

TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

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DENTAL PRODUCTS PANEL MEETING

OPEN SESSION - VOLUME I

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Pages 1 Thru 193

Rockville, Maryland
August 4, 1998

MILLER REPORTING COMPANY, INC.

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Washington, D.C. 20002

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Tuesday, August 4, 1998

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Rockville, Maryland 20850

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P R O C E E D I N G S

1
2 MS. SCOTT: Good morning and welcome to the Dental
3 Products Panel meeting. My name is Pamela Scott, and I
4 serve as the Executive Secretary for the Dental Products
5 Panel.

6 I would like to welcome you today, and if you have
7 not signed in, please do so at the sign-in desk just outside
8 of the room.

9 At the sign-in desk, you should have found agenda
10 booklets and information pertaining to today's meeting.

11 Meetings are held if there are issues or
12 applications that the agency needs to -- or chooses to bring
13 before the panel. Whether or not a meeting will be held is
14 determined about two months prior to the tentative meeting
15 date. When a decision is made, the information is made
16 available through the FDA Medical Advisory Committee
17 hotline. The phone number for the hotline is 800-741-8138,
18 or area code 301 443-0572. The code for the Dental Products
19 Panel is 12518.

20 Today we are here to discuss devices for the use
21 in diagnosis or treatment of temporomandibular joint
22 dysfunction and/or orofacial pain. And at this time I'd like
23 to introduce our panel for today.

24 Acting as our Chair for today is Dr. Janine
25 Janosky. She's ASsistant Professor with the Department of

1 Family Medicine and Clinical Epidemiology at the School of
2 Medicine at the University of Pittsburgh.

3 Our Consumer Representative for today is Dr.
4 Donald Altman. He's the Chief of the Office of Oral Health
5 with the Arizona Department of Health Services in Phoenix,
6 Arizona. And as I call your name, if you could raise your
7 hands to identify yourself?

8 We have Mr. Floyd Larson who is our Industry
9 Representative. He's the President of Pacific Materials and
10 Interfaces in San Diego, California.

11 We also have Dr. Peter Bertrand. He's the
12 Director of the Orofacial Pain Clinic and Specialty Advisor
13 for Orofacial Pain and TMD at the National Naval Medical
14 Center in Bethesda, Maryland.

15 We have Dr. Richard Burton, who's Assistant
16 Professor of Oral and Maxillofacial Surgery at the
17 Department of Hospital Dentistry at the University of Iowa
18 Hospitals and Clinics in Iowa City, Iowa.

19 We also have with us today Dr. Gilbert Gonzales.
20 He's Associate Professor of Neurology with the Memorial
21 Sloan Kettering Cancer Center at Cornell University in New
22 York.

23 We also have Dr. Allen Moses. He is a specialist
24 in temporomandibular joint dysfunction and orofacial pain.
25 He's also on the teaching staff at Michael Reese Hospital in

1 Chicago, Illinois.

2 We have Dr. Robert Talley who is also a specialist
3 in temporomandibular joint dysfunction and orofacial pain in
4 Norman, Oklahoma.

5 We have Dr. Diane Rekow, who is the Chairperson of
6 the Department of ORthodontics at the University of Medicine
7 and Dentistry of New Jersey in Newark, New Jersey.

8 And also we will be bringing in by speakerphone
9 Dr. Leslie Heffez who is professor and department head of
10 Oral and Maxillofacial Surgery at the University of Illinois
11 in Chicago.

12 The next item of business are three statements
13 that are to be read into the record.

14 First, I must read into the record the Conflict of
15 Interest statement for August the 4th 1998.

16 The following announcement addresses conflict of
17 interest issues associated with this meeting, and is made
18 part of the record to preclude even the appearance of an
19 impropriety.

20 "The conflict of interest statutes prohibit
21 special government employees from participating in matters
22 that could affect their or their employees' financial
23 interest. To determine if any conflict existed, the agency
24 reviewed the submitted agenda and all financial interests
25 reported by the committee participants. The agency has no

1 conflicts to report."

