the motion carries.

6 The next grouping is Group 2B, nonresorbable
7 barrier or membrane for the use of filling localized
8 nonperiodontal osseous defects and for localized
9 augmentation of the alveolar ridge, defined as a
10 nonresorbable barrier or membrane for use in filling
11 localized nonperiodontal osseous defects or for localized
12 augmentation of the alveolar ridge, a device that is
13 naturally or synthetically derived. It is intended to
14 function as a barrier that allows selective tissue ingrowth
15 to aid in the filling and repair of localized nonperiodontal
16 osseous defects and for localized augmentation of the
17 alveolar ridge. These devices are intended to be removed.

18 The Panel recommended Class II because, for
19 exactly the same reasons as we've described in 2A, the Panel
20 thought that special controls could be established to
21 provide reasonable assurance of safety and effectiveness,
22 and those special controls included guidance documents,
23 labeling to indicate the time point for removal of device
24 post-insertion, training, and clinical studies for the

1 introduction of new materials.

2 Any discussion?

3 DR. TYLEND: Does this include load-bearing and
4 nonload-bearing areas?

5 CHAIRMAN ROBERTSON: Dr. Patters?

6 DR. PATTERS: Yes.

7 DR. ROSAN: Wasn't there some discussion about
8 what we meant by localized, whether that should be included
9 in the guidance document?

10 CHAIRMAN ROBERTSON: It is. It is presently
11 because that was what the Panel concluded. You probably
12 need to speak into the microphone.

13 DR. ROSAN: I'm sorry. What we meant by
14 localized, size, or is there some limitation on that. I
15 think there was some discussion about that possibility, what
16 we meant by localized, how big an area is local.

17 CHAIRMAN ROBERTSON: Dr. Patters?

18 DR. PATTERS: Dr. Glowacki raised that issue, and
19 I believe she questioned Dr. Melanig, if he could define
20 localized, and he was unable to give a precise definition,
21 as am I. It's certainly less than generalized.

22 CHAIRMAN ROBERTSON: Yes. Well, less than the
23 entire maxilla or mandible, I think.

24 Further discussion?

1 MR. HLAVINKA: Yes, Mr. Chairperson. Previously
2 the Panel recommended Class III for this, and then the
3 recommendation as Class II, I assume you have completed a
4 classification sheet reflecting those changes.

5 CHAIRMAN ROBERTSON: I have.

6 MR. HLAVINKA: Very good.

7 CHAIRMAN ROBERTSON: And that's what I read.

8 Well, I have a motion, which has been seconded, to
9 recommend the grouping 2B, nonresorbable barrier or membrane
10 for the use in filling localized nonperiodontal osseous--I'm
11 sorry. Pam?

12 MS. SCOTT: Going back to Dr. Tylanda's question
13 regarding if this included load-bearing and nonload-bearing
14 regions, I just had a question for the panel. The devices
15 within this category that I know of, as far as if my memory
16 serves me correctly, were not indicated or even stated that
17 the device shouldn't be used in load-bearing regions or
18 applications. Some of the membranes, nonresorbable
19 membranes.

20 DR. TYLEND: Indicated that they should not be
21 used in a load-bearing situation?

22 MS. SCOTT: I don't know if Dr. Patters may want
23 to clarify that for us.

24 DR. PATTERS: My memory does not corroborate what

1 you just said. My memory is often faulty. But I don't
2 believe that there is any prohibition of the use of these
3 devices in load-bearing areas.

4 CHAIRMAN ROBERTSON: I can't recollect, Pam,
5 anything either in the literature or in the testimony that
6 dealt with load-bearing or nonload-bearing areas.

7 DR. TYLEND: Pam, have we cleared both load
8 bearing and nonload bearing?

9 CHAIRMAN ROBERTSON: I don't know that it's ever
10 been an issue.

11 MS. SCOTT: Generally, indication statements have
12 included periodontal defects, intraosseous gaps, voids and
13 clefts, and augmentation of the alveolar ridge.

14 CHAIRMAN ROBERTSON: Right, without any reference
15 to whether it's load bearing or nonload bearing.

16 MS. SCOTT: Yes, in the general indication
17 statements. But for some reason I remember seeing warning
18 statements that indicate that the device shouldn't be used
19 in load bearing.

20 CHAIRMAN ROBERTSON: I have no recollection of
21 that. I'll listen to any--

22 DR. PATTERS: I know that's true for certain of
23 the bone-filling materials, but I don't have knowledge that
24 that's true for any of the membrane or barrier membranes.

1 CHAIRMAN ROBERTSON: Ms. Kalbach? Jackie, can you
2 help us here? Would you reintroduce yourself?

3 MS. KALBACH: Yes. I'm Jacqueline Kalbach from
4 W.L. Gore and Associates. In terms of load bearing versus
5 nonload bearing, it seemed that there was a lot of
6 discussion from the Panel yesterday about what that means,
7 horizontal or vertical. But without that, let me read you
8 our indication statement and then something that I alluded
9 to yesterday during my presentation.

10 Our indication statement for Goretex regenerative
11 material is that it's intended to provide a mechanism for
12 the ingrowth of new hard and soft tissues and to bony
13 defects surrounding teeth and to augment ingrowth of hard
14 and soft tissues on alveolar ridges. However, as I
15 indicated yesterday, we do have a warning in here. It's a
16 contraindication. Goretex regenerative material is a
17 passive, nonload-bearing material. It is not intended for
18 use in load-bearing articulating situations such as
19 temporomandibular joint reconstruction.

20 Does that help?

21 CHAIRMAN ROBERTSON: Well, it raises the concerns,
22 I think, that were raised over here yesterday having to do
23 with the term load bearing in here on the temporomandibular
24 joint service. But in terms of the maxilla and mandible, I

1 don't know that it's an issue.

2 Mark?

3 DR. PATTERS: Ms. Kalbach, the way I understood
4 you read that was that the device itself cannot bear the
5 load, not that it is not capable of treating in an area
6 which will bear a load, but the device itself cannot bear
7 load. Is that correct?

8 MS. KALBACH: All I did is read it. As I said
9 yesterday, I'm not a scientist or an engineer. And
10 specifically, I think, about articulating situations such as
11 the temporomandibular joint, and that is, it is a passive,
12 nonload-bearing material. It is not intended for use in
13 load-bearing, articulating situations such as
14 temporomandibular joint reconstruction.

15 DR. PATTERS: My interpretation of that is that
16 the material cannot be placed in an area that's presently
17 load bearing, because the material is not suitable to
18 survive that situation. But it does not bear any light upon
19 whether the material can be used in an area which will bear
20 load.

21 CHAIRMAN ROBERTSON: Ultimately.

22 DR. PATTERS: Ultimately, correct.

23 CHAIRMAN ROBERTSON: Thank you.

24 MS. KALBACH: Thank you.

1 CHAIRMAN ROBERTSON: Well, we're back, Pam has
2 moved us back to discussing this. Pam, would you like any
3 further discussion?

4 MS. SCOTT: I guess as long as it's clear in terms
5 of where the device should and should not be used, and that
6 can be ironed out in the labeling for specific devices,
7 depending on the material and the form of the device, if
8 that's acceptable with the Panel in terms of their
9 recommendation.

10 CHAIRMAN ROBERTSON: Yes, I don't--and it may be
11 because of that very point that she raised, the notion that
12 you can't put the membrane somewhere where it's going to be
13 loaded at the time that you're trying to regenerate the
14 bone. That's quite different than the resulting bone, many,
15 many, many times of which the reason you're doing it is in
16 order to provide bone which can be loaded. So I don't think
17 the load bearing/nonload bearing is an issue.

18 MR. ULATOWSKI: Mr. Chairman, then reacting to
19 what Pam just mentioned on labeling, do you believe it's
20 necessary or not to tweak the labeling special control,
21 which just speaks of removal to indicate location or
22 whatever other restriction or limitation?

23 CHAIRMAN ROBERTSON: The issue was not--the
24 warning issue raised by the manufacturer here was not

1 anything to do with removal or non-removal.

2 MR. ULATOWSKI: No.

3 CHAIRMAN ROBERTSON: It had to do with placing the
4 membrane in an area which is loaded.

5 MR. ULATOWSKI: Exactly, which could be dealt with
6 in terms of a labeling special control. But the only thing
7 indicated here is the time of removal. What I'm saying is,
8 Do you wish to add to that to indicate limitations?

9 CHAIRMAN ROBERTSON: I think it's--there is a
10 warning there. It sounds reasonable to me.

11 MR. HLAVINKA: Mr. Chairperson, we could--

12 MS. JEFFRIES: The fact that it's there doesn't
13 mean that it's a requirement, that you're demanding. If you
14 want that location there, you should put it, specify, as Tim
15 is trying to suggest, that you modify your labeling thing to
16 indicate the time point for removal and any load-bearing
17 contraindications.

18 MR. HLAVINKA: Just a simple contraindication, do
19 not place in an area where there would be immediate loading,
20 and that should suffice.

21 CHAIRMAN ROBERTSON: Mark?

22 DR. PATTERS: I have no problem with that.

23 CHAIRMAN ROBERTSON: All right. So--

24 DR. PATTERS: I think the issue is the labeling

1 should indicate the appropriate sites for use.

2 CHAIRMAN ROBERTSON: Good. So we'll add the
3 labeling should indicate appropriate sites for use, in
4 addition to the time point for removal of the device post-
5 insertion.

6 All right. We have a motion, which has been
7 seconded, for a recommendation--I'll try this one more time.
8 Is there any further discussion?

9 [No response.]

10 CHAIRMAN ROBERTSON: We have a motion, which has
11 been seconded, for a recommendation of nonresorbable barrier
12 or membranes for use in filling localized nonperiodontal
13 osseous defects or for localized augmentation of the
14 alveolar ridge, with a recommended Class II, with the
15 special controls as we have listed them. All in favor of
16 the motion, please raise your hand.

17 [A show of hands.]

18 CHAIRMAN ROBERTSON: Opposed?

19 Let the record show that the voting members were
20 unanimous in support of the motion and that the motion
21 carries.

