

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

DENTAL PRODUCTS PANEL MEETING

VOLUME I

Monday, November 3, 1997

9:05 a.m.

Holiday Inn Bethesda
8120 Wisconsin Avenue
Bethesda, Maryland

P A R T I C I P A N T S

Robert J. Genco, DDS, Ph.D., Acting Chairperson
Pamela D. Scott, Executive Secretary

MEMBERS

Janine E. Janosky, Ph.D.
Donald S. Altman, DDS (Consumer Representative)
Floyd Larson (Industry Representative)

CONSULTANTS

Gilbert R. Gonzalez, DDS
Leslie Heffez, DMD, MS
Andrea Morgan, DDS
E. Diane Rekow, Ph.D., DDS

FDA

Timothy Ulatowski, MS
Robert Betz, DDS
Susan Runner, DDS, MA

GUESTS

Peter Bertrand DDS
Allen Moses, DDS
Barry Cooper, DDS, PC

C O N T E N T S

Welcome and Introductory Remarks	4
Update from Last Panel Meeting: Timothy Ulatowski, MS	8
ISSUE:	
DISCUSSION OF DEVICES FOR USE IN THE DIAGNOSIS AND/OR TREATMENT OF TEMPOROMANDIBULAR JOINT DYSFUNCTION AND ORAL-FACIAL PAIN	
FDA Presentation: Dr. Robert Betz	23
Open Public Hearing [No Speakers]	36
Presentations by Industry/Professional Organizations:	
John Radke	37
Roland Jankelson	48
Dr. Robert Jankelson	51
Dr. Kenneth Burrell	59
Dr. Peter Neff	68
Dr. Larry Tilley	69
Open Committee Discussion	86

1 At this time, I would now like to introduce the
2 members, consultants, and guests for our panel today.

3 As you know, Dr. Robert Genco is acting as our
4 Chair today. He is distinguished professor and chair of the
5 Department of Oral Biology in the School of Dental Medicine
6 at the State University of New York at Buffalo.

7 We also have Dr. Janine Janosky. She is assistant
8 professor with the Department of Family Medicine and
9 Clinical Epidemiology at the School of Medicine at the
10 University of Pittsburgh.

11 Our consumer representative is Dr. Donald Altman.
12 He is the chief of the Office of Oral Health with the
13 Arizona Department of Health Services.

14 Our industry representative is Mr. Floyd Larson,
15 and he is the president of Pacific Materials and Interfaces.

16 We also have with us here today Dr. Gilbert
17 Gonzalez. He is the assistant professor of neurology with
18 the Department of Neurology at the Mayo Clinic in
19 Scottsdale.

20 We have also Dr. Andrea Morgan. She is clinical
21 instructor with the Department of Restorative Dentistry at
22 the University of Maryland Dental School.

23 And we have Dr. Diane Rekow. She is the
24 chairperson of the Department of Orthodontics at the

1 University of Medicine and Dentistry of New Jersey.

2 Also joining us later today will be Dr. Leslie
3 Heffez. He is a professor and department head of Oral and
4 Maxillofacial Surgery at the University of Illinois at
5 Chicago.

6 The next items of business are three statements
7 that are to be read into the record. The first statement is
8 the conflict-of-interest statement.

9 The following announcement addresses conflict-of-
10 interest issues associated with this meeting and is made
11 part of the record to preclude even the appearance of an
12 impropriety. The conflict-of-interest statute prohibits
13 special government employees from participating in matters
14 that could affect their or their employer's financial
15 interest. To determine if any conflict existed, the agency
16 reviewed the submitted agenda and all financial interests
17 reported by the committee participants and has determined
18 that no conflict exists for today's participants.

19 In the event that the discussions involve any
20 other products or firms not already on the agenda for which
21 an FDA participant has a financial interest, the participant
22 should excuse him- or herself from such involvement, and the
23 exclusion will be noted for the record.

24 With respect to all other participants, we ask in

1 the interest of fairness that all persons making statements
2 or presentations disclose any current or previous financial
3 involvement with any firm whose products they may wish to
4 comment upon.

5 The next item is the appointment of temporary
6 panel chairperson. I appoint Robert J. Genco, D.D.S.,
7 Ph.D., to act as temporary chairman for the duration of the
8 Dental Products Panel Meeting on November 3 through 5, 1997.
9 For the record, Dr. Genco is a special government employee
10 and is a voting member of the Dental Products Panel. Dr.
11 Genco has undergone the customary conflict-of-interest
12 review. He has reviewed the issues to be considered at this
13 meeting. Signed, Dr. Bruce Burlington, Director for the
14 Center of Devices and Radiological Health, October 28, 1997.

15 At this time, I would like to introduce the guests
16 that have been invited to participate in today's panel
17 meeting. Our guests are: Dr. Allen Moses. He is a
18 practicing clinician, and he is on the teaching staff at the
19 Michael Reese Hospital in Chicago, Illinois.

20 We also have Dr. Peter Bertrand, who is a
21 specialty advisor for oral-facial pain and TMD at the
22 National Naval Medical Center.

23 We have Dr. Barry Cooper, who is also a practicing
24 clinician in Lawrence, New York.

1 At this time, I will turn the meeting over to Dr.
2 Genco.

3 DR. GENCO: Thank you.

4 Now I would like to introduce Mr. Timothy
5 Ulatowski, who is the Director of Division of Dental
6 Infection Control and General Hospital Devices, and he is
7 going to give us an update from the last panel meeting.

8 MR. ULATOWSKI: Mr. Chairman, Dr. Runner is going
9 to precede me since I am going to be speaking on two
10 subjects afterward. Dr. Runner is the branch chief for the
11 Dental Products Branch in the Office of Device Evaluation.

12 DR. RUNNER: I just have a few brief remarks to
13 update the panel on activities that have taken place in the
14 Dental Branch since the last panel meeting last February.

15 As you will recall, at the last panel meeting the
16 issue was brought forward to the panel as to whether the
17 temporary mandibular condyle implant should be down-
18 classified to class II. The panel at that time recommended
19 that the temporary mandibular condyle implant for
20 reconstruction of tumor patients be down-classified, and we
21 have proceeded with the writing of the Federal Register
22 notice to propose this. And so that should be coming out
23 shortly.

24 The Dental Branch has been involved in numerous

1 activities, but one of the most interesting that I think you
2 would be interested in is a recent memorandum of
3 understanding with the National Institute of Dental
4 Research. And under this memorandum, we are going to be
5 working very closely with members of the National Institute
6 of Dental Research on collaborative activities, possibly
7 trading panel members back and forth, possibly having a
8 resident come to FDA and people from FDA go to NIDR for
9 collaboration. And I think this will give us a lot of
10 interaction that will help as new products are coming before
11 NIDR for research grants and as they come to FDA for
12 marketing clearance.

13 So we're very excited about this, and this is I
14 think one of the very first memoranda that have been
15 established between NIH and FDA. And so this will sort of
16 be the test case. We are going to be beginning it this
17 year, and if you have any questions, please feel free.

18 DR. GENCO: Any questions about this interesting
19 new innovation, initiative?

20 [No response.]

21 DR. GENCO: Thank you very much, Susan.

22 MR. ULATOWSKI: Good morning. I'm going to bring
23 the panel up-to-date on one activity ongoing in this branch
24 and in every branch in the Office of Device Evaluation--

1 indeed, across the Center for Devices and Radiological
2 Health.

3 I'd like to bring you up-to-date very briefly
4 about an important activity of this branch. It concerns the
5 use of voluntary consensus standards in the evaluation of
6 dental devices. The Food and Drug Administration has been
7 directed to rely upon voluntary consensus standards, both
8 domestic and international, when feasible, consistent with
9 law and regulation. The purpose of this reliance is to
10 assist FDA in fulfilling its public health and regulatory
11 mission.

12 FDA will adopt voluntary consensus standards when
13 adoption will enhance: one, its ability to protect
14 consumers; and, two, the effectiveness or efficiency of its
15 regulatory efforts.

16 What is adoption of a standard? Adoption is
17 recognition of a standard by FDA through an assessment and
18 publication process. The adopted standard pertains to a
19 specified critical regulatory provision. If a person
20 certifies that their device or process meets the adopted
21 standard, in whole or in part, then FDA will accept that the
22 device meets the specified corresponding critical regulatory
23 provision to the extent covered by the certification, and
24 FDA will not require further documentation.

1 For example, if FDA recognizes a dental material
2 standard, then a person certifying that their device meets
3 the standard in whole will not need to submit supporting
4 data on the material that is addressed by the standard, in a
5 510(k) or a PMA, whatever the case may be.

6 FDA has, to a certain limited extent, already used
7 standards in its regulatory procedures, with some resource
8 savings to FDA and the industry. However, this new effort
9 under FDA's reengineering program is a full-blown effort to
10 transition the center to a standards-based organization to
11 the extent possible. FDA will be working with standards
12 development organizations to formulate scientifically sound
13 device design, manufacturing, and professional practice and
14 other standards that can be relied upon in our pre-market
15 and other programs.

16 The Dental Branch and other components of the
17 Center for Devices and Radiological Health are very actively
18 engaged in a process of identifying candidates for adoption
19 and assessing their merits vis-a-vis device safety and
20 effectiveness factors.

21 There is a publication on FDA's Internet site
22 concerning the first in a line of recognized standards, that
23 is, IEC60601 concerning electrical safety. A list of
24 additional adopted standards is being prepared for

1 publication in the near future.

2 Thank you. Any questions on this activity?

3 [No response.]

4 MR. ULATOWSKI: That's the end of our presentation
5 on current activities, Mr. Chairman.

6 DR. GENCO: Thank you very much.

xx

7
8 We'll now proceed to discussion of devices for use
9 in the diagnosis and/or treatment of temporomandibular joint
10 dysfunction and related oral-facial pain. The topic will be
11 introduced by Tim Ulatowski.

12 MR. ULATOWSKI: Today we'll be discussing the
13 existing classification status of medical devices used in
14 the diagnosis and treatment of temporomandibular joint
15 diseases and associated oral-facial pain. You will be asked
16 to answer some questions that will help FDA identify which
17 devices under the umbrella indication for use I just stated
18 are unclassified and must be considered by this committee or
19 another committee in the future.

20 In order to conduct business today, you will
21 discuss current classification regulations, the content of
22 existing labeling for devices, and hear comments between you
23 on the intended use of devices and their description. You
24 should not discuss the safety and effectiveness of any

1 devices or device types today. You may well discuss the
2 indications for use or intended use of devices as purported
3 in labeling, but whether or not they achieve the stated
4 purpose, the risks involved, or the clinical utility should
5 not be discussed today by the committee.

6 I ask that the guests likewise limit their
7 discussion in the same manner, but they are not under the
8 same limitation. They can speak as they wish.

9 Before a fair and open discussion may ensue on
10 safety and effectiveness issues, all interested parties must
11 have the opportunity to provide the committee data and
12 information relevant to the discussion. FDA will ask for
13 these data and provide it to the committee for a future
14 meeting when FDA will request classification
15 recommendations.

16 The committee may hear comments and opinions on
17 safety and effectiveness by those requesting to speak at the
18 podium today during the open session. That is their right.
19 We will ask that the committee consider those aspects of
20 their presentations in their deliberations on safety and
21 effectiveness at the future meeting when these issues will
22 be on the table.

23 Since the topic pertains to classification, I want
24 to ensure that you have a common baseline of understanding

1 on classification. This is the supplement, the information
2 that you received this morning during a training session. I
3 will present a very brief primer consisting of seven
4 overheads on how devices are classified and the end product
5 of the classification process.

6 There are very detailed regulations on
7 classification in the Code of Federal Regulations and a
8 wealth of plain-English information on the topic and
9 training that people should avail themselves of to fully
10 comprehend the process. I frequently see misstatements in
11 the press on the process such as the committee decided to
12 classify this way or that way. It is the FDA who decides.
13 The committee recommends.

14 [Slide.]

15 Before May 1976, there were a host of medical
16 devices on the market. Prior to May 1976, FDA had no
17 authority to regulate the pre-market introduction of medical
18 devices. The May 1976 medical device law directed FDA to
19 catalogue every device into generic types of devices and to
20 classify each generic type of device into one of three
21 classes, class I, II, or III.

22 As you've heard this morning in training, the
23 class establishes the degree of control needed to help
24 reasonably ensure the safety and effectiveness of devices in

1 each generic device type. Class I devices are subject to
2 so-called general controls. Class II devices are subject to
3 general and special controls. Class III devices are subject
4 to pre-market approval.

5 FDA categorized the devices it could identify in
6 and around 1976 and classified the generic types of devices
7 it identified. In classifying the devices, FDA considered
8 recommendations from expert advisory classification panels,
9 which were the precursors for the today's advisory
10 committees, and manufacturer and public input provided at
11 the classification meetings or through the public notice and
12 comment procedure. The rationale for generic groupings and
13 classifications are included to a varying extent in the
14 transcripts for the panel meetings and in the Federal
15 Registers associated with the classifications.

16 FDA did not identify some pre-1976 products. FDA
17 and the panels missed a few. Those are represented by the
18 small hatched circle on the overhead. Over 20 years later,
19 FDA is still engaged in classification proceedings of pre-
20 1976 and associated devices. From time to time, we still
21 discover another device type we missed that doesn't fit into
22 any other category of classified device.

23 We have to take the newly identified generic type
24 of device through a classification proceeding, which

1 includes the need for an advisory committee recommendation
2 on the class to assign. One or more of the generic types of
3 devices we are going to discuss today may be one of these
4 pre-1976 generic types of devices that were never
5 classified.

6 [Slide.]

7 Since May 1976, we all know that many new devices
8 have entered the marketplace. One regulatory mechanism for
9 this entry is the pre-market notification process or 510(k)
10 process. By this process, a person who intends to market
11 the device must notify FDA of their intent to market the
12 device by means of a 510(k) application to FDA. The
13 applicant bases their ability to market the device on their
14 claim that their device is substantially equivalent to a
15 legally marketed device and their device is subject to the
16 same marketing allowance by association.

17 FDA reviews the 510(k). FDA compares the labeling
18 of the candidate device, its technological features, and,
19 when needed, performance data, to the claimed legally
20 marketed device to determine whether the new device is
21 equivalent. The new device may have the same and/or
22 different indications for use from the claimed legally
23 marketed device. The new device may have specific
24 indications related to a general intended use of a legally

1 marketed device. FDA determines whether the indications
2 stated in labeling create a new intended use different from
3 the legally marketed device. If the new device has a new
4 intended use, then FDA finds the device not equivalent.

5 There are other reasons why FDA may find the
6 device not equivalent, such as FDA finds the device does not
7 perform in an equivalent manner to the other device, to the
8 legally marketed device. FDA informs the applicant in
9 writing that the device is either substantially equivalent
10 or not substantially equivalent.

11 The Advisory Committee has historically not been
12 involved in this decision by FDA, with rare exception.
13 However, committees may become increasingly involved in
14 these decisions.

15 As new devices enter the marketplace based on the
16 determination of equivalence, there is a chain of related
17 legally marketed devices created. The chain of equivalence
18 shown on the overhead is based upon at least one pre-1976
19 device or to any device--one pre-1976 device that was
20 classified under a generic device type. One pre-1976 device
21 classified under a generic device type.

22 A person may claim their new device is equivalent
23 to the pre-1976 device or to any device subsequently found
24 equivalent in the chain. Note device A and B were found

1 equivalent to the pre-1976 device. Alternatively, although
2 I don't show it on the overhead, device B could have been
3 found equivalent to product A in a chain.

4 If FDA finds that a device is not equivalent, then
5 it is automatically a class III device, as for product C,
6 and subject to pre-market approval. The person who intends
7 to market the device must submit a pre-market approval
8 application and obtain FDA approval before the device is
9 marketed, or may submit a reclassification petition or a PDP
10 as an alternative. Product development protocol, PDP.

11 [Slide.]

12 The 510(k) process is a classification process.
13 That is its fundamental purpose. When FDA finds a device to
14 be equivalent to a legally marketed device, then the new
15 device assumes the same class as the generic group of the
16 legally marketed device to which it was found equivalent.
17 As you see in my example, which is associated with the prior
18 one, the pre-1976 device was class I, determined by a
19 classification panel, and device A and B are equivalent and,
20 therefore, also class I. Many class I devices do not
21 require a 510(k). They are exempt from the need to submit
22 an application. The manufacturer makes the determination
23 whether their product falls into the generic group and,
24 therefore, class I and exempt, if that's how that particular

1 product type is classified. FDA may provide an opinion on
2 the class and status if requested.

3 As an aside, we are moving to exempt all class I
4 devices except for a very few that we will propose to move
5 to class II.

6 A person may also claim their device is equivalent
7 to an unclassified pre-1976 device. If FDA finds the device
8 equivalent, then the new device is considered in the generic
9 type of unclassified device. A chain of unclassified
10 equivalent devices can exist, and we've had a number of
11 these. Once the generic type of device is classified by FDA
12 through a classification proceeding, which includes an
13 Advisory Committee recommendation, then all the devices in
14 that generic type are subject to the controls of the
15 assigned class, I, II, or III.

16 [Slide.]

17 Entirely new devices first marketed after 1976,
18 including those found not substantially equivalent per a
19 510(k), are subject to pre-market approval. These devices
20 have no link to a pre-1976 device type or associated devices
21 in a chain. These entirely new devices cannot be marketed
22 until FDA approves a pre-market approval application for the
23 specific device. An Advisory Committee may be asked to
24 review the PMA data and render recommendations to FDA, as

1 you heard this morning in training. It is not a
2 classification proceeding, the PMA review. The device is
3 already class III.

4 A pre-1976 generic device type that FDA classified
5 class III is also ultimately subject to pre-market approval,
6 but all devices in the group or in the chain may continue to
7 be marketed until the date FDA requires that the generic
8 type be subject to an approved pre-market approval
9 application. A person may request a reclassification
10 instead of submitting a PMA, but the reclassification
11 affects all devices in the generic group. So, for example,
12 breast implants marketed prior to 1976, silicone implants,
13 were classified class III. Up until FDA called for the
14 PMAs, people could market silicone breast implants through a
15 510(k) process, claiming equivalence to the product, until
16 FDA required the PMA.

17 Class III devices that must be the subject of an
18 approved pre-market approval application have no chain of
19 equivalence. Each and every new device requires its own PMA
20 which establishes that it is safe and effective on its own
21 merits. And note I said devices that must be the subject of
22 an approved pre-market approval application. That's when we
23 call for the PMAs and we say you got to have a PMA on file.

24 A chain for 510(k) equivalence purposes can still

1 be created for these devices if the device type is
2 reclassified by FDA into class I or II. Then persons with
3 claimed equivalent devices may submit 510(k) submissions.
4 So once class III, not always class III, and once a PMA, not
5 necessarily always a PMA. It depends on its classification
6 status.

7 In summary to this point, you've seen that
8 classification of a device occurs by two means that are
9 relevant to today's discussion: one, the classification of
10 a pre-1976 unclassified generic device type and associated
11 devices by Advisory Committee recommendation, notice and
12 comment and the ultimate FDA decision on classification.
13 And the other method, method two, classification of a device
14 through a 510(k) into a classified generic device type.

15 All devices indicated for the treatment and
16 diagnosis of temporomandibular joint diseases and associated
17 orofacial pain are covered by one of these methods. The
18 committee will have to identify and deal with devices in the
19 former category, not the latter. In other words, FDA in its
20 review of 510(k)s does its thing with 510(k)s, and we will
21 classify devices, new devices submitted to us, as submitted
22 to us in 510(k)s. You're dealing with those unclassified
23 devices and what still needs to have the original
24 classification assigned to it.

1 [Slide.]

2 We are going to ask you some questions that will
3 help us determine what generic device types are unclassified
4 and how to describe these devices. When we send out notice
5 to the public requesting data on the unclassified devices,
6 we hope the list will be comprehensive and clear. I believe
7 you will appreciate the discussion even more if you see a
8 classification regulation and some variations that exist.

9 The classification regulations in the Code of
10 Federal Regulations, this is all the generic types of
11 devices, generic types of devices that FDA has classified.
12 There is a citation for each generic type of device. There
13 is a name listed for the generic type of device. The
14 generic type of device is identified and the class is
15 stated.

16 [Slide.]

17 This is an example of a classification regulation
18 in the dental area. Base plate shellac is the name, the
19 generic name of the product, the citation, and then the
20 description of the product is provided. It's very simple,
21 straightforward, not glamorous. And then the classification
22 is stated in the regulation.

23 [Slide.]

24 This is my last overhead, and please hold the

1 applause.

2 Classification regulations may have some
3 variations. They always include a generic type of device
4 heading and at least one description and class. A
5 classification citation may include some degree of physical
6 description of the generic type of device, including, for
7 example, energy source or accessories. A classification
8 citation may include indications for use of the generic type
9 of device. Some citations have sub-groups of generic
10 devices under an overall generic device type heading. Two
11 examples are shown here straight out of our regulations for
12 dental cement and the other product, which indicates
13 different classes for different sub-groups of those products
14 based on composition in this case. So we have a generic
15 name with some splitting.

16 In grand summary, we are asking you to discuss
17 devices used in the diagnosis and treatment of
18 temporomandibular joint disease and associated orofacial
19 pain. The desired output of your discussion today will be
20 to help develop a list of the generic device types that are
21 unclassified and to help generally describe these devices.
22 We are not discussing the safety and effectiveness of any of
23 the generic device types or any specific device. This is
24 off the table completely today.

1 Dr. Betz will now address the table provided to
2 you. Please excuse the slight redundancy in our
3 presentations. Consider those parts, only portions,
4 reinforcement of our message.

5 Thank you. Any questions?

6 DR. GENCO: Thank you. Comments, questions?

7 [No response.]

8 DR. GENCO: I'm sure that there will be later.

9 Thank you, Tim.

xx

10

11 DR. BETZ: Good morning. My name is Bob Betz, and
12 I'm a periodontist and a reviewer in the Dental Device
13 Branch of the Office of Device Evaluation of the Food and
14 Drug Administration. The FDA is required to classify all
15 medical devices into either class I, class II, or class III,
16 depending upon the level of control necessary to provide
17 reasonable assurance of their safety and effectiveness.
18 Today's panel meeting is one of several steps by which
19 previously unclassified pre-amendments devices are placed
20 into a regulatory classification. Devices to be discussed
21 today are intended for uses in the diagnosis and treatment
22 of temporomandibular joint disorders and associated
23 orofacial pain.

24 [Slide.]

1 Our Federal Register notice refers to
2 temporomandibular joint disorders and associated orofacial
3 pain, while our table on the World Wide Web of generic
4 devices that we will discuss today refers to
5 temporomandibular joint disorders and related myofascial
6 pain dysfunction. The terms "related," "associated,"
7 "myofascial," "orofacial," and "dysfunction" have been used
8 or omitted from one FDA document or another. Our
9 unintentional inconsistency reflects the less than total
10 agreement in the use of TMJ-related terminology in the
11 literature as well.

12 The Dental Branch of the Office of Device
13 Evaluation considers myofascial pain to be a subset of the
14 term "orofacial pain," and, therefore, we would prefer to
15 use the latter, more encompassing term. Your input
16 regarding this terminology is welcome.

17 The part of the classification process in which
18 you will participate will involve two steps. The first step
19 will be to aid FDA in the process of inventory and grouping.
20 We wish to solicit input from you in the identification of
21 generic types of devices that are reasonably considered to
22 be used in the diagnosis and treatment of temporomandibular
23 joint disorders and associated orofacial pain. The second
24 step, which will occur at a future Dental Products Panel

1 Meeting, will be for the device industry, the public, and
2 other interested parties, as well as the FDA, to present
3 sufficient information to use so that you will be able to
4 recommend to FDA a class for each generic type of device not
5 presently classified.

6 Today's meeting will be a discussion. We will not
7 evaluate the safety or effectiveness of generic types of
8 devices today. You will not be asked to provide any
9 classification recommendations today. Discussions today
10 should address only inventory and grouping of generic types
11 of devices used in the diagnosis and treatment of
12 temporomandibular joint disorders and associated orofacial
13 pain. Now is the time, however, for you to let the FDA, the
14 industry, the general public, and other interested persons
15 know what information or data you believe will help to
16 facilitate future device classification within the context
17 of what is required under Part 860 of the Code of Federal
18 Regulations, which are the regulations governing
19 classification procedures.

20 For each group of generic devices, we would like
21 you to discuss the following: Number one is the physical
22 description of the device; number two, indications for use
23 presented in the labeling; and, number three, the function
24 of the devices placed in the group. We hope to have at the

1 end of the day a panel-recommended chart which displays all
2 relevant generic types of devices, their descriptions,
3 intended uses, and functions of members of that group. We
4 will also need to know when you feel that consultation with
5 other device panels may be needed.

6 After today's panel meeting, the FDA will review
7 this device group chart, all recommendations and comments.
8 We will then publish a finalized chart of device groups.
9 Each group will have indications for use or uses under the
10 umbrella of intended use for the diagnosis and treatment of
11 temporomandibular joint disorders and associated orofacial
12 pain. This chart will identify devices to be classified at
13 a future Dental Products Panel Meeting.

14 In preparation for this classification effort, the
15 Dental Branch has been tasked with the job of generating a
16 draft list of generic device groups for discussion purposes.
17 Devices within each generic group will have common
18 characteristics and have common indications for use.

19 The Dental Branch has undertaken a good-faith
20 effort to be as complete as possible. If devices were
21 omitted, they were not intentionally omitted. During the
22 discussion, device groups may be added, deleted, or
23 modified. You may identify different sub-groups other than
24 those proposed. Custom intraoral devices were intentionally

1 omitted. These devices have been defined within Section
2 520, Part B of the Federal Food, Drug, and Cosmetic Act and
3 are not subject to pre-market review.

4 [Slide.]

5 The list of device groupings includes the
6 following: number one, electromyographic devices; number
7 two, sonographic devices; number three, stimulatory devices;

8 [Slide.]

9 Number four, kinesiology devices; number five,
10 ultrasound devices; number six, thermography devices; and
11 number seven, imaging devices. Included will be a device
12 description, intended use, and indications for use.

13 Indications for use are associated with the sponsor-derived
14 labeling, as derived from 510(k) submissions, while intended
15 use is related to the function of the device, as may be
16 stated in the Code of Federal Regulations or as possibly
17 characterized by the Food and Drug Administration.

18 [Slide.]

19 Number one, electromyographic devices, including
20 biofeedback devices, 21 CFR 890.1375 reviewed by the
21 Physical Medicine Panel states that a diagnostic
22 electromyograph is a device intended for medical purposes
23 such as to monitor and display bioelectric signals produced
24 by muscles, to stimulate peripheral nerves, and to monitor

1 and display electrical activity produced by nerves for the
2 diagnosis and prognosis of neuromuscular diseases.

3 Number two, they are class II devices. There are
4 no Dental Panel classification regulations under Part 872 of
5 the Code of Federal Regulations relative to these devices,
6 as electromyographic devices designed and intended for the
7 use in the diagnosis and treatment of temporomandibular
8 joint disorders and associated orofacial pain. Review of
9 510(k) submissions indicates that these devices are labeled
10 and intended for the measurement or quantification of muscle
11 activity present in the temporomandibular joint area. Some
12 510(k)s state that jaw position and muscle balance may also
13 be measured.

14 Item number 2, sonography devices. 21 CFR
15 870.1875B, reviewed by the Cardiovascular Panel, states that
16 an electronic stethoscope is an electronic amplified device
17 used to project sounds associated with heart, arteries,
18 veins, and other internal organs. These are class II
19 devices requiring performance standards. There are no
20 dental classification regulations under Part 872 of the Code
21 of Federal Regulations relative to these devices as
22 sonographic devices designed and intended for the use in the
23 diagnosis and treatment of temporomandibular joint disorders
24 and associated orofacial pain. Review of 510(k) submissions

1 submitted for these devices reveals that they are labeled
2 and are intended for use in the recording and measurement of
3 sounds of joints, the joint components. Some of these
4 devices may also visually represent sounds made by these
5 components.

6 Number three, stimulatory devices, including TENS
7 devices. 21 CFR 882.5890, reviewed by the Neurology Panel,
8 states that a transcutaneous electrical nerve stimulator for
9 pain relief is a device used to apply electrical current to
10 electrodes on the patient's skin to treat pain. These
11 devices are class II devices. They require performance
12 standards.

13 There are no dental classification regulations
14 under Part 872 of the Code of Federal Regulations relative
15 to these devices as stimulatory devices designed and
16 intended for the use in diagnosis and treatment of
17 temporomandibular joint disorders or associated orofacial
18 pain. Review of 510(k) submissions reveals that these
19 devices are labeled and are intended for use in the relief
20 of muscular pain and muscle spasm.

21 TENS devices are used to treat muscular components
22 of temporomandibular joint disorders and associated
23 orofacial pain. Their objective is to obtain muscle
24 relaxation. The use of these devices in electro-anesthesia

1 is not directly related to temporomandibular joint disorders
2 or associated orofacial pain, and they are not included in
3 this grouping.

4 [Slide.]

5 Number four are the kinesiology devices and
6 pantographic tracing devices. 21 CFR 888.1500, reviewed by
7 the Orthopedics Panel, describes a goniometer as an AC power
8 device intended to evaluate joint function by measuring and
9 recording ranges of motion, acceleration, or forces exerted
10 by a joint. These are class I devices. There is one Dental
11 Panel reference within the Code of Federal Regulations
12 relative to these devices. 21 CFR 8721.3730 describes a
13 pantograph as a device that is intended to be attached to
14 the patient's head to duplicate lower jaw movements to aid
15 in construction of restorative and prosthetic dental
16 devices. A marking pen is attached to the lower jaw portion
17 of the device, and as the patient's mouth opens, the pen
18 records on graph paper the angle between the upper and lower
19 jaw. It is a class I-exempt device.

20 However, not reflected in the CFR is the fact that
21 there are more than just this one measurement that may be
22 made with some pantographs currently in clinical use today.
23 In review of 510(k) submissions, we find that these devices
24 are devices that are labeled and are intended for use in the

1 measurement of joint position or jaw movement. They also
2 identify the space between the jaws, or freeway space, as
3 well as mandibular rest position. Some devices in this
4 group graphically record mandibular position or movement.

5 Number five, therapeutic ultrasound devices.
6 Based on examination of devices submitted for regulatory
7 review, therapeutic ultrasound devices appear to have no
8 indicated uses or specific labeling claims related to the
9 temporomandibular joint. However, 21 CFR 890.5860, Part A,
10 reviewed by the Physical Medicine Panel, describes an
11 ultrasonic device that is used to apply heat to an
12 anatomical structure. This is a class II use. All other
13 uses are covered by 21 CFR 890.5860, Part B, and are class
14 III uses. Unless discussion today reveals otherwise, there
15 are no other devices in this group with claims related to
16 the temporomandibular joint and associated orofacial pain.
17 No action is needed at this time.

18 Number six is thermography devices. Based on
19 examination of devices submitted for regulatory review,
20 thermographic devices appear to have no indicated uses or
21 specific labeling claims related to the temporomandibular
22 joint. However, 21 CFR 882.1570, reviewed by the Neurology
23 Panel, describes a powered, direct contact, temperature
24 measurement device. A powered, direct contact, temperature

1 measurement device is a device which contains a power source
2 and is used to measure the difference in temperature between
3 two points on the body. These are class II devices that
4 require performance standards. Unless discussion today
5 reveals otherwise, there are no other devices in this group
6 with claims related to the temporomandibular joint disorders
7 and associated orofacial pain. No action is needed at this
8 time.

9 [Slide.]

10 Number seven is imaging devices. Imaging devices
11 include radiology, magnetic imaging, tomographic imaging,
12 and ultrasound imaging. Radiography devices include
13 radiology devices previously classified by the Dental
14 Products Panel under 872.1800 and 872.1810. Both devices
15 are described as electrically powered devices that produce
16 X-rays and are intended for dental radiography examination
17 and diagnosis and treatment of the teeth, jaw, and oral
18 structures. Both types of devices are presently class II
19 and have already been classified by the Dental Products
20 Panel. There are other non-dental classifications for
21 radiology devices, but they will not be discussed today.

22 Tomography devices may be used to image the
23 temporomandibular joint. Reports of the use for diagnosis
24 of these disorders exist in the dental literature and are

1 presently displayed on Web sites on the Internet. 21 CFR
2 892.1750 describes a computer tomography device that
3 produces cross-sectional radiographic images of the body,
4 using computer reconstruction. They are class II devices
5 and are reviewed by the Radiology Panel.