2 "In the event that the discussions involved any
3 other products or firms not already on the agenda for which
4 an FDA participant has a financial interest, the participant
5 should excuse him or herself from such involvement, and the
6 exclusion will be noted for the record."

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

12 "Appointment to temporary voting status. Pursuant
13 to the authority granted under the Medical Devices Advisory
14 Committee Charter dated October 27, 1990, as amended April
15 20, 1995, I appoint the following people as voting members
16 of the Dental Products Panel for this Panel meeting on
17 August 4th through the 5th, 1998: Dr. Peter Bertrand, Dr.
18 Richard Burton, Dr. Gilbert Gonzales, Dr. Leslie Heffez, Dr.
19 Allen Moses, Dr. E. Diane Rekow, Dr. Robert Talley."

20 "For the record, these people are special
21 government employees and are consultants to this panel under
22 the Medical Devices Advisory Committee."

23 "I also appoint Dr. Janine Janosky to act as
24 Temporary Chairperson for the duration of the Dental
25 Products Panel Meeting. For the record, Dr. Janosky is a

1 special government employee and is a voting member of the
2 Dental Products Panel."

3 "The above individuals have undergone the
4 customary conflict of interest review. They have reviewed
5 the material to be considered at this meeting." Signed, Dr.
6 Bruce Burlington, Director for the Center for Devices and
7 Radiological Health, on July 31, 1998.

8 Each panel member has before him or her a folder
9 that contains information pertaining to the issues that will
10 be discussed today. In addition, there are reference copies
11 of the material provided to you by FDA, and also there are
12 reference copies of literature articles submitted to the
13 agency, and these references copies are on a small table
14 behind me to my right -- your left.

15 I will now turn the meeting over to Dr. Janosky.

16 CHAIRPERSON JANOSKY: Today the panel will discuss
17 the classification of devices used in the diagnosis and/or
18 treatment of TMD and orofacial pain, based on the table
19 previously provided by FDA.

20 We will begin today with a presentation by Dr.
21 Susan Alpert, the Director of the Office of Device
22 Evaluation.

23 DR. ALPERT: Thank you, Dr. Janosky. Good
24 morning, I'm Susan Alpert. I'm the Director of the Office
25 of Device Evaluation. I'd first like to welcome all of the

1 panel members, participants and guests for this meeting. In
2 addition, I'd like to thank the panel members in advance for
3 their work on this very important reechoes.

4 What I'd like to address this morning are several
5 issues which we at FDA believe are important to you as
6 background for the process we're involved with today. I'd
7 like to provide some historical context for this meeting;
8 address issues pertinent to the classification process
9 itself, including the activities that we will undertake in
10 these two days and others which follow this activity; and
11 I'm going to address a bit in detail the specific tasks that
12 we're asking the panel to perform.

13 In your package you find some background
14 information about the meeting, and I'd like to add to that.

15 We're here today to consider the classification of
16 two types of devices that we at FDA, and with input from the
17 regulated industry and a panel convened in November of 1997,
18 believe are of a type which were in commercial distribution
19 prior to May 28, 1976, but were not previously classified.
20 We call these "unclassified pre-amendments devices."

21 As you are all aware, we began this process almost
22 four years ago. In 1994 we convened a panel to address this
23 issue. However, due to procedural irregularities, that
24 panel's recommendations were set aside. In the interim,
25 there have been many discussions regarding the devices that

1 were considered at that meeting and the information that was
2 presented to that panel.

3 We at FDA have taken a number of steps to distance
4 today's proceedings from the 1994 process, and to assure
5 that the concerns raised following that meeting are avoided
6 for this meeting.

7 First, the FDA determined not to invite as its
8 advisors any of the non-agency individuals who participated
9 in any way at the '94 meeting. That is not intended to say
10 that all of the participants were responsible for the
11 outcome of that meeting, but to insulate this process and
12 avoid any appearance of bias on the part of the agency in
13 selecting some but not others of those who participated in
14 '94. What this means is that we did not invite to sit at
15 the table and vote, or offer to pay for the transportation
16 for any of those individuals; anyone who participated at all
17 in the '94 meeting.