22 The last group is 3A, resorbable barrier
23 membranes. 3A, resorbable barrier or membrane for use in
24 filling periodontal defects defined as a resorbable barrier

1 or membrane for use in filling periodontal defects, a device
2 that is naturally or synthetically derived and is intended
3 to function as a barrier that allows tissue ingrowth to aid
4 in the filling and repair of periodontal defects.

5 The Panel's discussion concluded the device was
6 not life sustaining or life supporting, was important in
7 human health. It did not present a potential unreasonable
8 risk of illness or injury, and the Panel concluded that
9 there was sufficient information to provide special controls
10 to provide reasonable assurance of safety and effectiveness.
11 That included voluntary standards, training, guidances, and
12 clinical studies for introduction of new material. In
13 addition, the Panel recommended that these materials be
14 restricted to use only by persons with specific training or
15 experience in its use. The device was an implant, and risks
16 to health included those post-operative complications
17 associated with periodontal flap procedures, and those
18 recommendations were based on testimony before the Panel and
19 review of the literature.

20 MS. JEFFRIES: Excuse me. Did you answer Question
21 7 on that supplemental data sheet? Because it is an
22 implant.

23 CHAIRMAN ROBERTSON: I did.

24 MS. JEFFRIES: Okay. I didn't hear it.

1 CHAIRMAN ROBERTSON: And I said yes.

2 MS. JEFFRIES: No. Question 7 is if it's an
3 implant, you have to justify why you didn't put it in Class
4 III. I'm sure you have an answer written in.

5 CHAIRMAN ROBERTSON: I'll read it to you. Special
6 controls are sufficient for the safe and effective use of
7 the device, including voluntary standards, guidances, and
8 specific training in the use of the device.

9 MS. JEFFRIES: Okay. Thank you.

10 CHAIRMAN ROBERTSON: So may I have a motion to
11 recommend the group 3A resorbable barrier membranes with a
12 recommended Class II, with the special controls I have
13 listed?

14 DR. NORMAN: So moved.

15 CHAIRMAN ROBERTSON: And a second?

16 DR. O'NEILL: Second.

17 CHAIRMAN ROBERTSON: And now we're ready for
18 discussion, and the discussion ought to include this notion,
19 again, I think--and maybe you can help us, Mark--of whether
20 for these resorbable membranes, whether we want to include
21 the same labeling instructions that we did for the
22 nonresorbable barrier.

23 DR. PATTERS: Well, in this case, we're only
24 recommending that these be used in filling of periodontal

1 defects.

2 CHAIRMAN ROBERTSON: And therefore?

3 DR. PATTERS: It's pretty obvious. The labeling
4 will say for filling of periodontal defects.

5 CHAIRMAN ROBERTSON: Good. Any further
6 discussion?

7 MR. HLAVINKA: Could you repeat those special
8 controls, please?

9 CHAIRMAN ROBERTSON: Yes. Voluntary standards,
10 training, guidance documents, and clinical studies for
11 introduction of new materials.

12 We had a discussion of some animal studies, I
13 think yesterday, and it was--

14 DR. PATTERS: Those were in reference to
15 introduction of new materials to determine their metabolism.

16 CHAIRMAN ROBERTSON: Because they had--we had
17 clinical studies. I suppose we could expand that to
18 clinical and animal studies. We just wanted clinical
19 studies of whatever kind were necessary to be able to
20 determine the resorbability and the inflammation and those
21 things associated with new materials. That's why we didn't
22 specifically say animal studies.

23 MR. HLAVINKA: That's fine.

24 CHAIRMAN ROBERTSON: I assume that's where you

1 were--

2 MR. HLAVINKA: Right. And also one minor point of
3 clarification. It probably ought to read other materials
4 versus new materials. The agency, when they see new
5 materials, nothing is known about that; whereas, with other
6 materials, if they have a long history of safe use for
7 another use and then they want to use them as a resorbable
8 membrane, then it's just a different material versus a new
9 material.

10 CHAIRMAN ROBERTSON: Okay. So I have added it to
11 the supplemental data sheet and the general device
12 classification sheet.

13 Any further discussion?

14 [No response.]

15 CHAIRMAN ROBERTSON: Fine. All in favor of the
16 motion to recommend resorbable barrier and membranes, our
17 grouping 3A, with a recommended Class II, with those special
18 controls we have discussed, please raise your hand.

19 [A show of hands.]

20 CHAIRMAN ROBERTSON: Let the record show the vote
21 is unanimous in support of the motion.

22 Would FDA like any other procedural dances?

23 MR. HLAVINKA: No. Thank you.

24 CHAIRMAN ROBERTSON: Fine. Thank you.

1 DR. TYLEND: I would like to thank the Panel for
2 their hard work on this issue over the past two years. This
3 was really a tremendous amount of work, and you did a
4 wonderful job. Thank you.

5 MR. HLAVINKA: We'd also like to thank Dr.
6 Glowacki. Unfortunately, she isn't here, but she spent a
7 tremendous amount of time, also Pam did, in this endeavor.

8 CHAIRMAN ROBERTSON: Fine. We'll take a short
9 break now, and beginning at 10 o'clock, we will begin our
10 discussion of device ingredient labeling with an open public
11 hearing so that the Panel can facilitate whatever
12 information those present want to give to us.

13 [Recess.]

XX 14 CHAIRMAN ROBERTSON: We are ready to begin a
15 discussion of dental device ingredient labeling, and Dr.
16 Deborah Greenspan will give us a brief overview of where we
17 have come from.

18 DR. GREENSPAN: At the Panel meeting in June of
19 1994, a subcommittee was formed, and the first meeting of
20 that subcommittee was on October 12th of last year, and our
21 tasks were to finalize a list of devices which were to be
22 labeled and also to recommend an order of priority and a
23 format for ingredient labeling.

24 We were provided with lists of dental devices

1 which had been prepared by the FDA staff, and the list
2 essentially was broken up into two groups: one, the devices
3 which were intended for long-term contact with human tissue,
4 and the second was a list of devices which only had short-
5 term or cursory contact with human tissue.

6 As a result of that meeting, we agreed to add
7 additional devices to that list which included filling
8 materials, crown and bridge alloys, full and partial denture
9 materials, and orthodontic materials. And at the end of the
10 meeting, we had developed a list, and there is a copy of the
11 list as it was developed in the blue book today of specific
12 product categories for which ingredient labeling would be
13 required and suggested relative priority for the ingredient
14 labeling. We rated those as either high priority, medium
15 priority, or low priority.

16 The committee comments were discussed by the full
17 Panel in October, but because of the short time that
18 remained, it was decided that the list would be circulated,
19 and then it could be reviewed and discussed at subsequent
20 Panel meetings.

21 In December, the Panel met again, and concerns
22 were raised about the possible overlap with the material
23 safety and data sheets which were required by OSHA; some
24 concerns about confidentiality were raised by industry; and

1 after some discussion at that meeting, we had several
2 unresolved questions. And the matter was deferred for more
3 information to be gathered, if possible, with regards to
4 possible overlap with OSHA and also for some more input from
5 the dental manufacturers. Therefore, the matter is again
6 before the Panel at our meeting today in August.

7 CHAIRMAN ROBERTSON: Thank you. Are there any
8 questions from the Panel, particularly those members who
9 might not have been at those meetings, for Dr. Greenspan to
10 bring everybody up to date?

11 [No response.]

XX 12 CHAIRMAN ROBERTSON: Good. Thank you, Deb.

13 We'll now hear from those who wish to give the
14 Panel some advice, which we are happy to have, and we will
15 start off with Mr. Scott Erickson from 3M Company.

16 I will remind any of those who wish to speak to
17 us, one, to tell us about your affiliation, and, two, maybe
18 to remind the Panel if they have given material in that we
19 need to be looking at as you go along.

20 MR. ERICKSON: Okay. Good morning. My name is
21 Mr. Scott Erickson, and I appear here today on behalf of 3M
22 Dental Products Division where I serve as a regulatory
23 affairs specialist. I have also presented 3M's position on
24 dental product ingredient labeling at previous FDA Dental

1 Panel meetings. The potential impact of the ingredient
2 labeling proposal is so large that 3M has directed me to
3 once again reemphasize crucial points that are important for
4 you to consider.

5 3M is opposed to the total ingredient labeling
6 proposal under consideration by the Dental Products Panel
7 for the following reasons:

8 Number one, the FDA Dental Products Panel has not
9 yet identified a problem of sufficient magnitude that it
10 justifies the ingredient labeling proposal. Past experience
11 has shown that reactions to dental materials have occurred
12 at a very low frequency and reported reactions have not been
13 severe. The January 1993 CCEHRP report on dental amalgam
14 has been cited as a foundation for proposing ingredient
15 labeling for dental restorative materials. However, the
16 CCEHRP report states under Section 3, Biocompatibility of
17 Dental Restorative Materials, that allergic reactions to
18 dental materials are rare and, again that "side effects to
19 dental materials are believed to be rare and, generally,
20 those that have been reported are mild"; and, again, that
21 the "local reactions that have been reported are not
22 severe."

23 The summary of the biocompatibility section states
24 that, "Local reactions to dental restorative materials have

1 been documented in a small percentage of individuals, and no
2 systemic toxic reactions have been reported in the
3 scientific literature."

4 Finally, the section of the CCEHRP report prepared
5 by the regulatory work group states that, "On the whole, use
6 of dental restorative materials has not generated
7 significant numbers of reports of adverse reactions. On the
8 contrary, the incidence of side effects from restorative
9 materials is reported to be very low."

10 The American Dental Association has a formal
11 complaint-handling system whereby dentists can contact the
12 ADA with concerns about dental products and ADA will, in
13 turn, contact the product manufacturer on the dentist's
14 behalf. In an effort to learn more about the current
15 history of adverse reactions to dental products, 3M
16 contacted Dr. Shearer, ADA counsel on scientific affairs,
17 who has managed the ADA complaint system for the last six
18 months. According to Dr. Shearer, the ADA has received zero
19 complaints from dentists regarding adverse reactions to
20 dental products during the last six months. 3M has not
21 received any complaints from the ADA over the last several
22 years that involved adverse reactions to 3M dental products.