6 Magnetic resonance imaging devices may also be
7 used to image the temporomandibular joint. Reports of their
8 use as diagnostic tools in soft tissue areas of the TM joint
9 also exist in dental literature and on the Internet. 21 CFR
10 892.1000 describes a device that produces images using
11 nuclear magnetic resonance. These are class II devices and
12 are also reviewed by the Dental Radiology Panel.

13 The last group is diagnostic ultrasound devices.
14 Unless discussion today reveals otherwise, there are no
15 other devices in this group with claims related to
16 temporomandibular joint disorders or associated orofacial
17 pain and no action is needed.

18 Again, we are not here today to classify any
19 devices used in the diagnosis and treatment of
20 temporomandibular joint disorders and associated orofacial
21 pain. We are here to request your assistance in the
22 grouping of all devices reasonably considered to be devices
23 with these claims. We recognize that there are many devices
24 that may add bits of diagnostic information about

1 temporomandibular joint disorders and orofacial pain.
2 Unless and until sponsors come forward to the FDA with
3 submissions for these devices and specific TMJ-related
4 claims, the FDA believes that this chart is reasonably
5 complete.

6 [Slide.]

7 Our charge to you today is to ask you to answer
8 the following questions: Number one, do you concur with the
9 basic construct of this grouping of devices as presented?
10 Number two, are there any groups or categories of devices
11 that you feel should be added or removed from this list?

12 [Slide.]

13 Question number three, for device groups or
14 categories discussed today, which groups have labeled
15 indication for use or intended use which relate to
16 temporomandibular joint disorders and associated orofacial
17 pain?

18 [Slide.]

19 For groups or categories discussed today for which
20 there are existing classifications, which groups do you
21 believe are groups of devices which have pre-1976 uses for
22 the diagnosis and treatment of temporomandibular disorders
23 and associated orofacial pain?

24 [Slide.]

1 Number five, for the groups or categories
2 discussed today for which there are existing classification,
3 which of these pre-1976 intended uses are not a subpart of
4 and are separate or distinct from any existing
5 classification discussed today? And we would like to know
6 your rationale for that.

7 [Slide.]

8 Question number six, for the same device groups or
9 categories for which there are no existing classifications,
10 which groups do you believe have a pre-1976 intended use in
11 temporomandibular joint disorders and associated orofacial
12 pain?

13 [Slide.]

14 Number seven, are there any questions that you
15 have that the FDA, the device industry, or other interested
16 persons should address and present to you prior to
17 classification of these devices?

18 Question number eight, and the final one, with
19 what priority--high, medium, or low--should FDA pursue
20 classification of these devices? We would like your
21 rationale for this decision.

22 Thank you very much.

23 DR. GENCO: Thank you, Dr. Betz.

24 Are there any questions or comments for Dr. Betz?

1 MR. ULATOWSKI: Mr. Chairman?

2 DR. GENCO: Yes?

3 MR. ULATOWSKI: That was quite a mouthful that Dr.
4 Betz just said. We're going to come back with you during
5 discussion to address each and every group once again to
6 again explain the history that we were able to uncover, and
7 then we can discuss each of those groups individually.

8 DR. GENCO: I'd like to thank you both on behalf
9 of the panel and the guests for a very complete description
10 of the area and for the clear charge.

xx

11

12 If there are no further comments or questions of
13 Mr. Ulatowski or Dr. Betz, then we'll proceed to the open
14 public hearing. This time is made available for the public
15 attendees to address the panel and to present data relevant
16 to the panel's activities with respect to devices for use in
17 the diagnosis and/or treatment of temporomandibular
18 dysfunction and related orofacial pain.

19 I would ask the speakers to identify themselves
20 and state whether they have any involvement, including, but
21 not limited to, financial involvement, with manufacturers of
22 products that they are discussing or with their competitors.

23 Any comments from the public?

24 [No response.]

1 DR. GENCO: Okay. I take it then--yes?

2 VOICE: Is there an order of presentations?

3 DR. GENCO: No, excuse me. This time is allowed
4 for non-programmed comments from the public, and I don't see
5 any. We will then have presentations by industry, and there
6 is an order, a very specific order for those of you who have
7 asked to be on the program. Of course, we will have time
8 for those who want to make further comments or who have not
9 been asked to be on the program. We want to make this
10 completely open.

11 MR. ULATOWSKI: Mr. Chairman?

12 DR. GENCO: Yes?

13 MR. ULATOWSKI: Just to reiterate process here,
14 panel process, anyone wishing to say anything, you need to
15 identify yourself and your association. It drives the
16 transcriptionist crazy when they try and figure out what
17 name to assign to something in the transcript. So you need
18 to come to the podium so they can hear you.

xx

19
20 DR. GENCO: Okay. Then hearing no open public
21 comment, we'll go to now our more formal presentations from
22 associations and industry.

23 The first presentation will be made by Mr. John
24 Radke from Bioresearch, Incorporated. Mr. Radke?

1 MR. RADKE: I am the president of Bioresearch,
2 Inc. We're a small company. We've been in business since
3 1965. I am one of the shareholders in the company. It's a
4 closely held private corporation.

5 This is somewhat of an emotional moment for me,
6 having been here three years ago at the kangaroo court which
7 was held here. Muscle monitoring devices at that time were
8 anything that was manufactured by Bioresearch and Myo-
9 Tronics and were unanimously voted to be put into a class
10 III category at the highest priority, in spite of the fact
11 that there was no real evidence that any harm had come to
12 the general public as a result of these products being on
13 the market for over 20 years.

14 The good news is I see a lot of fresh faces here
15 today, and hopefully we'll be on a different track today,
16 hopefully one of exposing truth.

17 I don't know what the background is of the panel
18 members, particularly. I know most of you are dentists,
19 have dental degrees and advanced degrees and so on. My
20 background is I'm an engineer, and I've worked in industry
21 all my life, about 25 years, actually.

22 You might be interested to know, if you don't
23 already know, that a company such as Bioresearch could not
24 consider applying for or expect to get a pre-market

1 approval. So if our products, any of them, suddenly become
2 class III, those products are finished, and whatever
3 benefits society has received from them, that goes out the
4 window.

5 Our products are limited to basically four devices
6 that I think fall within categories that have been
7 described. One of our products an electromyograph. It
8 happens to be used by dentists simply because we as a
9 company happen to sell to the dental marketplace and we work
10 with dentists and we are not in a position to sell to
11 physicians and neurologists. It does exactly the same
12 things that any other electromyograph does. It has
13 electrodes that are applied to muscles for surface
14 recordings. It has amplifiers which amplify the signals.
15 And it has the ability to display those amplified signals
16 graphically, just like any other electromyograph. There is
17 nothing special about a TMJ electromyograph.

18 We have something called a BioTENS, which is a
19 TENS device, and the indications for use are exactly the
20 same as other TENS devices. It has no curative effect.
21 It's for sometimes relief of pain, sometimes for muscle
22 relaxation.

23 We have a device for tracking jaw movements, and
24 sometimes doctors are interested in how the jaw moves when a

1 patient has a dysfunction. Of course, sometimes they're not
2 sure if it's a dysfunction or maybe it's a disorder or
3 possibly a disease, because under the disorders there's
4 probably a hundred different diseases. Of course, anybody
5 can have a dysfunction, TMJ or otherwise.

6 A jaw tracking device is equivalent to a device
7 which I helped to develop in the early '70s. There are
8 other types of devices. The one that we manufacture uses a
9 small permanent magnet which is attached to the lower
10 incisors. There are no electrical connections to the
11 patient. No one has ever been shocked by wearing one. It
12 records how wide the patient can open and whether or not the
13 patient can protrude or move laterally, to the left, to the
14 right.

15 It also has the ability to record the patient
16 during function, something that a pantograph doesn't
17 typically do that, as the patient can eat and swallow and so
18 on.

19 We also have a device called SonoPac, which is a
20 device for recording joint sounds from the temporomandibular
21 joint--joint sounds that can otherwise be listened to with a
22 stethoscope by a dentist but not with very good results,
23 according to the literature. You can also palpate the
24 temporomandibular joint with your fingers, but that's not

1 very effectiveness either.

2 As it turns out, if you record the sounds from the
3 joint and you display them graphically, dentists are much
4 better able to sort them out. They don't hear so good, but
5 they are much better visually at recognizing patterns and
6 associating them with what's going on in a joint, that is,
7 if you have an internal derangement, a displaced disk with
8 reduction or without reduction, degenerative changes in the
9 joint. It's complementary to joint imaging which shows you
10 the structure of the joint in that the sound recordings from
11 the joint are made while the joint is moving and while it's
12 loaded. And it gives you a little information that is
13 sometimes useful in making a diagnosis and helping the
14 dentist to understand what's going on inside the joint.

15 I guess I'm not exactly sure what the ultimate
16 purpose is here, whether we are charged with coming--or you
17 are charged with coming up with a single category and a
18 single classification for all devices in each one of these
19 groupings, or whether the individual devices would be, in
20 fact, classified individually. But I think what I heard was
21 that this was a generic classification, so anything that
22 falls in the area of sonography would have the same
23 classification regardless of whether it was a stethoscope or
24 something else, I guess.

1 The thing about TMJ, whatever you call it, is that
2 it's not a single thing, and so it's a lot of different
3 things, and as far as I know, there are no devices for the
4 diagnosis and treatment of temporomandibular disorders and
5 related myofascial pain dysfunction. There are a lot of
6 devices which can provide a little bit of information for
7 the diagnostic process for the clinician, who ultimately is
8 responsible for making the diagnosis.

9 There is possibly one exception to that statement.
10 I guess some of the psychometric tools, if you would call
11 them that, claim to be able to diagnose the presence or
12 absence of a temporomandibular disorder and differentiate
13 between some sort of a psychological disorder versus some
14 sort of a physiological condition. So maybe there is
15 something in that. Maybe there's--I think there are several
16 psychometric tests that are available which a clinician can
17 apply to a given patient to decide or help him decide or
18 apparently tell him if his patient has a physiologic or
19 psychological disorder, or both. You certainly can't do
20 that with an electromyograph.

21 From my point of view, I guess, it seems to me
22 that an electromyograph is best classified as an
23 electromyograph, regardless of whether we're looking at
24 shoulder muscles or leg muscles or facial muscles. It seems

1 like a TENS device is a TENS device. The fact that somebody
2 has a sore masseter muscle or temporalis muscle doesn't make
3 the device any different than if it's the trapezius or
4 rhomboid or some other muscle. TMJ or TMD patients do have
5 pain very often, and sometimes they benefit from application
6 of TENS.

7 I don't know whether it's appropriate or not, but
8 I think--and I don't know whether this is within the bounds
9 of what we're talking about today, but if you consider all
10 devices that in some way could affect somebody with a
11 cardiac problem, you could have a classification that would
12 include aspirin and an artificial heart. I don't think
13 anybody would classify them in the same classification.

14 Depending on what ends up being in the
15 classifications that are being considered today, the
16 disparity may not be so great.

17 Are there any questions? I would like to--if I
18 still have a minute or two left?

19 DR. GENCO: You have 20 minutes. You've been
20 talking about 15. You certainly have another five, if you'd
21 like, and longer if you need it.

22 MR. RADKE: If there are any questions from the
23 panel members about anything I've said right now, it would
24 be real handy--

1 DR. GENCO: So you're finished with--

2 MR. RADKE: I could still remember what I've said,
3 I think.

4 DR. GENCO: You've finished with your formal
5 comments?

6 MR. RADKE: Yes.

7 DR. GENCO: Okay. Thank you very much.

8 Are there any comments or questions from the panel
9 members? Yes, Dr. Moses?

10 DR. MOSES: Thank you.

11 One of the things that I would like to see the
12 panel address was regarding electromyographic devices. I
13 see that there are two categories here. One is measure
14 masticatory muscle activity, and so I would consider that a
15 measurement device in the context that Mr. Radke identified
16 his instrumentation. On the other hand, I see there's a
17 category, biofeedback muscle re-education. Now, I think
18 that might be considered in the realm of treatment rather
19 than in measurement. And so I'm wondering if along that
20 line the differentiation should be made by the panel.

21 Then the third point would be with regard to
22 electromyographic activity. I believe that there possibly
23 is a difference between surface electrodes and needle
24 electrodes in my mind being that the needle electrodes are

1 quite a bit more invasive. And I would like to know if we
2 could draw a clear differentiation there as well in terms of
3 categorizing these devices.

4 I would like to know your feeling on these.

5 DR. GENCO: Yes, Mr. Radke, would you comment?

6 MR. RADKE: Well, I think I would agree that the
7 biofeedback--I think it's probably both, though, because if
8 you hook somebody up to a biofeedback device, you are
9 thinking that they might be stressed out. And if there's a
10 lot of activity, your diagnosis is, you know, that there's a
11 lot of activity, the patient is tense, something like that.
12 So I suppose there could be a diagnostic component.

13 Certainly the muscle re-education thing, if you
14 can get the patient to relax, that would be, I think, in the
15 treatment category. So I would agree with that.

16 In terms of surface and needle, I don't know if
17 there's--maybe one of the FDA experts can say if there is a
18 differentiation now in the area of electromyography and
19 neurology. Is there any differentiation now between surface
20 and needle as far as classification?

21 MR. ULATOWSKI: Well, I can't speak to that
22 specifically because it's not in my panel area. We can
23 check on that, though, in our Code of Federal Regulations.

24 MR. RADKE: Obviously, the needle would be

1 invasive in the sense, you know, that it goes under the
2 skin. I don't think it's--I mean, it would be comparable in
3 risk, I suppose, to an injection or something like that.

4 But--

5 DR. GONZALEZ: Can I make a comment?

6 DR. GENCO: Yes, go ahead.

7 DR. GONZALEZ: There is a classification
8 difference by the American Academy of Neurology and the
9 American Academy of Electrodiagnostic Medicine where
10 statements have been made regarding utility and the
11 comparison between the utility. I won't comment right now
12 because I understand we're not getting into utility and the
13 function, safety issues, et cetera, but just to state that
14 there are statements by various academies regarding the
15 differences and utility and comparing the differences by
16 these various academies. So that separation has been made.

17 DR. GENCO: That's in terms of intended usage, but
18 the question was whether or not there was a difference in
19 the classification, like class I or class II or class III,
20 between surface and needle.

21 DR. GONZALEZ: Okay. That I can't answer in terms
22 of class I and class II by FDA, but in terms of statements
23 regarding utility and the fact that they're classified
24 differently as far as invasiveness, those statements have

1 been made.

2 DR. GENCO: So it seems that with respect to your
3 original comment about heterogeneity within that group of
4 electromyographic devices, there may be some heterogeneity.

5 DR. MOSES: Yes.

6 DR. GENCO: Related to surface electrode versus
7 needle. So that is something I think the FDA can be advised
8 or industry can be advised to advise us with respect to that
9 heterogeneity.

10 Mr. Radke, you did bring up heterogeneity. What
11 are your feelings about that? Do you think there's any
12 other heterogeneity? Of the four products that you
13 discussed, do you think they're single categories? How
14 would you advise us on that, the BioTENS, the jaw tracking,
15 the sonograms, the electromyographic? Is there
16 heterogeneity in your mind in any one of those, or are they
17 generic enough to be considered individual categories?

18 MR. RADKE: I don't know if I can--I don't know if
19 I feel that I could make a definite statement on that at
20 this time.

21 DR. GENCO: Well, that's fine. I think the issue
22 is out there. Certainly there will be time to discuss it
23 more.

24 MR. RADKE: I think it should be considered.

1 DR. GENCO: Surely.

2 The other issue you brought up or another issue
3 is--I think Dr. Moses brought it up, too: Should we be
4 considering diagnostic separate from treatment? Does it get
5 confusing to consider the two for each of these categories?
6 Did you want to further comment on that?

7 DR. MOSES: My opinion is that they should be
8 separate, and, again, regarding the other issue, I'm not an
9 expert in needle electrodes, Dr. Gonzalez, but my impression
10 is that there is a difference in use in that a surface
11 electrode is used to measure muscles, whereas the needle is
12 more to measure nerve conduction and things like atrophy.
13 And so I would go for the differentiation.

14 DR. GENCO: Thank you.

15 Dr. Gonzalez, do you want to further comment?

16 DR. GONZALEZ: That's true. The utility of the
17 surface as opposed to the needle EMG is felt to be so widely
18 different that statements have been made separating that out
19 in terms of the utility and the efficacy and safety issues
20 as well by various academies because of the feeling that
21 they are separate issues.

22 DR. GENCO: Dr. Moses?

23 DR. MOSES: This becomes an important issue,
24 probably not to the FDA but to the dentists in general,

1 because in various cases, when people aren't clear on the
2 differentiation, then insurance companies are rejecting
3 certain surface electromyography uses such as this one and
4 saying that it should have been a needle electrode. And I
5 think the FDA can help by making that distinction for
6 scientific purposes only. But they would help the
7 situation, clearly.

8 DR. GENCO: Okay. Thank you.

9 Mr. Radke, further comments, or panel, any further
10 comments for Mr. Radke?

11 [No response.]

12 DR. GENCO: Thank you very much.

13 The next presentation will be made by Mr. Roland
14 Jankelson of Myo-Tronics, Incorporated. Mr. Jankelson?

xx

15
16 MR. JANKELSON: Good morning. I would like to, if
17 I may, take just hopefully not more than a couple of
18 minutes, and then turn our period of time over to Dr. Robert
19 Jankelson for some additional comments.

20 My name is Roland Jankelson. I am the president
21 of Myo-Tronics, Inc. The company is approximately 25 years
22 old, I think has the proper distinction of being recognized
23 as a pioneer in certain technologies that are the subject--
24 some of the subjects that are being discussed this morning.

1 I really intended to stay away from any discussion
2 of the 1994 panel because this is a new group. Some of the
3 already insightful questions and comments that I've heard
4 from the panel this morning indicate that this really is a
5 different group. I think, however, some very brief comments
6 since Mr. Radke referred to the previous panel in 1994, and
7 I say this not in any--with any intent to do anything other
8 than to assist the FDA in moving forward with what is their
9 mandate, which is the classification process, which we
10 support.

11 I think, however, some brief comments are relevant
12 to indicate some sensitivity on the part of Myo-Tronics, and
13 as you've heard already, on the part of Bioresearch, based
14 upon some things that happened several years ago in
15 connection with a similar panel.

16 Let me just say that as a result of what happened
17 at that panel, and in connection with some other alleged
18 irregularities in connection with the treatment of Myo-
19 Tronics by the FDA, there was a two-year investigation by
20 the Office of Inspector General for Health and Human
21 Services. There were hearings before the U.S. House
22 Commerce Committee's Subcommittee on Oversight and
23 Investigations. Those of you who think that that background
24 has any relevance to understanding our sensitivity certainly

1 have access to those findings. I think clearly the FDA has
2 acknowledged some very real problems, for which we are
3 thankful. Four FDA employees--two permanent FDA employees,
4 two temporary government employees--have been disassociated
5 from service with the FDA.

6 In a letter written to me recently by Dr.
7 Friedman, I just want to read two sentences: "In closing, I
8 acknowledge that certain past actions and decisions by FDA
9 staff concerning the case excise(?) device were
10 inappropriate. I believe that we have taken forceful and
11 responsible actions to guard against such conduct in the
12 future." And I think this panel this morning, from what
13 I've already heard, is some evidence of that, so we at Myo-
14 Tronics thank all of you for your service today and in the
15 future on this matter.

16 I would finally like to submit for the record of
17 this meeting three--actually four letters and make it part
18 of the official record. Is that proper protocol?

19 MR. ULATOWSKI: Through the Executive Secretary.

20 MR. JANKELSON: For the record, the first letter
21 is a response from Roland Jankelson to Dr. Friedman, dated
22 October 21, 1997. The second is a letter from Roland
23 Jankelson to Dr. Alpert, dated October 24, 1997. The third
24 letter is a letter from Roland Jankelson, dated October 27,

1 1997, to Secretary Shalala, to Dr. Friedman, to Dr. Alpert,
2 and to Dr. Ulatowski. And the final letter is a letter from
3 Roland Jankelson to Secretary Shalala and Dr. Alpert, dated
4 September 11, 1997.

5 We have had responses to none of these letters
6 which raise issues that are, in fact, relevant to the
7 classification process that you folks are embarked on, as
8 well as other issues. It is my understanding, based on a
9 conversation with Dr. Alpert last week, that the FDA does
10 have the intention of responding in writing, which has been
11 our request, to the various issues raised in each of those
12 letters. And I would emphasize again our concern that that,
13 in fact, does happen.

14 I think at this point I'm going to stop my
15 presentation and invite Dr. Robert Jankelson. I might
16 comment, while he is on his way up, on the issue of the
17 generic classification versus a more finite device-by-device
18 classification, I'm sure he will make some comments
19 appropriate to that, but I think that is, in fact, a very
20 significant issue that does need to be correctly addressed.

21 Thank you.

22 DR. GENCO: Thank you, Mr. Jankelson.

23 Any comments from the panel?

24 [No response.]

1 DR. GENCO: Okay. Thank you very much.

2 MR. JANKELSON: Thank you.

3 DR. GENCO: Dr. Robert Jankelson?

4 DR. JANKELSON: Good morning. Mr. Chairman,
5 colleagues, ladies and gentlemen, I'm Dr. Robert Jankelson.

6 I've been in private clinical practice in Seattle,
7 Washington, since 1963, with a particular interest in
8 temporomandibular disorders since about 1970.

9 There are four major areas of discussion and
10 clarification specific to any determination of which devices
11 are appropriate "for use in the diagnosis and/or treatment
12 of temporomandibular joint dysfunction and oral-facial
13 pain." These issues are--and before I proceed, I should
14 identify that I am Director of Research and Development for
15 Myo-Tronics.

16 Issue No. 1 for this panel--and I think some steps
17 are being made already--is defining TMD. What is it?

18 The FDA characterization has advertised the
19 purpose of today's meeting to be to discuss previously
20 unclassified devices "used for diagnosis and/or treatment of
21 temporomandibular joint dysfunction and oral-facial pain."

22 I was very encouraged that Dr. Betz opened for discussion
23 the use of the terms "oral-facial pain."

24 What is TMD? The FDA Web site characterization of

1 TMD as "temporo-mandibular joint dysfunction and oral-facial
2 pain" may be misleading, imprecise, and is not consistent
3 with widely accepted models of TMD. This limited definition
4 does not encompass generic musculoskeletal pathologies
5 associated with TMD, does not encompass the cranio-
6 mandibular/cervical model of pathosis, does not encompass
7 the myofascial pain reference model, nor does it include
8 many of the primary and secondary signs and symptoms of TMD.
9 Before advancing to the question of which devices to include
10 in a category of "TMD diagnostic and treatment devices," it
11 is first necessary to adequately define the disease entity.

12 Issue No. 2, understanding the science and
13 politics of the two major TMD paradigms.

14 There are two major philosophical paradigms
15 presently being propagated to explain the etiology of TMD
16 signs and symptoms. For the past 60 years, dating from the
17 work of anatomist pioneer Harry Sicher, physiologist Hans
18 Selye, and clinicians such as Nathan Shore, Weldon Bell, and
19 many others, dentists have approached the problem as a
20 primarily physical, or biomechanical, problem, albeit with
21 secondary psychosocial overlays. This has been the reigning
22 clinical paradigm for 60 years. It is only recently that a
23 limited academic group have denied occlusal causality for
24 TMD. In its place, they have attempted to posture TMD as a

1 psychosocial disease caused by emotional stressors, et
2 cetera. The 1996 NIDR consensus meeting clearly defined the
3 biomechanical versus the psychosocial schism.

4 The masticatory system with its unique mechanism
5 of bilateral diarthrodial joints, precise tooth
6 intercuspation, and highly developed proprioception of the
7 trigeminal system suggests a biomechanical model of
8 occlusal, or orthopedic, contributory etiology to this
9 complex musculoskeletal dysfunction called TMD. For 60
10 years, treatment of the maxillo-mandibular occlusal
11 relationship has been the biomechanical paradigm for dental
12 treatment of TMD. The use of occlusal appliances to
13 provisionally alter the occlusal relationship of the
14 mandible to the cranium has been the operative dental
15 approach. Many studies in the literature and clinical
16 experience have verified the positive response of patients,
17 albeit not always predictable, to occlusal therapy in a high
18 percentage of patients.

19 Often overlooked in the debate is the fact that
20 both--and I stress both--biomechanical and psychosocial
21 stressors can impose stresses that exceed the accommodative
22 capacity of the organism, resulting in clinical dysfunction
23 and/or symptoms. Thus, the pathogenic model for TMD, if it
24 is to conform to the pathogenic model for other

1 musculoskeletal dysfunctions should logically embrace both
2 the biomechanical and the psychosocial model. One is not,
3 and should not, be exclusive to the other.

4 The present effort by a small academic group to
5 impose a strictly psychosocial model for TMD is more related
6 to political agendas, allocation of grants for TMD research,
7 IME consulting fee allocation, and pretense for denial of
8 insurance reimbursement rather than sound scientific
9 methodology.

10 The third issue is that of the scope of the
11 devices used for TMD diagnosis and treatment. What devices
12 should be included in a classification process "for use in
13 the diagnosis and/or treatment of temporomandibular joint
14 dysfunction and oral-facial pain," although I make it very
15 clear that I think this definition is not encompassing, is
16 misleading, and should be visited by this panel. The stated
17 purpose of today's meeting is to ensure that all devices
18 that are used in the diagnosis and treatment of TMD are
19 identified and included in the FDA classification process,
20 unlike the discredited and vacated October 1994 panel which
21 selected only four devices from among the many that are
22 appropriate for this consideration.

23 Using the biomechanical/psychosocial model,
24 devices to be classified "for the use in the diagnosis and

1 treatment of temporomandibular joint dysfunction and oral-
2 facial pain"--TMD, if you will--must logically include
3 devices that provide data used by the clinician to make
4 occlusal determinants necessary in fabrication of
5 therapeutic appliances or to alter the dental occlusion. It
6 must include devices used to fabricate occlusal therapeutic
7 appliances, devices used to aid the diagnosis of myogenous
8 TM dysfunction, devices that aid diagnosis and treatment of
9 intrinsic temporomandibular joint dysfunction, devices used
10 for occlusal therapy, physical therapy, and psychometric
11 testing.

12 The following is a list that is not necessarily
13 complete, but I feel it includes those devices that must be
14 included in devices used as aids in the diagnosis and/or
15 treatment of TMD:

16 One, TMD psychometric tests; two, computerized jaw
17 tracking devices; three, pantographic tracing devices; four,
18 axiographic jaw tracking devices; five, occlusal
19 registration devices used to fabricate TMD appliances; six,
20 cephalometric analysis software; seven, surface
21 electromyograph; eight, biofeedback EMG; nine, stethoscopic
22 and Doppler TMJ sound recording; ten, electrosonography; 11,
23 thermograph; 12, devices used to fabricate TMD occlusal
24 appliances or to modify occlusion in TMD patients--example,

1 Tech Scan, and articulators whose settings will influence
2 the outcome of the occlusal appliance plan; 13, TMD
3 diagnostic software--example, PT Diagnostic Software, Inc.;
4 14, ultrasound diathermy; 15, galvanic stimulators; 16, high
5 frequency transcutaneous electrical neural stimulators; 17,
6 low frequency transcutaneous electrical neural stimulators;
7 18, ultra-low frequency muscle relaxation stimulators--there
8 is still a great deal of confusion regarding the distinction
9 of these three categories of TENS devices; 19, iontophoresis
10 devices; 20, mechanical TMD therapy devices, such as the
11 Therabite or Aqualizer; 21, transcranial radiography; 22,
12 pantographic radiography; 23, tomography; 24, computer-
13 assisted tomography; and, 25, magnetic resonance imaging.

14 All of the above devices are used in diagnosis and
15 treatment of temporomandibular joint dysfunction and oral-
16 facial pain, or TMD. All provide data or determinants that
17 aid the clinician in diagnosis and/or treatment of TMD.

18 And, finally, the fourth issue is use of devices
19 as aids in diagnosis and treatment, i.e., measuring devices,
20 as opposed to devices that claim to make a diagnosis.

21 The fourth issue is the misplaced premise during
22 the 1994 Dental Advisory Panel which was advanced by certain
23 anti-instrumentation witnesses giving testimony, testimony
24 which has since been discarded as false and misleading, that

1 any of these devices, by themselves, make or must make a
2 diagnosis. A device that record physiologic or anatomic
3 data does not, in itself, make a diagnosis. The
4 differential diagnosis is always made by the doctor based
5 upon patient history, patient evaluation, subjective and
6 objective data. Anatomic imaging and/or physiologic
7 monitoring should be pertinent to the particular
8 patho/physiologic phenomena being considered. When
9 considering devices that aid in the diagnosis of TMD, or any
10 disease, three criteria are relevant, and this is most
11 important:

12 One, does that device measure a known physiologic
13 phenomena that is relevant to the disease or dysfunction
14 being considered?

15 Two, does it measure accurately? Is the data
16 precise and accurate?

17 And, three, does this data provide additional
18 information that is relevant to and adds to the diagnosis?

19 Those are the three criteria from which you must
20 evaluate measurement devices.

21 In final summary, if this panel is to perform its
22 mission, the panel must approach the subject matter with a
23 full understanding and appreciation of the scope and
24 complexity of the multi-etiological, multiple signs and

1 symptoms complex presently referred to as TMD; it must be
2 aware of the political and scientific history of the two
3 major TMD paradigms; it must consider the broad scope of
4 devices that are used for diagnosis and treatment of TMD;
5 and it must understand the distinction between measurement
6 devices that provide data to assist the clinician in TMD
7 diagnosis and treatment, as opposed to devices that are
8 claimed to independently make a diagnosis.

9 Again, I emphasize that this is a minimum
10 foundation to begin a classification process that is
11 objective, encompassing, and reflects the present state of
12 knowledge and understanding in the field of TMD and, most
13 importantly, will allow delivery of optimal, cost-effective
14 care for patients suffering from TMD.

15 I will be happy to answer any questions regarding
16 these issues at this time or later at any time during the
17 day's discussion.

18 Mr. Chairman, thank you.

19 DR. GENCO: Thank you, Dr. Jankelson.

20 Are there any questions or comments from the
21 panel, from the guests?

22 [No response.]

23 DR. GENCO: Thank you very much.

24 The next presentation is by Dr. Kenneth Burrell

1 from the American Dental Association.

2 DR. BURRELL: My name is Kenneth Burrell. I'm the
3 senior director for the American Dental Association's
4 Council on Scientific Affairs, and this council does three
5 main things: one is that it addresses scientific issues
6 that are of interest to dentistry; it evaluates products,
7 dental products, both over-the-counter and professional; and
8 it develops guidelines and standards. It's about this third
9 area that I would suggest that the panel pay particular
10 attention to, and I have provided this panel with
11 information about these standards activities. I believe you
12 have copies of the standards or the guidelines that would
13 apply to the devices that are being discussed today. So
14 what I am going to do now is to make a presentation on what
15 evaluation criteria are used within those guidelines.

16 Temporomandibular disorders, also referred to as
17 cranial-mandibular disorders, or simply TMD, encompass a
18 number of musculoskeletal conditions that involve one or
19 both temporomandibular joints, the masticatory muscles, or a
20 combination of both. As part of the ADA Acceptance Program,
21 the Council on Scientific Affairs has established guidelines
22 for evaluating instruments that aid in the treatment of TM
23 disorders as well as for devices that evaluate the TM
24 musculoskeletal complex.

1 For consideration for acceptance under the ADA
2 Seal Program, comprehensive product information must be
3 submitted. All claims of efficacy must be documented,
4 including all claims in advertising and promotional
5 material, and a detailed product description that explains
6 the principles of design is required.

7 We also review labeling, packaging, and
8 instructional materials to ensure that clear, accurate,
9 step-by-step directions for safe and efficacious use are
10 provided.

11 For TMD diagnostic aids, such as jaw tracking and
12 surface myography devices, instructions must delineate
13 exactly when in the context of clinical diagnostic efforts
14 the device is to be used. We also require that limitations
15 and sources of error in using the device be outlined in the
16 instructions.

17 For TMD treatment devices, precautions,
18 contraindications, and limitations must be listed along with
19 a discussion of when in the course of clinical therapeutic
20 efforts the device is warranted. For both categories of
21 devices, precise calibration procedures are a critical
22 component of the instructions.