18 I should note, however, that this is an open
19 process, and any individual who wishes to speak at this
20 meeting, regardless of their participating at the '94
21 session, is of course free to do so at their own expense,
22 and to participate in the open session.

23 Second, as already noted, there was a meeting in
24 November of '97 where the subject was the whole scope of
25 products used to diagnose and treat TMJ/TMD disorders. At

1 that meeting the panel was asked to identify the types of
2 devices used and the array of claims that were made for
3 those technologies.

4 Third, following that meeting, and using the
5 transcript and our available current classifications in the
6 Code of Federal Regulations -- and I have a copy of that
7 here -- the Dental Branch staff evaluated the classification
8 status of all of the device types identified at that
9 meeting. That assessment formed the basis of the grid which
10 was published for comment on FDA's WorldWideWeb site.

11 It was the determination following that process
12 that most of the devices could appropriately be considered
13 to have been classified already under existing regulations.
14 In many cases, that involved specific dental claims which
15 were found to fall within a more general claim identified in
16 a current regulation.

17 Two categories of devices, however -- jaw tracking
18 and sonography devices -- were identified by that process as
19 remaining unclassified pre-amendments devices, and they are
20 the main focus of this meeting.

21 In March, in preparation for this meeting, the
22 professional societies and the manufacturers of these device
23 types were asked to provide to FDA and this panel
24 information not previously provided for consideration in
25 these classification procedures. The November panel

1 specifically had been interested in recent studies and
2 reports of use of these products that could be pertinent to
3 today's discussions. Since no additional information had
4 been received in response to the March call, FDA provided
5 another opportunity for submission of new information in
6 June of this year. Again, no new information was received.

7 In order to provide background to the panel, FDA
8 staff then went to the bibliographies of published
9 literature and selected a sample of articles from across
10 that literature. This approach is important, in that FDA is
11 not allowed to rely on information that is within
12 proprietary submissions as a basis of classification panel
13 discussions. All of the information that we and the panel
14 can consider in this setting must be publicly available.

15 As those of you familiar with this area are well
16 aware, the literature is quite voluminous. There are over
17 600 publications that could be considered relevant. The
18 selection was narrowed to a sample of less than 40 peer-
19 reviewed publications, providing a sample of research and
20 conclusions regarding these device types, and the packages
21 were then made available to the panel and to the affected
22 manufacturers.

23 Following the packages' receipt by the industry,
24 we were contacted by several companies concerned about our
25 selections. In particular, among the papers provided to the

1 panel in the original set were approximately a third that
2 were viewed as negative on the issue of the use of
3 instrumentation in the TMJ arena. These papers were
4 authorized by well-recognized individuals who have made
5 their opinions and concerns known throughout the dental
6 field. FDA was aware of the position of these individuals,
7 but we believe it's important that we provide a broad set of
8 publications from across the scientific community
9 representing all of the voices identified in the literature.

10 Consistent with the FDA Modernization Act of 1997,
11 we provided the manufacturers an opportunity to provide
12 additional information from the literature to the panel
13 through FDA. The second package provided to the panel
14 included two sets of articles from companies, and several
15 additional publications that we at FDA identified as
16 important later in the process.

17 It should be noted that one of the companies asked
18 us to provide to you over 200 articles, stating that this
19 literature was a body of information that really needed to
20 be read in its entirety for the process to move forward.
21 FDA disagreed. We believed that to attempt to provide such
22 a large body of literature late in the process would not
23 have been productive. We determined that would have been
24 beyond our capacity to do in a short enough time to allow
25 you, of the panel, to come to grips with such a large volume

1 of information.

2 In addition, we believe that a representative
3 sample of the literature, and access to bibliographies of
4 additional publications for the panel, should any individual
5 desire to delve further, is what we should appropriately
6 provide to scientists like yourselves who are familiar with
7 how to read, interpret and access published literature.

8 We also agreed, as Pam noted, to make copies of
9 the entire set of submitted publications available to you at
10 this meeting and they are, in fact, in the binders on a
11 table.