23 What is the frequency and severity of the problem?
24 According to the CCEHRP report and information from the

1 American Dental Association, the frequency of adverse
2 reactions is very low, and the reactions are generally mild.
3 These findings certainly do not support a recommendation for
4 mandatory total ingredient labeling.

5 Number two, mechanisms are already in place at 3M
6 to disclose ingredient information as needed. 3M Dental
7 Division recognizes the need to ensure that patients,
8 dentists, and physicians receive the information they need
9 related to dental product ingredients. 3M Dental Products
10 Division already has implemented systems to ensure that this
11 type of information is available as needed. These systems
12 include material safety data sheets, precautionary product
13 labeling, and release of more detailed information on a
14 case-by-case basis.

15 It is rare for 3M Dental to be asked for
16 additional ingredient information beyond what is already
17 disclosed in the MSDS and precautionary labeling. In fact,
18 a recent review of 3M internal records of U.S. inquiries
19 found only four such requests over the last year related to
20 dental devices recommended for ingredient labeling. This is
21 significant because 3M Dental is a market share leader that
22 supplies large numbers of dental devices to the U.S. market.
23 How many hundreds of millions of restorations occur every
24 year in the U.S.? And we had four requests.

1 This very low frequency of requests for ingredient
2 information certainly does not indicate a need for mandatory
3 ingredient labeling. If there were a pressing need for this
4 regulation, wouldn't we be receiving more requests
5 currently?

6 Number three, dental device manufacturers are
7 already bearing up under the requirements of another federal
8 agency, OSHA, which has implemented its own brand of
9 ingredient disclosure requirements. 3M applauds FDA's
10 attempts to reach a compromise with OSHA to avoid
11 duplication. However, as of the December 5, 1994, Panel
12 meeting, prospects for such a compromise between agencies
13 appeared unlikely. As a result, FDA may at this time be
14 looking for your recommendation to add a second layer of
15 ingredient disclosure requirements rather than replacing the
16 OSHA requirements. If these two agencies fail to work
17 together in a spirit of cooperation, the likely outcome will
18 be excessive regulatory controls that do not add value
19 commensurate with the cost.

20 Number four, innovation is a key element for
21 growth and success in the competitive global marketplace.
22 Innovation is important because it provides our U.S.
23 patients with the latest in technology. 3M is a company
24 that invests heavily in research and development to support

1 innovation and, as a result, is a global supplier of state-
2 of-the-art dental products that contribute to a favorable
3 balance of trade. Yet for every 3M there are multitudes of
4 other companies around the world that bypass R&D by copying
5 new technologies as they emerge. The total ingredient
6 labeling proposal is unfriendly to innovation and all of the
7 resulting benefits because it facilitates transfer of
8 technical information from the innovator to those who would
9 duplicate the invention. The likely result would be a
10 decreased return on dollars invested in R&D, leading to a
11 decrease in both R&D and innovation.

12 In the event that the FDA Dental Products Panel
13 takes the position that it must recommend total ingredient
14 labeling for dental devices, the following should be taken
15 into consideration:

16 It is imperative that manufacturers be given the
17 option of satisfying any additional ingredient labeling
18 requirements by supplementing the ingredients section of the
19 product's MSDS. This approach, as opposed to requiring a
20 list of ingredients on a product container, would
21 significantly lessen the cost impact to the manufacturer,
22 dentist, and ultimately the patient.

23 The ingredient information would then be located
24 in a document that already contains other useful information

1 such as health hazard data that could be filed and readily
2 photocopied for the patient. In general, dental product
3 immediate containers are so small that adding a list of
4 ingredients to each container is not feasible.

5 I have a few examples I'd like to just pass out
6 here for you to take a look at.

7 You will notice that the containers are very small
8 and already are packed with required labeling information.
9 Dental product packaging and any labeling information
10 attached is often discarded in the dental office. It is
11 less likely that an MSDS will be discarded since OSHA has
12 been inspecting dental offices to ensure that required MSDS
13 documents are retained and accessible.

14 The process of determining which dental products
15 need to be selected for ingredient labeling should be based
16 on a history of significant adverse reactions and not simply
17 duration of patient contact with the product. If the
18 frequency and severity of adverse reactions to a dental
19 device have been low, the device should not be selected for
20 total ingredient labeling requirements. There must be some
21 allowance for trade secrets.

22 Most ingredients of dental devices are purchased
23 by device manufacturers from ingredient suppliers. Since
24 dental devices are typically made in relatively small

1 quantities, dental device manufacturers are small customers
2 that have little or no economic influence over ingredient
3 suppliers.

4 If total ingredient labeling is imposed by FDA, an
5 ingredient supplier claiming trade secret would be likely to
6 drop the dental device manufacturer's small-volume business
7 rather than disclose the ingredient's identity. This would
8 force the device manufacturer to discontinue a useful dental
9 device and perhaps go out of business.

10 In summary, 3M is opposed to the total ingredient
11 labeling proposal and recommends that you vote no. Such a
12 requirement would be costly to implement and would not add
13 significant value.

14 Adverse reactions to dental devices are reported
15 to be low in frequency and not severe. Mechanisms are
16 already in place to disclose ingredient information as
17 needed. Requiring dental device manufacturers to comply
18 with two sets of ingredient disclosure requirements, one
19 from OSHA and the other from FDA, would be overly burdensome
20 and further evidence of a regulatory climate that has become
21 unfriendly to innovation.

22 If the FDA decides to ignore the concerns of
23 dental manufacturers and proceed with total ingredient
24 labeling, the requirements should only apply to dental

1 devices that have demonstrated a significant history of
2 adverse reactions. There must be some provision to
3 accommodate trade secrets, and, finally, manufacturers must
4 be given the option of complying with any new ingredient
5 labeling requirements by simply adding ingredient
6 information to the product's MSDS.

7 3M would like to thank the FDA Dental Panel for
8 providing this opportunity to comment on this important
9 issue. Thank you. Are there any questions?

10 CHAIRMAN ROBERTSON: Any questions from the Panel?

11 [No response.]

12 CHAIRMAN ROBERTSON: Thank you. That was very
13 informative.

14 [Applause.]

15 CHAIRMAN ROBERTSON: The next presentation is from
16 Mr. Don McKenzie and Dr. Edward Shils from the Dental
17 Manufacturers of America.

18 MR. MCKENZIE: Good morning. My name is Don
19 McKenzie, and I appear here once again on behalf of the
20 Dental Manufacturers of America, Inc., DMA. DMA is a dental
21 trade association of manufacturers and has been in existence
22 for 63 years. DMA currently represents over 200 dental
23 manufacturing companies. I speak here on their behalf
24 today. As soon as I am finished, Dr. Shils will be

1 responding to one of the Panel's questions related to cost
2 that was posed last December.

3 I am employed by 3M Dental Products, which is a
4 member company of DMA as well as ADTA. In addition to that,
5 I am currently the DMA Chairman of the Regulatory/Technology
6 Committee.

7 The following represents the comments and
8 positions of those 200-plus DMA members.

9 First of all, DMA agrees with and supports the
10 comments and positions opposing additional FDA labeling
11 regulations such as those stated earlier meetings by the
12 American Dental Trade Association and just prior stated by
13 3M Dental Products company and other manufacturers who have
14 spoken in the past.

15 DMA is extremely concerned with this issue and
16 urges that the Dental Panel's final recommendation to FDA be
17 based on scientific fact rather than a political agenda and
18 be based as well on an understanding of the economic impact
19 to the industry. A risk analysis, including a realistic
20 cost/benefit analysis, is certainly indicated for this
21 important issue, and it is expected by industry.

22 DMA appreciates the opportunity to work closely
23 with the Panel and with FDA to provide input that continues
24 to result in safe use of professional dental materials, yet

1 does not overburden this small industry with redundant and
2 unwarranted government controls. This is especially
3 important now at a time when the political direction is to
4 demand less government controls, especially when the current
5 industry systems are functional and successful.

6 Secondly, DMA acknowledges that there is a very
7 low level of risk of adverse reaction to patients and the
8 dental staff related to handling and use of those dental
9 materials containing certain known allergens. For this
10 reason, DMA fully supports the concept that information
11 relating to potential allergic response to dental materials
12 be made available for us by the dentist, staff, and patient.

13 But it must be noted that there is currently in
14 place--there is currently in place a very workable system to
15 provide the appropriate safety information. This system
16 consists of three main elements, and these are a combination
17 of: the material safety data sheets as required by OSHA;
18 product precautions which further alert the dentist, and
19 these are included in the product insert or other labeling,
20 where appropriate; and, third, the manufacturer's
21 willingness and capability to provide information upon
22 request by the dentist, allergist, or patient when questions
23 arise related to suspected patient or dental staff allergy.

24 You have already been given data from

1 manufacturers indicating the low number of ingredient
2 inquiries to manufacturers from dentists or even patients.
3 Since this number is extremely low, and typically has been
4 over the years, this system has proven to be very effective,
5 efficient, and affordable to the manufacturer without adding
6 additional or unnecessary costs to the dental health care
7 delivery. The present system is also consistent with the
8 political mandate to more conservative, or at least more
9 appropriate government controls.

10 Third, DMA members are very much opposed to the
11 proposal for FDA-mandated ingredient labeling of dental
12 materials. It is unduly burdensome in time, efforts, and
13 costs, not to mention redundant. Further, it has not been
14 demonstrated to DMA that a real problem exists, or a
15 potential problem exists, that is not already being
16 addressed by the current systems in place. DMA actually
17 poses the question to the Panel: Where is the manifestation
18 of a problem? Where is the evidence that the current system
19 is failing to address that problem? And where has the need
20 been demonstrated for this proposed regulation? What's the
21 problem that we're trying to solve here?