23 To demonstrate safety, all electronic instruments
24 must have data to show compliance with specifications set

1 forth by Underwriters Laboratories. Clinical studies for
2 efficacy also can be used for safety assessments where
3 appropriate.

4 For TMD diagnostic aids, the nature of supporting
5 documentation for efficacy claims depends on the specific
6 claim the device carries. If the claimed efficacy and
7 utility of the instrument involves measurement that is part
8 of the biological or psychological phenomena associated with
9 disorders of the temporomandibular musculoskeletal complex,
10 evidence of good performance is required with respect to the
11 measurement. If the claim states that the device measures a
12 parameter that is independently diagnostic of a particular
13 disorder, the validity of the diagnostic claim has to be
14 documented by appropriate clinical studies.

15 We require two independent scientific studies to
16 demonstrate a diagnostic device's reliability and validity,
17 and data on diagnostic sensitivity and diagnostic
18 specificity are required for each disorder or sub-category
19 of temporomandibular affliction that the device claims to
20 help diagnose.

21 For TMD treatment devices, the disorder or sub-
22 category of disorders, as well as those signs and symptoms
23 the device is reported to treat, must be fully described.
24 In identifying a particular disorder, companies have to use

1 a generally accepted classification system based on
2 diagnostic criteria. In addition, all efficacy claims must
3 be supported by documentation that shows the instrument has
4 a specific therapeutic effect in contrast to other possible
5 mechanisms.

6 We also require clarification of whether the
7 instrument itself is able to provide definitive therapy or
8 if it must be supplemented by adjunctive therapies. If
9 other types of therapy are required, we need evidence that
10 the combined therapeutic effect is greater than that of the
11 supplemental therapies alone.

12 Testing the validity of efficacy claims for a
13 treatment modality or instrument requires two independent
14 randomized clinical trials that employ pre-defined criteria
15 for choosing the study population, as well as appropriate
16 outcome measures for quantifying specific therapeutic
17 effects. Blind comparisons to untreated controls, placebo
18 groups, or active controls also must be part of the study
19 model's criteria.

20 For TMD or a sub-category of TMD, trial
21 populations are identified via defined inclusion and
22 exclusion criteria that are applied to the chief complaint,
23 history, clinical examination, and, when indicated, TMJ
24 imaging of the subject.

1 Outcome measures must be well accepted and
2 quantifiable and must clearly relate to the patient's
3 condition. Examples include the visual analog scale, the
4 McGill pain questionnaire, and signs and symptoms that are
5 well correlated to TMD conditions, that is, range of motion
6 and tenderness on palpation. Concepts such as achieving
7 muscle balance are not good outcome measures.

8 It should be noted that TMD diagnosis and
9 assessment of the temporomandibular musculoskeletal complex
10 can be performed in a number of ways, and the association
11 considers instruments only as aids in diagnosis of
12 temporomandibular disorders. Currently accepted instruments
13 measure muscle activity, interincisal distance, and joint
14 sounds. They cannot, however, replace the diagnostic
15 method, that is, the clinician's evaluation, the patient's
16 chief complaint, medical history, the physical exam, and the
17 results of diagnostic tests.

18 The fact that these instruments are not to be used
19 alone to diagnose disorders of the masticatory
20 musculoskeletal system is clearly indicated in the
21 guidelines. The association's position on the value and
22 limitation of these instruments is further presented in the
23 statement that accompanies the ADA's seal on accepted
24 products: "This product is accepted as a measurement device

1 for the evaluation of the temporomandibular musculoskeletal
2 complex. Responsibility for proper selection of patients
3 for testing and the interpretation of test results rests
4 with the dentist."

5 Because of the variables associated with TMD
6 treatment devices, for example, which specific disorder or
7 sub-category of TMD disorder the device is designed to
8 treat, whether the instrument is to be used for stand-alone
9 or adjunctive therapy, the statement that accepted TMD
10 treatment devices carry is determined by the ADA Council on
11 Scientific Affairs upon approval of each product.

12 Currently, seven devices for the evaluation of
13 temporomandibular musculoskeletal complex carry the ADA seal
14 of acceptance. There are no products on the association's
15 list of accepted products that have been shown to be useful
16 in the treatment of TMD.

17 DR. GENCO: Thank you very much, Dr. Burrell.

18 DR. BURRELL: Thank you.

19 DR. GENCO: Are there any comments from the panel
20 or guests? I'm here at this table. It's hard for me to see
21 the two ends. So if you do have a comment, I'd appreciate
22 if you'd just raise your hand or let me know somehow.

23 Yes?

24 DR. MOSES: What I guess I'm asking primarily, to

1 start out, because I have a lot that at some point I'd like
2 to discuss about this, is relative to what Mr. Ulatowski
3 said this morning. Are you offering this as a voluntary
4 consensus standard?

5 DR. BURRELL: Yes.

6 DR. MOSES: Okay. Thank you. Is that going to be
7 acceptable, that this might be considered a voluntary
8 consensus standard? Is that a possibility? Is that what
9 you have in mind as well?

10 MR. ULATOWSKI: The type of standard we're
11 discussing are standards that have been created under a
12 consensus process, including individuals from the public or
13 in an open format where there's open participation in
14 formulating the outcome. There are standards by ADA that we
15 certainly will be considering. Whether or not we will be
16 adopting any standards remains to be seen as we go through
17 this assessment process, but certainly they're candidates.

18 DR. MOSES: This is a possibility, then, that this
19 could be accepted?

20 MR. ULATOWSKI: They're candidates, yes.

21 DR. MOSES: Okay.

22 DR. GENCO: Further comments, questions? Yes?

23 DR. MOSES: Then I would like to make a few
24 comments, in that there are several terms that we--either

1 they're referred to in here--although I will say that I
2 believe that you're fair in that when you're talking about
3 measurement, you're talking about the temporomandibular
4 musculoskeletal complex rather than TMD as a disease.

5 DR. GENCO: Correct.

6 DR. MOSES: Okay. That's an important
7 differentiation. But when you talk about diagnostic
8 specificity and sensitivity, again, I have to get back to
9 Dr. Jankelson's comments because you're dealing with a
10 disease then, and with regard to that disease, I don't
11 believe that you've established what disease it is, what
12 disease criteria there are, who has the disease and who
13 doesn't, what people are diseased and what people are
14 disease-free, what constitutes normal for this disease, what
15 constitutes abnormal. And we haven't even defined whether
16 this is a disease. One of the issues in the models that he
17 discussed is whether this is a disease or an illness in
18 reality. And I think that before this is accepted on that
19 kind of a basis, these issues have to be dealt with.

20 DR. GENCO: Do you want to comment, Ken?

21 DR. BURRELL: Well, I think there are two parts to
22 the guidelines, and one, if a manufacturer chooses to submit
23 a device that is simply measuring physiological phenomena,
24 then what they have to do is measure good performance in

1 this area. In other words, if a device is to measure
2 interincisal distance, then data has to be provided to show
3 that it can do this in a reliable manner.

4 Now, if a manufacturer wishes to claim that the
5 device does in some way diagnose or identify some sign or
6 symptoms that is pathognomonic of the condition, then the
7 clinical trials would be required. So there's a difference
8 between the levels of the kind of device.

9 DR. MOSES: So you're really narrowing it down in
10 that it would have to be pathognomonic. I mean, that's a
11 high degree of--

12 DR. BURRELL: Yes.

13 DR. MOSES: --specificity, we'll call it, for lack
14 of a better term. Okay.

15 DR. GENCO: Further comments, discussion?

16 [No response.]

17 DR. GENCO: Thank you very much, Dr. Burrell.

18 DR. BURRELL: Thank you, Mr. Chairman.

19 DR. GENCO: I think we will take a break, 15
20 minutes, so let's get back here at 11:25. Thank you.

21 [Recess.]

22 DR. GENCO: We will now hear from Dr. Peter Neff.

23 DR. NEFF: Mr. Chairman, panel, presenters, I
24 would like to express my sincere thanks for inviting our

1 society to this meeting. Dr. Terri-Ross Icyda asked me to
2 represent him to this meeting at kind of the last minute
3 because apparently with the changes we had in the office, he
4 did not receive his information until late. So the standard
5 of our society, the American Equilibration society, is the
6 fact that no instrument or any devices determine the
7 diagnosis of a patient, nor the treatment of a patient. The
8 clinician is the person responsible for. Instrumentation,
9 yes, by all means, you have always accepted, respected the
10 fact that it will aid in our diagnosis, without a question,
11 and will help in our direction for the possible treatment we
12 can render to our patients. But the clinician is the person
13 that is going to do the final diagnosis and the treatment
14 management that this patient may need.

15 This is the stand of the American Equilibration
16 Society, and this is what I am representing Dr. Icyda for.

17 Thank you.

18 DR. GENCO: Comments, questions from the panel?

19 DR. NEFF: Forgive me, Mr. Chairman. It happened
20 that I was also a person that I was responsible as an
21 advisor in 1982 to the guidelines of the ADA, and I had
22 worked in that capacity then as advisor and author and
23 editor of these guidelines that we still have in this
24 direction and we are still holding to as official

1 guidelines. So if there are any questions from that time to
2 the present, I would appreciate it and would be happy to
3 answer.

4 DR. GENCO: Okay. Thank you.

5 Questions, comments?

6 [No response.]

7 DR. GENCO: Thank you very much.

8 On the program, we also have Dr. Larry Tilley,
9 American Academy of Head, Neck, and Facial Pain. He was
10 scheduled for this afternoon, but if he is here and it is
11 convenient to present, we invite him to come up. Thank you.

12 DR. TILLEY: Good morning, and thank you for
13 having me. On behalf of the American Alliance of TMD
14 organizations, I would like to thank you for the opportunity
15 to be here and share with you some of the things that we
16 think are very important as we look at this issue of TMD and
17 instrumentation revolving around it.

18 The alliance is an organization made up of nine
19 major organizations and several regional and foreign
20 organizations. It has over 10,000 members total as a result
21 of those different organizations.

22 Our mission statement is pretty simple. On behalf
23 of the patient's well-being, the American Alliance of TMD
24 Organizations' mission is to support and protect the rights

1 and freedom of clinicians to practice in the field of TMD
2 within the scope of their care, skill, knowledge, and
3 judgment, and scientific information. The idea of the
4 alliance came about in about 1993 as a result of some things
5 that were going on, but really the thing that crystallized
6 the alliance was the FDA hearing of 1994.

7 To understand the implications of that meeting,
8 the concerns that we have for this and the following
9 classification meeting, it is imperative that the panel
10 understand the problems which have occurred in the field
11 over the years. TMD, in general, has become a very divisive
12 and emotional issue. It is important to take the emotion
13 out of this discussion and address the facts. To do that,
14 we need to look at it from a historical perspective and
15 point out the actions of certain individuals and
16 organizations as they reflect on TMD over the years.

17 I have no intent to malign anyone, but the
18 information I am going to share with you regarding
19 activities surrounding neuromuscular instrumentation is fact
20 and can be supported by this documentation that I have with
21 me. You are welcome to any or all of this information, if
22 you care to look at it.

23 The problem really goes back to 1996 when the ADA
24 Council on Dental Materials, Instruments, and Equipment

1 awarded the seal of recognition to Myo-Tronics, calling
2 their equipment safe and effectiveness as an aid in the
3 diagnosis and treatment of muscle tension and pain
4 associated with TMD and MPD. As a result, some academicians
5 became concerned that instrumentation would become the
6 standard of care, and the first time it was in writing that
7 I know of was when IADR with the Neuroscience Group, the TMD
8 Subcommittee of the Neuroscience Group of IADR, published in
9 their newsletter the fact of their concern.

10 In 1987, the House of Delegates demanded or asked
11 that the ADA convene a TMD workshop. According to Dr.
12 Green, the ADA commissioned Dr. Mohl to select a group of
13 experienced investigators to develop a position paper. This
14 paper basically said that there was nothing of value in the
15 diagnosis and treatment of TMD with the exception of devices
16 developed for a electromyographic biofeedback.

17 Prior to the meeting, this paper was clearly
18 marked "Draft only, not to be referenced," and despite that
19 fact, it was submitted pretty widely and was being used by
20 insurance companies to deny claims prior to that 1988
21 meeting. As a result of that, the American Academy of Head,
22 Neck, and Facial Pain filed a lawsuit, and, in fact, got an
23 injunction which prevented the continued use of this
24 document. And the publications that came out really gave

1 them a black eye for that action, and in retrospect, I would
2 think probably it was a wise thing to do.

3 Despite the rejection of the report by the ADA
4 Council which had requested it, and because of the power of
5 the individuals involved, it was published in its entirety
6 in the Journal of Prosthetic Dentistry. Because of this, it
7 has been the basis for many additional papers, often with
8 the same wording, and perceived as the position of the
9 profession.

10 Because of the immediate and aggressive responses
11 by the neuromuscular instrumentation users and
12 manufacturers, it was perceived to be an instrumentation
13 issue. The lawsuit and the conflict that arose at that
14 meeting was considered by most to be related just to the
15 instrumentation users, as I said. Some of us felt that it
16 was a very different issue and that, in fact, it was an
17 issue of the freedom of practice and was, in fact, drawing a
18 new parallel to TMD, what it meant to us as practitioners
19 and patients alike.

20 During that period, there were 41 positive
21 articles reflecting the successful utilization or the
22 efficacy of jaw tracking. There were 36 positive articles
23 on joint vibration analysis. There were 110 articles,
24 positive articles, on the efficacy of EMG. And yet none of

1 those were ever considered in the publications that we
2 continue to see. A total that I had come up with during
3 that period of time, that three-year period, was 46 negative
4 articles and 14 presentations that all reflected the
5 negative aspect of instrumentation. So it has been
6 something that has beat up for quite a while.

7 During the period, the Neuroscience Group of the
8 IADR petitioned ADA to remove or discontinue, withdraw,
9 rather, their recognition of neuromuscular instrumentation.
10 In 1989, the ADA did decide to discontinue their recognition
11 program and in 1991 developed their acceptance program,
12 which was awarded to the instrumentation in 1992.

13 One of the comments from one of the reviewers was,
14 I think, very substantial in regard to instrumentation. He
15 said that, and I quote, "It is a pleasure to have a company
16 place emphasis on the neuromuscular system and objective
17 measures which can be recorded and kept on record. This
18 objective assessment in dentistry assists the field as it
19 improves its understanding of a problem and accurately
20 defines its parameters.

21 In 1993, I was contacted by CNN to ask me to do an
22 interview for them in regard to neuromuscular
23 instrumentation, and, in fact, Dr. Mohl and myself were on
24 that interview, and there was nothing really bad that came

1 out of it. They asked a lot of prying questions of over-
2 utilization, were there many false positives, were people
3 treated excessively as a result of instrumentation, and I
4 answered those to the best of my ability.

5 The presentation itself aired one evening and was
6 really very generic, as CNN tends to want to do sometimes.
7 Its closing comment was that patients who carefully weigh
8 their options are most likely to enjoy any of the
9 technological benefits and avoid its pitfalls. So nothing
10 really came out of that other than the fact that they had
11 been approached by Dr. Mohl regarding this.

12 In 1993, another article came out in the New York
13 State Dental Journal by Dr. Mohl. The title was "The Role
14 of Electronic Devices in Diagnosis of Temporomandibular
15 Disorders." It again was a negative review article
16 regarding instrumentation. Dr. Bob Kull, one of the
17 graduate students from Buffalo, responded. He said that the
18 author's criticisms are not based on scientific evidence.
19 It is much easier to resurrect old data and claim the new
20 procedure does not work. Intellectual honest would require
21 a researcher to test a questioned hypothesis in his or her
22 own laboratory to corroborate or invalidate a theory.

23 To date, there is not a single publication
24 anywhere in the literature that specifically invalidates the

1 current technology.

2 This negative attack against the instrumentation
3 continued. In the January 1994 issue of the Journal of the
4 American Dental Association, with the heading of "The
5 National Institute of Dental Research," another negative
6 article, which was a review article, was placed. The very
7 next month, in the same publication, the article entitled
8 "Dental Quackery" listed many of the instruments that you're
9 going to evaluate as "dental quackery."

10 In July 1994, the ADA temporarily suspended the
11 instrumentation seal of acceptance halfway through its
12 three-year approval, and one of the manufacturers made the
13 statement that, despite specific requests, manufacturers
14 were given no rationale for this action, no safety or
15 efficacy issues were cited, no violations of guidelines were
16 cited, and no new research which would reflect doubt on the
17 value of objective measurements were cited.

18 We were then told, however, the ADA president and
19 select trustees were approached by certain clinicians
20 critical of the classification for TMJ instruments and the
21 way in which it had been administered. It was pointed out
22 that the council members were receiving a lot of input from
23 a very small group of individuals. Right after that, the
24 ADA, the AGD, in their AGD Impact, again published a

1 negative article in relation to that.

2 This leads us up to the 1994 Dental Products
3 Panel. I have a letter from Dr. Green requesting their
4 being able to present the NIH Neuroscience Group's feelings
5 regarding instrumentation at that meeting. And in the
6 proceedings--if you haven't seen that, you certainly need
7 to--he said he'd like to speak as president of the AADR as a
8 clinical scientist and as a clinician with expertise in this
9 area. And the sad thing, at about the same time, in a
10 deposition right around the same time, he stated that he had
11 never used any of the machines personally, never taken any
12 courses on any of the instruments nor studied any technical
13 manuals on how they work.

14 You need to certainly ask these questions to any
15 of the naysayers that speak about instrumentation. Are they
16 really familiar with them, or are they dealing with
17 literature reviews? All of you know that a literature
18 review certainly can be--you can look until you find the
19 things you want to prove, and then you can ignore opposing
20 literature. So that is a dangerous way to make decisions.

21 As you know, the FDA hearing, the recommendation
22 was for these instruments to be class III with urgency, and
23 the panel recommendation was dismissed. But immediately
24 after the hearing, there were several publications that said

1 that FDA was seeking adversely affected patients. This was
2 in the Terrant (?) County Physician, and this is a
3 newsletter from the National Council Against Health Fraud.
4 When asked about where that came from, we were told that one
5 of the panel members requested it, and so they assumed it
6 came from FDA directly.

7 At the same time, a letter came out from Dr.
8 Stohler to the Association of University Teachers of Oral-
9 Facial Pain programs requesting information to corroborate,
10 as he says, "our testimony at the FDA." These kind of
11 issues continue and have continued over the years, and a
12 couple of affidavits here speak to the problems that we are
13 facing when you look at instrumentation. These are two
14 affidavits from Dr. Lars Christianson, and he was speaking
15 to Dr. Rue, who said that the clinicians who use TMJ
16 instrumentation make too much money and they and the guys at
17 the ADA will now have to learn to obey the rules of the FDA.
18 Also, the ADA guidelines have never been followed by Myo-
19 Tronics and Bioresearch; they were grandfathered into the
20 program because they could really not adhere to the
21 guidelines. And, of course, we know that is not so.

22 Another affidavit from him regarding some comments
23 from Dr. Seligman, he says that a new policy or plan, the
24 AAOP, is not again to try to influence the policies of

1 federal agencies with regard to TMJ instrumentation. We
2 will not try to influence and interfere with the FDA
3 classification of instruments. The FDA will eventually have
4 to classify the instruments, and the classification must be
5 class III because the instruments are dangerous. Therefore,
6 all insurance companies will realize that they cannot
7 acknowledge claims that are based on TMJ diagnostic and
8 therapeutic instruments. Logically, we will kill off all
9 TMJ instrument users through non-reimbursement. If a
10 dentist sees that the patient is not reimbursed, then he
11 will not use the instruments. In our new edition of the
12 guidelines, we will point out that all TMJ instruments used
13 for diagnosis and treatment are of no use, that they are
14 dangerous, and the guidelines will then be given to all
15 insurance companies so they can deny reimbursement by
16 referring to these guidelines. That's the way it works in
17 the U.S. You simply starve the dentist who uses TMJ
18 instrumentation.

19 The next thing that occurred in relation to
20 instrumentation was the NIH pamphlet that was produced, and
21 we never have found out who the author of that is, despite
22 repeated requests, and then the publication packet that was
23 sent along with it, again pointing out the negatives of
24 instrumentation and the problem of its use.

1 Closely followed by that was the NIH conference
2 on--technology assessment conference. The presenters--I
3 lost my place. I'm sorry. The presenters, several of the
4 presenters were clinicians, one talking about
5 instrumentations, one talking about treatment devices, and
6 one about equilibration. All has presenters to come
7 immediately after them to refute what they had to say,
8 despite the fact that the other people weren't supposed to
9 have information regarding their presentations.

10 It was indeed a free-for-all with emotions running
11 high, and the crux of the finding was that TMJ is not a
12 structural or physiologic problem, but a psychosocial one,
13 and only EMG biofeedback and cognitive behavioral therapy
14 had been proven to be effectiveness. Dr. Dworkin pointed
15 out that a great deal of more research in behavioral therapy
16 was needed. Dr. Marbach pointed out that when you organize,
17 you can influence the institutions that set policy and
18 research. And that has surely been done over the years.

19 If you look at the research, which, according to
20 the Washington letter, has doubled in relation to TMD
21 research, you will find that in the last couple of years
22 \$7.3 million has been spent, and most of it has been spent
23 on psychosocial research. Clinicians around the country,
24 clinical academicians, have complained bitterly about the

1 fact that they have trouble getting grants for clinical
2 research.

3 We as clinicians are criticized for not having
4 research to back up what we do. The fact is we must treat
5 patients and cannot withhold treatment in order to have an
6 untreated group. One of the comments made at the NIH
7 conference was that the greatest deterrent to scientific
8 research is clinical success. Unfortunately, clinical
9 success is exactly what we and patients want.

10 The American Academy of Head, Neck, and Facial
11 Pain is in the process of doing some outcome studies which
12 now number about 2,000, so we hope we have those answers.

13 So is this a psychosocial issue? One of the
14 speakers earlier said you have to define that. I wish you
15 well if you tackle that subject. It is a very difficult
16 one. Fortunately, you don't really have to debate that.

17 The British Society of Occlusal Studies, though,
18 says that 88.6 percent of their patients are primarily
19 physical in origin and that only 6.8 percent require
20 antidepressants. So they feel definitely that it's a
21 structural problem.

22 If you look at clinical examination, you will find
23 that as low as 14 percent in inter-examiner reliability is
24 there, some as high as 50, but very poor inter-relater

1 reliability. So one of the things we have to address is a
2 way to improve that.

3 Dr. Clark wrote an article in the AAOP journal,
4 and he spoke about these parameters that we look at that
5 everybody agrees we need to evaluate. He said that range of
6 motion measurement and recording of mandibular motion should
7 be completed for opening, lateral, and protrusive movements.
8 The quality and symmetry of jaw movement should be noted and
9 diagrammed. There is no way to do that very effectively
10 without some sort of jaw tracking device, and there is no
11 jaw tracking device simpler than the magnetic jaw tracking
12 that these gentlemen spoke about.

13 He goes on to say about joint sounds, he says:
14 Audible joint sounds, palpable clicks, and momentary
15 interference with smooth motion during movement should be
16 described in severity, repeatability, frequency, and timing
17 during the jaw movement cycle documents. Any manipulated or
18 altered jaw position or maneuver, such as chewing wax, that
19 eliminates, aggravates, or ameliorates the joint sounds in
20 coordination should also be noted. There is absolutely no
21 way to show that without some kind of sonography or
22 vibratography study.

23 He goes on to say, in looking at muscles, he says
24 that spasm implies a continuous muscle contraction, and it

1 can only be differentiated with electromyography
2 verification.

3 Some of the finest studies about sonography have
4 come from the University of Buffalo where Dr. Bissett has
5 shown as high as 96.6 percent sensitivity in some of those
6 studies. So it is really incredible results.

7 The Georgia Dental Association and several other
8 States have passed bills that are entitled "Equal Coverage
9 for Anatomic Parts." They say that insurance companies
10 can't discriminate against the TMJ and favor other body
11 parts. Now, granted, TMJ works very differently, but it is
12 still made up of muscles, joints, and fascia. And if you
13 look at the class II instrumentation that we've already
14 talked about--high voltage, ultrasound, things like that--
15 265 articles are in this quick review that we did that
16 support the efficacy of utilizing that instrumentation for
17 muscle problems and joint problems.

18 As we continue to look at the problem, I think the
19 best way to sum it up is to read to you what Dr. William
20 Howard said in an editorial in the AGD Impact. He says that
21 electronic instrumentation detractors, who are mostly
22 university-based dentists, would have you to believe that
23 such instrumentation, which includes surface
24 electromyography, sonography, and jaw trackers, force

1 dentists into making diagnoses based on factors that have
2 very little to do with the patient's condition. They call
3 it machine arrogance. The arrogance in this case is more on
4 the part of the detractors, some of whom either haven't used
5 the devices themselves or who rely on the small body of
6 review articles addressing these devices, who totally ignore
7 studies that indicate these devices have some clinical
8 value. Credibility is lost when they claim that positive
9 articles haven't been published in credible journals. In
10 fact, they have.

11 Further, I have a hard time believing that
12 electronic instrumentation has no use or else why would the
13 American Dental Association have approved their use?

14 Detractors also claim that instrumentation users
15 are bound to over-treat based on the machine's diagnosis
16 which almost guarantees a bad outcome. More than 1,500
17 dentists use instrumentation, yet detractors can't show any
18 actual examples of how instrumentation made a dentist over-
19 treat. It's time to stop throwing mud, regardless if the
20 FDA recommends a high risk category or a medium risk
21 category. More studies are needed to help form a consensus
22 regarding electronic instrumentation. The best way to do
23 that is teamwork between manufacturers, instrumentation
24 users, and universities, who have the means to conduct large

1 double-blind studies and will prove their efficacy once and
2 for all. Conclusive results will take considerable time to
3 achieve.

4 Myo-Tronics president, W. Bill Trimmingham, said it
5 best: Devices don't diagnose TMD; dentists do. We aren't
6 stupid enough to allow instrumentation or any other new-
7 fangled device to run our office and treat our patients.

8 I think that sums up the impact of everything
9 quite well.

10 It would be remiss of me if I didn't tell you that
11 abuses occur. I have seen cases, being on the TMD committee
12 in Georgia, where thousands of dollars were spent on
13 radiology, thousands of dollars were spent on excessive
14 physical medicine modalities, and thousands of dollars were
15 spent on excessive utilization of this instrumentation that
16 we are talking about. But I have also seen crowns done on
17 patients who would better be served with more conservative
18 treatment.

19 None of these abuses are a result of the
20 instrumentation. They are a result of the ethics of the
21 individual. And, unfortunately, we or no other agency can
22 legislate morality.

23 You must realize that signs and symptoms and pain
24 and dysfunction don't always go together. We see

1 significant signs with few symptoms, significant symptoms
2 with few signs. We see much dysfunction with no pain.

3 To sum up the situation you face with
4 instrumentation is best done, as I said, from that AGD
5 article. The duties and significance of this committee to
6 me seemed to be enlarged by all of these facts. Your
7 decisions will be far-reaching. The most important thing
8 that you can do is to take a diligent, thoughtful, measured
9 approach as you view these issues, and, most importantly,
10 just be simply a committee of integrity.

11 Thank you for your time. I appreciate your
12 attention.

13 DR. GENCO: Thank you, Dr. Tilley.

14 Any comments, questions from the panel or the
15 guests?

16 [No response.]

17 DR. GENCO: Okay. Thank you very much.

18 DR. TILLEY: Thank you.

19 DR. GENCO: What we will do now is take a break
20 for lunch, and it seems that we should get back here by 1
21 o'clock. You think an hour and a half would be more
22 appropriate, given the restaurant. Okay. 1:30, then, and I
23 would like to reiterate, if any of the--because we were out
24 of order, if any of these individuals would like to

1 readdress us this afternoon, they are certainly welcome to.
2 This afternoon will be spent, however, primarily on open
3 discussion of the panel.

4 Thank you.

5 [Whereupon, at 12 o'clock p.m., the proceedings
6 were recessed, to reconvene at 1:30 p.m.]

1 A F T E R N O O N S E S S I O N

2 [1:30 p.m.]

3 DR. GENCO: Before we get started, I'd like to ask
4 Dr. Larry Tilley, invite him to come back up to the podium.

5 DR. TILLEY: I just wanted to make a comment, Dr.
6 Genco. I was two hours ahead of my schedule and a little
7 rattled, so I didn't start off the way you asked us to. I
8 have in the past--I'm a general practitioner, and very
9 active in treating head and neck pain and TMJ. And I have
10 in the past lectured for both of the manufacturers of
11 neuromuscular instrumentation, and I just wanted to make
12 that clear so that would be on the record.

13 Thank you, sir.

14 DR. GENCO: Okay. Thank you.

15 To help frame the discussion this afternoon, Tim
16 Ulatowski is going to give us some opening comments. Tim?

17 MR. ULATOWSKI: I think I'll go to the podium so I
18 can look everyone in the eye.

19 I appreciate the comments presented by the public
20 and by industry and association participants this morning.
21 I think it's been an excellent input to help guide the panel
22 this afternoon in their deliberations. For example,
23 certainly the point raised that we have to have a common
24 base of understanding of definitions to the extent possible.

1 Perhaps we can't achieve a consensus opinion, perhaps, but
2 at least we need to have a working definition for our
3 purposes for our discussion today. So if there is on
4 anyone's part some lack of clarity on the scope of products
5 that we're talking about today, then we need to bring that
6 up.

7 FDA's intention was to cast a very broad net of
8 devices that are used in the diagnosis and treatment of TMD,
9 TMJ, and oral-facial pain and the other characterizations
10 that were made this morning.

11 I think it's important to recognize that in this
12 proceeding and in the following proceedings on
13 classification, it's not FDA's intent to regulate the
14 practice of dentistry. We're regulating medical devices and
15 trying to classify devices--devices that have claims, that
16 have indications for use and intended uses stated in
17 labeling.

18 Now, with a legally marketed device, dentists,
19 physicians, other professionals can utilize devices as they
20 see fit in their practice for whatever purpose they feel is
21 appropriate based upon their training, experience, knowledge
22 base. But that's not truly what is in front of us today.

23 What we are discussing today is the regulation of
24 devices and classification of specific device generic types.

1 That's not to say that the practice and what people do out
2 there is unimportant. It's certainly important in
3 identifying what sorts of devices are on the table here
4 today. But, again, practice does not translate to the need
5 to classify.

6 We are regulating devices as they are defined as
7 devices and as they are labeled as devices. Again, we're
8 trying to regulate products that are medical devices. And
9 some products or procedures that were mentioned in the
10 comments this morning I would speculate that they are not
11 necessarily medical devices under the definition of a
12 medical device. For example, a psychological test
13 instrument, for example, used in some process for diagnosis,
14 these are not medical devices as far as I'm aware. That's
15 not to say they're not important in this process, but,
16 again, we're dealing with medical devices that are used for
17 these purposes.

18 We talked about generic devices, and there was
19 some appropriate discussion talking about homogeneity,
20 heterogeneity regarding devices. And what we are trying to
21 attempt to do is to find the highest common denominator of
22 generic device that needs to be classified. And in the
23 regulations, 860.3I defines a generic type of device as a
24 means of grouping devices that do not differ significantly

1 in purpose, design, materials, energy source, function, or
2 any other feature related to safety and effectiveness and
3 for which similar regulatory controls are sufficient to
4 provide reasonable assurance of safety and effectiveness.

5 So we're trying to group devices within this area
6 of similarity of purpose, design, function, and these other
7 factors. And as you see from our dental regulations, we
8 didn't lump all diagnostic devices into one group called
9 diagnostic devices and all therapeutic devices into one
10 group. The panel at the time identified differences in
11 function and purpose and design, and then went forward with
12 the classification process once they identified these
13 different generic types of devices subject to
14 classification.

15 We use the indication for use aspect to get us in
16 the ballpark, but your attention has to be turned towards
17 indication of use in temporomandibular joint diseases and
18 related orofacial pain. But in identifying generic types of
19 devices, you have to consider these other aspects--the
20 function of the device, the purpose of the device, and those
21 other things I mentioned, start to find these homogeneities
22 or differences.

23 Well, with that in mind, again, we had some
24 questions before you, and just to reiterate those questions,

1 to get us to some baseline, we wanted to get your opinion on
2 ultimately the construction of the list that we presented to
3 you and what will come out of this meeting with at the end
4 of today.