12 It's interesting for us to note how difficult it
13 is to select from within a set of literature, when one is
14 looking for a reasonably sized sample. And, in fact, we
15 noted that the two manufacturers' sets that were submitted
16 to us as being critical for the meeting were almost non-
17 overlapping representations from the literature.

18 So this was a very difficult task, and we
19 appreciate the work that the manufacturers did in providing
20 additional information to the panel.

21 That concludes my comments on the background for
22 this meeting, and I'd like to now move to the actual process
23 of the meeting itself.

24 What we would like to accomplish in these two days
25 is a discussion of data available to us on the two

1 categories of devices that are the focus of the meeting --
2 sonography and jaw tracking -- with the result that we hope
3 the panel will make a recommendation to us regarding the
4 appropriate classification for those two categories of
5 product.

6 . I would note, however, that a question has been
7 raised as to whether these two categories also could be
8 considered to have been previously classified. As I noted,
9 the FDA review of the transcript and the existing
10 classifications did not find that to be true. But it is a
11 question that is possible to re-address.

12 The panel is being asked to address the safety and
13 effectiveness of the categories of devices; that is, to
14 assess if there is valid scientific evidence available that
15 provides a reasonable assurance of safety and effectiveness
16 for these devices under their conditions of use; that is,
17 the device, when used according to its directions for use --
18 it's labeling -- provides clinically significant results in
19 a significant portion of the target population, and that the
20 probable benefits of this use outweigh any probable risks.

21 I'm emphasizing, because it's not required that we
22 find that everyone in the community agree that every patient
23 will get the same benefit. It is a reasonable assurance for
24 a significant portion of the population; not absolute
25 unanimity.

1 Valid scientific evidence, in the case of pre-
2 amendments devices, include evidence from well-controlled
3 investigations, partially-controlled studies, and objective
4 trials without matched controls; well-documented case
5 histories and reports of significant human experience with a
6 marketed device -- and these are legally marketed devices.
7 From these types of evidence, the question is: can it
8 reasonably be concluded by qualified experts -- in this
9 case, yourselves -- that there is a reasonable assurance of
10 safety and effectiveness, as I defined them.

11 Based on your review of the evidence of the safety
12 and effectiveness of each device type, and applying the
13 definitions of device classes -- Classes I through III --
14 you're being asked to recommend a classification.

15 Let me just step back for a moment and remind all
16 of us what the classes are.

17 Class I devices are those where general controls
18 are considered sufficient to assure that new products
19 entering the market in these categories will remain safe and
20 effective. Today, since the passage of FDAMA, most devices
21 in Class I are exempt from pre-market review by statute,
22 unless they are found to be of substantial importance in
23 preventing impairment of human health, or are a Class I
24 device that presents a potential unreasonable risk of
25 illness or injury. Other than that, Class I devices are

1 exempt from pre-market review -- from 510(k), but are
2 controlled by good manufacturing, by reporting of adverse
3 events, and by appropriate labeling.

4 Devices that go into Class II are those which
5 cannot be classified in Class I, because general controls
6 are insufficient to provide a reasonable assurance of safety
7 and effectiveness, but for which there is sufficient
8 information to establish special controls. Special controls
9 include such things as guidance for what must be contained
10 in a submission -- a pre-market submission. They can
11 include labeling specifications, special testing, and can
12 even include clinical testing.

13 Those devices which are placed in Class III are
14 those that cannot be placed in I or II, because insufficient
15 information exists, and the device presents an unreasonable
16 risk of illness or injury. That's a lot to come to grips
17 with. What does it mean, and how do we get there?

18 Well, the devices that we're focusing on today are
19 diagnostic products. The panel's responsibility, therefore,
20 is to determine if, overall, in their judgment -- in your
21 judgment -- there is sufficient valid scientific evidence
22 that demonstrates that these devices provide meaningful
23 information and are safe to use.

24 The claims being made for each type of product
25 impact these decisions. For example, a diagnostic product

1 labeled to provide information used as part of a diagnostic
2 work-up may have lower risks than the same product if it's
3 labeled to provide independent diagnostic information --
4 diagnostic information used alone. That is, if information
5 is used to differentiate affected from unaffected patients -
6 -this piece of information alone -- error may pose more risk
7 than when the same product is used in conjunction with other
8 patient information and diagnostic information to make a
9 final determination about the classification of the patient.