22 Further, it has not been demonstrated that
23 ingredient labeling would, in actual use by the dental
24 staff, be of any added benefit or of benefit commensurate

1 with the very high costs of the additional labeling and
2 subsequent additional ongoing FDA GMP control of the extra
3 labeling. This would include inspections and possible mis-
4 branding situations and recall procedures that the FDA needs
5 to get involved in. For an industry of upwards of 700
6 manufacturers and only about 100,000 to 110,000 customers in
7 the entire United States, the total impact would be very
8 significant in terms of costs to the health care delivery
9 system by these 100,000 dentists and only questionable added
10 benefit to patient safety.

11 When an allergic response does occur, the
12 investigation should actually be performed not by the
13 dentist, but by a licensed physician certified in the
14 allergy field. This is currently done in concert with the
15 manufacturer's and dentist's information. This system has
16 proved to be scientific and effective for the dental staff
17 and the patient as well as the allergist. The
18 manufacturer's responsibility in this case is already
19 regulated by FDA's Medical Device Reporting regulation plus
20 the Good Manufacturing Practice regulation as it relates to
21 complaint handling. Additional FDA labeling controls added
22 on top of these regulations are unnecessary and far too
23 overburdening, let alone redundant with OSHA regulations.

24 There are other concerns also about the Panel's

1 labeling proposal. In the dental business, it is not
2 uncommon that the device manufacturer utilized certain
3 ingredients for which their vendors will not divulge the
4 identity, only the safety profile. For example, certain
5 modified resins and flavoring additives can fall into this
6 category. Flavors alone can often contain up to 20
7 different ingredients. Where the identity could be
8 determined via reverse engineering, the resulting long list
9 of ingredients on the labeling would do little to facilitate
10 evaluation of an allergic response or potential response any
11 better than the current system. In fact, the current system
12 actually highlights the potential allergenic ingredients.

13 In addition, it is generally recognized that the
14 safety risks related to proper use of dental materials are
15 extremely low. The question of reaction incidents from
16 dental materials compared to the hundreds of millions of
17 dental procedures performed is very low; this is based on
18 actual information from individual manufacturers, as you've
19 heard in the past and this morning also. It is also
20 available from MDR records, from numerous articles available
21 in the literature, and from the 1991 findings of the NIH
22 Technology Assessment Conference on the "Effects and Side
23 Effects of Dental Restorative Materials," as well as the
24 findings of the January 1993 CCEHRP report on amalgam.

1 Despite the low level of risks in question and the
2 low rate of incidence, DMA members realize the importance of
3 acknowledging the presence of allergens or hazardous
4 components in their products. DMA firmly believes that the
5 present controls and systems are adequate to address the
6 issue at hand. There is no known evidence to suggest
7 otherwise.

8 In summary, DMA indicates that the risks involved
9 in the use of dental materials are low; we know that. The
10 manufacturers have already adequately systems currently in
11 place to address the identified risks. In addition, the
12 dental staff has important responsibilities related to safe
13 product usage. These include being knowledgeable about the
14 low levels potential risk of adverse reactions; effectively
15 screening patient susceptibility to known reactions, and
16 communicating observations and special needs to the
17 manufacturer. The Panel's ingredient labeling proposal does
18 not add any value to the current system, nor does it address
19 the key dental staff responsibilities. Ingredient labeling
20 will be extremely costly and burdensome in terms of
21 additional GMP labeling controls. These are costs both for
22 industry and for FDA, so we're not just talking about just
23 manufacturers but the additional cost to run the government,
24 costs for essentially no return of added patient safety.

1 One could view this as another example of government out of
2 control.

3 The DMA does sincerely thank the Dental Panel for
4 this opportunity to provide comments here today on an issue
5 that is key to the very livelihood of our small industry.
6 We look forward to the Panel taking a rational approach to a
7 decision on the ingredient labeling issue, a decision that
8 hopefully tables this proposal.

9 If there are any questions, I would be glad to try
10 to answer them. In addition, I'd like to point out that DMA
11 has, at the last meeting in December, provided the Panel
12 with an alternative approach to the FDA proposal, and I will
13 not take your time to read that because of the limited time
14 given here. But I have provided a copy to Dr. Tylanda, and
15 I am not sure if it is attached to your information or not.

16 It is? Okay, fine. Otherwise, I've got extra
17 copies here. I will read that through if you would give me
18 the time. It's up to you.

19 CHAIRMAN ROBERTSON: I think we all have it.

20 MR. MCKENZIE: Okay. And I do have a response to
21 the Panel's question to DMA posed last December regarding
22 the cost to the industry if the ingredient labeling proposal
23 was to be brought forward, and I would like to ask Dr. Ed
24 Shils, the Executive Director of the DMA, response with the

1 results of a survey he conducted to address your question.

2 Dr. Shils?

3 DR. SHILS: Good morning. I appreciate the
4 opportunity of giving you a minute or two of my findings.

5 Thank you, Dr. Robertson, Dr. Tylenda, and members
6 of the Panel, for permitting me to make this presentation.
7 It's really in response to an inquiry that came, I believe,
8 from Dr. Tylenda or her office with respect to have we any
9 hard data on costs. And the net result is--and I am sure
10 that you have a copy of my handout, which is my letter to
11 Dr. Tylenda of July 21st, in which we have identified the
12 estimated cost provided by 29 respondents.

13 You must keep in mind that we have over 200
14 members, and as was stated earlier, there are over 700
15 manufacturers.

16 I am quite familiar with the industry. I am the
17 director emeritus and founder of the Wharton Entrepreneurial
18 Center at the University of Pennsylvania, still teaching,
19 but I have been the Executive Director of this group for 43
20 years, and I have seen it grow primarily because of what has
21 been described as the innovative opportunities in dentistry.
22 So the vast majority of our members are not dense supply
23 level, but their companies are doing anywhere between \$5-15
24 million. Increasing costs to them sometimes can be a

1 nightmare.

2 Now, in my study, where I received 29 responses,
3 the total potential cost was estimated to be \$48 million,
4 \$48,243,550. These were the questions that we asked:

5 Label changes, the cost of--this is domestic costs
6 only. Initial label changes: A, the additional cost of
7 changing more complex; B, the additional cost of providing
8 package inserts that may be required, \$6,526,400.

9 Updating all written GMP operating procedures,
10 \$812,150.

11 Resulted increase in GMP (labeling) control and
12 GMP inspection for compliance, \$805,000.

13 Segmenting inventory for U.S. distribution only,
14 A, the extra cost of maintaining dual or multiple
15 inventories, \$4,066,000.

16 Potential product recalls, or product exchanges,
17 and their resultant increased costs, \$4,410,000.

18 Proprietary information losses, loss of
19 exclusivity, \$18,418,000.

20 Possible loss of vendor sources that refuse to
21 divulge detailed chemical descriptions, small volume dental
22 manufacturers are especially susceptible, \$12,154,000.

23 Possible MSDS changes, \$1,052,000.

24 Total, \$4,243,550.

1 Now, the 29 companies that were responding were
2 generally representative of small, medium, and large
3 companies, and I sent this to Dr. Tylanda. I indicated of
4 the 29 that nine respondents were estimated to be between
5 \$15 million and \$100 million, five between \$5 million and
6 \$15 million, six between \$2.5 million and \$5 million; seven
7 between \$1 million and \$2.5 million, and two less than a
8 million.

9 Now, had we more time and were I to send out
10 another such inquiry, I am sure that I could probably get
11 100 responses. But if I were to estimate simply on a range
12 of what could be anywhere between 300 manufacturers and 700
13 manufacturers, we're really talking about something over a
14 quarter of a billion dollars to perhaps a half a billion
15 dollars.

16 Now, I have reviewed completely the discussions at
17 President Clinton's recent White House conference, and he is
18 genuinely concerned about the survival of small business in
19 America. We are small business. And as small business, we
20 are also responsible for a great deal of the innovation and
21 creativity that has been reported. I don't think I can tell
22 you any more than that, except thank you very much for
23 including me. I appreciate it.

24 If you have any questions, I will be right here.

1 CHAIRMAN ROBERTSON: Thank you. Are there any
2 questions from the Panel?

3 [No response.]

4 CHAIRMAN ROBERTSON: Thank you. That was very
5 informative.

6 Next we'll hear from Dr. Tom Fise of the American
7 Dental Trade Association.

8 MR. FISE: Thank you, Dr. Robertson. My name is
9 Tom Fise, and I am not a doctor, but I do appear here today
10 on behalf of the American Dental Trade Association and serve
11 as their special counsel on regulatory affairs. I am
12 accompanied by Nick Petrovic, who is the President of the
13 American Dental Trade Association, and we have distributed
14 to you--and you should have it--a copy of the statement we
15 have prepared.

16 Actually, this marks the fourth appearance that we
17 have made before the Panel on the issue of dental product
18 ingredient labeling dating back to December of 1993. The
19 record includes our statements to you on December 3, 1993,
20 on June 29, 1994, and on December 5, 1994 also, and this
21 statement today. So I would not be offended if any of you
22 are somewhat tired of seeing us approach you on this issue,
23 but we have not been alone. Certainly, Scott Erickson and
24 Don McKenzie of 3M have also been here with you on four

1 occasions; Jeff Lane and Steve Jefferies from Dentsply have
2 appeared on three occasions; and others have appeared as
3 well. I mention this and recount this to say that the
4 dental trade industry continues to stand united in its
5 opposition to FDA's dental product ingredient labeling
6 initiative.

7 We will use the few minutes that we have here
8 today primarily to summarize some of the key arguments and
9 provisions that we have articulated and underscored in our
10 previous testimony, as well as to provide you with a few
11 pieces of new information in some relevant areas.

12 We have reported to you previously:

13 A, that the dental industry is opposed to this
14 proposal, as has been demonstrated by previous and current
15 testimony by some of the folks who are here today, and also
16 by ADTA's having entered into the record at your most recent
17 meeting a letter signed by the chief executive officers of
18 Kerr/Sybron, Johnson & Johnson, GC America, Dentsply, and
19 3M.

20 B, before proceeding with any proposed regulations
21 on dental product ingredient labeling, FDA must conduct a
22 thorough impact analysis. Prior ADTA testimony recounted
23 that survey data projected per company start-up costs of
24 about \$1 million for a medium-sized dental company. We also

1 have referred previously to economic projections recited by
2 3M and Dentsply, and you have heard other such projections
3 in the presentations preceding us today.