5 Do you concur with the basic construct? That was
6 the first question.

7 The second question: Are there groups of devices
8 or categories that you feel should be added to, removed, or
9 modified in this list?

10 Question 3 was: For device groups or categories
11 discussed today, which groups have labeled indications for
12 use or an intended use which relate to temporomandibular
13 joint disorders and associated orofacial pain? To try and
14 get us into this ballpark that we're trying to discuss
15 today. Again, we're talking about devices that are labeled
16 by the manufacturer to have claims in terms of this product,
17 in terms of this use. Again, if dentists wish to use any
18 device for any situation, that doesn't necessarily translate
19 to a need to classify a device. It's only as promoted, as
20 presented, to professionals by the manufacturer that defines
21 the area of need for classification.

22 No. 4, For the groups or categories discussed
23 today, for which there are existing classifications, any
24 existing classifications, which groups--devices or groups

1 have 1976, pre-1976 intended uses related to the diagnosis
2 and treatment of TMD and the other conditions discussed this
3 morning? In that chain of devices that I discussed this
4 morning, we have to establish the pre-amendments nature of
5 the product and the chain of equivalents, either of the
6 product was classified in some manner or unclassified in
7 some manner. We have to consider this pre-1976 derivation.

8 Next question: For the groups or categories
9 discussed today for which there are existing
10 classifications, which of these pre-1976 intended uses are
11 not a subpart of, nor separate from or distinct from any
12 existing classifications? We're going to talk about some
13 devices that were mentioned this morning and during the
14 discussion for which there are classifications, and we'll
15 consider, we'll discuss whether or not we are talking about
16 separate products, a separate generic group, or whether the
17 claimed indications for use as presented by the manufacturer
18 really fall under existing classifications or possibly fall
19 under.

20 Next question: For these same device groups or
21 categories for which there are no existing classifications,
22 which groups do you believe have a pre-1976 intended use
23 related to TMD?

24 Seventh question: Are there any questions that

1 you have that FDA, the device industry, or other interested
2 persons should address and present to you prior to
3 classification of these devices? And that's within the
4 context, again, of the classification regulation, which, as
5 you heard in training this morning, the classification
6 regulation defines the type of valid scientific evidence
7 that any person presenting a device for classification has
8 to bring forward to the panel, but within that context that
9 there's some general information or other information you
10 believe might be helpful to those bringing a product forward
11 for your consideration, you can certainly offer that advice
12 and opinion.

13 The last question, priority of classification, as
14 much you can establish today, be there no priority, or if
15 that's the case, we can do it randomly or alphabetically or
16 whatever the case may be. We've done it all numbers of
17 ways. But if there is some opinion on priority, then we'll
18 entertain that.

19 Thank you.

20 DR. GENCO: Thank you, Tim.

21 Dr. Betz, were you going to make some comments
22 also?

23 DR. BETZ: No.

24 DR. GENCO: Okay. Thank you.

1 Any questions of the panel or guests for Tim?

2 Yes/

3 DR. REKOW: I have a question. I'm not sure that
4 I understand what the 1976 categories were. That would help
5 me a lot in determining where we are and where we're going.
6 Are those categories the ones that are on this sheet?

7 MR. ULATOWSKI: For purposes of that sheet, we
8 tried to capture device generic types that we believed at
9 FDA, as far as we could establish from the record, had a
10 condition of use in the diagnosis and treatment of
11 temporomandibular joint diseases, so on and so forth, just
12 to throw the net out to see what possibilities existed.

13 But, ultimately, discussion will have to ensue for
14 each of those devices and any other types of devices we
15 identify, what's the classification status of each of those
16 devices? What are they labeled for? How are they currently
17 classified? Do we need to classify any products in those
18 generic types? Are they unclassified?

19 So it's going to be a range of questions. That
20 list, again, is just a grab bag of possibilities that we
21 could identify. And we heard possibly some others this
22 morning that should fall on the list as well. It didn't
23 state a classification or a status, but we'll discuss that
24 as we move from each class, from each type to type.

1 DR. GENCO: Tim, maybe I could rephrase that? Are
2 all of those devices pre-'96, those on your list of universe
3 of devices? Were all of those on the market before '96?

4 MR. ULATOWSKI: I believe that within generic
5 devices all, those devices are pre-1976 devices.

6 DR. GENCO: Right. And in the medical area, some
7 have been classified. In the dental area--

8 MR. ULATOWSKI: Some have been classified.
9 Radiological devices, some have been classified, for
10 example, for a particular intended use.

11 DR. GENCO: But with the exception of--it seems
12 that the kinesiology and imaging devices, the Dental
13 Products Panel has not classified the others, only those
14 two.

15 MR. ULATOWSKI: We're trying to conclude that
16 that's the case as a result of this discussion and from
17 comment that may come afterwards at FDA and from any other
18 public comment that you may wish to entertain.

19 MS. SCOTT: Before we move ahead, if I could just
20 ask all the participants to state your name before speaking,
21 just for the purposes of our transcriptionist and the
22 summary minutes writer.

23 DR. COOPER: Dr. Barry Cooper. I have a question
24 about the fact that the instruments that basically are on

1 the list within that table all relate in some way to jaw
2 function or masticatory muscle function, but the title of
3 this whole overview is TMD and oral-facial pain. I don't
4 think that we have a working definition of either the easy
5 one, which is TMD, or the very difficult one, which is oral-
6 facial pain.

7 DR. GENCO: I realize that. The way I'd like to
8 handle this, Tim made a presentation that I'd like to have
9 some discussion on the points that he made, and then I think
10 we should deal with that, definition of disease and also
11 definition of devices. What are devices? Is a psychosocial
12 scale a device? Tim can give us some definitions there.
13 Then what does generic grouping mean? So we have a very
14 clear idea. And then go on to the table, if you'd like.

15 Any further questions on what Tim said?

16 [No response.]

17 DR. GENCO: Okay. What I'd like to do is to put
18 on the floor what several people this morning and Tim again
19 reiterated, definition of disease condition. What are we
20 dealing with?

21 Let me start by articulating or just reading what
22 the FDA staff have designated as a description of what we're
23 dealing with. Let's start with that.

24 Temporomandibular joint disorders and associated

1 oral-facial pain. Did I quote that right? That's what
2 we're dealing with. Temporomandibular disorders and
3 associated oral-facial pain.

4 Okay. Now, we heard this morning that it's
5 broader than that, that it's less than that. What are your
6 feelings? Anybody want to comment on that? Is that what it
7 is?

8 Now, the language says "disorder" and "pain"
9 associated with that disorder. Is there more to it? Less
10 to it? Yes?

11 DR. MOSES: I believe--I've been studying this
12 problem, and--my name is Allen Moses. I've been studying
13 the literature, and I believe that there's about 145 to 150
14 different--I believe in my studying I have found that
15 there's between 145 to 150, roughly, give or take a few,
16 conditions which would be classified as oral-facial pain
17 which a diagnostician would have to rule out in arriving at
18 a diagnosis of one or other of the 20 to 25 conditions that
19 would be considered masticatory disorders or temporo-
20 mandibular disorders, depending on how you choose to define
21 the term "temporomandibular disorder."

22 Should I be more specific?

23 DR. GENCO: Yes. Help us to understand what you
24 just said.

1 DR. MOSES: Can I give you a handout?

2 DR. GENCO: That would be wonderful. Do you have
3 some pictures?

4 DR. MOSES: No, no pictures, but words.

5 DR. GENCO: No, seriously. A handout would be
6 helpful. Thank you.

7 DR. COOPER: Can I add something while they're
8 distributing that? I think part of our problem is whether
9 or not we attempt, which is quite an attempt, as Allen will
10 show you, to deal with every variation of head and neck pain
11 and its causes, or whether we stay to the wordage that you
12 just read, which is that it begins with TMD and it's pain
13 conditions that are associated with it. That is a much more
14 limited environment that we have to work in, so that's
15 something we should consider.

16 DR. MOSES: If I could speak to this, what I was
17 saying before, what I decided to as part of the way I study
18 a problem, I went to the literature to see how many
19 variables are involved in the diagnosis of oral-facial pain,
20 because I consider myself a diagnostician or oral-facial
21 pain and temporomandibular disorders. The context in which
22 I feel that this is important is, if you'll take a look at
23 the sheet, if I diagnose a patient as having a masticatory
24 disorder, say muscle splinting, I don't want to--I want to

1 make sure that I've ruled out, say, a malignant lesion so
2 that if, God forbid, it should be a malignant lesion on one
3 of my patients, that I didn't miss that diagnosis. So I
4 feel that we have to be concerned with these diagnoses when
5 we deal with them.

6 So I went to the literature, and I found that
7 there's roughly 17--if you look at page 1, there's a little
8 1 and a 2--all through characteristic signs from the top of
9 page 1 through characteristic signs, there's roughly 17
10 variables involved in making the diagnosis. Each one of
11 these has between 5 and 17 choices. The number of
12 permutations and combinations possible, juts to put this
13 issue in perspective, is roughly 1.5 times 10 to the 55th.
14 If a doctor--let me just--if a doctor were to consider one
15 permutation per second, it would take from the beginning of
16 time of the Big Bang to the present to do one diagnosis.

S5

17
18 So we have to be thoughtful and perceptive, and we
19 have to chunk things together. In reality, the human mind,
20 according to other psychological studies, can contemplate
21 four to six variables in making a complex decision. So I
22 think what we have to do is chunk these things together, and
23 the way that I've chunked them is the way that you see in
24 front of you on the big sheet. Thus and such, I came up

1 with an organized scheme, and within this scheme, there's
2 various diagnoses of temporomandibular disorder.

3 If you go back to a NIH conference in 1993, for
4 example, I found that Dr. Dworkin defined disease as "an
5 objective biologic event involving disruption of specific
6 body structures or organ systems caused by pathologic,
7 anatomic, or physiologic changes." He defined illness as "a
8 subjective experience or self-attribution that a disease is
9 present yielding physical discomfort, emotional stress,
10 behavioral limitations, and psychosocial disruption." He
11 stated that progressive pathophysiologic change cannot be
12 reliably diagnosed in TMDs and concludes that TMD is more
13 usefully characterized as an illness.

14 So if I were to classify that definition, I would
15 go over to the far right under psychogenic, and I would put
16 "TMD" under eating disorder. But what I think that most
17 dentists deal with in their practice in reality, clinicians,
18 is the realm under extracranial, non-neoplastic, non-
19 infectious masticatory disorders, non-arthrogenous,
20 arthrogenous, myogenous deviation in form and inflammatory.
21 And, again, this is not cast in stone. This is just a basis
22 for discussion in that when I conceptualize the problem of
23 temporomandibular disorder, as I see it in my life, I think
24 of masticatory disorders, and I don't even see the need to

1 use the word "TMD" or "temporomandibular disorders" in that
2 context, because I think it's misleading. But that's
3 opinion.

4 But within the context of this discussion, I think
5 you have a complex list of the masticatory disorders that
6 might commonly be considered within the realm of TMDs there.

7 DR. GENCO: Okay. So your suggestion is that
8 within this term "temporomandibular joint disorders and
9 associated pain" that we consider only the masticatory,
10 articular and periarticular?

11 DR. MOSES: No. Articular--yes, and
12 periarticular. Arthrogeous, non-arthrogeous, myogeous--
13 yes--

14 DR. GENCO: Everything under those two.

15 DR. MOSES: That's correct.

16 DR. GENCO: How about the psychogenic? You would
17 not include the psychogenic?

18 DR. MOSES: That's my opinion.

19 DR. GENCO: Just so we're clear. I'm not
20 challenging--

21 DR. MOSES: That's my opinion, yes. Yes, that is
22 my opinion.

23 DR. GENCO: I just want to clarify what you said.

24 DR. MOSES: That is my opinion, yes.

1 DR. GENCO: So what you said is that if we wanted
2 to--you're not objecting to that term, "temporomandibular
3 joint disorder"--

4 DR. MOSES: I'm not objecting to TMD.

5 DR. GENCO: --"and associated pain," but you're
6 saying to beef that up, to define it, it's these masticatory
7 articular-periarticular, and underneath that--and
8 psychogenic, that would be included.

9 DR. MOSES: That's right. I feel that
10 temporomandibular disorder is not specific enough that we
11 could direct treatment at TMD without being more specific,
12 appropriately, clinically, in treating the more specific.
13 That's not to say you can't have a myositis in conjunction
14 with osteoarthritis either. You could have multiple
15 diagnoses. I think that's commonly accepted within this
16 field. But I just feel that to say you're treating TMD--and
17 you would treat a chronic disk displacement the same as you
18 might treat a myofascial pain, I don't that cuts it
19 clinically.

20 DR. GENCO: Further comments? Dr. Bertrand?

21 DR. BERTRAND: I'm Peter Bertrand with Navy. I
22 think what we're talking about is a differential diagnosis
23 to fill a definition. The trigeminal nerve controls jaw
24 motion. It also controls the tightness of the eardrum and

1 eustachian tube, its patency, but that's all it does motor-
2 wise. It's mostly a sensory nerve, and I think if you're
3 talking about pain and dysfunction in the head and neck, you
4 have to look at the full extent of the receptive fields for
5 the trigeminal system. And virtually everything in some
6 studies in cervical nerve 4 or 5 up goes directly into the
7 trigeminal system.

8 So if we're using a restrictive diagnosis, just
9 looking at jaw joint and jaw muscles, we're not looking at
10 the other parts organically that play a role in function, in
11 speech, in swallowing, in kissing, in eating, and we're not
12 looking at dysfunction associated with those types of
13 activities.

14 As far as the concept of psychogenic, there is a
15 bad stigma attached to that. There is an abundance of
16 neuroanatomic literature that shows that everything that is
17 stopped(?) and activates thalamocortical basal ganglia
18 circuits will have direct motor input down through the
19 corpus callosum back into trigeminal motor nuclei and
20 sensory nuclei, as well as other cranial nerves.

21 So I think when we're looking at whatever TMD is
22 and we're trying to decide what type of modalities we are
23 going to use to make a diagnosis, we need to keep in mind
24 the full extent of the trigeminal system.

1 I think terms like "psychogenic" and
2 "psychosomatic" are incredibly misleading, that they were
3 invented in order to make up for when we don't have the guts
4 to say we don't understand neurogenically what's going on.
5 I think there is a big chasm between the basic science of
6 what a basic scientist can tell you neuroanatomically is
7 happening and what our symptoms are, and I think that chasm
8 is diminishing all the time.

9 So I think if we're going to make a decision on
10 what types of modalities we're going to use, we have to keep
11 all of that in mind, the full extent of the trigeminal
12 system. I think Dr. Gonzalez could probably talk about that
13 better than I can, but it is not unusual for patients to
14 have perceptions of TMD instilled by a dentist or physician
15 when somebody says, gee, there's a click there, and
16 everybody focuses on that. Well, the anxiety associated
17 with that diagnosis is very real, very powerful, at a
18 neurovascular basis. So I think you might have to look at
19 psychogenic as being neurovascular. This is just further
20 comment.

21 DR. GENCO: So just to put that in the context of
22 this definition, temporomandibular joint dysfunction and
23 associated pain, you think that is not sufficient and you
24 would like to add more to that in terms of--

1 DR. BERTRAND: There is nobody in this room that
2 when they bring their teeth together to swallow particulate
3 food that doesn't utilize their neck musculature, also. If
4 your neck musculature isn't working, then swallowing becomes
5 more difficult. That minimal dysfunction affects the
6 autonomic nervous system, and I think you need to say, hey,
7 what's happening at a neurogenic basis?

8 So when we're talking about this definition that
9 we're working with by the ADA, the temporomandibular joints
10 and the masticatory muscles or a combination of both, that's
11 very restrictive if you're trying to establish which
12 diagnostic modalities you're going to use.

13 DR. GENCO: Which terms would you add to the
14 phrase to beef it up, to convey this?

15 DR. BERTRAND: I would argue that in the function
16 of the jaw and in the--tissues that send proprioceptive and
17 nociceptive input into the trigeminal system, I think
18 encompass the full dimension in the differential diagnosis
19 of TMD. So that means almost anything in the head, neck,
20 throat, and brain. Vascular headaches refer into the
21 trigeminal system. The function of the larynx refers into
22 the trigeminal system. Insertions of the neck refer into
23 the trigeminal system.

24 Now, I think that's what Dr. Moses was talking

1 about, but I also know that anxiety refers into the
2 trigeminal system and affects immediate early gene activity
3 and will mediate allodynia and hyperalgesia. Those are all
4 parts of this system.

5 So I get worried about a form that is making
6 decisions on what is going to restrict diagnosticians when
7 we don't understand the definition and the variables we're
8 dealing with. So I would urge you, if you're going to talk
9 about TMD, to make a differential diagnosis of everything
10 that happens with the trigeminal nerve system.

11 DR. GENCO: Further comments? Yes, Dr. Heffez?

12 DR. HEFFEZ: My name is Leslie Heffez. I concur
13 that what we're looking at is a differential diagnosis, but
14 that would be a differential diagnosis whether we were
15 dealing with knee pathology or hip pathology. We'd all have
16 to deal with that. I think the bottom line is we have to
17 move forward and we have to classify these devices. So we
18 have to come to some agreement what we're talking about, but
19 to try to sit here to try to come to some agreement as far
20 as what all encompassing diseases we have to deal with, I
21 think we won't be able to deal with the matter at hand,
22 which is the classification of the medical devices. So I do
23 think we have to come to some agreement we are dealing with
24 the masticatory system proper and devices related to

1 diagnosing that or eliminating other diagnoses.

2 DR. GENCO: Other comments? Dr. Cooper?

3 DR. COOPER: Maybe that's the key. Maybe what we
4 really have to do is to respect the fact that there is a
5 bigger illness or bigger possible implication and, in
6 respecting it, evolve a classification system for those
7 things that are a part of it that we can now classify, while
8 acknowledging that the field is still open to discussion and
9 knowledge and there will be other things that will be proven
10 to be involved in it, and they, too, will have their own
11 classifications in this larger--there's got to be blanks
12 left, in other words, for testing out the things that Dr.
13 Bertrand is talking about that are not at this point--may
14 not at this point be testable, and there may not be devices
15 to do those tests. But we do have devices that are being
16 used for that masticatory part of this TMD and associated
17 orofacial pain. Maybe that limits our task.

18 DR. GENCO: Yes?

19 DR. MOSES: I think in putting it, again, in a
20 different perspective, some of us are dealing with the scars
21 of the '94 meeting where they said that some of these things
22 that we're dealing with on a day-to-day basis are life-
23 threatening, and we're saying, wait, please listen carefully
24 and don't restrict us too carefully because some of the

1 tests at this particular point, while we're dealing with
2 non-threatening, non-invasive instrumentation, we don't want
3 to be so restricted that we can't do these kinds of testing,
4 either. A lot of this testing evolves out of clinical
5 studies, and we are--I think what I am feeling is I don't
6 want to be restricted by a classification that is so
7 oppressive and restrictive that these things can't be easily
8 testing, because we're basically using non-invasive
9 equipment.

10 DR. GENCO: Maybe I could, in my simple-minded way
11 of looking at things, I understand the complexity of the
12 differential diagnosis, but in your chart, Dr. Moses,
13 orofacial pain, would you--is pain all right in that
14 definition? TMJ disorders and associated orofacial pain.

15 DR. MOSES: I'm comfortable with it.

16 DR. GENCO: Or I'll say facial disease.

17 DR. MOSES: What I'm saying is I'm giving you my
18 perception of orofacial pain as encompassing those 150 or
19 145 diagnoses that I have there.

20 DR. GENCO: Are you suggesting that pain should be
21 in the definition? Let me put it that way. In other words,
22 as the FDA has presented it, it is in the definition.
23 You're agreeing with that?

24 DR. MOSES: I think I--

1 DR. GENCO: There's no condition to be dealt with
2 unless there's pain.

3 DR. MOSES: That is correct. That seems to be
4 where we're going, I think. I'm not disagreeing with you at
5 this point.

6 DR. GENCO: In other words, it could be--you use
7 the term "muscle splinting." Could that occur without pain?
8 Could you get clicking without pain? Are there symptoms
9 that could occur, or signs that don't occur with it?

10 DR. MOSES: Yes. Sure, you can, but we're not
11 going to--the asymptomatic patient is not usually the one
12 that we're going to treat. But, again, you are dealing with
13 other issues in the--I think that as dentists we think of
14 ourselves as performing a preventive service. In other
15 words, in my office, for example--let me be specific again.

16 If a patient comes into my office and they're
17 asymptomatic, I'm not going to treat them for a disease.
18 But, on the other hand, I may want to make them an appliance
19 for grinding.

20 Now, if I couple that with clicking and I couple
21 that with, well, their jaw's a little tight in the morning
22 and they're uncomfortable with the tightness in the muscles
23 and they're worried if their teeth are breaking and
24 fracturing, or they're grinding them away to nothing, I want

1 to be able to make that appliance without feeling that I'm
2 not treating--in other words, I want to treat them for that.
3 If they agree that they need it and I need it but I don't
4 want to be limited that that's not a disease per se, sure,
5 they're going to suffer from muscle splinting. But, in
6 other words, if they come in for treatment and pain, that's
7 a potential diagnosis. But, on the other hand, we're in a
8 vague area. We can't define at this point who's diseased
9 and who's disease-free in terms of controlled studies. That
10 gets back to the basic definition. Who's normal in this?

11 If we look at the epidemiological studies done on
12 temporomandibular disorder in the literature, the range is
13 between 20 and 88 percent in the various studies for joint
14 sounds. It's more normal to have joint sounds than to not
15 have joint sounds. How do we do a controlled study? What's
16 normal when we do these controlled studies?

17 DR. GENCO: That's why I bring up pain. The pain-

18 DR. MOSES: We're using pain--okay. Fine.

19 DR. GENCO: --is the symptom that tells us that
20 there's a difference between a problem or disease and no
21 disease. It doesn't mean that there aren't predictive
22 changes that eventually would result in pain. I mean,
23 that's a very important distinction.

24 DR. MOSES: It is a very important distinction.

1 But we also have patients who lie about pain in automobile
2 accidents.

3 DR. GENCO: Well, you know--

4 DR. MOSES: It's a complicated question.

5 DR. GENCO: Exactly. Yes?

6 DR. COOPER: I think that I will be a help in one
7 way and probably a hindrance in another. The help is that
8 if we consider the word "pain" to be joined with pain or
9 dysfunction, then we allow for muscle dysfunction, jaw
10 dysfunction, which doesn't hurt, but you can't speak, you
11 can't eat, it affects breathing and so on and so forth. So
12 that's my helping part of it. So wherever we use the pain
13 word, if it's orofacial pain, it should be pain or
14 dysfunction, that helps us.

15 My part that isn't helpful is that, listening to
16 Dr. Bertrand, he's talking about swallowing problems, neck
17 problems, as interrelated. If we use the word "orofacial,"
18 it sounds to me like it's in front of the ears and below the
19 eyes. That's a very narrow focus.

20 If that's what we intend to do, that's fine, but
21 we have to know that that word has some implications to its
22 borders. It may be a good one or a bad one.

23 DR. GENCO: You made, it seems, two very important
24 points. Let's go with the first one. I want the panel to

1 join here.

2 We are working this definition, TMJ disorders and
3 associated orofacial pain, and you'd like to add dysfunction
4 or--

5 DR. COOPER: Pain or dysfunction.

6 DR. GENCO: Okay.

7 DR. COOPER: And it's not TMJ. TMD. J nails it
8 only to a joint. It's TMD, temporomandibular disorders.

9 DR. GENCO: Okay. I'm going with what was
10 presented to us by the FDA. You want temporomandibular D?

11 DR. COOPER: I think the ADA--maybe Dr. Burrell
12 could help us. I think that the term is temporomandibular
13 disorders, and I don't think the word "joint" is operative
14 anymore.

15 DR. GENCO: You're suggesting we leave out the
16 word "joint."

17 DR. COOPER: Temporomandibular disorders, because
18 that includes both muscle and joint problems.

19 DR. GENCO: So let's go over it. You made two
20 suggestions. The original FDA proposal, which is put up as
21 a strum(?), and we know that. Temporomandibular joint
22 disorders, you want to leave out "joint." And then the
23 other term was "and associated orofacial pain," you want to
24 add "and dysfunction."

1 DR. COOPER: Right.

2 DR. GENCO: Okay. What does the panel feel about
3 that? Now we're defining--

4 DR. COOPER: I don't know if we're going to be
5 happy with "orofacial," but if that's a generally good
6 statement, we can work on that word next.

7 DR. GENCO: We can work on that later. So let's--
8 and we can come back to your comment, to Dr. Bertrand's
9 comment. We've made two major changes, I think, or
10 suggested changes in the definition of what we're dealing
11 with. Devices which we make suggestions to classify to deal
12 with this condition. The condition is defined, as
13 suggested, temporomandibular joint--no, temporomandibular
14 disorders--omit joint--and associated orofacial pain and
15 dysfunction. Okay.

16 Anybody on the panel want to comment to that? Are
17 you reasonably happy with that? Leslie?

18 DR. HEFFEZ: Yes, I feel that's an adequate title.
19 It's not a definition.

20 DR. GENCO: No, but it defines--

21 DR. HEFFEZ: The rubric that we want to work--

22 DR. GENCO: --the devices to which we're directing
23 our attention, do something for this.

24 DR. HEFFEZ: Yes, I think it's--I agree with it.

1 DR. GENCO: Unfortunately, it's not diabetes,
2 which is--you know, one word defines it. Well, that gets
3 complicated too, doesn't it?

4 Okay. Now, does anybody else want to comment to
5 that? Yes?

6 MR. LARSON: Floyd Larson. Just the word
7 "associated" in that definition implies that a partial
8 diagnosis has been made by the time these devices are
9 brought into function, and I wonder whether in the broad
10 sense of pain, whether orofacial or otherwise, whether using
11 the word "associated" works for us here. I'm sorry to come
12 back to something that may have seemed like a fairly trivial
13 word in there, but it does, I think, imply a diagnosis.

14 DR. GENCO: If I could just make a comment to
15 that, and maybe Dr. Moses could expand. I think what Dr.
16 Moses is saying, there's a lot of things that cause pain,
17 like tumors. We're not dealing with that. We're dealing
18 with that pain that's associated with the temporomandibular
19 structures.

20 MR. LARSON: Okay. If we're willing to accept
21 that that means the diagnosis--

22 DR. GENCO: Well, that's what's on the floor.

23 MR. LARSON: If we accept the part that the
24 diagnosis has been made already and that it has been

1 narrowed down to associated pain, then these devices are
2 brought into function.

3 DR. GENCO: I think Dr. Bertrand would like to
4 expand that to more than temporomandibular. Maybe you can
5 discuss that.

6 DR. BERTRAND: I think it's impossible for anybody
7 to swallow just using their jaw muscles and tongue.

8 DR. GENCO: Do you have another term rather than
9 "temporomandibular" that encapsulates what you're trying to
10 say? Something to do with the trigeminal and associated--

11 DR. BERTRAND: How about trigeminal-mandibular
12 disorders? That tells you that you need to look at all the
13 musculature, any of the musculature involved in swallowing
14 feeds into the trigeminal system. So, I mean, it also
15 brings to mind that if you're going to make a diagnosis on
16 whether joint pathology imaged on a X-ray that may have been
17 there for 25 years, if you're going to make that as the
18 nidus of your diagnosis, you better rule out everything else
19 involved with what makes those bones rotate about that
20 joint. Can neck muscle, myofascial pain prevent somebody
21 from opening their jaws? Certainly. And if that isn't
22 included in your differential and it's involved in the basic
23 function of the jaw, then you're missing part of the ball
24 game, which is probably part of the reason we have all this

1 controversy right now.

2 In this extensive diagram that Dr. Moses has here,
3 a lot of the psychogenic influence in the United States
4 concerning TMD comes from particular universities, and some
5 of their epidemiological literature on what is and what
6 isn't TMD says that if there's a painful insertion of the
7 SCM, that is irrelevant to whatever TMD is.

8 I would say if you look at the neuroanatomic and
9 neuromotor activity and the neurosensory activity, that's a
10 dangerous statement to have made. I think you need to
11 include how neck muscles work when you talk about the jaw.

12 So the only way I could use a single term to
13 encompass all that would be trigeminal-mandibular.

14 DR. GENCO: Comments? Yes?

15 DR. HEFFEZ: Leslie Heffez. Maybe we can just
16 back into it so that we can--the devices that we're looking
17 at today are relating to--what? I'll put it as a question
18 as opposed to a statement, and I'll throw it to you. What
19 are the devices that we are considering today? They relate
20 to what?

21 DR. BERTRAND: How efficiently somebody can use
22 their head-neck structures in the process of speaking,
23 eating, singing.

24 DR. HEFFEZ: Because if we have such a global

1 definition, then we have to include a tremendous number of
2 devices that are not listed here.

3 DR. BERTRAND: Maybe we don't have to include many
4 devices at all. Maybe we have to be able to say
5 physiologically what's going wrong with this particular
6 patient, and not necessarily mask it with devices.
7 Sometimes maybe if we use devices, we don't understand
8 physiologically what's going on in the first place.

9 So the question is here what devices are we going
10 to use. If we are going to restrict it just to the joint
11 the dentist focused on, and the jaw muscles, then we will
12 use modalities and devices incorrectly. So I know--

13 DR. HEFFEZ: We're not in a position to say who is
14 going to use the devices correctly or incorrectly. The
15 devices exist, and I think the purpose is to classify them.
16 And you can't control one individual or another, how he's
17 going to use those devices.

18 DR. BERTRAND: That's true.

19 DR. HEFFEZ: So the purpose is the devices exist,
20 the conditions that encompass temporomandibular disorders
21 exist. We have to limit ourselves to some of those
22 conditions, because there are certain devices that are in
23 question. This is a living document. It doesn't mean that
24 tomorrow someone comes up with something else--

1 DR. BERTRAND: Sure.

2 DR. HEFFEZ: --and we have to consider another
3 device and, you know, redefine or relook at our title that
4 is being utilized to look at these devices. So I think we
5 have to be realistic and say that there are certain devices
6 that we are talking about today and they relate to the
7 masticatory--basically to the masticatory system. I think
8 if we can limit that definition to that discussion, then we
9 can move onward.

10 DR. GENCO: Yes, Dr. Moses?

11 DR. MOSES: Well, I think we're getting somewhere,
12 but I'd like to summarize what I'm hearing, though. We're
13 not denying--I don't hear anybody denying that there's a
14 psychogenic component, but what we're saying is that there's
15 definitely a physiologic component and that these devices
16 that we're talking about are restricted to the physiologic
17 way of dealing with these problems. They don't have
18 anything to do with the psychometric or the psychosocial
19 part. So once we get to that point, we're dealing with
20 physiology and not sociology, and that's important. That's
21 an important differentiation when you get there.

22 DR. GENCO: Are you agreeing with the trigeminal-
23 mandibular terminology?

24 DR. MOSES: I'm not disagreeing. I'm just saying

1 that, in other words, when we get into this discussion, we
2 should--maybe the word is just physiologic, period;
3 physiologic mandibular problems. That is, that's less
4 limiting than trigeminal. But what I'm--my point again is
5 that what we're saying is that we're dealing with these
6 problems physiologically and not psychosocially. These
7 devices do not relate to psychosocial treatment, and these
8 problems, these physiologic problems are very real.

9 I think we're both treating in the range of
10 physiology and not psychosocial.

11 DR. GENCO: Would you agree with that?

12 DR. BERTRAND: The question of pain came up and
13 what is pain. It is a physiologic disturbance, letting you
14 know something is wrong. So we're trying to focus on where
15 it is, whether it's the traditional definition of jaw
16 muscles and joints, or whether it's, as you said, Mr.
17 Larson, the associated structures, which preconceives a
18 diagnosis already.

19 I would just rely on what the physiologic function
20 of the system is in developing a diagnosis by which you're
21 going to somehow use various modes to make the diagnosis.

22 DR. HEFFEZ: A psychiatrist would argue that
23 there's a physiological basis to psychiatric disease.

24 DR. BERTRAND: Absolutely.

1 DR. HEFFEZ: But the point here is that devices--I
2 don't believe--and I may stand corrected by some panel
3 members, but devices for psychomotor testing are not
4 considered here. I mean, period. So I think if we--would
5 it be correct in saying that the term "temporomandibular
6 disorders" is an all-encompassing term, that it encompasses
7 many disorders in the differential diagnosis? Would that be
8 a fair statement?

9 [Dr. Bertrand nodding.]