10 What gets classified, therefore, is the product
11 and its labeling. The same physical product, the same piece
12 of equipment, the same tests, may be in Class I, therefore,
13 for one claim, and in Class II or III for a different claim
14 -- one that is believed to pose higher risk. For example, a
15 diagnostic labeled for use with other tests may be in Class
16 I, while a screening claim for the same device may be in
17 Class II or III.

18 It's a common consideration that we take in
19 diagnostic products, and we're very luck today to have as
20 the Acting Division Director Dr. Stephen Gutman. He's
21 currently on detail in the Division of Dental Infection
22 Control and General Hospital Devices, but in his home
23 division -- the Division of Clinical Laboratory Devices --
24 he is the Center's expert on diagnostics -- in vitro
25 diagnostics, in particular, but on the way we evaluate

1 diagnostic claims. So his presence at the panel is very
2 welcome.

3 We've provided almost two days for this process
4 because we believe there needs to be a sufficient time for
5 the panel to hear from manufacturers and other experts in
6 the field, and to discuss the scientific information
7 available regarding these products before being asked to
8 recommend a classification for them. As the panel was told
9 earlier today in their training session, the classification
10 process for the panel includes filling out a classification
11 questionnaire and a supplemental information sheet in most
12 cases.

13 Let me remind everyone that a recommendation made
14 by this panel is preliminary, until the FDA has reviewed it,
15 discussed it with the panel if necessary, and published a
16 proposed regulation. It is a recommendation to the agency,
17 and not a final determination.

18 Before I provide an opportunity for the panel to
19 ask questions, I would like to thank all of you once again
20 for your participating in this meeting, and I look forward
21 to a very productive two days.

22 And, with that, I'd like to open it up for
23 questions -- from the panel.

24 [No response.]

25 DR. ALPERT: Thank you.

1 CHAIRPERSON JANOSKY: The next presentation will
2 be by Dr. Susan Runner, who is the Branch Chief for the
3 Dental Devices Branch.

4 DR. RUNNER: Good morning.

5 One thing that I have learned since beginning to
6 work for the government is to try to speak in plain
7 language. So I'm going to attempt to do that this morning,
8 even though it is a complicated topic.

9 I'm going to tell you what we've got; I'm going to
10 tell you how we got there; and I'm going to tell you what we
11 hope you can do.

12 So I hope if I repeat myself, and if I repeat some
13 of the things that Dr. Alpert said, please forgive me, but I
14 think it bears repeating.

15 Now, we're getting very fancy here with the -- we
16 may not get fancy.

17 [Pause.]

18 DR. RUNNER: Okay. Well, I'll start.

19 What we have, as Dr. Alpert did mention to you
20 before, is that we have determined, subsequent to the
21 November 1997 panel meeting, that two classes of devices
22 require classification. Those two classes of devices are
23 the sonographic devices and the jaw kinesiology or jaw
24 tracking devices.

25 Some of you were present at the November 1997

1 panel meeting, and during that meeting the panel was
2 presented with broad categories of devices for the diagnosis
3 and/or treatment of temporomandibular joint disorders and
4 orofacial pain. We enumerated, at that time of that panel
5 meeting, devices used in the practice of dentistry that
6 contribute to or provide information on TMD orofacial pain.

7 This meeting was an opportunity for the Dental
8 Products Advisory Panel, professional organizations,
9 interested persons, to provide comments on the types of
10 devices that are already included in present device
11 classifications and the types of devices that are presently
12 unclassified.

13 During this --

14 -- aha -- next slide, please. Could we turn the
15 lights down a little bit? Not all the way. Thank you.

16 During this November Panel meeting there was open
17 discussion of device types, indications for use were
18 resented, and the labeling and function of the devices was
19 discussed. The Panel, as Dr. Alpert said, was also
20 requested at the meeting that any available data related to
21 the use of these devices in the diagnosis and/or treatment
22 of TMD and orofacial pain be submitted to the Panel. As she
23 said, the Panel requested information on recently controlled
24 clinical studies, uncontrolled studies, clinical reports,
25 and other information about these devices since they have

1 been on the market. This information was to be used to
2 support device classification. At that November '97 meeting
3 the safety and effectiveness of the devices was not
4 discussed.