4 C, neither FDA nor the Panel has demonstrated any
5 significant risk, in terms of frequency or severity of
6 allergic reactions to support imposing this new regulatory
7 burden. All of the evidence presented, such as the data
8 that was submitted by 3M today or data submitted by Dentsply
9 in December of 1994 indicates a very small number, and each
10 company could be counted on one hand, among the many
11 procedures that are performed.

12 D, the potential for dental malpractice cases may
13 expand if dental product ingredient labeling is mandated by
14 FDA. Dentists will be held to a higher standard: number
15 one, to secure an extensive history of allergic
16 sensitivities from all patients--and perhaps they should be
17 doing that already; but also to cross-reference the
18 materials they use with that allergic sensitivity history.
19 We will reference below some new information on this item.

20 E, FDA has not resolved the issue of overlapping
21 or duplicative regulation with OSHA. As things stand now,
22 FDA and OSHA could require manufacturers to list much of the
23 same information in different forms, in different places.
24 We have new and somewhat encouraging news on this issue, but

1 this matter remains without any definitive resolution.

2 F, the substantial cost of compliance with these
3 proposed regulations across the entire range of dental
4 materials will fall on the dentists who purchase these
5 products and ultimately their patients. FDA has just
6 announced a new and exceedingly onerous and costly
7 regulation, which I have here today, all 112 pages of it.
8 These are new regulations on Good Manufacturing Practice
9 regulations. FDA has rejected advice in areas that would
10 limit the economic burden, proposes to expand its rules to
11 apply to distributors, servicers, installers, and others.
12 Dentists and their customers will likely already be bearing
13 their share of the compliance costs which FDA has estimated
14 at \$84.5 million. Actually, we think the FDA's estimate
15 understates the actual cost that is likely to ensue from
16 those regulations. So our message is: Don't compound the
17 increased cost to dentists and users by adding yet another
18 costly and unnecessary regulation on dental product
19 ingredient labeling.

20 G, any requirement to institute a listing of all
21 ingredients raises proprietary concerns as to the potential
22 of a compromise of confidential trade-secret information, as
23 well as some problems in international marketing. This is
24 another area that we will touch upon with some new

1 information.

2 Actually, we want to report in two general areas
3 some new information, and these are reflected in three
4 appendices that accompany the statement we have submitted.

5 Number I--and this relates to Items D and G in our
6 presentation--we have previously raised our concerns about
7 the potential exposure of dentists to malpractice claims
8 arising with respect to patient allergic reactions and the
9 fact that this could be heightened once the ingredient
10 information is readily available, that the dentist's legal
11 duty may, in fact, increase. We have also been asked by
12 ADTA member companies to determine whether there may be a
13 constitutional or some other legal bar to FDA dental product
14 ingredient labeling regulations with respect to the
15 compromise of trade-secret information. We have referred
16 both of these issues to outside counsel with a request for
17 opinion. You have attached a preliminary letter indicating
18 that the matter has not yet been resolved, but promising
19 submission of a formal opinion within the next three weeks.
20 Certainly when that is available, we will submit it to Dr.
21 Tylanda for the use of the Panel.

22 The second area that we want to bring you some new
23 information on relates to a series of meetings with OSHA.
24 In June we had the opportunity to participate in an

1 important meeting with OSHA Administrator, Assistant
2 Secretary Joseph Dear, with Representative William Goodling,
3 the Chair of the congressional committee that has oversight
4 responsibility over OSHA matters.

5 ADTA coordinated arrangements for this meeting,
6 which was also attended by the CEO and general counsel of
7 Dentsply, as well as staff from the congressional committee.
8 OSHA Administrator Dear, after hearing some of the
9 difficulties of overlap, promised a prompt and sincere
10 effort to remedy the problems which the profession and the
11 industry have had with OSHA MSDSs. In accordance with that
12 promise, a follow-up meeting was held on July 20th with key
13 OSHA staff. While there were no FDA representatives in the
14 initial meeting with Secretary Dear and Representative
15 Goodling, Dr. Singleton did participate in the July 20th
16 meeting, and we have attached for your information two brief
17 memoranda that summarize those two meetings.

18 In conclusion, we have covered much ground since
19 the first time we appeared before you in December 1993.
20 There are still some unanswered questions relating to OSHA,
21 relating to some of the trade-secret and other legal aspects
22 of this that might justify a further deferral of a decision
23 until a later point. If action is to be taken today,
24 however, we believe for all of the reasons stated above that

1 there are compelling reasons and adverse consequences that
2 would accrue if this proposal were enacted. The number of
3 requests for information is very small. The prospective
4 costs of implementing these regulations is very high. It is
5 compounded by the new and exceedingly costly burden of FDA's
6 GMP regulations and by the prevailing prospect of
7 compounding the regulatory burden by overlapping regulation
8 of labeling by OSHA and FDA.

9 In the end, there is no public health reason of
10 sufficient magnitude to justify a new, expensive regulation
11 for dental product ingredient labeling. Convenience and
12 desirability are not enough to mandate another regulatory
13 action.

14 We urge your expert advice to the FDA that it
15 should not proceed with dental product ingredient labeling.

16 Thank you, and I would be happy to answer
17 questions.

18 CHAIRMAN ROBERTSON: Thank you.

19 Questions from the Panel? Dr. Greenspan?

20 DR. GREENSPAN: This may not be a fair question to
21 ask you because it has come up with the speakers that went
22 before you. But one of the issues that is raised is that of
23 cost, cost of the labeling. Labels are obviously made in
24 bulk, but labels are changed for many reasons. The

1 manufacturer may choose to make it more attractive or to
2 include some more information.

3 Why are the costs so high when manufacturers will
4 be making labels anyway and when, over a period of time,
5 these labels are likely to be changed? And can labeling
6 requirements and costs be mitigated if phased in over time?

7 MR. FISE: Let me answer the second question
8 first. Certainly if there were an action to implement these
9 proposals, the longer lead time that could be provided, the
10 better. But let me address, I think, the more serious
11 question, which is: Where is this cost? We have told you a
12 medium-sized company's costs would start at around \$1
13 million. You have heard industry-wide estimates up to \$250
14 million.

15 Let me say that very little of this is involved in
16 printing labels, but there are other issues that come into
17 this. When one changes labeling in a regulated product,
18 there are GMP ramifications to that, and so there are
19 compliance costs that are tied in there. To the extent that
20 the labeling provides information that currently is
21 protected by trade secret, there may be some diminution in
22 the product's value by virtue of disclosing that.

23 We have talked before about the international
24 marketing ramifications of this where a product that comes

1 off the assembly line may have to be segregated so that
2 there is U.S. labeling and there is labeling for other
3 markets.

4 So there are a good many things beyond simply the
5 cost of producing the labeling that are involved here.
6 Again, our point is that if there were a major public health
7 problem, if we saw a lot of complaints with FDA, ADA or
8 whatever, maybe that would be justified. But we don't think
9 so in the absence of those.

10 DR. GREENSPAN: Thank you. My follow-up question
11 to that is about the comment you made about separation for
12 different markets. It is my understanding that the EC are
13 going to come up with some requirements for labeling. Will
14 this not mean, then, that there will be separation anyway?
15 If there was no labeling here, if products were to be sold
16 to different markets, as different requirements are
17 developed, there may be separation of the product?

18 MR. FISE: Well, I think probably just the
19 contrary. In other words, the FDA has made serious efforts-
20 -and this is a purported byproduct of that effort, although
21 we certainly don't agree with it--to harmonize with the
22 European Community and with other international regulations
23 so that, in fact, compliance in one area will satisfy the
24 regulatory requirements in other countries. So to the

1 extent that there were international rules on this,
2 hopefully they would match, or the FDA's situation would be
3 flexible enough to match up with those rather than having a
4 pre-existing situation like this where there are regulations
5 on the books and they might not match with the
6 internationals.

7 So, you know, it is a fact that we don't know what
8 is going to happen with EC or some of these other things,
9 but the objective should be to have our situation flexible
10 enough that there's only one requirement, and compliance in
11 one place will match up with compliance in others as well.

12 CHAIRMAN ROBERTSON: Yes, please, reintroduce
13 yourself.

14 MR. MCKENZIE: Don McKenzie with 3M. I can
15 address your last question, Dr. Greenspan, in that we are in
16 compliance currently with the EC regulations as far as the
17 CE mark for dental materials. And the labeling that we have
18 had to do is such that it can be used on a global basis
19 without any problem; whereas, in total ingredient labeling
20 for the United States, this is just one country that we do
21 business in. We also sell into somewhat in excess of 100
22 countries. There are no other countries requiring this type
23 of labeling, and we would probably require that that
24 information be restricted just to the United States if it

1 were to come about.

2 DR. GREENSPAN: But you're telling me that there
3 is some labeling on it already and that you're not
4 separating product, whether it goes to EC countries or
5 whether it goes to, let's say, Southeast Asia.

6 MR. MCKENZIE: That's basically correct. There is
7 an issue with translations. We do have to comply with the
8 various local language requirements, but which we currently
9 are doing all on one labeling.

10 DR. GREENSPAN: So, in other words, to continue
11 along those lines, when products go to non-English-speaking
12 countries, you are providing separate labeling in that
13 country's language?

14 MR. MCKENZIE: It's the same labeling. It's
15 translated several times on the label.

16 DR. GREENSPAN: On the same piece of paper?

17 MR. MCKENZIE: Yes.

18 DR. GREENSPAN: So, in other words, you're getting
19 a lot of information onto a piece of paper?

20 MR. MCKENZIE: Yes.

21 CHAIRMAN ROBERTSON: Thank you.

22 I would now like to invite others who wish to
23 address the Panel on this issue. Would those who would like
24 to address the Panel please stand for me so I have a sense?

1 Fine. If you could keep your comments to around five
2 minutes, please. Maybe we will start here, and would you
3 please introduce yourself and tell us what affiliations you
4 have?