10 DR. HEFFEZ: Could I have a nod from everybody
11 or...

12 DR. MOSES: Would you agree that when you said
13 temporomandibular disorders, in that context you're using
14 physiologic temporomandibular disorders a la a more specific
15 thing than that nebulous category TMD?

16 DR. HEFFEZ: Right.

17 DR. MOSES: So if we can acknowledge that, then
18 perhaps we can put just temporomandibular disorders in the
19 title, put an asterisk on the name, qualify it below, saying
20 that in this document we are considering devices
21 specifically related to the masticatory system and just deal
22 with these devices that we're talking about. We have to
23 limit our discussion or else we're not going to go anywhere.

24 DR. COOPER: Correct.

1 DR. GENCO: So the proposal now is go back to
2 temporomandibular disorders and associated orofacial pain
3 and dysfunction, but to define those temporomandibular
4 disorders how? Limit them to what? What is your
5 suggestion?

6 DR. HEFFEZ: My suggestion was just say
7 temporomandibular disorders and don't mention associated
8 pain and dysfunction because those are symptoms--or signs, I
9 mean. Those are signs. So you're just qualifying
10 temporomandibular disorders. If you just said
11 temporomandibular disorders and put an asterisk and say that
12 we are dealing with those devices related to the function of
13 the masticatory system, and I would accept adjectives.

14 DR. GENCO: What's a disorder? Is click a
15 disorder?

16 DR. HEFFEZ: No. A click is a sign. It may be a
17 sign of an internal derangement, which is a disorder.

18 DR. COOPER: If I may, we could define the
19 disorders as abnormalities in form or function of the parts
20 involved. That makes it structural. That means a click is
21 a disorder because a quiet joint is healthy, is normal, is
22 ideal, is wonderful, whatever. But it doesn't mean that--I
23 think that we have to define our role as opposed to the role
24 of others involved in the field. Our role is to classify

1 devices, or your role, to classify devices used. It's not
2 to fully--to find out this ill-defined structure. It's to
3 give some form to a presence. As you've said, there is
4 stuff that has to be used, that is used, has to be
5 classified, and we may not in this panel be able to solve
6 all the problems that an entire NIDR conference couldn't
7 solve in terms of what is it, what's it called, how does it
8 go, what's the best treatment and everything else.

9 So as Dr. Hefez said, let's try to keep our focus
10 doable. Let's deal with the quantity of an illness
11 condition that we can deal with. Then we will be able to
12 list what devices are used in its diagnosis or treatment,
13 and then finally sometime in the future how we classify
14 those. If we get too big--and that is how I started out--we
15 will accomplish nothing because we won't even be able to
16 define the terms. So I think the tighter we can keep it for
17 now, giving the panel the ability to expand its name, device
18 categories and everything else in the future, we have to
19 start from something.

20 DR. GENCO: I'm not taking a stand. I just want
21 to see if this is clear what's being presented. If we use
22 the temporomandibular disorder as the definition, the
23 devices are going to be categorized against what they can do
24 for temporomandibular disorder. That would seem to me to

1 contain a very large number of conditions, including--

2 DR. COOPER: That's enough conditions without us
3 getting into the entire--

4 DR. GENCO: Not really disease. There may be
5 anatomic abnormalities. If you add the associated pain or
6 dysfunction, then you've brought this into the realm of
7 something that needs something to be done, patients in pain,
8 so it's a disease or an illness, however you define it.

9 DR. COOPER: I'm comfortable with--

10 DR. GENCO: Or dysfunction. They can't open their
11 mouth, they can't chew. If you leave that phrase out, you
12 risk the chance of just having a series of devices to
13 measure anatomic variations. Nose size would be comparable,
14 you know, so there's a device that measures nose size. So
15 what? You know, if there's no pathology associated with it,
16 it's probably of less interest to know what the size of the
17 nose is.

18 So would you think we should add back that phrase
19 "and associated pain or dysfunction"?

20 DR. MOSES: I'm agreeing because what I--if you'll
21 look at that chart for a moment, everything that's under
22 masticatory is definitively dysfunctional, period.

23 DR. GENCO: I think your hierarchy starts out with
24 pain.

1 DR. MOSES: Absolutely.

2 DR. GENCO: The patient comes in with pain. Now,
3 why?

4 DR. MOSES: Okay. But every one of those
5 masticatory are dysfunctional.

6 DR. GENCO: Dr. Bertrand, are we comfortable going
7 back to--does the temporomandibular encompass--if we think
8 of it that way, all of those other associated structures
9 that could affect the temporomandibular--

10 DR. BERTRAND: If you kept in a broader scope, I
11 can live with temporomandibular disorders. I think implicit
12 in disorders is pain. If there is no pain, there isn't
13 really a disorder, despite what the signs anatomically say.

14 DR. GENCO: But the danger is that--we may
15 understand that, but maybe who we're communicating to may
16 not, because a disorder could be defined. It's a very vague
17 term, in my mind. I think if you nail it down to "and
18 associated pain and dysfunction," then it becomes very
19 clear.

20 DR. BERTRAND: That's acceptable.

21 DR. GENCO: Clearer. Yes?

22 DR. COOPER: If we eliminate the word "oral-
23 facial" and just have temporomandibular disorders and
24 associated pain or dysfunction," or "pain and dysfunction,"

1 then I think we've gotten as global as we have to be, and
2 whatever proves out to be associated in the future, whether
3 it's cervical sources, central nervous system sources, if
4 they ultimately affect this unit of the body, it's the
5 dentist who is going to be dealing with it, at least on a
6 diagnostic basis first order, and, therefore, it's the
7 Dental Panel that should be giving some guidance as to
8 classification.

9 So we start with TMD, we give it "and associated
10 pain or dysfunction"--and/or, it doesn't matter--then we
11 have given it enough of a global scope without giving
12 ourselves a Herculean task in terms of what we can ever
13 dream to accomplish today.

14 DR. GENCO: Is there more than oral-facial pain
15 that's associated with TMD disorders?

16 DR. COOPER: What we just heard is that there can
17 be cervical--

18 DR. GENCO: I think Dr. Bertrand said that can be
19 the source. Can it also be the organ that shows the
20 symptom?

21 DR. BERTRAND: You're getting into definitions of
22 site versus sources of pain. I don't think we want to get
23 into that. But--

24 DR. GENCO: But how do you feel about leaving

1 oral-facial pain--"oral-facial" out?

2 DR. BERTRAND: I kind of like the idea of TMD with
3 pain and dysfunction.

4 DR. GENCO: Okay, good.

5 Dr. Heffez? Others?

6 DR. HEFFEZ: I agree in the spirit of moving on.

7 [Laughter.]

8 DR. REKOW: I have a little question, though, and
9 it may not be a little question. Is it "and dysfunction" or
10 "or dysfunction"?

11 DR. GENCO: And/or. Do I hear "and/or"?

12 Okay. What I hear, then, in terms of sharpening
13 our definition, let me just put it out there.

14 "Temporomandibular disorders and associated pain and/or
15 dysfunction" is what we're talking about, and we've had
16 expansion on that which will be in the record for the
17 subsequent panel and also for industry who wants to then
18 direct their attention to devices which deal with the
19 condition that we just described.

20 Yes? Take the microphone, please, and please give
21 your name for the record.

22 DR. NEFF: My name is Peter Neff. The reason I am
23 saying that is because we started to do the TMD in 1982 when
24 we made the guidelines with the ADA. And it stuck there,

1 and it stayed there. And at that time we were limited in
2 our knowledge as we called it TMD. As we realized, and
3 since then, and expanded more on it, TMD is no longer
4 limited to TMD. We are not dealing with the temporal bone.
5 We are dealing actually with the cranial structures. As we
6 already know, we are dealing more structures within the
7 cranium.

8 So, really, calling it TMD --and that's why a lot
9 of people are still having a problem and argue about it--TMD
10 is a limited name. It should be really, if nothing else,
11 truly, as we call it anatomically, cranio-mandibular, or
12 CMD, if we want to call it that way. And we get away from
13 the question always what is TMD and what is TMD. It is
14 cranio-mandibular disorders that we are dealing with.

15 Thank you.

16 DR. GENCO: Thank you.

17 DR. RUNNER: This is Susan Runner from FDA. I
18 think one of the reasons we placed that term into our
19 categories here is because that is how we see the labeling
20 on the devices that we have cleared to this date, not
21 because we're making up a term but that's how the devices
22 came to us as labeled and indicated for use.

23 DR. NEFF: As I said, I realize where it came
24 from. It came from our, you know, again, limited

1 understanding in 1982. And what I'm saying today, it's
2 1997, and we have been wrestling with this term. In 1988
3 there was another conference held, and at that time nothing
4 even happened because they were to update the TMD to a
5 different direction, and nothing happened because of what
6 happened those two days.

7 And we say now in 1997 we have really grown both
8 in knowledge, understanding, and so on and so forth. Why
9 should we be stuck to that and not to expand it to the
10 proper term?

11 DR. RUNNER: The only thing I'm saying is that we
12 can't make up a term that's not in the labeling of the
13 devices. The devices that we have seen have that labeling.
14 If in the future devices come to us with a different
15 terminology, we certainly can deal with it at that time.
16 But at this time, the devices that we have seen are labeled
17 for TMD or TMJ disorders, or any number of variations.

18 MR. ULATOWSKI: Mr. Chairman?

19 DR. GENCO: Yes?

20 MR. ULATOWSKI: Just to concur with Dr. Runner,
21 we're trying to classify devices that are pre-1976 devices
22 that were labeled for specific indications for use and
23 functional purposes pre-1976. We're not trying to create
24 today any new characterizations. If someone wished to claim

1 cranio-mandibular disorders, whatever, in a 510(k), we'd
2 certainly entertain that, but only under the broad
3 classification--indication--only under the indications we've
4 seen in labeling to date are we really entertaining that.

5 DR. GENCO: Okay. Has this "temporomandibular
6 disorders and associated pain and/or dysfunction" sharpened
7 up the definition against which the devices can be judged?

8 [No response.]

9 DR. GENCO: Okay. Further discussion of that,
10 then? I mean, that is really the issue.

11 Okay. Do we need to talk about what is a device
12 and what isn't? Are we instructed by, Tim, that the
13 psychosocial scales are not devices? I think Dr. Jankelson
14 brought up software. Are those devices?

15 MR. ULATOWSKI: Mr. Chairman, I think software
16 that's used in the medical arena, dental arena, that's an
17 emerging area of policy, say, for FDA and I don't believe
18 we've come to a conclusion regarding what constitutes a
19 device or not a device in terms of software definitively.

20 For example, there have been discussions of
21 software being an exposition of information on the one hand
22 or software being an iterative program of some sort that
23 leads to diagnosis or treatment with or without the
24 inclusion of the physician or dentist. And those are

1 different situations, but I don't believe we've established
2 a situation as to what constitutes a device or not.

3 We'll explore that, since the issue has been
4 brought up, appropriately, and when we revise our list, we
5 will include it with a note as to how it's fallen out, if
6 it's a device or not a device.

7 DR. GENCO: Okay. Thank you.

8 Yes?

9 DR. COOPER: I'll yield to Bob Jankelson in a
10 moment. When we're talking about software, are we talking
11 about software that is independent of the devices that we
12 know we're going to be analyzing, like free-standing
13 software that's not part of any of these, or the software
14 that's part of these?

15 MR. ULATOWSKI: I consider the discussion to be
16 free-standing software for diagnostic or therapeutic
17 purposes, not part of the device, hardware or software in
18 the device, or firm-ware.

19 DR. GENCO: What I'd like to do is have any
20 further comments from the panel and guests on that issue,
21 that is, what is a device, and then we'll open it up to the
22 public for comments.

23 Any further comments either to definition or to
24 issue of what is a device? Reasonably clear? Yes?

1 DR. REKOW: Tim, did I hear you say that the
2 custom intraoral devices would not be called a device?

3 MR. ULATOWSKI: That's mentioned, yes.

4 DR. REKOW: Those are not devices.

5 DR. BETZ: Yes, that's correct.

6 MR. ULATOWSKI: Those being custom devices, they
7 are not subject to pre-market clearance, so we don't need to
8 classify them.

9 DR. BERTRAND: Mr. Chairman, one question.
10 Psychometric inventories are not being considered devices
11 for temporomandibular disorders and associated pain and
12 dysfunction?

13 DR. GENCO: Tim, would you give us some direction,
14 or Bob?

15 MR. ULATOWSKI: I guess I need to understand
16 precisely what the product is that you're describing, and
17 it's a labeling. And from that we can determine whether or
18 not the product may be a device and subject to
19 classification or it falls under an existing classification.
20 So if it's some psychological test of some sort, I proffer
21 those have not been considered in the past to be medical
22 devices per se.

23 DR. GENCO: There are some, for example--I am sure
24 this is what you're thinking of--patented D'Arrigoto scale,

1 83 questions in a certain order. That's not--I mean, that's
2 a questionnaire but it's more than just something that the
3 dentist dreams up or puts in his record. It's something you
4 buy, maybe?

5 DR. BERTRAND: Psychometric devices are very
6 powerful tools in the whole quandary of what TMD is and
7 diagnostic criteria right now. It's a little frightening to
8 think we're just focusing on some type of physical modality.
9 I know that's not the point of this panel but--

10 DR. GENCO: Not the importance, but is it
11 technically a device?

12 MR. ULATOWSKI: Well, we're using terms of art,
13 sociological terms, psychological terms of art, devices or
14 instruments, but it's not within the meaning of a medical
15 device under our law.

16 DR. GENCO: But the point has been made, I think,
17 that it's not the issue of importance but the issue of
18 definition of device and regulation by the FDA as such.
19 Now, maybe it falls between the cracks. That's an
20 interesting point. Non-regulated, possibly, or little
21 regulated.

22 Yes?

23 DR. COOPER: There are a host of psychometric
24 tests that have nothing to do with TMD. They're just

1 psychological profiling. But one that comes to mind is the
2 TMJ scale, which is a specific TMJ-oriented psychological
3 test that has an evaluating program to interpret the
4 results, and it gives a weighted scale of the amount of
5 psychological versus somatic component of a patient, at
6 least in their response to a questionnaire. So in that
7 regard, it is used as a differential diagnostic tool, maybe-
8 -I'm sure, not free-standing and, you know, not
9 independently diagnostic. But it is used as a diagnostic
10 aid specifically in TMD, and I don't know that it really
11 should not be included in some classification schema,
12 because the implications are that its outcome affects one's
13 decision to treat.

14 MR. ULATOWSKI: It may be a candidate. I suppose
15 what needs to be done afterwards is for you, Doctor, to
16 identify this particular product to us in turn so that we
17 can get information on it and then run it through the mill.

18 DR. GENCO: A definition of what is the device. I
19 think that was very useful for all of us.

20 DR. HEFFEZ: Just a point of clarification. So if
21 something is custom made for a patient it is not--can't be
22 considered as a device.

23 DR. GENCO: That's what I understand.

24 MR. ULATOWSKI: Mr. Chairman, it is a medical

1 device, but custom devices as defined are not subject to
2 pre-market clearance so, therefore, do not need to be
3 classified into one of three categories. It's off the table
4 for discussion purposes. That's not say it's not a device.

5 DR. HEFFEZ: Again, just for my own clarification,
6 for example, at one point in time we were discussing the
7 temporomandibular joint prostheses which were custom made
8 prostheses, yet--they were custom made, but--

9 DR. RUNNER: That was determined that the Cad/Cam
10 technology was not custom per se, even though it was patient
11 fitted, it was not--the variations and the forms that were
12 produced and the technology associated was not custom.
13 We're talking about splints and so forth, the materials of
14 which are regulated but the actual device itself and its
15 form is not regulated.

16 DR. GENCO: Okay. Thank you for that discussion.

17 Let's now open it up to the audience. Of course,
18 the audience can participate, in my mind, at any time but
19 just for some semblance of order. The two issues on the
20 floor--and you can bring up others, of course, but I'd like
21 you to think about the new--I'd like to think of this as a
22 sharpened definition of what devices are going to be
23 measured against, the definition of the condition and
24 definition of devices. I saw a hand back there. Yes?

1 Please come up to the microphone and identify yourself.

2 MR. JANKELSON: My name is Roland Jankelson with
3 Myo-Tronics.

4 I'm listening with some amazement at some of the
5 things that I'm hearing from FDA staff. In view of the fact
6 that what happened with respect to the 1994 panel was so
7 intricately involved with the differences between the group
8 that maintains the psychosocial aspect of this whole field
9 versus the clinicians that you're hearing today, who I think
10 are offering a very different perspective, to listen to what
11 I perceived to be an agenda from FDA staff to limit the
12 classification process to only those devices or defined
13 technologies defined by FDA staff as devices to those that
14 deal with the physical side of this situation is really
15 preposterous. It puts us right back to the agenda that we
16 lived through in 1994 that we have been trying to overcome,
17 and it simply should not be allowed by this panel.

18 DR. GENCO: Does anybody want to make a comment to
19 that?

20 MR. ULATOWSKI: Well, Mr. Chairman, I'm not quite
21 sure if the gentleman heard what I said. I'm not excluding
22 any medical devices from this discussion. I think all that
23 was said was we're uncertain whether certain products or
24 whatever are medical devices--and we're going to explore

1 that and have them on the table if they are medical devices.

2 That's simply all I said.

3 DR. GENCO: Yes?

4 DR. JANKELSON: Dr. Robert Jankelson, and deja-vu,
5 October 13, 1994. I believe, Doctor, you were also present
6 at that panel, which has since been discarded. And I will
7 quote you in your opening comment: "I do not consider
8 psychometric tests are medical devices."

9 Now, for the enlightenment of the rest of you,
10 many of the psychometric tests are software programs, and
11 there is an analysis that identifies and ascribes a certain
12 proportionment of the patient's condition to the physical
13 versus the psychosocial. That, ladies and gentlemen, is a
14 TMD, or whatever we want to call it, device.

15 Those of you in the FDA also know that device
16 manufacturers, when they make a software change that is
17 deemed in any way to affect safety and efficacy, we are
18 bound to submit a 510(k). So I ask you: Why, when device
19 manufacturers must submit 510(k)s for software changes that
20 are deemed to have safety and efficacy issues, would we
21 exclude a software program that ascribes a certain
22 diagnostic component to the physical versus the
23 psychosocial?

24 Thank you.

1 DR. GENCO: Thank you.

2 Any further comments?

3 MR. ULATOWSKI: Yes, Mr. Chairman.

4 DR. GENCO: Yes.

5 MR. ULATOWSKI: Well, I'm not excluding any
6 product or asking the panel to exclude any product at this
7 time. Where it's uncertain whether a product is a device,
8 it will be on the table for classification purposes, for
9 discussion purposes.

10 Inasmuch as software that's contained in the
11 device is the case, then certainly the discussion was
12 appropriate as to changes in the software. And as I
13 mentioned, other free-standing software, the agency's policy
14 on whether or not free-standing software, whatever it does,
15 whether it's a medical device, is still being formulated.
16 And I think once information comes to us on this software
17 that's being discussed or other instruments or whatever that
18 were discussed, once this comes to us so we can identify it,
19 we can understand it and we can evaluate under the
20 definition of a device whether it is a medical device and
21 subject to classification, it will be included. I'm not
22 excluding any product at this time.

23 When I spoke of psychological instruments, I was
24 speaking of Rast tests and within that context of

1 information, but I'm not excluding any product. Let me make
2 that perfectly clear.

3 DR. GENCO: Further comments from the panel or the
4 public with respect to the issue of the definition or what
5 is the device?

6 [No response.]

7 DR. GENCO: Well, I'd like to thank you all. I
8 think that was very useful, and clearly I'd like to
9 reiterate what Tim said. The discussions today are clearly
10 to reveal new areas, new devices, to make sure that we don't
11 exclude anything that might reasonably be considered a
12 device, and also to define anything that might be reasonably
13 considered in the context of this disease condition that
14 we're dealing with. And I think we've made progress. And
15 realize that between now and the next meeting or two, or
16 whatever, there is plenty of time for input from those who
17 have differing opinions or have further information, and I
18 think we welcome that.

19 Okay. Let's proceed now with the nitty-gritty.
20 Do you concur with the basic construct of this grouping of
21 devices as presented? Again, Tim and Bob and their staff
22 have put together--it's always an act of courage to do this--
23 -a straw man for us to look at, and that's this table. Are
24 there any comments about the items in the table with respect

1 to grouping, this universe of devices? Yes?

2 DR. ALTMAN: I guess I have a question of whoever
3 put this together why they grouped things that measure and
4 things that treat. Why were they thought to be classified
5 together or grouped together?

6 DR. GENCO: I'm sorry. What was your question?

7 DR. ALTMAN: Why devices that are used to measure
8 and those that are used to treat are being grouped together.

9 DR. BETZ: I did it basically for convenience. I
10 figured measuring things go with measuring things and
11 treatment things go with treatment things.

12 DR. ALTMAN: Well, maybe I'm confused, but are we
13 trying to--are we considering measuring and treatment as one
14 group? Are we looking at each one of these things
15 individually or as a group?

16 DR. RUNNER: I think the way that we're looking at
17 them is pertaining to the claims or the labels that are
18 placed on the devices and the universe of devices had in
19 particular diagnosis and/or treatment claims, and combined.
20 If you feel that it's worthwhile to discuss separating them,
21 I think that's worthy of discussion as well.

22 MR. ULATOWSKI: Mr. Chairman, it's simply a
23 display, if you will, of information that we gathered with
24 no connotation of subcategorization or any other implication

1 here, and as a first shot--as you said, the straw man.

2 DR. BETZ: So based upon the indications, claims
3 are being made that some of these devices are used for both
4 diagnosis and treatment; therefore, that device was--those
5 devices are all included in each of these generic--proposed
6 generic categories.

7 Are you suggesting we dissect them out, those
8 devices for diagnosis, aid in diagnosis, and those devices
9 for aid in therapy?

10 DR. ALTMAN: I'm not making any suggestion. It
11 was simply a question. But I think in earlier
12 conversations, the very first one, the electromyograph,
13 there was some discussion about the number one under that
14 being something to measure, the second being more of a
15 treatment.

16 DR. MOSES: In fact, I think I made that point
17 this morning, but I am suggesting that under
18 electromyographic devices that that be electromyographic
19 devices for measurement, number one; and number two would be
20 electromyographic devices to aid in biofeedback/muscle
21 reeducation as treatment, that there be two separate
22 categories. I am suggesting and I had suggested, and I
23 bring that up to the table.

24 There's a heterogeneity. I think to be evaluated

1 together would be counterproductive, that they should be
2 evaluated separately.

3 DR. REKOW: I, in philosophy, agree with that, but
4 from a practical perspective, if I'm a dentist and I buy an
5 EMG, how are you going to know how I'm going to use it?

6 DR. MOSES: There are different devices. The
7 treatment devices don't give measurement in electro--in
8 microvolts of electrical activity. They're usually going to
9 be with an audio signal, and you'll hear the biofeedback
10 signal, either high or low or high frequency or low
11 frequency, to tell you whether the muscles are relaxing more
12 than they were previously in contrast to a measurement
13 device, which will say that that muscle at rest is
14 generating 4 microvolts on the left and 3 on the right, say.

15 DR. REKOW: Is it now likely that in the near
16 future one device will be able to do both? I'm asking.

17 DR. MOSES: It's not likely, and my opinion, to do
18 biofeedback, I would spend the money to get that higher
19 quality device when I can get a device for a fraction of the
20 amount that will do the audio feedback. And the evaluation
21 of the two devices is different for different purposes. I
22 think it's much more scientifically sound to do the separate
23 evaluation.

24 DR. REKOW: Thank you.

1 DR. GENCO: Yes?

2 DR. COOPER: I think that also goes to what you
3 had said before, which was that a device can be used by a
4 person who owns that device in multiple ways. It has to do
5 with the manufacturer designates as the use of the device.
6 And, again, if our role is eventually going to be to
7 classify these and set up criteria for their evaluation,
8 then by separating them we give the manufacturer less of a
9 task if that instrument is meant to be used as a home
10 temperature, you know, measuring biofeedback device in terms
11 of its safety, efficacy, versus one that's supposed to be
12 used by a doctor in an office to aid in diagnosis.

13 So I think my suggestion is we keep the general
14 category and then specify within it, in the appropriate
15 places, where there is a potential dual function of the same
16 named instrument, but really different instrument, that it
17 can be EMG instruments for diagnosis, that would be one
18 line, and EMG instruments for therapy; and the same thing
19 may go into many other things that will come up. We'll give
20 it a subdivision. Rather than having EMG appear as two
21 separate complete boxes in two separate places on a larger
22 chart, just designate two separate--and then an instrument
23 manufacturer or device manufacturer would say I want to
24 qualify it as an EMG for the purpose of one or two.

1 DR. GENCO: Dr. Gonzalez, do you agree with that?
2 You had some discussion this morning about--these are all
3 surface electrode devices--about the needle electrode. You
4 had a third category here.

5 DR. GONZALEZ: Without getting into efficacy and
6 safety and just looking at it from the standpoint of
7 classification, that would be another classification that is
8 used very differently from what surface electrodes can be
9 used for, so that I think that needle electrodes, of course,
10 because of the invasiveness and because of the pain
11 associated with it, is oftentimes shied away. But because
12 of the kinds of diagnoses that you're looking for, the
13 needle electrode is far more accurate for a number of
14 different diagnoses than what you would ever use a surface
15 electrode for. In fact, you would never use a surface
16 electrode for a large number of diagnoses.

17 Again, that's not really the discussion here.
18 It's really classification. But I do think that since
19 needle electrodes can be used for the same purpose, that is
20 to say, could be used for temporomandibular disorders, it
21 may be that classification that utilizes or puts into it the
22 fact that needle electrodes are different, separate--because
23 of the risks, because of the infections, and because of
24 other aspects of doing needle electrodes, it may be

1 worthwhile categorizing that separately such that surface
2 electrodes, because they are far safer--again, not
3 commenting on efficacy or the utility of this, because there
4 are different statements regarding that, and I think we're
5 going to get to that in a future meeting.

6 But I think it would be useful to definitely
7 separate out, as brought up earlier, the fact that there's a
8 gamut of different uses for the two, and that surface
9 electrodes are generally used for greater different purposes
10 than what needle electrodes are used for, that is to say,
11 the needle electrodes are diagnostic for different
12 disorders, different diseases, than what the surface
13 electrode would be used for. Therefore, I would separate
14 them out because a needle electrode could also be used for
15 the same purpose and, therefore, would be in this
16 categorization that's being used of temporomandibular
17 disorders.

18 Both the surface electrode and the needle
19 electrode could be used--theoretically, the needle electrode
20 could be used for biofeedback. I think it's rarely used. I
21 don't think anybody would want to use it for that. But,
22 again, I think that because of that--and I don't think
23 anyone is using it for that purpose--I would not break
24 biofeedback into two categories, unlike the measurement of

1 electrical activity. I think I would shy away from making a
2 separate surface and needle electrode for biofeedback. I
3 would stick with the surface.

4 DR. GENCO: So, just to summarize, what I think
5 I've heard is the generic group is electromyographic
6 devices, two main categories, one for measuring electrical
7 potential used in the diagnosis, and that could be
8 subdivided into two categories, surface and needle; and
9 then, two, the second division is for biofeedback.

10 DR. GONZALEZ: Yes.

11 DR. GENCO: Is everybody happy with that?

12 So there's no question that this is a generic
13 category, electromyographic devices, but it has
14 subdivisions. It's heterogeneous. Okay.

15 Okay. Let's go on to the next one, unless there's
16 comments from the public about that issue.

17 Okay. Sonography devices, to measure and
18 graphically display or represent sounds made by the TMJ
19 components. Is this a generic category?

20 MR. ULATOWSKI: I think, Mr. Chairman, as we look
21 at each category, electromyographic devices, for example,
22 perhaps--so we don't have to keep coming back around and
23 around and around as we approach each question--it might be
24 helpful to run through the questions for each group so that

1 we understand the existing status of electromyographic
2 devices, classification status, and once we're all done with
3 that category, we can then move on and look at the next
4 section comprehensively, the sonography devices, for
5 example.

6 DR. GENCO: Okay.

7 MR. ULATOWSKI: Because you asked--your question
8 pertained to really Question 3, 4, and 5.

9 DR. GENCO: Okay. So we'll go to Question 3. No.
10 2 is really relevant only for the total classification. Is
11 that true?

12 DR. BETZ: Yes.

13 DR. GENCO: In other words, your Question 2 means
14 are there any other generic groups?

15 DR. BETZ: Yes.

16 DR. GENCO: And we can come back to that at the
17 end.

18 MR. ULATOWSKI: Right.

19 DR. BETZ: May I add something else? There is a
20 CFR listing for powered electric biofeedback equipment.

21 MR. ULATOWSKI: Well, that's what we're getting to
22 now, Bob.

23 DR. BETZ: Oh, okay.

24 DR. GENCO: All right. So your Question 3: For

1 the group that we just discussed, electromyographic devices,
2 what are the labeled indications, intended uses, which
3 related to TMD and associated pain/dysfunction? You've
4 presented two of them: to measure masticatory muscle
5 activity, so that's diagnostic--or am I adding a concept
6 that's not necessary to that? Just measure activity.
7 That's the intended use.

8 DR. COOPER: That's just what I was going to ask.
9 Do we have to sign on to all of the descriptors in the
10 right-hand column, or is it sufficient if we generalize at
11 this point?

12 DR. GENCO: That's what we're discussing. What
13 should those current indications--but we're going to have to
14 be instructed by the FDA because they've looked at the
15 intended use that the manufacturers have suggested, and some
16 of the manufacturers are here, too. We're going to be
17 instructed by them.

18 We're not making any decision or comment about
19 safety or efficacy, only about what is the intended use out
20 there in the field, as I understand this.

21 MR. ULATOWSKI: Mr. Chairman, yes, what's the
22 labeling described for these products currently.

23 DR. GENCO: Okay. Label indications for use.

24 DR. COOPER: May I go on? Then the example that's

1 used in parentheses is only an example--to quantify the
2 amount of tension in muscles of mastication? I have used
3 EMG for many, many years. I don't think that I measure
4 tension in muscles. I measure electrical activity in
5 muscles. That has to be incorrect.

6 DR. GENCO: So you would suggest leaving out that
7 phrase, "to quantify the amount of tension"?

8 DR. COOPER: I would say to measure masticatory
9 electrical activity, muscle electrical activity. That's
10 what EMG does. I mean, we can become more detailed, but I
11 think that the manufacturers themselves will be more
12 detailed.

13 DR. GENCO: We're trying to second-guess what's on
14 the label. You've already seen what's on the label.

15 DR. RUNNER: The descriptions here are a
16 compilation of the claims that have been on the labels. We
17 have seen the claim for tension as well, which is why it was
18 included.

19 DR. GENCO: So you want the panel's comments on
20 those labels? Okay. So your comment--they're giving us
21 what's on the label. Your comment is relative to what's on
22 the label. And in the submissions, then, from the companies
23 in the future, they will have been instructed by how the
24 panel feels with respect to that particular labeling. Is

1 that what we're doing?

2 MR. ULATOWSKI: That's fine.

3 DR. GENCO: Okay. Good. Any other comments about
4 the electromyographic devices? The second one is to aid in
5 biofeedback/muscle reeducation. You took this from the
6 labeling. What's the panel's reaction to that, and then
7 we'll get to the public.

8 MR. ULATOWSKI: Mr. Chairman, in regard to those
9 statements, when we get to the classification panel meeting,
10 we're going to be--the panel will be faced with a category,
11 a generic type of device in front of them, and a description
12 of the device for classification purposes. So in this
13 discussion of what's in labeling, one of the components of
14 that discussion is trying to get to a description of the
15 product that's subject to classification. So that's why we
16 look at the labeling and see what people say about it and
17 what the list includes.

18 DR. GENCO: Okay. So we had some reaction to
19 number one, measure masticatory muscle--electrical activity
20 is what Dr. Cooper would suggest rather--and leave out the
21 quantification of muscle tension.

22 DR. COOPER: I just fear that we try to do
23 something that's very specific, and it's not all inclusive,
24 and it may--you know, it may disenfranchise somebody else

1 who has a very legitimate purpose which is a variant of
2 measuring activity, but it's not specifically tension. So I
3 think if we're being generic at this point, let's be generic
4 in terms of usage also, at least at today's level.

5 MR. ULATOWSKI: Right. The ultimate description
6 ideally would be generous enough to allow a number of
7 devices to fall into that group. Typically that's the way
8 it's listed.