5 Next slide, Angela.

6 In the intervening months, FDA's charge was to
7 review in detail the transcript of the November '97 meeting.
8 And in that process, we reviewed and investigated all of the
9 types of devices and device classification regulations. We
10 have also formally asked industry to submit additional
11 information. As a result of that work, you have this
12 classification grid that we have all sent to you, and that
13 was p[la]ced on our web site in June of 1998. This grid
14 indicates the devices that FDA believes have already been
15 classified, and those devices that do not fall within a
16 present device classification and thus remain unclassified.

17 Next slide.

18 The grid that you all have delineates the devices
19 that we discussed, and it identifies the generic name of the
20 device, the FDA's determination of whether the product is a
21 medical device, any relevant device classifications from the
22 21 CFR, and a classification description of any specific TMD
23 or orofacial pain claims.

24 The Panel charge, therefore, is a classification
25 recommendation to us for those products that are medical

1 devices which are intended for the treatment and/or
2 diagnosis of TMD and/or orofacial pain, and do not already
3 fall within a present device classification.

4 Next slide.

5 We have determined that several generic types of
6 products that are listed are already classified, and other
7 device categories remain unclassified. We're going over
8 this over and over again, but I want to be sure you
9 understand the grid.

10 Each numbered item on the grid refers to the
11 reason for that determination, or its classification, and
12 the reason -- or the reason that the device does not require
13 further classification. Again, we consider some devices
14 already to be classified under existing classification
15 regulations.

16 I'll go over briefly the reasons that we used.

17 The following reasons are reasons FDA has
18 determined that some products are not in need of further
19 classification.

20 Number one is the generic type of product is not a
21 medical device as defined in the Food, Drug and Cosmetic
22 Act.

23 Next slide.

24 Two: the generic type of device is classified; the
25 general intended use in the classification regulation

1 encompasses the use of the device for the treatment and/or
2 diagnosis of TMD and/or; and there are no specific TMD
3 indications for use in the labeling of any legally marketed
4 devices that FDA has identified. Therefore, this generic
5 type does not require further classification.

6 . Next slide.

7 The third reason would be that the generic type of
8 device is classified; there are legally marketed devices
9 with TMD related claims, and the FDA has determined that any
10 legally marketed devices within this generic type with a TMD
11 and/or orofacial pain indication is within the generic
12 device classification. Therefore this may modify previous
13 determinations on the classification status of specific
14 devices and require notification of the affected parties.

15 Next slide, please.

16 For the following reasons, FDA has determined that
17 some devices are not adequately classified.

18 Reason four: the specific indication for the
19 treatment and/or diagnosis of TMD and/or orofacial pain
20 within the generic type of device is not encompassed by the
21 general indication for use, nor is the specific product.
22 Because of this, new types of safety and effectiveness
23 issues are of concern, and therefore classification is
24 required. The Center will assess any differences in
25 indications, in terms of safety and effectiveness questions

1 that the different indication may raise. After
2 consideration of these factors and recommendations from
3 experts such as you, a classification will be recommended.

4 The generic type -- and, number five, next slide -
5 -and the fifth reason would be that the generic type of
6 device is not classified, and there are no classification
7 generic types.

8 It is important to remember that, notwithstanding
9 the classification and the labeling of devices, health care
10 practitioners who are authorized to prescribe and administer
11 medical devices may use legally marketed devices for any
12 purposes that they believe are appropriate for their
13 patients. Therefore, there may be instances where products
14 and devices are being used for the treatment and/or
15 diagnosis of TMD and/or orofacial pain, but are not labeled
16 for such use. These are not under the parameters of FDA
17 classification, clearance or approval, but are considered
18 the practice of medicine and dentistry. Persons who market
19 and promote devices, however, for new uses are subject to
20 pre-market requirements. The public should refer to the FDA
21 Modernization Act for further information in this regard.