5 MR. MONTEMURRO: My comments will be very brief.
6 Tony Montemurro, I'm President of Lactona Universal Dental
7 Corporation and also President of the Dental Manufacturers
8 of America. I'm speaking more on behalf of Lactona
9 Corporation. Just to give you a contrast between the 3M
10 Company which is considerably bigger, significantly bigger
11 than Lactona, we're probably in the class that Dr. Shils had
12 mentioned earlier of a smaller manufacturer.

13 We are against ingredient labeling also for the
14 same reasons, basically, that have been presented before
15 you. However, just to give you a small contrast, one of the
16 products that Lactona Universal Dental manufactures is
17 artificial teeth, both porcelain teeth and acrylic teeth.
18 And it would be an extremely expensive burden and very
19 impractical for us to try and include ingredient labeling
20 with the teeth product that we make. The amount of space
21 that we would have to put the ingredient labeling on is
22 very, very limited and very difficult. But probably more
23 importantly, if you just look at something like porcelain
24 teeth and the need for it, porcelain teeth is basically an

1 inert material which offers very, very little possibility of
2 any kind of allergenic reaction and any kind of danger.

3 Porcelain teeth, just to give you an example
4 again, is lumped in with this whole group of products which
5 really, to us, we cannot see the reason for it. So I just
6 wanted to point something out to you that perhaps is not
7 realized when you look at it in the total picture.

8 Thank you.

9 CHAIRMAN ROBERTSON: Thank you very much.

10 Questions from the Panel?

11 [No response.]

12 CHAIRMAN ROBERTSON: Thank you.

13 MR. HEIMANN: Good morning. My name is Les
14 Heimann, and I'm Director of Quality for Sultan Chemists,
15 and we also fit into this category of the small dental
16 manufacturer who is between the \$5-15 million volume.

17 I want to point out this morning some of the
18 innovative solutions that we've put together in order to
19 satisfy some of these ingredient requirements in the past.
20 What we're looking for today is to encourage this type of
21 innovation from the small companies and just lay out a basic
22 principle, and that principle is to get this information to
23 the end user and to satisfy the requirements of all
24 government and all manufacturers by allowing a very broad

1 definition of what labeling is. That definition should
2 include the MSDS sheets; it should include product inserts;
3 and the least important is what's just on that bottle and on
4 that container.

5 The reason that that is least important is because
6 that's the smallest area that we have to work with. When we
7 look at the dental drugs and medicaments that we make, many
8 of them are in these one-ounce tiny bottles. And what
9 Sultan Chemists has done is we've shrink-wrapped this, and
10 in the shrink wrap we have included our product inserts and
11 the MSDS sheets, and on the top of the labels we've put in
12 these DOT hazard labels to indicate what type of a hazard is
13 contained, if any.

14 One of the innovations that we've done is that
15 we've silk-screened the label directly on the container, and
16 this container we try to use only for one product. So that
17 eliminates the very severe risk of mislabeling. Mislabeling
18 is one of the most serious defects that we can have. And
19 when we introduce like on this smaller container a paper
20 wrap-around label and we allow the possibility of
21 ingredients to be put on there, we greatly magnify the risk
22 of mislabeling.

23 So if you provide us with the principle of getting
24 this information out into the industry, to the practitioner,

1 the dentist, to the end user, and leave it to us as to how
2 to get that information best out there, we will come out
3 with these innovative solutions. And Sultan is a company
4 that has embraced the use of the MSDS sheets and has gone
5 through a lot of original thinking in getting this out.

6 As I said, I'm the Director of Quality. I handle
7 these calls everyday, and I'm quite pleased as to the
8 effectiveness of the MSDS sheets. The dentists do have them
9 on hand; if not, it's introduced with every product. And
10 the adverse reaction section and the ingredient section in
11 the MSDS sheets seems to satisfy the requirements. And I
12 would just encourage that we should work with one government
13 and not several governments each which may have their own
14 agenda. So let's try to define labeling in the broadest
15 sense, and then we can accomplish this in the most
16 innovative fashion.

17 Thank you very much.

18 CHAIRMAN ROBERTSON: Thank you.

19 Questions from the Panel? Dr. Greenspan?

20 DR. GREENSPAN: Thank you very much for the
21 presentation and describing the different way that your
22 products are labeled. I may have gotten the wrong
23 impression, but my impression from your comments is that you
24 have some concerns about how the information would be

1 produced if labeling is required and that the package insert
2 may be more attractive than actually having to put something
3 on the label. Is that correct?

4 MR. HEIMANN: Absolutely correct.

5 DR. GREENSPAN: Thank you.

6 CHAIRMAN ROBERTSON: Thank you.

7 Welcome. Please introduce yourself and your
8 affiliation.

9 MR. JEFFERIES: Thank you, Dr. Robertson. I
10 believe Dr. Tylenda has circulated my comments in your
11 packages. My name is Steven Jefferies, and I am Vice
12 President and Director of Product Development with Dentsply
13 International on whose behalf I am here today.

14 Prior to assuming this position, I was a clinical
15 research dentist within the Clinical Research Department of
16 the Caulk Division of Dentsply International from 1986
17 through 1990, and subsequently Director of Clinical Research
18 within the same department from 1990 to 1994.

19 During that period of time at the Caulk Division,
20 I had contact with other dentists through the 1-800 line
21 provided for direct contact with clinicians. Furthermore,
22 from time to time during that same time period, I was
23 directly involved in the infrequent requests for specific
24 ingredient or product composition information requested by

1 practitioners.

2 In addition, I was engaged in the full-time
3 practice of dentistry for five years prior to joining
4 Dentsply International and continued to practice on a part-
5 time basis in Milford, Delaware, from 1986 through 1994.

6 Therefore, I believe my comments today come from a
7 slightly different perspective from those prior statements
8 that have been made to the Panel.

9 As a practitioner who is involved in dental
10 product development, I can clearly reaffirm earlier
11 statements made during past Panel meetings that the
12 ingredients of dental products must be made available to
13 dentists and physicians to protect the health and safety of
14 patients. There is no debate on this issue. Patient safety
15 and support to the licensed professional must be our
16 paramount concern in all issues. What is in question is
17 what mechanism best provides this information in a clear and
18 effective fashion.

19 In this context, I would like to relate some brief
20 observations regarding my experience when dealing with
21 fellow dentists in reference to this issue.

22 First of all, I can confirm earlier comments made
23 to the Panel that the number of inquiries concerning
24 ingredient content of products and complaints regarding

1 allergic responses are low. And I would emphasize very low.
2 Of the limited number of responses received, the vast
3 majority of these inquiries involved products which already
4 carry identification of known or potential sensitizers or
5 allergens on the product label.

6 With respect to the current practice of providing
7 product ingredient information on a case-by-case basis in a
8 timely fashion, my experience has been that the system works
9 extremely well for all parties concerned. Usually the
10 practitioner needs clarification concerning alternative
11 terminology or trade names for specific ingredients. Such
12 information and clarification can only be provided in a one-
13 to-one direct contact situation.

14 One concern about placement of ingredient
15 information on the product label or labeling is the
16 practical concern about future availability to the dentist.
17 In my experience, many dentists do not retain the product
18 label or package, and just as frequently, the package insert
19 and technique sheet are also discarded after initial
20 reading. Practically speaking, if ingredient information is
21 placed on product labeling, it may no be available for
22 future use.

23 Another significant concern to practitioners based
24 on recent comments concerning the increasing overhead costs

1 in dentistry may be the costs passed on to dentists and
2 patients if ingredient labeling becomes mandatory.
3 Manufacturers will inevitably pass the increased cost of
4 these changes in packaging onto dentists via the price
5 charged for their products, and in turn, dentists will be
6 forced to pass these costs onto their patients.

7 Perhaps one way of dealing with this issue is to
8 formalize the procedure for providing product ingredient
9 information to dentists and physicians and, in so doing, to
10 their patients. One approach could be to require that
11 manufacturers immediately relay requested verbal information
12 and confirm this via fax to the dentist or physician within
13 a specific time frame, for example, 24 hours.

14 Since ingredient information has no immediate
15 benefit in altering the mode of treatment of either a mild
16 or severe allergic reaction and ingredient information
17 knowledge appears useful only to possibly prevent future
18 exposure, 24 hours is a reasonable time period in which to
19 provide the requested information. If the ingredient
20 labeling contained proprietary information which the
21 manufacturer wished to maintain confidential due to patent
22 or trade-secret concerns, the procedure could provide for a
23 verbal or written understanding that this information would
24 be used for the purpose of patient treatment and would be

1 maintained as confidential or privileged information within
2 the patient-doctor relationship.

3 Finally, let me make one last point. Innovation
4 in dental materials over the past three decades has allowed
5 dentists to deliver an unprecedented level of dental care to
6 their patients. One illustration of this point among
7 countless examples are developments in restorative dental
8 adhesives, which have made operative and restorative
9 procedures possible that were thought unthinkable just one
10 decade ago.

11 Notwithstanding our overriding concern for patient
12 health and safety, the current method of providing dental
13 ingredient information to dentists on an individual case-by-
14 case basis balances the patient's and dentist's legitimate
15 need for ingredient information versus the need and legal
16 right to maintain certain proprietary information on a
17 limited confidential basis. The legal mechanism and the
18 right to pursue patents and maintain trade secrets does far
19 more than merely protect the manufacturer's interest. More
20 importantly, it ensures that patients and practitioners
21 receive the most advanced, safe, and efficacious dental
22 products.

23 In my limited regulatory experience, it appears
24 that the agency and the Panel have always recognized the

1 importance of not unreasonably interfering in the innovative
2 process for the benefit it provides to patients, while
3 vigorously ensuring that all products and procedures are
4 safe and efficacious.

5 We all trust that the final decision reached by
6 the Panel and the agency in this matter will be one which
7 clearly protects the public health while maintaining the
8 legitimate and necessary interest of all parties involved.

9 Thank you very much for the opportunity to present
10 this brief statement, and I will be happy to answer any
11 questions.