9 DR. GENCO: Okay. The next one, to aid in
10 biofeedback and muscle reeducation. Any comments with
11 respect to that?

12 DR. COOPER: I'm sorry to be dominant. I don't
13 know that reeducation is the general enough term. Maybe
14 it's muscle relaxation. That's what biofeedback is meant to
15 do: You train yourself to relax your muscles. I don't know
16 if "reeducation" is a scientific term.

17 DR. GENCO: Further comments? Yes?

18 DR. BETZ: Again, this comes directly from
19 510(k)s.

20 DR. GENCO: Yes, I guess--what are we doing?
21 You're giving us what the companies have said, and we're
22 reacting to it. And it's like advance notice that when the
23 companies come back in, this is the way the panel feels
24 about certain terms used in the labeling.

1 DR. BETZ: Yes. This whole column basically is
2 the distillation of what has come from 510(k)s.

3 DR. GENCO: Exactly. And Dr. Cooper and others
4 are going to react to that and say, wait a minute, I don't
5 exactly agree with that term "reeducation." Is that going
6 to be useful to you and to the industry?

7 DR. RUNNER: I think it will be useful to have the
8 most general term indication for use so that we can fit
9 things under it.

10 DR. GENCO: Okay.

11 MR. ULATOWSKI: Mr. Chairman, to reiterate what
12 Dr. Runner just said, we have gone through the labeling to
13 identify indications for use that get us into the product,
14 into the ballpark of the claim we have just--the use we have
15 just tried to describe up top. In the classification
16 regulation, ultimately we are going to have to have a
17 product description. So we don't need to argue the uses per
18 se, but as we transform this to a description of the
19 product, any comment or input one may have on
20 generalizations of this product under these indications
21 would be very helpful.

22 DR. GENCO: Okay. From the indication, you would
23 like us to say, well, a generic--or a generalized--

24 MR. ULATOWSKI: An electromyographic device is

1 intended to...what?

2 DR. GENCO: And then the companies can make more
3 specific claims or labeling.

4 MR. ULATOWSKI: Right. May have in the past or in
5 the future.

6 DR. GENCO: Okay, I'm clear. I didn't understand.

7 MR. ULATOWSKI: Related to that intended use.

8 DR. GENCO: Dr. Cooper, would that change anything
9 that you've said so far?

10 DR. COOPER: No, I'm going for the more generic
11 statement to use.

12 DR. GENCO: Thank you.

13 Any further comments about electromyographic
14 devices and this--from the labeling and indications for use
15 which might describe the device?

16 DR. GONZALEZ: One comment. As just another
17 descriptor here, to aid in biofeedback in order to decrease
18 muscle activity? I heard the term "relaxation" as opposed
19 to "reeducation." I agree with that. "Reeducation" I don't
20 think is a good term. "Relaxation" I think is a good term,
21 but I think also "decreased muscle activity" is more
22 descriptive of what really is happening without any
23 implications of what it's doing in terms of the end result
24 of the patient, and relaxation implies that something good

1 has happened--hopefully, it has, but I think decreased
2 muscle activity is just more accurate.

3 DR. GENCO: Dr. Cooper, are you in agreement with
4 that?

5 DR. COOPER: Yes.

6 DR. GENCO: Any further comments to that? Dr.
7 Heffez--

8 DR. COOPER: It's to aid through biofeedback, not
9 to aid in biofeedback; right? To aid through biofeedback
10 in--

11 MR. ULATOWSKI: Through biofeedback, yes.

12 DR. HEFFEZ: What is the definition of
13 biofeedback?

14 DR. BETZ: I think the definition of biofeedback
15 indicates that there's going to be muscle relaxation. So if
16 you just state it to aid in biofeedback, that would be all
17 encompassing.

18 DR. GENCO: Does it also reduce blood pressure?
19 I'm just asking. Does it do other than reduce muscle--relax
20 muscles?

21 DR. HEFFEZ: Yes, it can, but--it can be used for
22 that also.

23 DR. GENCO: So you think the more general term is
24 to aid biofeedback, whatever it does.

1 DR. HEFFEZ: I think it's just a generic term.

2 DR. GONZALEZ: Well, biofeedback is a
3 physiological term, which means a closed loop with afferent
4 and efferent connections occurring in biological,
5 physiological conditions, and that's the definition. I
6 think in the way it's being used, that's correct. I would
7 favor keeping that term biofeedback because that's what it's
8 doing.

9 DR. GENCO: Okay. Yes?

10 DR. MOSES: There are biofeedbacks that do blood
11 pressure. There are biofeedbacks that train galvanic skin
12 response. This is very specifically EMG, so I think you
13 have to keep muscle in there. Muscle activity. This is a
14 very specific--this is a very specific biofeedback tool.
15 Perhaps other biofeedback devices have to be included, but
16 this indication is specifically electromyographic.

17 DR. GENCO: So you're arguing to put back in the
18 phrase--

19 DR. MOSES: Muscle--lower muscle activity.

20 DR. GENCO: Reduce muscle activity. So that's
21 more relevant to the particular dental use, then.

22 DR. MOSES: Particularly relevant to the
23 electromyographic use, which is what they're testing here,
24 not the blood pressure or the galvanic skin response, which

1 are other biofeedback instruments.

2 DR. GENCO: Okay. Yes?

3 DR. BETZ: Would it be helpful to read back the
4 definition under 882.5050, biofeedback device?

5 DR. GENCO: Yes, please do.

6 DR. BETZ: A biofeedback device is an instrument
7 that provides a visual or auditory signal corresponding to
8 the status of one or more of a patient's physiological
9 parameters such as brain alpha wave activity, muscle
10 activity, skin temperature, et cetera, so that the patient
11 can control voluntarily these physiological parameters,
12 classification 2 performance standards.

13 DR. GENCO: Are there devices other than
14 electromyographic devices that are used or that have been
15 classified or are used for TMD, other biofeedback devices
16 other than the electromyographic? In other words, do we
17 need a category of biofeedback?

18 DR. MOSES: That's the point. We probably do.

19 DR. GENCO: Do we?

20 DR. MOSES: Is that what you think? Cut it from
21 electromyographic and just have electromyographic for
22 measurement and biofeedback for everything else. You're
23 right.

24 DR. GENCO: So then you'd have a generic

1 classification of biofeedback, which could be various
2 devices, some electromyographic, some--what are the others?

3 DR. MOSES: So, in effect, he's eliminating it
4 from the category electromyographic devices, and he's
5 putting it into a separate category, biofeedback devices.
6 So in that case, all electromyographic devices would be
7 purely measurement, not biofeedback. That makes sense.

8 MR. ULATOWSKI: Mr. Chairman, I think Dr. Betz
9 jumped the gun a little bit here in that once we got to a
10 generic description within the dental arena, then the next
11 question got us into the area of, okay, now that we have
12 something described here and its use condition, let's take a
13 look at other classifications and their definitions, their
14 classifications, and comment upon whether this product falls
15 in there or whether it's unclassified, it's an unclassified
16 pre-1976 device. So he jumped the gun a little bit, but
17 that's the context of the next question as we go along, and
18 for every other category as we get to it.

19 DR. GENCO: So go back to the electromyographic
20 biofeedback device. You would leave it in this category as
21 subcategory 2 and--but its use or description would include
22 to aid through biofeedback in reducing muscle activity. Is
23 that where we are with that now? Is everybody happy with
24 that?

1 DR. COOPER: For the time being, subject to maybe
2 another classification later on of biofeedback devices
3 themselves, then it can refer to Section 1, No. 2.

4 DR. GENCO: Okay. Good. Now, with respect to
5 electromyographic devices, are there any comments from the
6 observers with respect to the subcategorization and the
7 indications for use? Yes, Dr. Jankelson first, and then--
8 why don't you come up to the microphone?

9 DR. JANKELSON: My question would be relative to
10 measure masticatory muscle activity. I'd first like to say,
11 Dr. Bertrand, I very much appreciate your profiling of the
12 pathogenesis. And I think we must have an understanding
13 that masticatory muscles includes the cervical mechanism.
14 One cannot swallow, breathe, speak, or masticate without
15 involvement of the cervical muscles, the suprahyoids, the
16 gastrics, infrahyoids, sternocleidomastoid, splenius
17 capitus, semispinalis capitus, trapezius. And so I think we
18 should have a very clear understanding, and I would insert
19 in parentheses "to measure masticatory muscle activity,
20 including cervical musculature" in this category.

21 Clinicians will tell you this has been an area of
22 contention. Despite all the logic behind the foregoing
23 statement, it has been a contention in standard of care,
24 insurance coverage, and I think that it behooves this panel

1 to very clearly make that distinction so that during the
2 review process there is no confusion.

3 Thank you.

4 DR. GENCO: Dr. Jankelson, before you go,
5 masticatory and associated, does that cover it? You
6 specifically said cervical. Are there other--

7 DR. JANKELSON: I would not--

8 DR. GENCO: You said trapezius, which I don't know
9 if that's cervical muscle or not. I don't think it is but--

10 DR. JANKELSON: Well, when you bite a carrot and
11 you incise the carrot and you pull back on the bolus to
12 incise, you utilize the trapezius.

13 DR. GENCO: Is that cervical? I'm just--it's
14 terminology.

15 DR. JANKELSON: Yes. I would put including--
16 that's reasonable. Associated is acceptable. Yes, thank
17 you.

18 DR. REKOW: Why don't you just not say
19 masticatory? Just say muscles.

20 DR. GENCO: In the most generic, and that means
21 you wouldn't be measuring the gastric nemius, of course, for
22 TMD. Maybe I shouldn't say that. Some people will run and
23 chew at the same time.

24 [Laughter.]

1 DR. GENCO: I've tried it.

2 Okay. What's the panel's feeling? The suggestion
3 is--we're getting more and more general. The suggestion is
4 to measure masticatory and associated muscle electrical
5 activity or to leave out the masticatory at all, to measure
6 muscle electrical activity. Dr. Gonzalez?

7 DR. GONZALEZ: With the purpose being to
8 categorize as precisely as possible, I think that defining
9 it, limiting the definition to the masticatory and
10 associated muscles would be more appropriate than just
11 leaving out masticatory muscles altogether and just saying
12 muscles. It's more of a sense of trying to be specific
13 rather than a turf, if you will, type discussion. So it's
14 just really a bias right now, but I think that--it just
15 seems to me more accurate and more defining, and I think it
16 says what--it would not limit individuals into doing the
17 muscles that are necessary to try to make the appropriate
18 diagnosis.

19 DR. GENCO: Further comments? Are you happy with
20 that?

21 DR. REKOW: Yes.

22 DR. GENCO: Okay. Thank you. So the suggestion
23 here is that under the current indication for
24 electromyographic device to measure masticatory and

1 associated muscle electrical activity. Further comments?

2 [No response.]

3 DR. GENCO: Okay. Let's proceed now to this group
4 of questions, 4, 5, and 6. We're going to need some help
5 here, either Dr. Betz or Tim. Where are we with these
6 electromyographic devices used either for measuring
7 electrical muscle activity or biofeedback? Are they all
8 pre-1976?

9 DR. RUNNER: Yes.

10 MR. ULATOWSKI: Well, Bob, we can run through
11 that. In terms of the 510(k)s, for example, that were
12 examined in which you discovered these indications for use,
13 these intended uses, what was the status of those 510(k)s in
14 terms of their classification as identified by FDA in the
15 510(k)s? Unclassified or what?

16 DR. RUNNER: In reviewing the 510(k)s, they were
17 all suggested to be unclassified for this use, and claiming
18 equivalence to a pre-1976 device.

19 DR. GENCO: Okay. Is that clear to the panel?
20 They're unclassified.

21 DR. BETZ: Or equivalent to something that was
22 unclassified.

23 DR. GENCO: Or equivalent to something that was
24 unclassified, legally on the market before 1976.

1 MR. ULATOWSKI: By that we have said that there
2 was a pre-1976 electromyographic device for this use.

3 DR. GENCO: Right.

4 MR. ULATOWSKI: But was unclassified and unrelated
5 to any other classification per our determination.

6 DR. GENCO: Okay, and that's only for the
7 temporomandibular use. It's obviously not for the medical
8 use.

9 MR. ULATOWSKI: Well, there was Bob--Dr. Betz did
10 mention another classification. I think we need to flesh
11 that out for purposes of the record.

12 DR. RUNNER: Would you like me to read that?

13 DR. GENCO: Please.

14 DR. RUNNER: The other classification, as
15 classified under 890.1375, is a physical medicine device, a
16 diagnostic electromyograph. A diagnostic electromyograph is
17 a device intended for medical purposes such as to monitor
18 and display the bioelectric signals produced by muscles, to
19 stimulate peripheral nerves, and to monitor and display the
20 electrical activity produced by nerves for the diagnosis and
21 prognosis of neuromuscular disease. Classification is class
22 II.

23 DR. GENCO: Okay. Thank you.

24 What would you like from us now with respect to

1 that?

2 MR. ULATOWSKI: In our historical evaluation, what
3 that tells me is that when a 510(k) came in, the applicant
4 identified--perhaps might have identified one of the
5 physical medicine devices that were classified, perhaps, or
6 another pre-1976 device with the same indications and the
7 FDA made a determination per its classification process per
8 510(k)s, as I mentioned early on in the day, through that
9 classification process determined if it compared to the
10 physical medicine device, we in all likelihood determined
11 the product to be not equivalent or a separate product
12 altogether, as classified as a separate product altogether.

S7

13

14 The fact of the matter is that the record shows
15 that we did consider it to be unclassified for these
16 indications for use.

17 DR. BETZ: That's my understanding, yes.

18 MR. ULATOWSKI: Therefore, a candidate for
19 classification by the panel at the next meeting, subsequent
20 meeting--not lumped into the other classification,
21 historically.

22 DR. GENCO: Okay. Is the panel comfortable with
23 that? Yes?

24 DR. HEFFEZ: Just a question. Is it possible that

1 eventually a different classification can come out from the
2 panel and be in conflict with the classification that has
3 been defined previously for physical rehabilitation?

4 MR. ULATOWSKI: That's possible, certainly. I'm
5 not ruling that out. It could be well the case based on the
6 data presented to the panel and the public comment and all
7 that. You could decide--that was class II, Bob, that
8 physical medicine device?

9 DR. RUNNER: Yes.

10 MR. ULATOWSKI: You could find it I, II, or III.

11 DR. HEFFEZ: And as a result, is there a joint
12 meeting between--or these devices are always evaluated by
13 their strict intended use?

14 MR. ULATOWSKI: No, in the past we have had
15 individual panel members who have participated in
16 discussions of similar devices for other panels. We have a
17 neurology panel participant, for example, today to enter
18 into discussions. So we could reflect upon that other
19 classification, its risks and benefits, and compare it to
20 the condition here and make a decision.

21 DR. HEFFEZ: Thank you.

22 DR. GENCO: Further comments, questions about this
23 issue?

24 [No response.]

1 DR. GENCO: Okay. Can we go to No. 7, then? Any
2 questions that the panel thinks should be addressed prior to
3 classification of the electromyographic devices?

4 DR. MOSES: Yes, I have an issue. I'm very
5 sensitive to what went on in 1994, again, and so what I
6 wanted to bring to the table for discussion is the fact that
7 I've been getting a quarterly bulletin from the FDA for
8 about 25 years now, and now I see that the similar form for
9 reporting--every one of those had an adverse reaction report
10 attached to it.

11 It's my impression that if I see an adverse
12 reaction to anything, it's my responsibility to report it.
13 And I see now that the MedWatch form for adverse reaction
14 reporting is now on the Web site. So I feel that this ought
15 to be relevant and that we're talking about devices that are
16 pre-market--in other words, basically were in existence,
17 from what I'm hearing from the Jankelsons and from
18 Bioreserach is that these are appliances that have basically
19 been around for 20 years.

20 So I would like the FDA to make available to the
21 panel the results of any adverse reaction reports on these
22 appliances so that it's not just a mystery. They say, well,
23 I have what I think might be no adverse reaction reports,
24 because I think that would significantly impact the panel in

1 making a decision. If there are no adverse reaction reports
2 for a period of 20 years, I think it would be very hard to
3 find that appliance, if it's not invasive, to be a class
4 III, and that should impact on the decision.

5 And so I would like the adverse reaction reports
6 on any of the products mentioned here to be made available
7 to the panel at the time of classification. Is that a--
8 would you--

9 MR. ULATOWSKI: That's entirely appropriate, and I
10 would apply that to all the groups. I think that's an
11 excellent suggestion.

12 DR. MOSES: Will you make that available?

13 MR. ULATOWSKI: Yes.

14 DR. MOSES: Thank you.

15 DR. GENCO: Further comments about what you'd like
16 to see before making a recommendation for classification of
17 the two types of electromyographic devices--actually, the
18 three types?

19 Any specific comments about the electromyographic
20 devices to measure masticatory and associated muscle
21 electric activity? What kind of evidence would the panel
22 like to see? Yes?

23 DR. MOSES: I'd like to see the appropriate
24 literature reports.

1 DR. GENCO: More specifically, what kind--

2 DR. MOSES: On the clinical use of these
3 modalities. It would impact me more if I saw that these
4 things were reported in 200 papers than if they're reported
5 in two papers.

6 DR. GENCO: It would seem to me that it's possible
7 to discuss two types of use of a diagnostic aid in general.
8 One is predictive. You make a measurement, and that
9 measurement says that within a year, within six months, a
10 disease is going to occur. So it's predictive, early
11 diagnostic. And the other is diagnosis of a condition that
12 is occurring at the present time, in the diagnosis of. So
13 would you like to see--what would you like to see relative
14 to that, or isn't that a relevant question with respect to
15 these devices?

16 DR. MOSES: It's not relevant to mine. I want to
17 know how does that relate to these studies relative to
18 safety and efficacy in that if these things are safe--in
19 other words, they're more likely to be approved by an
20 institutional review board for studies if they're safe, and
21 if there's 200 papers on the subject or 165, that's going to
22 certainly reflect that an institutional review board felt
23 that they were safer than if there's two papers.

24 Again, we're not dealing with equipment that just

1 got off the counter, that's just come off the racks. This
2 is stuff that's been around.

3 DR. GENCO: You're addressing safety. I guess I
4 was asking the question about efficacy.

5 DR. MOSES: Safety and efficacy, yes.

6 DR. GENCO: What kind of evidence would you all
7 like to see with respect to efficacy? Yes?

8 DR. HEFFEZ: I was just going to say, it's not the
9 number of papers that defines whether an instrument has
10 indications. It's the quality. But I do believe there's a
11 great deal of body of evidence regarding electromyography in
12 general, and I just wanted to make that statement.

13 DR. GENCO: So you'd like to see the general as
14 well as the specific to TMD.

15 DR. HEFFEZ: I see it as measuring masticatory
16 muscle electrical activity. In my point of view, it can
17 measure whether the muscle is in your head or is in your
18 leg. It's going to measure muscle electrical activity. So
19 I don't see the value of bringing out evidence, a body of
20 evidence, that it measures muscle activity in the head and
21 neck. It can do so in the leg.

22 DR. GENCO: Okay. What about relationship to this
23 associated oral-facial pain and dysfunction, the muscle
24 activity, electrical activity associated with oral-facial

1 pain and/or dysfunction?

2 DR. HEFFEZ: I think the biggest contention in the
3 profession is whether this electrical activity--I mean, it's
4 clear, to say it out loud, that there are groups of people
5 who feel that measuring electrical activity is just
6 measuring electrical activity and that you cannot use it as
7 a parameter for defining your care.

8 Now, there are others, obviously, who feel the
9 opposite, but that's not the question. The question is:
10 Does it measure electrical activity? And whether it's in
11 the neck or in the mouth or the leg, it measures electrical
12 activity.

13 DR. GENCO: So you're not so concerned about its
14 relationship to pain or associated dysfunction?

15 DR. HEFFEZ: No. It's an instrument that can
16 measure electrical activity, and people who have spasm in
17 their muscles or pain in their muscles, obviously electrical
18 activity will be higher. But it's--I mean, that would be
19 the same regardless of what part of the body that you deal
20 with.

21 DR. GENCO: Further comments about the kind of
22 evidence you'd like to see? Is this a question of
23 predictive versus aid in diagnosis of existing condition
24 relevant here? Would anyone like to see that kind of data?

1 In other words, if you have an alteration, will it predict
2 disease? Or if you have an alteration, will it aid in the
3 diagnosis of existing disease? Is that relevant here? Yes?

4 DR. COOPER: From my experience, I think the
5 latter not the former. I think that my experience with EMG
6 is that it's relative a person to that person and many times
7 more so than a person to another person. So your evaluation
8 of a person at the time you're making a diagnosis and how
9 that implements on diagnosis and treatment is more
10 appropriate than it would be as I'm going to examine this
11 patient as a routine scan type of thing to decide whether or
12 not they're predisposed to a problem for the future. I
13 don't think that really is apropos with EMG and TMD.

14 DR. GENCO: Okay. So the evidence that you'd like
15 to see would be that it measures muscle activity and that
16 relates somehow to current diagnosis.

17 DR. COOPER: Safety and efficacy in current
18 diagnosis.

19 DR. GENCO: In terms of efficacy. Safety is a
20 whole other issue.

21 DR. COOPER: Okay. Efficacy in terms of diagnosis
22 and treatment. That's the two things that we are
23 evaluating.

24 DR. GENCO: In terms of diagnosis--

1 DR. COOPER: I guess diagnosis. EMG is only
2 diagnostic at this point.

3 DR. GENCO: Okay. Does everybody agree? I think
4 that gives some direction to the kinds of data and if it's
5 out there, it's summary and it's interpretation, and we
6 could have a good discussion based upon seeing the actual
7 studies.

8 Dr. Bertrand, do you want to make any comments
9 about the kinds of data that you'd like to see?

10 DR. BERTRAND: Anything that can show predictive
11 value would be great, but I'm not sure we have that with EMG
12 data. I think if you can show a difference in EMG activity
13 baseline in an asymptomatic patient versus a symptomatic
14 patient, and then show the difference after, that would be
15 wonderful data. Does that exist? I think that's part of
16 what the debate is.

17 DR. GENCO: Well, that's why I bring it up.

18 Now, comments? Yes? Please, go up to the
19 microphone.

20 MR. JANKELSON: Roland Jankelson with Myo-Tronics.
21 Under the category of information that I think might be
22 helpful to the panel, I alluded earlier in my opening
23 statements about a letter that I had directed to Dr. Alpert
24 as well as to Secretary Shalala. It referred to earlier

1 activities of the FDA, specifically to solicit information
2 about harmed patients with respect to the various categories
3 of instrumentation manufactured by Myo-Tronics.

4 In my letter, I simply asked for a response as to
5 whether there was any such information, which, of course, we
6 believe to not be true--not to exist. The nature of that
7 information, some clarification as to how it was gathered.
8 I think if, in fact, any such information exists, it
9 certainly should be made available to the panel, but also to
10 Myo-Tronics, and we have asked for it in this letter, again
11 asked for it. As we suspect, it doesn't exist, but simply
12 the fact that the FDA made a concerted effort to dig it out
13 I think suggests something about--is relevant. If it
14 doesn't exist, I think that's relevant information for the
15 panel. If there is something that the FDA has that has not
16 been disclosed to us, I think that should also be disclosed
17 to the panel.

18 Thank you.

19 DR. GENCO: Thank you.

20 Dr. Tilley, did you want to make a comment?

21 DR. TILLEY: No.

22 DR. GENCO: Thank you. Okay, I think the next
23 issue is--

24 DR. REKOW: Can I say one more thing? One of the

1 things that frustrates me as a panel member when I review
2 literature--and it's not peculiar to this body of
3 literature; it's literature in general--is case reports are
4 interesting and valuable, but it's very hard to make
5 scientific decisions on case reports. And so the literature
6 that gets brought to the panel needs to be on studies that
7 are carefully controlled, have statistical analysis, and are
8 more than just patient one and patient two and patient
9 three. And that's a criticism in general of literature, not
10 of this specific body of literature.

11 DR. GENCO: So you're arguing for, as much as
12 possible, randomized controlled trials?

13 DR. REKOW: If that's possible, but certainly--

14 DR. GENCO: How are calculations done so they're
15 adequate size, all the principles of good quality clinical
16 trials.

17 DR. MOSES: I'm sorry, Doctor, but I take issue
18 with that in the field of temporomandibular disorders
19 because basically there's no general agreement on the
20 definition, there's no general agreement on who has the
21 disease and who doesn't, there's no general agreement on
22 what is normal and what is abnormal. And so to do a
23 controlled study for these variables, like the psychosocial
24 variables, it's virtually impossible. It's also virtually

1 impossible for a doctor to not know if he's adjusting the
2 occlusion in a study, and so to do this double-blind study
3 on some of these things becomes a physical impossibility as
4 well as technical.

5 And so a case study relative to my case, that
6 represents to me evidence, whereas what you're looking at in
7 a controlled study is inference. And I think that it's
8 stronger to relate as a clinician an evidentiary study than
9 it is an inferential study, in many cases, if it's the same
10 disease.

11 DR. REKOW: Then I would propose that at least the
12 studies be in sequential patients and all of them get
13 reported and the dropouts get reported for why they dropped
14 out. You know that there are many cases where you start
15 with 50 patients and you end up with the 25 that worked or
16 you chose 25. Not you, but you know that those--

17 DR. MOSES: I understand what you're saying. I
18 think those things--what I fear is that these kinds of
19 studies that you're looking for here are simply not
20 available. They simply haven't been done at the quality
21 that you're looking for. That's the point I'm making.

22 And so to ask for quality studies when there are
23 none is an unfair standard to put upon these manufacturers
24 to produce. That's my point.

1 MR. ULATOWSKI: Mr. Chairman, under the definition
2 of valid scientific evidence in Part 860 for classification,
3 there's a range of information that's eligible to be
4 presented, and it includes controlled or uncontrolled
5 studies or various types of other data. And it defines only
6 a few instances that data is really not valid scientific
7 evidence, random case reports, for example. So there is an
8 allowance for quite a range of information.

9 Of course, the quality of the information provided
10 gives you more or less better information that you can deal
11 with, but there is the opportunity to present, for the
12 people to present to you a range of information.

13 DR. GONZALEZ: I think that regarding literature,
14 rather than try to reinvent the wheel for each one of these
15 categories, it's true that there's not a lot of literature
16 in some of these areas, but in other areas there are. And
17 there have been groups of people, academies, associations,
18 who have gone through and have at least come up with a
19 statement saying there isn't sufficient evidence or have
20 made a statement about safety of some of these, even though
21 they may not necessarily be effective. And I'm referring to
22 the American Academy of Physical Medicine and
23 Rehabilitation, American Academy of Electrodiagnostic
24 Medicine, American Academy of Neurology with its physical

1 treatment of chronic pain, and a number of others, where
2 they've gone through the world's literature on this,
3 including case reports, and categorized all of the
4 literature all the way up to double-blind controlled
5 studies, and at least for some of these--at least three that
6 I see here, I know that those statements exist that are
7 fairly recent in the last couple of years.

8 So I think we should get at least that, the
9 Academy statements, where this work has already been done
10 for some of these areas, and then we can take off from that
11 point, accept or reject it.

12 DR. GENCO: So your suggestion is that the panel
13 also be given the summary statements for--not the TMD use
14 but the other medical uses of these devices for a context.

15 DR. GONZALEZ: Yes, and which also includes some
16 statements, I believe for TMJ as well.

17 DR. GENCO: Thank you.

18 Further comments about the type of evidence?

19 [No response.]

20 DR. GENCO: Okay. The FDA wants to know from us
21 with what priority should they pursue classification, and we
22 will talk about specifically the electromyographic devices.
23 Anybody want to start the discussion? Yes?

24 DR. MOSES: Are you looking at me?

1 DR. GENCO: I just thought you wanted to make a
2 comment.

3 DR. MOSES: I'll be happy to make a comment. I
4 think that the priority is not very high. I don't know that
5 we've seen--again, Tim, you could answer this question
6 better in terms of have there been adverse reaction reports
7 between 1994 and 1997, the significant numbers on this,
8 because if we're talking about devices that are, frankly, 20
9 years old in use already, I don't know that they're so
10 dangerous that they need an immediate classification, that
11 this is the highest priority item for the FDA.

12 MR. ULATOWSKI: I'm not familiar with the database
13 on the MDRs and other information right now. But your point
14 is well taken. It's something for the panel to consider in
15 view of your comment.

16 DR. GENCO: Further comments about priority?

17 [No response.]

18 DR. GENCO: Okay. Thank you.

19 Let's take a break. We've got a lot to do in the
20 next hour and a half or so. We've got to go through the
21 other devices because we have a schedule for tomorrow. So
22 get your thoughts together, have a cup of coffee, and meet
23 you back here in 10 minutes.

24 [Recess.]

1 DR. GENCO: Let's proceed now to the sonography
2 devices. Does anybody want to discuss whether that is a
3 generic category? Yes?

4 Excuse me. Actually, someone has to leave and has
5 requested that we talk about TENS next. So if there's no
6 objection, let's go to the TENS devices. Is that a generic
7 classification?

8 DR. COOPER: There are variations in that theme.
9 There are high-frequency TENS, low-frequency, and ultra-low-
10 frequency. I think we should differentiate. They have
11 different therapeutic purposes.

12 DR. GENCO: Similar to electromyographics, single
13 generic classification with 1, 2, 3 subcategories?

14 DR. COOPER: Right, I would think so.

15 DR. GENCO: And there's a rationale for each?

16 DR. COOPER: Right.

17 DR. GENCO: Could you give them again?

18 DR. COOPER: High-frequency TENS is used as a pain
19 suppressor; low-frequency and ultra-low-frequency are used
20 as stimulators for muscle relaxation. That is my
21 understanding, but we have a neurologist on board.

22 DR. GONZALEZ: It's more complex than that when
23 we're talking about pain. I can get off on Y dynamic
24 neurons and Y--you know, low-frequency with a very high

1 internal frequency is better, and central pain, where a
2 high-frequency TENS is probably better than low-frequency
3 with an internal high frequency, and the classification by
4 Clifford Wolf and other classifications. And I'm not sure
5 that ultimately the frequency that's being used--the
6 classification or categorizing the frequency as opposed to,
7 let's say, how the TENS unit is being used in terms of which
8 patient may benefit. So I think that the general
9 classification, if you did want to break it down into high
10 and low frequency, my question would be: Does that mean
11 that the machinery that's being asked to go through FDA for
12 categorization and approval will limit a machine like that?

13 And I even bring that up because when I was
14 hearing the discussion about the hierarchy regarding the
15 types of disorders, I started thinking about, for instance,
16 central pain, which is not listed on this very elegant
17 diagram, or phantom region or phantom limb or phantom
18 structure pain, which are not listed there either. And
19 those different diagnoses that are centrally mediated and
20 centrally generated conditions, depending on who you read,
21 the frequency is going to be different.

22 So I think a general--and I'm going right back to
23 agreeing with you, Dr. Cooper, that I think that having low
24 and high frequency is useful, because we think in that way;

1 but, in fact, a TENS unit, depending on, again, who you read
2 and who you believe, is much more complex. And the pundits
3 of, you know, low frequency--you know, tell you, no, that's
4 the Y dynamic neurons, and others will tell you that it's
5 the lateral, thalamic, ventral basal nuclei--you know, on
6 and on and on.

7 So basically what I'm saying, just to try to put
8 this aside, when the details come out, I'm not sure it's
9 going to be very clear. I think it's going to be, you know,
10 just really quite difficult to make heads or tails of it.
11 And I think knowing that in the background, you can still
12 categorize--and I'm coming right back to what you said, and
13 I'm agreeing with you; that you can come right back to high-
14 and low-frequency TENS, but let's just be aware that just as
15 in the categorization--the very first thing that we talked
16 about in that is how we're going to classify, what title are
17 we giving this. Well, you know, the titles, the names of
18 everything are changing so rapidly. On your list here, the
19 reflex sympathetic dystrophy that Dr. Moses put together,
20 you know, it's changed in the last three years to
21 sympathetically mediated pain, in the last year and a half
22 to complex regional pain disorder. And it's about to change
23 again.

24 So in the same way, if this categorization can

1 reflect that, that is to say, that we understand--if we can
2 put some sort of notation that we understand that it's much
3 more complex than that, but for the time being understand
4 that most people really who are giving therapy in terms of a
5 TENS unit think of high and low frequency, but there are low
6 frequency with an internalized high frequency, and all sorts
7 of variations to that, according to Clifford Wolf and others
8 that I've mentioned.