22 Again, for the purposes of classification and this
23 Panel, FDA has determined that the specific devices
24 requiring classification because of reason number 4 -- could
25 you go back to reason number 4, Angela? -- are sonographic

1 devices and kinesiographic or jaw tracking devices. These
2 are the only two categories that the Panel will be asked to
3 provide classification recommendations on over the course of
4 this meeting.

5 We have received comments, as Dr. Alpert said, on
6 our classification grid; specifically on devices that we
7 have determined are already classified. The opinion has
8 been expressed that additional classification should be
9 considered. We have taken note of these comments and would
10 like to encourage this panel to comment on our grid at the
11 appropriate time.

12 Alternate classification recommendations for other
13 device categories, however, will be discussed, as
14 appropriate, in future meetings and not at this meeting.
15 Any alternate classification recommendations would require
16 the usual FDA procedures of petition, notice and comment and
17 rule-making. Again, at this meeting FDA is requesting the
18 classification recommendation only on sonographic devices
19 and kinesiographic devices.

20 I'm going to briefly go over some of the comments
21 that we received on our grid, and I will then go into more
22 detail when it gets closer to the classification process so
23 that you will be aware of comments from interested persons.

24 As I mentioned, we did receive one comment on our
25 grid that the EMG category of devices should require further

1 classification. If you note on our grid, we have said that
2 it is already adequately classified by the existing
3 classification regulation. This party felt that the present
4 classification does not adequately reflect the uses in the
5 treatment and/or diagnosis of TMD.

6 Another series of comments were received on the
7 sonographic, EMG, and kinesiographic, and TENS devices. And
8 I'm going to briefly summarize these comments now, and later
9 I will go into more detail.

10 First, there was concern about combining
11 indications for the more invasive needle EMG with the
12 surface EMG.

13 There was also concern that the sonogram should be
14 classified as a Class I device because the other relevant
15 device classification of Class II for the electronic
16 stethoscope is for diagnosis of potentially life-threatening
17 pathology. And this person felt that the sonogram functions
18 as a recording and display device only, with no interpretive
19 function.

20 There was also concern that the kinesiograph would
21 be considered a device that analyzes and interprets data.
22 This party felt that the kinesiograph produces data that is
23 used by the clinician, together with all other information,
24 to arrive at a diagnosis.

25 And, fourth, there was concern that although the

1 Class II designation is appropriate for TENS units, a
2 distinction between high and low frequency TENS units should
3 be made clear to the panel, and the physiologic effect of
4 low frequency TENS is different from that of high frequency
5 TENS.

6 . Again, I'll go into more detail on these concerns
7 at a later point, if you're interested.

8 So, once again, bottom-line up front: we're asking
9 you for a recommendation on the kinesigraphic and
10 sonographic devices today, as well as comments on our grid
11 as we have presented it to you.

12 Thank you.

13 CHAIRPERSON JANOSKY: Do any of the panel members
14 have any question for Dr. Runner?

15 [No response.]

16 CHAIRPERSON JANOSKY: Dr. Runner, was there a
17 comment received via FAX that could be read into the record
18 at this time?

19 DR. RUNNER: As a part of our process, we did seek
20 information from -- or opinions from other experts in the
21 field that were unable to participate in the meeting. And
22 we did receive two comments, which I will try to do justice
23 to. They're fairly complex, but I will try to do justice to
24 them.

25 One comment was from Dr. Peter Chase at the

1 University of the Pacific. And I'm going to try to
2 generalize it at first, and then I'll be specific.

3 He felt that one of the basic problems with the
4 classification process is the vocabulary that we use to
5 describe these devices. And he made extensive changes on
6 our grid, in terms of the description of the different
7 classifications of devices. He felt that vocabulary is
8 everything, and that we should change the vocabulary of even
9 existing classification regulations to more adequately
10 reflect the use of the devices.