12 CHAIRMAN ROBERTSON: Thank you.

13 Are there questions from the Panel? Dr.
14 Greenspan?

15 DR. GREENSPAN: If you can help me with this piece
16 of information, I would appreciate it. You are talking
17 about proprietary information with some of these products.
18 How much of that is protected by patent law?

19 MR. JEFFERIES: Well, it would be impossible for
20 me to give you, based on the entire industry, a totally
21 accurate estimate. I would say that in many of the products
22 that are evolving very rapidly in the field of restorative
23 dentistry, in the field of some of the subject matter, for
24 example, approached by the Panel in this very session, I

1 would say that the percentage would be relatively high.
2 There are obviously products that are more well established,
3 and their composition is more well known because that
4 information is provided in textbooks and in longstanding
5 articles and publications.

6 So I would say we really have a bimodal situation
7 here. We have a rapidly expanding group of new and
8 innovative products that have a lot of proprietary
9 information, either be it patents or trade secrets, and then
10 we have another group, substantial but fairly static, which
11 has well-established--

12 DR. GREENSPAN: Which is already on--

13 MR. JEFFERIES: --ingredient information, yes.

14 DR. GREENSPAN: Thank you.

15 CHAIRMAN ROBERTSON: Other questions from the
16 Panel?

17 [No response.]

18 CHAIRMAN ROBERTSON: Thank you very much.

19 Is there anyone else here who would like to
20 address the Panel? Is there anyone else who would like to
21 address the Panel?

22 [No response.]

23 CHAIRMAN ROBERTSON: Well, thank you very much.

24 I would like to remind those here and the Panel

1 that this Panel is advisory to the FDA and provides FDA
2 advice and recommendations on issues raised by the FDA. But
3 the Panel does not make policy. It simply provides advice.

4 In the context of ingredient labeling, the Panel
5 was asked to serve as a forum to get on the record for use
6 of FDA the advantages and disadvantages, problems associated
7 with ingredient labeling. And I think actually the
8 committee has done that quite well.

9 On the record at this meeting and previous
10 meetings have been placed concerns about the magnitude of
11 the problem with adverse reactions occurring to dental
12 materials, the many mechanisms already in place, the
13 problems with duplication of effort with agencies within the
14 Government, the dangers to innovation, and a number of
15 alternative plans, particularly including MSDS, for
16 providing public safety on dental materials. And all of
17 that information is in the record and will be considered by
18 FDA staff.

19 The Panel has not actually been asked to judge
20 whether ingredient labeling should or should not occur. The
21 FDA may in the future choose to do that, but has not up to
22 this point.

23 What FDA has asked the Panel to do is to provide
24 general principles which could be applied to a list of

1 ingredients should those ingredients be incorporated into
2 some scheme for labeling. And that is the advice that FDA
3 asked the Panel, to try to develop some general principles
4 for listing those dental devices for ingredient labeling
5 under whatever system FDA chooses or chooses not to
6 incorporate. And that is what Dr. Greenspan will repeat for
7 us again here in a minute, those general principles used for
8 ingredient labeling.

9 What we would like to do now is to, as a Panel, go
10 through those general principles and identify those
11 ingredients based on those general principles that might be
12 recommended for ingredient labeling. To help us with some
13 background there from the FDA perspective, we will now hear
14 first from Dr. Greg Singleton.

15 DR. SINGLETON: Yes, thank you. Good morning.
16 Originally, I was going to go ahead and introduce,
17 reintroduce the topic of device ingredient labeling to the
18 Panel, but I think Dr. Greenspan did a very nice job of
19 giving the historical perspective as to how the Panel has
20 viewed the topic--

21 DR. TYLEND: Excuse me. Can everyone in the
22 audience hear Dr. Singleton?

23 VOICES: No.

24 DR. TYLEND: That's what I thought.

1 DR. SINGLETON: Originally I was going to
2 reintroduce the topic of ingredient labeling to the Panel,
3 but Dr. Greenspan did a very nice job of giving a
4 perspective as to what the history was of the labeling
5 initiative and what the Panel has done and what the
6 subcommittee has done so far. And I know that the issue of
7 cost to industry is paramount, and certainly FDA has to take
8 those factors into consideration. And I just wanted to take
9 this opportunity to just look at the list right now as it
10 has been formulated, and actually I made a couple of
11 calculations. Of the 94 generic devices that were on the
12 list, 35 were included in a list not to have ingredient
13 labeling. Of the remaining, 27 were considered to be of
14 high priority; of those, there are 4 OTC products which are
15 in Class III, which eventually we're going to get premarket
16 approval application. So I think we're really down to 23
17 types of devices. Of the remaining devices, there are 28
18 that were found to be low priority and 4 medium.

19 So I guess the question I would ask of industry--
20 and I think Dr. Shils might be the person that could respond
21 to this most readily--would be: When the industry was asked
22 to provide some kind of an indication of what the costs
23 would be, were the manufacturers of all these devices, 94,
24 asked to do this? Or were they limited to the ones that

1 were actually on the list for ingredient labeling? I think
2 that might make a tremendous difference in terms of what the
3 calculations might be.

4 Of the 28 low and 4 medium, I think those would be
5 certainly on a list for consideration to perhaps not even be
6 considered for labeling in the future, or if it was, it
7 would be in the distant future. So I think those are issues
8 that we have to look at also.

9 I realize that cost is still going to be a factor,
10 and certainly we have to look at that, but I think we have
11 to put this into perspective as to what the list is actually
12 saying at this point.

13 That was just the comment I wanted to make. Thank
14 you.

15 CHAIRMAN ROBERTSON: I wonder if you would please
16 come up to the microphone and reintroduce yourself, please.

17 DR. SHILS: I'm Edward Shils, the Executive
18 Director of the Dental Manufacturers of America.

19 Actually, the problem of communications is one
20 that we all share together. I did send the questionnaire
21 out to 200 members. I'm not certain as to whether or not
22 every one of them has product that falls under these
23 categories that are now being questioned. I'm not quite
24 certain as to whether or not the classifications that you've

1 put in tentatively as to high, medium, and low were known to
2 us at that particular time.

3 It would seem that we have to do a better job of
4 communicating. What we really do is we create fear in terms
5 of what can be eventual costs unless we know for a fact that
6 we have hard knowledge.

7 We do know this--and since you, Dr. Singleton, are
8 with FDA, rather than discussing this with the Panel, I
9 think I can ask you the question. In view of the fact that
10 FDA staff is limited, in view of the fact that Congress is
11 watching every dollar for every regulatory agency, in view
12 of the fact that you are now considering third-party
13 delegation with respect to GMPs, in view of the fact that
14 you're dropping the distributor requirement, it's obvious to
15 me as a professor of management that your agency is under a
16 great deal of stress.

17 Even though this Panel doesn't have the mandate to
18 ask you the question about your organization, I think as a
19 good citizen I do have that right. And I would hope that
20 whatever the Panel's recommendations are, that in
21 considering alternatives both to save stress and cost both
22 within your agency and within our industry, you would
23 continue to consider it. Knowing your reputation, I know
24 that you will.

1 Thank you.

2 CHAIRMAN ROBERTSON: Are you going to make any
3 response to that?

4 DR. SINGLETON: No.

5 [Laughter.]

6 DR. SINGLETON: I think that was a rhetorical
7 question, actually.

8 CHAIRMAN ROBERTSON: Thank you, anyway.

9 Further comments from FDA, from Tim Ulatowski.

10 MR. ULATOWSKI: Thank you, Mr. Chairman. I would
11 be happy to speak about my stress, actually.

12 I would like to give the Panel an update on the
13 status of the dental device labeling initiative, what has
14 been happening within FDA. Briefly, I have made at least
15 one presentation, and perhaps more, on this issue in the
16 past, on MSDS and related elements of the initiative.

17 First, we realize that the duplication of
18 regulatory requirements of FDA's labeling initiative and
19 OSHA's MSDS requirements under the hazard communication
20 standard is a significant concern to the dental device
21 industry. The panel itself has expressed concerns in the
22 past to FDA. I want to reassure the Panel, the industry,
23 and others that FDA and OSHA are continuing our discussions
24 on this issue. In fact, I am more encouraged now than

1 before with regard to alternatives and possibilities that
2 might arise out of ongoing discussions with OSHA. We have
3 an OSHA representative here whom we've been working with,
4 and this is not a closed issue. There's still an open door
5 on possibilities for relief to the industry as FDA considers
6 its own initiative. So that door remains open, and I think
7 the industry and others can, as I said, feel reassured about
8 our intent to maintain our open lines of communication and
9 develop what we can to provide as much relief as possible.

10 Secondly, FDA fully intends to provide the public
11 ample opportunity for comment on any proposal that may be
12 developed. We are seriously considering the comments
13 already received in anticipation of our proposal, some of
14 which you've heard today. I cannot state with certainty
15 when an FDA proposal will be ready for comment. I can only
16 report that work has begun. We've made some significant
17 progress in anticipation of the Panel's proceeding here
18 today and after examining some of the comments.

19 It is premature and, I think, even misleading to
20 discuss any particulars right now since proposals within the
21 agency typically are often changed as a result of internal
22 review and other input. I think in addition to my comment
23 here, we have heard from the industry on very important and
24 very relevant issues, not trivial by any means. But I think

1 it is prudent for the agency to give the rest of the public
2 ample opportunity for input, that being practitioners,
3 consumers, and others who are very interested in dental
4 products, labeling, adverse effects, and other issues.

5 So I am talking about a process, and a process of
6 inclusion of all views, and how it comes out depends upon
7 the strength of those views, the law, and we'll see how
8 things come out in the end.

9 We thank the Panel for their input on this issue
10 and their help and recommendations on prioritization that
11 you are going to discuss. We will keep you closely advised
12 on the labeling initiative at succeeding meetings, and I
13 think we will probably ask for additional advice and input
14 as things develop.