9 So I think it's technically useful right now to
10 say high and low frequency, but understanding that further
11 classification may become important in the future.

12 DR. COOPER: Can we then further--your addendum is
13 fine. It may have to have an asterisk, again. Can we
14 further generalize and say the TENS is used for pain
15 amelioration and/or muscle relaxation, and will it be then
16 the responsibility of a manufacturer of a device to then
17 specify, A, which type of TENS they're manufacturing, and,
18 B, what its intended use is? In other words, can we be
19 doubled in terms of the whole thing: A, the type of TENS,
20 and, B, its usage, and then permit within that box a
21 manufacturer then to submit an application for an
22 evaluation, classification based on that specific instrument
23 that's on the table? It's either a high or a low and it's
24 supposed to do this or that, and then the obligation on the

1 manufacturer is then to specify I can prove that it does
2 this or that?

3 DR. GONZALEZ: My understanding right now is TENS
4 is used for pain control and not for muscle relaxation.
5 Just the opposition, it produces muscle contraction. The
6 risk--and we'll talk about this in future meetings. The
7 risk, of course, is that frequencies can produce sustained
8 muscle contraction which can produce necrosis or at least
9 over-contraction, fatigue, and injury to muscles. So I
10 think that first of all I would say that the TENS unit in
11 this context should be for pain--specified as for pain
12 control, not for muscle relaxation, not for any other
13 purpose. Although TENS and electrical stimulation may have
14 other utilities, my understanding is that it would be
15 specifically for pain. Is that--

16 DR. COOPER: No. In TMD, not so. The reverse.
17 In TMD it's used more for muscle relaxation, as monitored by
18 EMG, lowers EMG activity. So for chronic pain, TENS high
19 frequency is used as pain relief.

20 DR. GONZALEZ: My comments are strictly for pain
21 control in terms of high and low frequency.

22 DR. COOPER: But in TMD, the other is the
23 dominant. So I would acknowledge that both are uses, maybe
24 not of the same machine, but both are uses. So we have to

1 list them both.

2 DR. GENCO: So are you comfortable, then, the
3 panel, with that subdivision into high and low frequency?
4 And then further comment with use, to treat by application
5 of electrical energy for muscle relaxation and pain control?

6 DR. COOPER: And/or pain control.

7 DR. GENCO: And/or. Further comments?

8 DR. HEFFEZ: I have a question for Dr. Gonzalez.
9 In the body of literature, what does it state about TENS as
10 far as muscle relaxation is concerned?

11 DR. GONZALEZ: This is getting into efficacy. If
12 we want to get into efficacy, I sure can. But I was a
13 facilitator on the American Academy of Neurology, the
14 physical treatments of chronic pain, and we came up with
15 some statements regarding TENS unit for chronic pain.

16 But I'm not sure it's relevant to the
17 temporomandibular. We had very specific types of pain that
18 we were addressing, and it did not address, to my knowledge,
19 temporomandibular--it would be my--it was specifically not
20 included, but it was one of those that would be included
21 later.

22 DR. HEFFEZ: For example, has TENS unit been used
23 for lower back pain with lower back muscle spasm?

24 DR. GONZALEZ: It has, yes.

1 DR. HEFFEZ: Okay. It is used for muscle
2 relaxation or pain modulation in those cases?

3 DR. GONZALEZ: We're looking at the outcome, not
4 in the physiological effects necessarily. Just the outcome
5 in terms of studies that were looking at outcome, how
6 patients did after.

7 DR. HEFFEZ: So, therefore, we're looking at just
8 pain modulation as an outcome.

9 DR. GONZALEZ: Yes.

10 DR. HEFFEZ: Because it's one thing, I think, to
11 separate out and say TMD is a separate sort of category and
12 we have to treat that differently, and then on the other
13 hand try to embrace TMD saying it's very close to other
14 pathological conditions. So we can't have it both ways.
15 There are muscles in the head, and there are muscles
16 somewhere else in the body.

17 I could maybe make the argument that if you reduce
18 pain, patients will indirectly have less muscle spasm or
19 less tension in their muscles, and, therefore, the
20 biofeedback or the EMG will indicate less muscle electrical
21 activity. It's very hard for me to detect whether it
22 actually is causing muscle relaxation or is just pain
23 modulation and indirectly giving me my effect on the
24 muscles.

1 It will go down to Question 7, which is
2 essentially provide me the scientific evidence--

3 DR. GENCO: Right, the kinds of evidence that
4 you'd like to see. I think we've gone into that.

5 Further comments then about the use statement?
6 Does anybody--is everybody happy with the TENS designation?
7 Dr. Gonzalez, you said the nomenclature is changing? Is
8 this the term that's being used?

9 DR. GONZALEZ: TENS?

10 DR. GENCO: Yes.

11 DR. GONZALEZ: Yes, transcutaneous electrical
12 nerve stimulation.

13 DR. GENCO: Okay, so we're happy with that, then.

14 Further comments about this as a generic
15 classification, two subcategories, high and low, and pain
16 and muscle relaxation, electrical stimulation for pain and
17 muscle relaxation.

18 Yes?

19 DR. TILLEY: Larry Tilley. I just have to wonder
20 if this isn't where iontophoretic therapy, iontophoretic
21 stimulation, micro current, high volt, things like that,
22 would not be classified in that section also.

23 DR. GENCO: Can anybody on the panel comment to
24 that? No? Okay. Dr. Tilley has brought up another group

1 of instruments that could be categorized in with the TENS.
2 And iontophoresis. So you're expanding this as a generic
3 group of any device that delivers electrical current to the
4 body. Yes?

5 DR. MOSES: Well, the category there says
6 stimulatory devices, things like the alpha stim. There's a
7 lot of them.

8 DR. GENCO: Does TENS include iontophoresis? I
9 guess that--so do we need another name for this generic
10 category?

11 DR. MOSES: The generic category it says there is
12 stimulatory devices on my sheet.

13 DR. GENCO: Okay. So the TENS is an example.

14 DR. MOSES: Is an example of a stimulatory device.

15 DR. GENCO: All right.

16 DR. MOSES: As is the alpha stim, as is
17 iontophoresis, as is high voltage.

18 DR. GENCO: Okay. I misread that. I'm sorry.

19 DR. COOPER: If we do that, which is fine, that
20 would broaden the category of electrical stimulating
21 devices. Then you also have to broaden the characteristics
22 of what they do. Iontophoresis delivers analgesics or anti-
23 inflammatories. So there has to be an increase in the list
24 of the possible therapeutic applications. So it can't be

1 just muscle relaxation or pain relief. It also could be
2 anti--I don't know how we want to word it. Somebody else
3 help. But it can be--

4 DR. GONZALEZ: Anti-inflammatory or--

5 DR. COOPER: Anti-inflammatory or pain--well, pain
6 we've dealt with, so if it's an anesthetic being applied--
7 it's probably--somebody can help us. It's probably the--
8 there's probably no other function of an electric
9 stimulator, is there? In this usage. I don't mean to grow
10 nerves.

11 DR. GONZALEZ: Actually, yes. I mean, anti-
12 nociception by electrical stimulation, I think the way it's
13 being used, or TENS unit, would be the gate control theory
14 of pain to reduce pain, whereas other cranial stimulation,
15 like limoges(?) transcranial stimulation, which is used for
16 pain control, also it's been used in the past as an anti-
17 anxiety method, which is literally low-amplitude, low-
18 frequency transcranial electrical stimulation of the head
19 used in France and Russia, as an analgesic method.

20 I don't believe--and there's very little
21 literature on this--it works in the same way as TENS is used
22 peripherally. No one knows how limoges works, if it works
23 at all.

24 My concern with this classification of stimulatory

1 devices is exactly that, throwing in devices like limoges,
2 transcranial stimulation, and others. I'm not sure I'm
3 resolving this at all. I think, you know, I'm just trying
4 to think about other problems that could develop if we say
5 in a global way, well, this includes all stimulatory
6 devices, because I would be very concerned. In fact, that's
7 up for a lot of discussion right now. In fact, it's the
8 subject of a lot of discussion in a number of groups, things
9 like transcranial electrical stimulation, galvanic
10 stimulation, and others.

11 So maybe stimulatory devices should be more
12 specific to state TENS and then maybe be very specific for
13 other devices, and to state those devices up front. Again,
14 maybe it could be added on to later. Maybe, you know, it
15 needs to be refined more. But I'm concerned about the term
16 "stimulatory devices."

17 Dr. COOPER: Can we be site specific again? Can
18 we say electrical stimulatory devices to the masticatory and
19 associated muscles and temporomandibular joints? That keeps
20 you closer into home. That means you can apply something to
21 the TMJ capsule. You can apply something to masticatory
22 muscles. You can apply something to the posterior cervical
23 muscles. I'm trying to keep it home to you, trying to keep
24 it narrowed for the sake of--the brain is--this is a Dental

1 Products Panel. We shouldn't be stimulating brains. I
2 mean, we should be stimulating each other's, but not outside
3 this room.

4 DR. GENCO: So what is your feeling about that?
5 In other words, leave it as stimulatory devices, and then
6 make it site specific, to treat by application of electrical
7 energy to masticatory and associated muscles.

8 DR. COOPER: And temporomandibular joints.

9 DR. GENCO: Okay, and joint.

10 DR. COOPER: Because iontophoresis is applied to a
11 joint.

12 DR. GONZALEZ: And trigeminal nerve. I mean,
13 isn't that what TENS does? It works through peripheral
14 nerves for central activation of the gate control theory of
15 pain. So it would be structures in the temporomandibular
16 joint region, including muscle, trigeminal nerve, and--

17 DR. COOPER: And joint, temporomandibular joint.

18 DR. GENCO: Okay. Then to just finish this, used
19 for relief of pain and for muscle relaxation.

20 DR. COOPER: And delivery of medication.

21 DR. GENCO: And delivery of medication.

22 DR. COOPER: I hope that would be--would that be
23 describing iontophoresis.

24 DR. GENCO: The iontophoresis.

1 DR. COOPER: We can then subset--that TENS can be
2 categorized as high or low frequency.

3 DR. GENCO: Right.

4 DR. GONZALEZ: Well, iontophoresis, my
5 understanding is that it transcutaneously delivers medicine,
6 but it's not necessarily site specific. It diffuses once
7 it's delivered. Are we really treating deep structures such
8 as the temporomandibular muscles, the joint, the bone, the
9 periosteum, using iontophoresis? I don't believe that
10 that's been looked at. The companies that have
11 iontophoresis devices, one English and I think Alza in
12 California, and a couple of others that are working on this,
13 make statements about diffusion subcutaneously into fatty
14 and other tissues. I don't believe that they're stating
15 they're delivering it to muscle. I don't believe they're
16 making that kind of a statement. So wouldn't that fall out
17 of this categorization?

18 DR. COOPER: I'm not sure.

19 MR. ULATOWSKI: Mr. Chairman?

20 DR. GENCO: Yes.

21 MR. ULATOWSKI: I think that point is well taken,
22 that we are trying to consider devices that are pre-
23 amendments or are substantially unclassified devices and not
24 devices that have garnered some new uses along the way or

1 something post-1976. And in regard to the stimulatory
2 device category, it was a construct that we did at FDA, but
3 I think FDA would tend to be splitters and not lumpers in
4 terms of this particular category in terms of the definition
5 of a generic device type, where you have different purposes
6 and designs and functions in amongst this group that
7 differentiate one from another.

8 DR. GENCO: So you're suggesting we ought to
9 consider leaving iontophoresis out of this category?

10 MR. ULATOWSKI: Defining the category, the generic
11 type in a manner that's succinct and doesn't capture or
12 garner a bunch of things that really fall outside or is an
13 entirely different function from a TENS device.

14 DR. COOPER: In other words, stay with TENS for
15 the moment and we have enough subdivision and with this the
16 possibility of then setting up a category for other
17 electrical stimulators as more knowledge comes in.

18 MR. ULATOWSKI: Exactly, yes.

19 DR. GENCO: So presently you have no 510(k)
20 related to iontophoresis devices, so there's no need to
21 reclassify them?

22 MR. ULATOWSKI: We do have an iontophoresis device
23 classification.

24 DR. GENCO: Okay.

1 DR. RUNNER: But not in relation to TMD.

2 DR. GENCO: Okay.

3 MR. ULATOWSKI: There's no claims for TMD. No
4 pre-amendments claims for TMD whatsoever.

5 DR. GENCO: Okay. Yes?

6 DR. TILLEY: Larry Tilley. There is a company
7 that makes claims about iontophoresis for the use and
8 treatment of TMD.

9 MR. ULATOWSKI: Well, we'd have to understand what
10 that device is and when it entered the market and what it
11 was claimed equivalent to if it was found equivalent.

12 DR. TILLEY: It is not a stimulatory device.
13 Iontophoresis by the characteristics--the definition,
14 rather, make it not a stimulatory device. I'd also ask you
15 about infrared diodes, helium, neon, infrared lasers, things
16 like that that we're seeing used more and more. There
17 obviously needs to be another category because they don't
18 necessarily fit into stimulatory devices.

19 MR. ULATOWSKI: If I could ask, as before, if you
20 have information on those specific devices that we could
21 research and list appropriately.

22 DR. GENCO: Further discussion of the stimulatory
23 devices?

24 [No response.]

1 DR. GENCO: I think we have come to the suggestion
2 that we limit that to TENS type, high and low frequency, and
3 then to treat by application of electrical energy to the
4 temporomandibular region for reducing pain--for pain control
5 and reducing muscle--relaxing muscle.

6 Okay. With respect to--what is the status? These
7 are like the EMG? There's a chain of evidence, a chain of
8 devices based upon a non-classified device for dental, but
9 the TENS is classified category 2 for medical, just like
10 electromyographic.

11 MR. ULATOWSKI: Yes, Bob--Mr. Chairman?

12 DR. GENCO: Yes.

13 MR. ULATOWSKI: To ask Dr. Betz--

14 DR. BETZ: Can you ask that again?

15 MR. ULATOWSKI: To ask you, Bob, this indication
16 for use for this TENS device was gathered in from a 510(k).
17 Correct?

18 DR. RUNNER: Yes.

19 MR. ULATOWSKI: And what was the status of that
20 510(k) as far as its claimed equivalence? What was the
21 predicate, a classified device or an unclassified device?

22 DR. BETZ: It's my recollection--I don't want to
23 sound like a lawyer, but it's my recollection that it was
24 unclassified.

1 MR. ULATOWSKI: For that claim, for that intended
2 use?

3 DR. BETZ: To the best of my knowledge, yes.

4 MR. ULATOWSKI: Well, we'll have to research it
5 just to make certain one way or the other. If it was found
6 equivalent to the classified TENS devices, and there are
7 classified TENS devices, then the panel doesn't have to take
8 any action. It's already classified per that 510(k).

9 DR. GENCO: I thought in your opening comments,
10 Bob, you said it had no dental classification.

11 DR. BETZ: That's correct, specifically.

12 DR. GENCO: But the question now is was it--
13 devices that have been approved by a 510(k) with the
14 predicate device a classified medical device. If so, then
15 we don't have to deal with it. If not, if it's
16 unclassified, then we have to deal with it. That's the
17 issue. What is the predicate device, pre-1976?

18 DR. RUNNER: I believe the one with the TMJ uses
19 is unclassified.

20 DR. GENCO: Okay. What about evidence? Any
21 different lines of evidence for this group of devices than
22 for the electromyographic? Any unique kinds of information?
23 I think for the electromyographic, we've agreed, of course,
24 with the FDA that the kinds of evidence that can be

1 presented can be anywhere along the hierarchy. Of course,
2 it's more convincing the more close you get to randomized
3 controlled trials. Is there anything different about this
4 group, any unique feature of this group, any pitfalls in the
5 experiments, the evidence?

6 DR. GONZALEZ: One comment about that. With TENS
7 unit, it is very difficult to do controlled studies. The
8 outcome of utility of TENS is the induction of paresthesias,
9 a feeling. You use that to measure the fact that you have a
10 proper amount of energy being delivered. If you have a
11 control, you have to deliver less energy. In other words,
12 not induce paresthesias. So it is--some people feel it is
13 impossible to ever do controlled studies on patients for
14 TENS because of that fact.

15 The same goes for spinal cord stimulator, but for
16 TENS you do need the induction of paresthesias, and people
17 who have tried TENS before know when you give them not
18 enough energy, not enough electrical stimulation to produce
19 activity and pain reduction. So just a caveat is that when
20 we look at the information regarding TENS, the information
21 which we've done already, the American Academy of Neurology,
22 is not going to be studies that are double-blind, or at
23 least believable double-blind studies. And so the level, if
24 you will, of type of studies that we're going to look at

1 will be less convincing. Just for those of us who are
2 sticklers for academics, we're just not going to achieve
3 that. So we have to be cautious in saying that it doesn't
4 work and disregarding it because studies have not been done.
5 You may not be able to do those studies. It may depend more
6 on large numbers of reports.

7 DR. GENCO: Are there alternate designs, like
8 intractable pain treated longitudinally, baseline, or treat
9 with a placebo?

10 DR. GONZALEZ: There have been trials of on and
11 off and in varying limbs for patients with bilateral lower
12 extremity or upper extremity pain, but the bottom line is
13 the criticism of all of those that have tried very hard to
14 be objective is always the same criticism--that is, you
15 don't have truly double-blind studies. And we just need to
16 keep that in mind and try to be objective in that respect
17 and not discount it because they haven't done a double-blind
18 study yet, because it may not be achievable.

19 DR. GENCO: Okay. Thank you very much.

20 Any further comments about the order of--or the
21 level of science, the types of design?

22 [No response.]

23 DR. GENCO: Okay. What about the priority for
24 these? What is your opinion as to the priority to classify

1 the TENS type devices? Yes?

2 DR. COOPER: I would consider it low priority. I
3 can't say--I've been using TENS for 18 years, so I can't see
4 any potential harm. You either relax people or you
5 eliminate pain, or you don't. You can't do too much of it,
6 at least in the instruments that I'm familiar with. So I
7 don't think that there's any great imminent danger. So it
8 can go into the group of low priority.

9 DR. GENCO: Any other comments? Yes?

10 DR. GONZALEZ: I definitely agree with that, that
11 it should be given a low priority.

12 DR. GENCO: Okay. Any other comments about TENS
13 and stimulatory devices? Yes, go ahead, Dr. Jankelson.

14 DR. JANKELSON: Again, this is not unusual that
15 there is confusion regarding TENS. I don't know whether
16 I'll add or detract from the subject, but it's one that I'm
17 very, very familiar with, working in the area and publishing
18 in the area for the last 25 years.

19 There are really three types of TENS, exclusive of
20 variable wavelengths and forms. The high-frequency TENS
21 typically have a frequency between 80 and 100 hertz, work,
22 as Dr. Gonzalez said, through some gate mechanism, Melzak
23 wall, probably some issue of C fibers versus A fibers,
24 loading up the alpha fibers, and it's a pain blocker. It is

1 in most, I believe, 510(k)s defined as effective for
2 blocking pain.

3 We then have the low-frequency TENS. Low-
4 frequency TENS in the literature is defined as having a
5 frequency of between 1 and 4 hertz. This isn't complicated.
6 And the early Swedish literature, Scandinavian literature,
7 you often refer to it as acupuncture-like TENS.
8 Specifically, it was designed for muscle relaxation. The
9 mediation is very different. With high-frequency TENS you
10 do not get visible muscle contracture until you have an
11 amplitude sufficient to provide tetany, and Dr. Gonzalez
12 addressed that issue.

13 The low-frequency TENS, it is impossible to
14 achieve a state of tetany. The characteristic of low-
15 frequency TENS is involuntary muscle contraction coordinate
16 with the number of stimuli per second.

17 There's actually--and I believe the FDA--correct
18 me if I'm wrong--prefers a third category that has not been
19 mentioned, and that is what we call the ultra-low-frequency
20 TENS, below 1 hertz. And, again, I believe that is
21 presently and recently being referred to as muscle
22 stimulators. So we really have three categories. That also
23 is based upon initiating involuntary muscle contraction and
24 the subsequent relaxation due to circulatory lymphatic

1 changes. And to my knowledge, there are no claims specific
2 to pain blockage, only amelioration of pain that is a result
3 of muscle relaxation.

4 So I hope that clarifies more clearly the status
5 of actually the three categories of TENS.

6 Now, I'm somewhat confused because it appears that
7 we again summarily dismissed the physical therapy devices
8 which were alliterated by Dr. Tilley. And the reasoning was
9 that these devices, such as iontophoresis, have 510(k)s--

10 DR. GENCO: Excuse me, Doctor. We have not
11 dismissed them. They're going to be discussed.

12 DR. JANKELSON: Okay. They will be?

13 DR. GENCO: Oh, sure.

14 DR. JANKELSON: Very good. But there was this
15 issue of will they be considered outside the general 510(k)
16 classification presently or specific to either site or
17 disease? I think this is a very important issue. If, in
18 fact, we do not consider them site or disease specific, then
19 we must go back and revisit the issue of TENS as site or
20 disease specific, i.e., we must consider whether we should
21 be considering the TENS categories because they are site or
22 disease specific--something I think for the panel to
23 consider.

24 Thank you.

1 DR. GENCO: Thank you. I think we're discussing
2 all of these as site specific, and, in fact, in the
3 stimulatory device use, the suggestion was made to
4 specifically talk about temporomandibular joint application
5 of the TENS.

6 DR. HEFFEZ: I was going to suggest that maybe the
7 TENS be separated out as a separate category, not used as
8 stimulatory device as it prefix. I think it would work; it
9 would be more appropriate just to call it TENS unit.

10 DR. GENCO: It looks like that's where we're
11 headed. Any objection to that? Okay. So Tim has advised
12 us that they would prefer, for many reasons, I'm sure, to
13 split these rather than lump. So that's a generic group.
14 It sounds like it's a complex group, and in enough
15 complexity that we shouldn't add other things to it. Okay.
16 Thank you. Dr. Gonzalez? Okay.

17 Let's proceed now to sonography devices. Anyone
18 want to--does everybody agree that this is a generic
19 category? How about the use, to measure and graphically
20 display or represent sounds made by the TMJ components?
21 Does that encapsulate the use? Yes?

22 DR. COOPER: I think we can also add not just
23 measure but analyze. I think the present usage approves
24 spectral analysis of sound coming out of the joint from some

1 of the devices. It may not from a stethoscope, but it does
2 from some of the more highly technological ones.

3 DR. GENCO: It says measure and graphically
4 display or represent. How would you--to measure and analyze
5 sounds made by TMJ components?

6 DR. COOPER: Right.

7 DR. GENCO: To measure and analyze sounds made by
8 the temporomandibular joint components.

9 DR. COOPER: Correct.

10 MR. ULATOWSKI: Mr. Chairman?

11 DR. GENCO: Yes?

12 MR. ULATOWSKI: Once again, in terms of products
13 that are legally marketed and what they've been cleared for,
14 we don't want in this exercise to add uses that have not ben
15 through a clearance process. We're classifying things on
16 the market right now that have been through a clearance
17 process and identifying whether they're classified or
18 unclassified. So they may well--was the analysis a part of
19 labeling of a marketed device?

20 DR. COOPER: Let's ask the manufacturer. I don't
21 know.

22 DR. GENCO: We need some direction here with
23 respect to the term "analyze."

24 DR. JANKELSON: I would say the representation

1 that analyze is not correct in our present 510(k). Recent
2 510(k) changes expanded the way that you can look at data,
3 but it would not be correct to categorize it as a change in
4 the analysis program.

5 DR. GENCO: So to graphically display or represent
6 sounds, to measure and graphically display or represent
7 sounds made by TMJ--it's a reasonable description of what
8 these devices do today.

9 DR. JANKELSON: I think the FDA representation is
10 quite reasonable here, yes.

11 DR. GENCO: So that also would account for the
12 future, reasonable--

13 DR. JANKELSON: I think so.

14 DR. GENCO: Okay.

15 MR. ULATOWSKI: Again, Mr. Chairman, if someone
16 wanted to add that aspect to labeling, they'd submit a
17 510(k) and get that in their labeling.

18 DR. GENCO: Okay. Fine.

19 Dr. Cooper, are you comfortable with that?

20 DR. COOPER: That's fine. I'd defer to the people
21 who are manufacturing. Sonography is also used as Doppler.
22 Now, is Doppler a separate classification of device, or is
23 Doppler considered a kind of sound recording? That's a two-
24 part question. The first is as Doppler is used to record

1 sound from a joint. The other is that Doppler is used to
2 measure blood flow in temporal arteries, for instance, which
3 I have seen dentists doing. So that now takes the recording
4 of sound away from the joint, but it's recording of the
5 sound just the same.

6 DR. GENCO: Does anybody want to comment to that?
7 Yes?

8 DR. RUNNER: If Doppler's are being used in the
9 TMD area, that's within the practice of medicine at this
10 point. We have no specific applications requesting that as
11 a claim on a Doppler device at this point in time.

12 DR. GENCO: All right. Now, this is, again, a
13 class II, if I remember your comments, medical device but no
14 dental classification; therefore, it's unclassified. The
15 predicate devices are unclassified, so, therefore, there's a
16 requirement or a need to classify for dental application or
17 the TMD application.

18 MR. ULATOWSKI: Mr. Chairman, let me rephrase
19 that. And, again, Dr. Betz, this 510(k) that you culled the
20 indications from, it was found substantially equivalent to
21 something.

22 DR. RUNNER: Those were found substantially
23 equivalent to pre-amendments devices--

24 MR. ULATOWSKI: Unclassified.

1 DR. RUNNER: Unclassified.

2 DR. GENCO: All right. Then we get right to the
3 question of what kind--is there any unique aspect--and the
4 intent is to be helpful to industry for the submission. Is
5 there any unique aspect of the data that should be
6 emphasized that you'd like to see? We can go through the
7 whole discussion of hierarchy of evidence. I think we
8 understand that. But are there any unique aspects of the
9 design of testing of these devices that should be
10 emphasized, you'd like to see expanded?

11 [No response.]

12 DR. GENCO: Okay. How about priority for
13 classification of the sonographic devices? Does anybody
14 have an opinion on that? Yes, Dr. Moses?

15 DR. MOSES: Again, I feel that having been around
16 for such a long time, and with a tremendous safety factor,
17 that the priority ought to be low.

18 DR. HEFFEZ: I would concur.

19 DR. GENCO: All right. Let's now go to the jaw
20 kinesiology and pantagraphic tracing devices. Is this one
21 generic group, in your mind? Any objection to them being in
22 one generic group?

23 DR. COOPER: I think they're all one group. Just
24 one I think is--kinesiology probably is more dynamic;

1 therefore, it probably relates to the electronic type of
2 devices, the other the more mechanical type of devices. But
3 as a big group, they measure jaw movement or position.

4 DR. GENCO: So the common denominator here is the
5 measurement of jaw movement and jaw position. They vary in
6 how they do that. But that's not an essential attribute of
7 their safety and efficacy.

8 DR. COOPER: Right. You added in a word that
9 isn't on the descriptor, and that is jaw movement and
10 position, which is--you're accurate, so it should say jaw
11 movement and position.

12 DR. GENCO: I remember my occlusion lectures.

13 Okay. So then we get into the indication for use:
14 to measure and graphically record (trace) jaw movement and
15 position in three dimensions. Any comments on that? Does
16 that adequately describe these instruments?

17 [No response.]

18 DR. GENCO: Okay. Again, are these in that same
19 category--oh, no, these are already classified as category
20 1, the pantagraphic tracing devices, category 1.

21 DR. RUNNER: Class I.

22 DR. GENCO: According to your discussion this
23 morning.

24 DR. RUNNER: There is a classification for a

1 pantagraph that is class I, yes.

2 DR. GENCO: All right. If the recommendation is
3 to put all of these in one category, does that mean they're
4 all class I, category 1?

5 DR. RUNNER: I think we would like you to decide
6 whether these devices fit with this classification as it is
7 defined. If you would like me to read it, I will. The
8 definition in the CFR does not specifically mention TMD
9 uses. It's a more general--

10 DR. GENCO: Oh, I see. Dental uses rather than
11 TMD.

12 DR. RUNNER: Correct.

13 DR. GENCO: Do you understand that? In other
14 words--okay. This is used for construction of prostheses,
15 for studying mandibular movement, position, but not
16 specifically for diagnosis or treatment of TMD.

17 DR. BETZ: That's correct. Restorative and
18 prosthetic versus TMD.

19 DR. GENCO: Okay.

20 DR. HEFFEZ: The information that you obtain,
21 though, is not different than whether you would be using it
22 for TMD reasons. It's the same information, but you can
23 choose to apply it any way you want. So I'm not clear on
24 whether it should have to be reclassified or relooked at.

1 DR. RUNNER: Correct, although the--go ahead.

2 MR. ULATOWSKI: Mr. Chairman, we listed jaw
3 kinesiology and pantagraphic tracing devices for a
4 particular use, and, again, you know the drill: What
5 510(k)s were there and how do we classify it?

6 DR. RUNNER: The 510(k)s that we saw had specific
7 claims for TMD and were pre-1976 claims and were claimed to
8 be unclass--and were unclassified as saw them in the--

9 MR. ULATOWSKI: Both types of devices? Both?

10 DR. BETZ: No. The pantagraph is a separate
11 classification that had been approved by the Dental Products
12 Panel under 18 872.3730, I believe, and that is a class I, I
13 think maybe even exempt. It's either a class I or a class I
14 exempt device. The ones related to TMJ have no predicate
15 devices as such in dental.

16 DR. GENCO: Okay. So it's an appropriate topic,
17 and industry should present data to the panel. The panel
18 will consider that classification in due course.

19 DR. BETZ: For the jaw kinesiology and not the
20 pantagraph. The pantagraph is already a done deal, if you
21 will.

22 DR. GENCO: Okay. Is that clear? Yes?

23 DR. COOPER: It's clear, but it's not logical. If
24 the pantagraph is approved in the fabrication of dentures

1 and oral reconstruction and, as Dr. Heffez said, in the
2 treatment of a different person who walks into the room and
3 the same appliance is put on to record mandibular position
4 to produce an orthotic appliance, it's the exact same usage.
5 One's a temporary occlusion; one's a durable occlusion. If
6 somebody does phase 2 TMJ therapy, they are going to use the
7 same thing to make dentures or to make reconstruction or
8 long-term orthoses.

9 My feeling is that they're all the same thing and
10 we're splitting hairs; and if the pantagraph has one usage
11 and it's the same usage, so does any kind of jaw tracking.
12 All you're doing is recording where's the jaw and space.
13 Your uses of it probably are going to be the same. The
14 patient complaint to you walking in the door may be
15 different, but if the use is the same, then the
16 classification should be the same. And it's quite possible
17 that the whole thing should be class I. It's all the same--
18 one may be higher technology, but it's the same--you're
19 doing it for the same ultimate reasons.

20 DR. GENCO: Yes, Susan?

21 DR. RUNNER: So you're saying that that should be
22 a subpart of the existing classification. That's one of the
23 questions we're asking.

24 DR. GENCO: Other panel members have any opinion

1 on this? Agreed?

2 DR. ALTMAN: I agree.

3 DR. GENCO: Okay. So the opinion of the panel is
4 that this should be a sub-classification. And, of course,
5 the rest of the other questions wouldn't be relevant, then.

6 Let's go on to ultrasound--

7 MR. ULATOWSKI: Mr. Chairman?

8 DR. GENCO: Yes?

9 MR. ULATOWSKI: I guess I'm not real clear there,
10 just to come back to it. The jaw kinesiology devices, we
11 have 510(k)s for such devices, for those claims you stated,
12 Bob.

13 DR. BETZ: That's correct.

14 MR. ULATOWSKI: And they have been found
15 equivalent to pre-1976 devices that were classified.

16 DR. BETZ: That's my understanding, yes.

17 No, these things were--the jaw kinesiology devices
18 were not--they did not use the pantagraph as a predicate
19 device. Did I answer the question?

20 DR. RUNNER: So, in other words, they were found
21 equivalent to pre-1976 devices, but they were unclassified.

22 DR. GENCO: Therefore, they should be looked at.

23 MR. ULATOWSKI: Then they need to be classified.

24 DR. RUNNER: Correct.

1 MR. ULATOWSKI: The pantagraphic devices.

2 DR. BETZ: Pantagraphic devices are already
3 cleared under 872.3730.

4 DR. GENCO: For TMD?

5 DR. BETZ: Not for TMD. For prosthetic and
6 restorative. No mention of TMD that I've been able to pick
7 up.

8 DR. GENCO: So neither have been cleared for TMD.

9 MR. ULATOWSKI: Is there a claim for TMD in
10 labeling for pantagraphic devices?

11 DR. BETZ: No, not for pantagraphic devices that
12 I'm aware of.

13 MR. ULATOWSKI: Well, then, how one would be
14 classified would be to submit a 510(k) with a TMD claim and
15 to be found substantially equivalent to a classified
16 pantagraphic device. We're not creating uses. We're
17 talking about existing labeling in classifications.

18 DR. GENCO: I guess we're going to need some help
19 here in terms of sorting that out. Would the opinion be
20 that if these devices were claiming to diagnose or treat
21 TMD, that there's no classification--no prior device that's
22 classified pre-1976, pre-predicate device for that claim?

23 DR. RUNNER: Correct.

24 DR. GENCO: Okay. For both.

1 DR. BETZ: Not the pantagraph.

2 DR. RUNNER: For the pantagraph there is a
3 classification. For the jaw kinesiology devices, there is
4 no classification.

5 DR. GENCO: Okay. Does that change your opinion?

6 DR. COOPER: No, but I think we probably have to
7 go through the process of classifying it.

8 DR. GENCO: Okay. Dr. Tilley?

9 DR. TILLEY: Just a point of information. The
10 Danar pantagraph and its reproducibility index was
11 advertised by them to be able to be used to diagnose TMD.

12 DR. GENCO: I think that's what Bob has said, but
13 not the jaw kinesiology devices.

14 DR. TILLEY: No. He said that it wasn't
15 advertised and it wasn't approved for TMD, the pantagraph.
16 And, in fact, it was advertised that way with that
17 reproducibility index.

18 DR. GENCO: Maybe I misheard you. I'm sorry.

19 DR. RUNNER: No, I don't think you misheard us.
20 We have no cleared any devices--the pantagraph is a separate
21 classification for the rehabilitation, reconstructive
22 aspects. If we saw a device that came in with a TMD claim,
23 that would be--could be looked at under that same
24 classification with supporting data.

1 MR. ULATOWSKI: Mr. Chairman, the 510(k) process
2 being the classification process would classify that new
3 claim for that pantagraphic device, and the panel doesn't
4 have to get involved in that.

5 DR. GENCO: Okay. And that's happened?

6 MR. ULATOWSKI: Unless there's one on the market
7 already that has claimed--

8 DR. GENCO: That's what Dr. Tilley said.

9 MR. ULATOWSKI: Then the question, as before with
10 the other products, is: When was it cleared? We'd have to
11 research what it was found equivalent to, blah, blah, blah.

12 DR. GENCO: Okay. Good.

13 MR. ULATOWSKI: So we'll need information there as
14 well to research that.

15 DR. GENCO: All right. So there's the possibility
16 of reclassifying.

17 MR. ULATOWSKI: There's a possibility.

18 DR. GENCO: And also jaw kinesiology, a greater--
19 there's a probability, a high probability of that being--

20 MR. ULATOWSKI: Yes, yes.

21 DR. GENCO: Now, what is the panel's opinion as to
22 unique data here? Any unique features of the studies?

23 [No response.]

24 DR. GENCO: Okay. What about priority for

1 classification of this group?

2 DR. COOPER: I would say low priority.

3 DR. GENCO: Okay. Let's go to ultrasound, then.

4 DR. HEFFEZ: Can I make one point?

5 DR. GENCO: Yes.

6 DR. HEFFEZ: Maybe the category should not be jaw
7 kinesiology and pantagraphic tracing devices, but jaw
8 tracking devices and then have sub-categories of each of
9 them. It seems it would be easier to classify them, and
10 then as other jaw tracking devices were developed, they
11 would fit easier into the system.

12 DR. GENCO: Any objection to that? So we're
13 suggesting jaw tracking devices as the name for this
14 category.

15 Further comments on this category?

16 [No response.]

17 DR. GENCO: Let's proceed, then, to ultrasound.
18 Before we go on, there's at least three other groups, maybe
19 a fourth, and that is ultrasound, thermography, imaging
20 devices, and then the physical therapy devices like
21 iontophoresis. What is our responsibility--what would you
22 like from us about those? Are TMJ claims being made for the
23 ultrasound, thermography, and imaging? It says no specific
24 TMJ claims. So what is our role here?

1 MR. ULATOWSKI: Mr. Chairman, we're trying to
2 identify devices that are unclassified for products to use
3 in the area defined by the panel and guests. If one has
4 not--a manufacturer has not presented a device with a claim,
5 then it may not be a candidate for classification. There
6 are classified ultrasound devices which have intended uses
7 in their classification, and within the practice of
8 dentistry and medicine, one may well use products, as I
9 said, however they feel fit for their patients. But that
10 doesn't translate to a labeling claim for the product. That
11 needs to be classified, for example, with X-ray devices
12 where an image is taken of a particular anatomical
13 structure, that's essentially the intended use, and we
14 haven't cut it any other way to say you take a picture of
15 this or a picture of that or a picture of whatever. It's
16 imaging sites. So very general and all encompassing and
17 would include imaging of the TMJ and any other structures,
18 in our estimation, if one so wishes to use it for that
19 purpose.

20 DR. GENCO: So we should go through each one of
21 these as if there were claims, or there may be claims, or
22 they're used off-label, so to speak?

23 MR. ULATOWSKI: Well, no. If there's no claims or
24 no claims are revealed to us by anyone now or later, they're

1 really not eligible for classification.

2 DR. GENCO: Okay. So that takes care of those
3 three categories. Yes?

4 DR. RUNNER: One of the reasons that we included
5 those categories was to be all inclusive of all devices that
6 could possibly be used so that the discussion was as broad
7 as possible.

8 DR. GENCO: Okay. So the question to the panel
9 is: Do you agree that these are out of the domain of the
10 devices to be classified, from what the FDA has told us,
11 from what your experience is, what your expertise is? Yes?

12 DR. COOPER: I don't think that that's what our
13 experience is. Our experience is that some of these devices
14 are very specifically used for TMD, and I think that the
15 problem we're all facing with it is we don't know what's in
16 the advertised claim in writing. The FDA doesn't
17 necessarily know what's in the advertised claim or in the
18 teaching of the uses of these things.

19 If you have a TMJ MRI, that's a specific surface
20 coil used to image the TMJ or the middle-ear bones. That's
21 a specific usage. And I think that the issue we'll have to
22 all deal with, next time, probably, is whether or not we
23 will generalize or site-specific-ize what we're doing.
24 Because if we're being site specific, then each of these

1 things has a specific usage in TMJ. If we're going to
2 accept that radiography is radiography whether it's a knee
3 or a TMJ, so is EMG, so is TENS, so is all these things.
4 And I won't even accept on that light level jaw tracking
5 because that's no different than arm tracking and all of the
6 other goniometers that are used.

7 So it's a major issue we'll all have to address as
8 to whether the fact that an instrument is used in our
9 specific area makes it a specific use, or are we being
10 prejudicial and it really should be thought of in its more
11 general sense. We'll have to visit this issue sometime
12 before the end of the next session.

13 DR. GENCO: And, similarly, for the physical
14 devices like iontophoresis.

15 MR. ULATOWSKI: Correct. Every one of them.

16 DR. GENCO: Okay. Yes, I think there was a
17 gentleman--you first, and then Dr. Jankelson.

18 MR. RADKE: John Radke with Bioresearch. There
19 are specific radiographic devices, obviously, for the
20 imaging of the TM joint that are used only for that
21 particular image. There are also or have been thermography
22 devices that are specifically for imaging of the side of the
23 face as a TMJ-type device that I'm aware of. I don't know
24 what the manufacturing claims are just offhand because we

1 don't make them, but those devices do exist, and I think
2 that they need to be looked at.

3 DR. GENCO: So the issue is the claim. Obviously,
4 TMJ X-ray, radiograph, would be used for many things,
5 including dealing with temporomandibular joint dysfunction
6 and associated pain.

7 MR. RADKE: I think most people would agree, if
8 they're involved in TMJ treatment, that they're going to
9 take an X-ray of the joint. That's a pretty--you know, as
10 part of your diagnostic work, you're taking a joint X-ray of
11 some kind.

12 DR. GENCO: The issue is maybe the claim that if
13 you don't do this--or if you do this, you are better able to
14 diagnose or treat. I mean, is there some implicit claim
15 that this is a necessary or very useful device? I guess, is
16 that the issue?

17 MR. RADKE: Well, if there's a suspected internal
18 derangement, then a lot of times they will, you know, even
19 do an MRI or something to try to image it before they get
20 involved in therapy to really be certain of the
21 appropriateness of the therapy.

22 DR. GENCO: Does that help you in terms of whether
23 or not we should deal with these in classification? I'm
24 asking the FDA.

1 MR. ULATOWSKI: Mr. Chairman, I think it's
2 certainly appropriate, as mentioned, if there's some
3 advertising or some pronouncements by a manufacturer or a
4 training session by a manufacturer that alludes to a
5 specific use condition within the realm of what we're
6 discussing today, and I think that may produce a condition
7 for a classification effort. But without such information,
8 we can only conclude what we see in the 510(k)s and in the
9 historical record when these products were classified, which
10 is it's everything and anything with these products, with
11 imaging, and there's no linkage in the classification
12 history that we read, and the classification regulations, no
13 linkage to any specific condition or use.

S9

14
15 DR. JANKELSON: Once again, I get the amazing
16 feeling of deja-vu, October 13, 1994. I look at your
17 groupings, your classifications. I was at this same podium
18 a few moments ago when we were discussing the four products
19 that deal with Myo-Tronics and Bioresearch product line. I
20 asked the question: Are these products subject to site or
21 disease specificity? And I think, Mr. Chairman, it was made
22 very, very clear, and I think you did a very excellent job
23 in moderating this: Yes, they are.

24 Then we get to the rest of the categories, and

1 once again there seems to be a summary dismissal of the
2 previous statement that we must be site and disease
3 specific. We as clinicians know that all of these devices
4 have been and are being used specifically for diagnosis and
5 treatment of TMD, and what we are told, it is already
6 classified under a different category.

7 I think that the time has arrived that we have an
8 explanation for this position because it's now 5 o'clock and
9 I'm beginning to have the same feeling I did October 13,
10 1994, that we basically are back to the same four categories
11 that are going to be subject to the classification process,
12 and rightfully so.

13 However, we also have the appearance of a vast
14 category of devices that have been given, if not
15 deferential, differential treatment. So I think that we can
16 expect as a panel at this time an explanation from the FDA
17 regarding this dichotomy.

18 Thank you.

19 DR. GENCO: Thank you. And we certainly have
20 asked for that.

21 MR. ULATOWSKI: Mr. Chairman, can I respond?

22 DR. GENCO: Yes.

23 MR. ULATOWSKI: The major difference in terms of
24 these product groupings for classification purposes, as

1 stated up front by me and during discussion, is existing
2 labeling and claims made for products. We're not trying to
3 create something out of the blue, but to reflect upon
4 current labeling and existing classifications in pre-
5 amendment status to come to a decision whether or not
6 certain products needs to be classified. And as I said, in
7 terms of the three products, to our knowledge, unless
8 comments or whatever is revealed to us otherwise, now or
9 later, we're not aware of any specific TMJ claims for the
10 latter three categories. But if there is some information
11 in this regard, then we certainly would consider that and
12 add those products to the list for consideration for
13 classification.

14 DR. GENCO: Further comments to this question?

15 DR. HEFFEZ: So it is possible to have a device in
16 use with application to the temporomandibular joint, et
17 cetera, region, and the company not making a statement to
18 that effect that it is specifically doing it for the
19 temporomandibular joint, and, therefore, they don't have to
20 alter their 510(k)?

21 MR. ULATOWSKI: A product, once cleared and
22 legally on the market, can be used as you feel fit for your
23 patient.

24 DR. HEFFEZ: So as long as they do not make a

1 specific statement that it is used for temporomandibular
2 joint--

3 MR. ULATOWSKI: No labeling claims, no stated
4 intended uses, through such vehicles as statements in
5 labeling, labels or labeling, advertising material,
6 pronouncements by sales staff that can be documented,
7 training, those sorts of things, we can't--we're not going
8 to regulate the practice of dentistry inasmuch as people use
9 products.

10 DR. HEFFEZ: So I think that's an important
11 statement for everybody to understand.

12 DR. GENCO: Yes, Dr. Moses?

13 DR. MOSES: I'm still--I try and hear everything
14 you say, and yet I can't grasp why, if these manufacturers
15 fill out a 510(k) saying it's equivalent to a product in
16 function that performs a similar function elsewhere, and now
17 it's doing it for the TMD, that it has to get a complete
18 panel review and that that classification can't be
19 arbitrarily applied to that product as part of this
20 classification system. Or is that just going to be a rubber
21 stamp by the panel? Why this uniqueness here, that they
22 file the form appropriately explaining that similarity to
23 the other appliance, why are we--why is this procedure
24 taking place over more than one day?

1 MR. ULATOWSKI: I think Dr. Runner perhaps wants
2 to respond.

3 DR. RUNNER: I think that initially when the
4 510(k)s came into the agency, equivalence was claimed to the
5 pre-amendment device with that same claim, and not
6 specifically to the other panel classifications. They were
7 claiming pre-amendment status as a device that had a
8 specific TMD claim.

9 DR. MOSES: So it may be no more complex for these
10 manufacturers than to refile their 510(k) equivalent--
11 equivocating it to an appliance that's currently classified,
12 and then be a paper procedure; is that correct?

13 DR. GENCO: Maybe the FDA would like to address
14 that.

15 MR. ULATOWSKI: Well, they've already been subject
16 to a process, a 510(k) process, or were already pre-1976
17 and, therefore, legally marketed until classified, if
18 considered unclassified. There's always the opportunity for
19 a reconsideration on the part of FDA of its 510(k)
20 determination. There's a process after a determination, a
21 process of appeal. But there is an established history for
22 these products. There's an established history of filings
23 by manufacturers stating their unclassified status and any
24 subsequent "me too" device being unclassified. 510(k)s, in

1 our examination of 510(k)s, there have been determinations
2 that products were not equivalent to those other products,
3 to other classified devices for reasons that include a
4 number of things as we go through an equivalence
5 determination. It may have the same uses. It may have
6 different technological characteristics, or the particular
7 use may pose different types of questions compared to the
8 other product legally on the market.

9 There are a number of questions that we're
10 presented with that we need to answer in our evaluation, but
11 I guess the long and short of it is, as we examine this list
12 and these preliminary comments, I think we have every
13 intention to look back again and research several of these
14 issues to determine whether or not we can revisit this issue
15 on regrouping or classification status. So I don't think
16 it's an end-all to do all today, but we're going to look
17 back, gathering the comments now and afterwards, now that
18 the public and everyone has heard discussion here. We're
19 certainly going to entertain any comments that anyone has to
20 say about this, as we've discussed it today. But,
21 ultimately, then we'd have to come up with a final list that
22 we believe is appropriate for classification. But we're
23 entertaining discussion today, and your point is well taken.

24 DR. GENCO: I think that if I could emphasize what

1 I hear the panel say is that these ultrasound, thermography,
2 imaging devices, iontophoresis, are indeed being used for
3 TMD, and there's a concern that they're not regulated for
4 TMD. So I think that's a very clear statement from this
5 panel of a concern of, as I put it, off-label use, and
6 that's not unusual. I've read statistics where drugs are
7 used off-label 60 percent of the time. So, I mean, it's a
8 big concern, and I think this panel is responsible in
9 addressing that. We're not sweeping anything under the
10 floor. We're saying this should be addressed.

11 Yes?

12 DR. COOPER: Could I expand the discussion just
13 because I know that we're getting to a late time? We
14 earlier discussed psychometric testing, which is specific
15 psychometric testing vis-a-vis TMD. Something that has
16 never come on the floor but was mentioned in one of the
17 presentations was occlusion evaluating devices, such as Tech
18 Scan. For your benefit, if you don't know, you clench on
19 something which is a pressure sensor electronic and it maps
20 out occlusion and is used, therefore, to analyze occlusion
21 and to design a treatment to improve occlusion.

22 So I would like to consider--I don't know how far
23 we'll go today, but not only psychometric testing--occlusion
24 evaluating devices and, finally, devices that are used for

1 the implementation of occlusal therapy, because that is a
2 significant part of the clinical practice of TMD treatment.
3 So there are devices with which you begin your treatment or
4 help you in the treatment and whatever.

5 So I just--whatever we accomplish at the end of
6 today, I just wanted to have on the table that there are a
7 few other areas other than electrical stimulating devices
8 that yet have to be talked about.

9 MR. ULATOWSKI: Mr. Chairman, I'd like to agree
10 with that. I've already listed for my own purposes, after
11 we go away from this discussion, the additional devices
12 discussed today for our research and evaluation, free-
13 standing software, iontophoretic devices and other devices
14 that you've mentioned. But you've got to help us out here.
15 You've got to provide information to us, if you can, so that
16 we can determine its legal status, when it was marketed, and
17 what it was marketed for, so that we can determine whether
18 it's pre-1976 and the panel maybe needs to do something
19 about it, or whether it's post-1976 and we'll have to deal
20 with it in a different manner. So give us a little help
21 here if you can, or anyone reading this transcript or behind
22 you.

23 DR. GENCO: So the other areas you mentioned are
24 pressure sensors for occlusal--

1 DR. COOPER: I would just say in general, as a
2 general generic group, occlusal evaluating devices.

3 DR. GENCO: Okay. And then--

4 DR. COOPER: Devices for implementing occlusal
5 therapy.

6 DR. GENCO: Okay. What are those? Are you
7 talking about--are these custom devices or are these--

8 DR. COOPER: No, no. Off the top of my head, even
9 things like adjustable articulators are used.

10 DR. GENCO: Okay. If TMJ claims are used--or if
11 they're being used to somehow suggest to a patient that this
12 is important for TMJ.

13 DR. COOPER: And this is how I'm going to treat
14 you initially or long term or whatever.

15 DR. GENCO: The implication being this is a
16 important device for your relief of pain, et cetera.

17 DR. COOPER: Right. And/or dysfunction.

18 DR. GENCO: And that's our concern. Okay.

19 Further comments about that issue? I think we've
20 added four possible categories, in addition to the
21 ultrasound, thermography, and imaging devices, so there's
22 seven new categories--four new and three older to be looked
23 at, all in this domain of effectively or in practice being
24 used in the opinion of clinicians here with TMJ claims

1 implicit?

2 DR. COOPER: Some, yes.

3 DR. GENCO: Or expressed?

4 DR. COOPER: I would say if you--

5 DR. GENCO: But maybe not made by the
6 manufacturers.

7 DR. COOPER: In some cases, yes, made by the
8 manufacturers.

9 DR. GENCO: Not in the 510(k), possibly.

10 DR. COOPER: We don't know that. We don't know
11 the technical status, but we know that is--

12 DR. GENCO: Or maybe not in the advertising.

13 DR. COOPER: Correct.

14 DR. GENCO: Okay. So that the public is aware of
15 this, and we are aware of this, and we need this
16 information, as Tim said. Let's get as much of this as
17 possible.

18 DR. COOPER: Right.

19 DR. GENCO: Good. Further comments? Yes?

20 DR. HEFFEZ: Just a question. If research is
21 performed with the support of a company and the clinician
22 then finds that the instrument can be used specifically for
23 temporomandibular joint reasons, is that taken as a need to
24 alter the 510(k)?

1 DR. GENCO: Tim, do you want to comment?

2 MR. ULATOWSKI: Could you restate that? I think I
3 understand what you're getting at.

4 DR. HEFFEZ: If research is performed by a
5 clinician with the support of the company and that research
6 is geared toward applying the device toward temporo-
7 mandibular joint specificity, does that mean that the
8 company then needs to alter its 510(k)?

9 MR. ULATOWSKI: Well, if you want to promote and
10 advertise the product for a new intended use, a new
11 indication for use, you have to take stock of what you
12 already say and whether that use falls within the cleared
13 indications. If it is a new indication for use, you need to
14 submit a 510(k).

15 DR. HEFFEZ: But it would be the clinician who
16 would be promoting--

17 MR. ULATOWSKI: The clinician is doing the
18 research to support--

19 DR. HEFFEZ: But he would be promoting it as well.

20 MR. ULATOWSKI: The clinician is promoting it?
21 Well, that's not the manufacturer. I'm sure clinicians say
22 a lot of things out there about a lot of devices, but that's
23 not promotion by a manufacturer.

24 DR. GENCO: So promotion by manufacturers, 510(k)

1 statements, labeling statements, statements by the
2 manufacturer's representatives, the salespersons,
3 representations of--

4 MR. ULATOWSKI: Of course, that's always tough to
5 get. Anything in writing--

6 DR. GENCO: But not what clinicians doing the
7 research say.

8 Yes?

9 DR. TILLEY: I just wanted to say I was surprised
10 at what you said, too, about the FDA not being familiar with
11 these. Every iontophoresis company, every high-voltage
12 company, everybody that makes any of this instrumentation
13 shows clearly in their training manuals, they teach people
14 in their classes to use it for TMD or for jaw and face
15 muscles. The other thing that really floors me is the
16 radiographic implications. There are units, like the
17 transcranial radiographic unit, that can be used for nothing
18 except TMD X-rays, and it went through--

19 DR. GENCO: We went through that. TMD X-rays are
20 not specifically for relief of pain. You take them for a
21 hundred reasons, including relief of TMD problems.

22 DR. TILLEY: Okay. I'm sorry.

23 DR. GENCO: I mean, that's a subtle point, but you
24 have to also understand what the FDA's role is and what

1 their job is.

2 DR. TILLEY: I'm sorry.

3 DR. GENCO: Okay. Thank you.

4 DR. MOSES: I've got to go back to that. Isn't
5 this for the diagnosis and treatment of these diseases? Our
6 charge is diagnosis and treatment, not just treatment. The
7 radiograph is diagnostic.

8 DR. GENCO: Well, it's on the list.

9 DR. MOSES: Yes, well, I don't want to see it off
10 the list.

11 MR. ULATOWSKI: Mr. Chairman, the point is in
12 regard to what's being said out there--well, I don't want to
13 seem like we have our head in the sand as far as what's
14 being said out there, but sometimes the only information we
15 get on what's being said out there is from people who supply
16 us information. The information we have in hand is what's
17 in 510(k)s, from meetings we attend with our limited
18 budgets, what we can read in the press. So as I said, any
19 help is wonderful.

20 DR. GENCO: Yes?

21 DR. HEFFEZ: The title that we gave to this was--
22 could you repeat it, the title for this universe of devices?
23 What is the--

24 DR. GENCO: Let me go back to my notes.

1 Temporomandibular disorders and associated pain
2 and/or dysfunction.

3 DR. HEFFEZ: So it has to be associated with pain
4 and dysfunction?

5 DR. GENCO: I think this is what the panel felt.

6 DR. HEFFEZ: I'm just trying to address Dr. Moses'
7 point concerning the radiographs.

8 DR. GENCO: Yes?

9 MR. JANKELSON: I'm still a little confused, and
10 maybe some people on the panel are, too. Roland Jankelson
11 with Myo-Tronics. I would like to address a couple of
12 questions to Mr. Ulatowski.

13 Hypothetically, if Myo-Tronics were to remove in
14 its labeling any reference to TMD, and recognizing that its
15 instrumentation is utilized for a broad spectrum of dental
16 activity, and that TMD is only one, and if we were to
17 substitute in its place only claims that the instrumentation
18 was for the purpose of tracking jaw motion, measuring joint
19 sounds, measuring muscle electrical activity, and in the
20 case of the TENS product for relaxing muscle, would then we
21 have--would this particular classification process have no
22 jurisdiction over our product? And are we, in fact, as a
23 consequence of our simply being forthright with respect to
24 the claim that one application of these devices manufactured

1 by Myo-Tronics is in the field of TMD, whereas the other
2 device manufacturers in this category that I believe is
3 being dismissed, even though Mr. Ulatowski makes it clear
4 that somehow in the process this whole issue will be
5 revisited, I think the purpose of the panel today was to
6 provide some clarification, not only for FDA staff but for
7 the manufacturers so the manufacturers have some sense of
8 structure with respect to going back and operating their
9 businesses, investing in research and development, et
10 cetera. And these gray areas that are going to somehow be
11 revisited by FDA staff at some future time I believe fall,
12 should fall under the purview of this panel.

13 I would be much more comfortable in the process
14 knowing that the panel was providing direction to FDA staff,
15 given our experience in the past, than that FDA staff was
16 making these determinations after this panel had disbanded
17 and each of you have done your separate ways.

18 So that was a long question, but I think the point
19 is obvious. Are these other device manufacturers escaping
20 the same classification process simply because they avoid
21 specifically--if they do in some cases, and I think we've
22 heard enough testimony to suggest that people here have
23 knowledge that in other cases there are specific claims made
24 that should clearly obligate this panel to include those

1 devices in the TMD category. But are they simply avoiding
2 the classification process by being less forthright than
3 perhaps Myo-Tronics and Bioreserach?

4 That's my question, because we can solve this
5 problem for our two companies I think fairly easily: by
6 making specific claims regarding what the instrumentation
7 does without specifically claiming their use in the area of
8 TMD, because that's what we're seeing--that's the
9 circumstance that's been described with a whole range of
10 other devices. So I leave that as a question, not a
11 statement.

12 Thank you.

13 DR. GENCO: Yes, do you want to answer that?

14 MR. ULATOWSKI: Yes, I'll be happy to answer it,
15 perhaps with a general answer in one regard.

16 A product is what a product says it does, and by
17 that I mean a product may or may not be a device, for
18 example, based on its labeling. A pillow is a pillow, but a
19 pillow that makes a claim that it serves to support the
20 spine for post-op whatever makes it a medical device.

21 Inasmuch as people get more and more specific in
22 regard to labeling claims, it becomes possibly a situation
23 where you get into another avenue for classification
24 purposes. We look at the existing classification. The

1 manufacturer, when they submit the 510(k)s, for example,
2 make a claim for equivalence to some product, legally
3 marketed product, be it classified or unclassified. And we
4 examine the labeling, the claims for the product, the
5 candidate product, to the legally marketed device that they
6 claim equivalence to. And we make a determination whether
7 it's the same intended use or a different intended use.

8 If you make a specific indication for use that's
9 not in the predicate, it may render the product as having a
10 new intended use and, therefore, not equivalent.

11 So the answer to your question is there is a
12 possibility that changing uses could get you into a
13 classified situation. Intended use is defined very
14 specifically in the regulations, so you have to be cautious
15 in that if you say a product is generally for this or that,
16 then you cannot by your actions as a manufacturer present it
17 in another light, for example, present it at training
18 sessions or make statements about it, or whatever, that go
19 beyond what labeling says so that you create a new intended
20 use for it by those statements. So it's not just what's in
21 labeling. It's what you say about the product as a
22 manufacturer.

23 But there's a possibility--and we have people
24 every day with 510(k)s where we say, look, you've listed all

1 this stuff about your product, the wonderful things it does,
2 but half this stuff isn't in the predicate. And if you're
3 going to keep half this stuff, all this stuff in there,
4 we're going to have to find you non-equivalent. Change your
5 labeling, look at the predicate, line it up, and you're out
6 of here. So it works that way.

7 There was another aspect to your question.

8 MR. JANKELSON: The other aspect has to do with
9 the fact that there's many, many devices than those four
10 that we've narrowed down today. Basically we're back to
11 where we were in October 1994 looking at four devices that
12 just happen to be manufactured by two companies. I'm
13 addressing these remarks to FDA staff and not to the panel.

14 MR. ULATOWSKI: Okay. Well--

15 MR. JANKELSON: But the other half of the
16 question, Mr. Ulatowski, was: Are you suggesting that those
17 devices that are clearly being marketed without specific
18 claims being put under the nose of the FDA that are clearly
19 intended for use in this field are not subject to
20 classification simply because the manufacturers are being
21 less forthright than we are?

22 MR. ULATOWSKI: Well, I can only react per our
23 procedures to what manufacturers state for their product by
24 those means that I mentioned. And we will act on that

1 basis.

2 If what you say is the case--and it may well be
3 the case that they have used those in conditions--then you
4 have to provide us that information and we can act on it. I
5 can't act on no information.

6 DR. GENCO: Further comments, discussion? Yes?

7 DR. MOSES: Let me rephrase this perhaps another
8 way. If, in fact, we have all stated here--and perhaps
9 we've convinced the panel. Maybe we haven't. But let's
10 assume for a second that the panel now has a new perspective
11 on perhaps the safety and efficacy of these devices relative
12 to what the FDA had in 1994. Couldn't the burden of proof
13 then be--rather than to prove--to do this--wouldn't it be--
14 in other words, lacking substantial evidence that these
15 devices are substantially different or that the
16 temporomandibular condition or the problem for which they're
17 being used in this instance is substantially different from
18 the others, that they just go according to the equivalency?

19 In other words, yes, it's temporomandibular
20 disorder, but in lieu of substantial evidence that this
21 condition is substantially different than the other
22 conditions, there's a different burden of proof and
23 substantiation involved. Couldn't it be considered on that
24 basis?

1 MR. ULATOWSKI: Well, I'm not ruling out that
2 possibility, and I think to provide some reassurance, as we
3 examine discussion today and your position and others', as
4 we believe we need to come back to the table for further
5 discussion before classification proceedings, we'll do that.
6 But I think we do need to take stock of what was mentioned
7 here today and to get additional information to take the
8 next step to fine-tuning the list and seeing where we stand
9 with it. I think there's been a lot of information stated
10 here today, and I think it's going to help clarify issues in
11 some way. But we'll provide further information after this
12 meeting to the public in regard to what we believe is the
13 case with these particular devices discussed today.

14 DR. MOSES: I would like to thank the panel and
15 the FDA representatives for their tolerance, for their
16 understanding, and for their patience in listening to these
17 issues. I thank you personally.

18 MR. ULATOWSKI: Well, I thank you for your input.

19 DR. GENCO: Further comments? Panel, FDA
20 representatives, the audience? Yes?

21 DR. JANKELSON: Dr. Robert Jankelson. Once again
22 for the record, I would like to make note that at the
23 conclusion of this hearing, we have arrived at a disposition
24 of four categories of instrumentation, clearly understood.

1 These are the same four categories that were considered in
2 the 1994 panel. There has been no disposition in the same
3 manner of any of the other categories. And if you would
4 please enter that into the record, it would be much
5 appreciated.

6 Thank you.

7 DR. GENCO: Everything that's said is in the
8 record. That's why you give your name.

9 Okay. Any further comments or discussion?

10 [No response.]

11 DR. GENCO: I also would like to thank the panel
12 and the guests and the FDA for being particularly helpful,
13 and also those from industry. Hopefully what we've done is
14 established some guidelines, some sense of where the experts
15 on the panel feel the data should be, where the field is, as
16 a continuing process in terms of classification of these
17 devices. I don't say it's easy. It's difficult. But I
18 feel personally we've made major progress today. Read the
19 transcript carefully. There's a lot of good information
20 that has come from this panel and from our guests.

21 Yes?

22 DR. COOPER: Thank you. I, too, would like to
23 thank you all and the FDA for giving us the opportunity to
24 participate. It is a very different panel than the last one

1 I spoke before. And I would also like to just agree with
2 Tim's last comment, that I think at least there was a
3 possibility there is so much unanswered at this juncture,
4 this may not take a day to do because everybody has become
5 familiar with the subject, which took a while today; but I
6 think that before the process finalizes to a point of
7 actually assigning classifications, we should try to
8 collectively gather all the information on all of the
9 question marks on seven other classes of devices, even if it
10 means that we all have to get together another time. But by
11 the time we get to classifying, we'll know everything that's
12 on the table, and then we just have the simple task--I hope--
13 --of just assigning it a classification, but at least we
14 won't have to revisit what should be classified.

15 MR. ULATOWSKI: Mr. Chairman, I absolutely agree.

16 DR. GENCO: Okay. Thank you all. I'd like to
17 invite the panel back at 7:30 tomorrow morning for the
18 training session.

19 [Laughter.]

20 DR. GENCO: Enjoy the evening, and thank you
21 again.

22 [Whereupon, at 5:25 p.m., the meeting was
23 recessed, to reconvene at 7:30 a.m., Tuesday, November 4,
24 1997.]

- 1
- 2
- 3
- 4