15 Thank you.

16 CHAIRMAN ROBERTSON: Thank you.

17 Well, I'd like to begin--maybe before I do that,
18 are there any remarks or questions from the Panel to the
19 FDA?

20 DR. BOUWSMA: In response to one of the things I
21 think I just heard you say, with regards to the OSHA and FDA
22 overlapping of things, rather than have that dialogue and
23 various rules and so forth take place after the fact, it
24 would seem to make sense to have all of that dialogue happen

1 on the front end and establish whatever the rule--hopefully
2 one rule--would be so that there's not that kind of overlap.

3 And the second thing, I think when we went through
4 and categorized everything initially, we did so on the basis
5 of tissue contact. And I know a lot of that was factored
6 into that, and I would think also that when you review that,
7 that high, medium, low, you also factor into it the relative
8 safety/allergic perspective into that so that there's maybe
9 the high, medium, and low category based on tissue contact,
10 but also the potential for safety concerns, and maybe that
11 might alter the actual placement of those materials,
12 devices.

13 MR. ULATOWSKI: Your point is well taken. Thank
14 you.

15 CHAIRMAN ROBERTSON: Other questions of FDA?

16 [No response.]

17 CHAIRMAN ROBERTSON: Good. Well, then, I would
18 like to begin, independent of the issue of what such a
19 system will be and even whether such a system will be, to
20 try to complete the answer that FDA asked us--that is, to
21 facilitate whatever system might arise, what would the Panel
22 recommend as a principle and then apply that principle to
23 specific materials? And those kinds of conversations and
24 work have been going on with the Panel for several previous

1 meetings.

2 What I would like to do is have Deborah
3 rearticulate for us that principle, and then we will begin
4 and break for lunch, and continue after lunch. I would like
5 to go through by category each of these dental devices and
6 make sure we're all comfortable, given those principles from
7 Deb, both including the material on a list recommended for
8 labeling and comfortable with the priority, and then amend
9 either the device to be included on the list or the priority
10 within each category, and then in the end we will vote on
11 the entire list as a recommendation to FDA.

12 Dr. Greenspan, if you would again rearticulate the
13 general principle which is driving the presence of a
14 particular device on the list and its priority.

15 DR. GREENSPAN: We were provided with a long list
16 of devices to look at, and we divided them into those which
17 had long-term contact with the mucosa and those that had
18 short-term contact with the mucosa. As a principle when we
19 got started, we felt that everything that came into long-
20 term contact with the mucosa should be considered and put
21 that aside.

22 We then looked at those products which had cursory
23 contact with the mucosa and selected a certain number of
24 those which we felt should be considered for labeling, and

1 left aside the other ones which had cursory contact which we
2 did not feel should be considered for labeling.

3 So, essentially, the list that is in the book
4 primarily concerns products and devices which have long-term
5 contact with the mucosa and then a few, such as oral cavity
6 polishing agents, which have short-term contact with the
7 mucosa.

8 Having then established this list of devices which
9 should be considered for labeling, we then went through the
10 list and discussed a level of concern and whether these
11 should be listed for high, medium, or low priority. And
12 that is how this list is derived.

13 Those products that we decided were of high
14 priority were those which the subcommittee and then the
15 Panel felt were most likely to need, require labeling either
16 because of reported problems or difficulty of getting
17 information or the length of time and the way the product
18 was used, the device was used.

19 So that is how this list was generated. It was
20 produced for discussion. And so you will see that we have,
21 beginning with--would you like me to go through it, Dr.
22 Robertson?

23 CHAIRMAN ROBERTSON: Sure. Can I ask a question
24 since I was not involved in that? Was it more than mucosa?

1 Actually, I know mucosa is what you do, but it could be
2 bone?

3 DR. GREENSPAN: Yes. We actually said long-term
4 contact with human tissue.

5 CHAIRMAN ROBERTSON: Okay.

6 DR. GREENSPAN: It could be bone or mucosa, yes.

7 We started then with the implant materials, which
8 included endo-osseous implants, sub-periosteal implants, the
9 bone-filling materials, bone plates, intraosseous fixation
10 screws and wires, and TMJ implants, all of which were given
11 high priority.

12 CHAIRMAN ROBERTSON: Is there any comment or
13 amendment on the part of the Panel? Is the Panel
14 comfortable with that general--with that grouping? Any item
15 there that any Panel member is not comfortable with?

16 [No response.]

17 CHAIRMAN ROBERTSON: Good.

18 DR. GREENSPAN: We then looked at filling
19 materials, and we felt the filling materials could be
20 considered in several of the categories. So I will read
21 them one by one:

22 That amalgam was a high priority; gold foil, low;
23 resin bonding agent, high; calcium hydroxide, medium; cavity
24 varnish, low; glass ionomer cement, high; zinc phosphate

1 cement, low; zinc silicate cement, low; zinc oxide in
2 Eugenol used as a temporary filling material, high; and
3 tooth shade resin, including sealants, as high.

4 CHAIRMAN ROBERTSON: Does any member of the Panel
5 have questions, amendments, concerns about either being on
6 the list or the priority? Dr. Patters?

7 DR. PATTERS: Could you tell me the logic that
8 went into classifying zinc oxide Eugenol temporary materials
9 as high, since they're in contact for a relatively short
10 time, being a temporary material?

11 DR. GREENSPAN: My memory of that was actually
12 based on reports of Eugenol producing mucosal irritation. I
13 would be happy for anybody who was there at that time to add
14 to that.

15 CHAIRMAN ROBERTSON: Dr. Drummond?

16 DR. DRUMMOND: Where would we place endodontic
17 sealers at?

18 CHAIRMAN ROBERTSON: Under endodontic materials,
19 doesn't include sealers. Can you remember, Greg or Tim,
20 whether it either wasn't included or got put on the not
21 recommended?

22 DR. SINGLETON: This could be based on what the
23 dental device list actually states. I don't think there's a
24 specific endodontic sealer on the list. That is probably

1 why it was not on there.

2 DR. TYLEND: And that's true. We have no
3 specific device listing for endodontic sealer. But, Greg,
4 if an endodontic sealer came in, do you recall what device
5 category listing it would go under?

6 DR. SINGLETON: It would most likely go under
7 somewhere probably with the resin, along with the resin.

8 DR. DRUMMOND: It would go under zinc oxide
9 Eugenol.

10 DR. TYLEND: Well, no. I mean, you might put it
11 under there, but where would we put it? We have a system
12 and we have a certain number of pro codes, and we try to be
13 consistent. And certain types of products that are
14 accessory to another product they have to be used with go
15 under that same product. I'm just trying to recall where we
16 would put endodontic sealer. We didn't bring that list with
17 us, I don't believe.

18 DR. SINGLETON: I think certainly this might be a
19 good topic for the Panel to discuss based on their knowledge
20 of sealers, where they would want to put it on this
21 particular list.

22 DR. TYLEND: That's true. You just tell us where
23 you'd want to put it, and we'll make sure it gets in the
24 proper heading.

1 DR. NORMAN: If you want to put it with the
2 product with which it is used, it would come under Gutta
3 percha.

4 DR. TYLEND: It may. Right now we're not
5 deciding that. We already put it somewhere. We're just not
6 sure where we put it right now without checking the records.
7 But we will make sure--

8 DR. NORMAN: There are materials that are
9 manufactured that do not contain Eugenol which are used in
10 that manner, too, but there's still a complex alcohol
11 structure, like Eugenol. That's where I would put it, with
12 zinc oxide Eugenol.

13 CHAIRMAN ROBERTSON: Well, I think that's a
14 problem to note for FDA staff. One of the issues raised
15 here is that I heard, I think, is that Deb's concerns, the
16 concerns of the subcommittee were related to the Eugenol in
17 zinc oxide and Eugenol temporary filling cements. The
18 second point here is that there may be some temporary
19 filling cements that don't contain Eugenol and would there
20 be the same concern. Did I do that right?

21 DR. NORMAN: Pretty good for a--

22 CHAIRMAN ROBERTSON: For a periodontist it wasn't
23 bad, right? And I think it's a point well taken. So for
24 zinc oxide and Eugenol, given the literature, there is some

1 concern about mucosa contact. But for non-Eugenol-
2 containing temporary filling materials, that priority might
3 be quite different, maybe unknown.

4 I had similar concerns about tooth shade resins,
5 and I didn't know why that was high. I understood that they
6 were in contact with oral tissues for an extended period of
7 time, but I didn't know why it was a high priority.

8 DR. GREENSPAN: I believe--and I would have to go
9 back to the record and look at some of the discussions, but
10 I have a sense that it was related to the curing and the
11 time of curing and adequate curing that could be involved
12 with the use of both resins and sealants. I think Mark was
13 on that subcommittee.

14 DR. PATTERS: No.

15 DR. GREENSPAN: You weren't. Okay.

16 DR. TYLEND: Dr. Duncanson.

17 DR. GREENSPAN: Dr. Duncanson was, if he
18 remembers.

19 DR. DUNCANSON: I think it was principally a
20 concern that there might be residual monomer, the handling
21 characteristics of the material, how long it was actually in
22 contact before it reached a safe degree of cure.

23 CHAIRMAN ROBERTSON: I'm not trying to second-
24 guess the subcommittee here.

1 DR. GREENSPAN: No.

2 CHAIRMAN ROBERTSON: I am just--I think this is
3 the time for all of us to look and raise any questions.

4 DR. NORMAN: The extended problem of free monomer,
5 which in some cases could be as high 10 percent for periods
6 of time.

7 CHAIRMAN ROBERTSON: All right. Any other
8 questions? Yes?

9 DR. DRUMMOND: I have a second question in terms
10 of maybe it's just classification again, but where did
11 polycarboxylate and resin cements fall in? Are they
12 included under these other categories?

13 CHAIRMAN ROBERTSON: FDA will have to help there.

14 DR. TYLEND: I think we'll call upon Lou. Among
15 us, I think he has the best memory for these lists that we
16 use. Or Pam. Is Pam Scott still here?

17 DR. SINGLETON: There is a general category called
18 dental cement on our list. That is kind of a catch-all for
19 a number of different products that could very well fall
20 into that category.

21 DR. TYLEND: But regardless of how many
22 categories we have, if you want to subdivide, if you think
23 the polycarboxylate cements should be in one priority
24 assignment, assigned group, and the other cements in