11 I'm going to read his first generalized paragraph
12 first.

13 "The information sent to me is inaccurate and
14 misleading and confusing. In simple terms,
15 electromyography, sonography, and kinesiography measure
16 bioelectric, biomechanical, musculoskeletal function and
17 dysfunction. TENS, ultrasound and EGS are treatment devices
18 for musculoskeletal disorders. The doctor interprets
19 bioelectric and biomechanical information and uses the data
20 to support the diagnosis, and in evaluation of treatment
21 effectiveness. The treatment choices could include TENS,
22 ultrasound, EGS, etcetera. It's simple," he said.

23 And I'm going to not go over every change that he
24 made on this grid, but it will be available to panel members
25 if they would like to look at it later, because it's a

1 little too complicated to go into.

2 The second comment was from Dr. Pamela Steed, who
3 I believe is in private practice in Indianapolis, Indiana.
4 She comments that, "I have reviewed the classification,
5 along with the grid, and I find the classification to be
6 acceptable as they stand. Dr. Runner, please be aware that
7 dentistry is a branch of physical medicine. The Division of
8 Dentistry should be addressed in the same fashion -- " --
9 I'm sorry -- " -- the devices of dentistry should be
10 addressed in the same fashion as the devices of medicine.
11 In Europe, dentistry is a branch of medicine, and thus most
12 dentists are double-degreed. The only Class III device
13 listed on the grid was that of iontophoresis, utilizing a
14 drug into the body for medical purposes. I agree that such
15 iontophoresis is an excellent treatment modality that must
16 be utilized by physicians with a DEA license."

17 "My attendance at an international thermographic
18 meeting last month was enlightening. Many Europeans and
19 Asians sent researchers and clinicians with impressive
20 findings in the area of diagnosis and treatment prognosis."
21 And that was essentially her comment.

22 CHAIRPERSON JANOSKY: Thank you, Dr. Runner. Do
23 any of the panel members have any questions or comments for
24 Dr. Runner or Dr. Alpert?

25 [No response.]

1 CHAIRPERSON JANOSKY: If there are no questions or
2 comments, I would like to proceed with the open public
3 hearing, and there has been agreement by the first presenter
4 during the open public meeting -- Ms. Terrie Cowley. Before
5 she begins, let me please read some information concerning
6 public hearing.

7 At this time we open the floor to the public.
8 Those who have signed up and those later who would like to
9 speak, I will also give you a chance to speak.

10 I would ask that all persons addressing the Panel
11 come forward to the microphone and speak clearly, as a
12 transcriptionist and note-taker are dependent on this means
13 of providing an accurate transcription of the proceedings of
14 the meeting.

15 In addition, we request that all persons making
16 statements, either during the open public hearing or the
17 open committee discussion portions of the meeting disclose
18 whether they have financial interests in any medical device
19 company before making your presentation to the Panel. In
20 addition to stating your name and affiliation, please state
21 the nature of financial interest, if any.

22 At this time we will hear from Ms. Terrie Cowley,
23 whose organization affiliation is TMJ Association.

24 You have 20 minutes to speak.

25 MS. COWLEY: Okay. Thank you.

1 I am Terrie Cowley. I am co-founder and president
2 of the TMJ Association. I don't have any financial interest
3 in any device manufacturing company.

4 The TMJ Association is a non-profit patient
5 advocacy organization for people suffering from what the
6 dental professionals tell us we have -- and, by the way, I
7 will try to speak clearly -- TMJ. It is also the term most
8 familiar to the patients and the public. Thus, we use that
9 term.

10 I am not here to evaluate the scientific merits of
11 the devices being assessed today, for that is your charge.
12 However, as a TMJ patient and patient representative, I am
13 personally affected by every decision made by professional
14 organizations and governmental agencies on TMJ disease and
15 disorder issues. For that reason, I feel compelled to
16 address certain topics which were directly discussed or
17 incidentally referred to in the November 1997 FDA Dental
18 Products Panel meeting.

19 It is first appropriate to address the issue of
20 what exactly is this medical/dental/mental malady we refer
21 to as TMJ/TMD, and a myriad of other letter combinations?
22 The November '97 meeting took almost of a day of discussions
23 for the panel to come to a working agreement on the meaning
24 of "temporomandibular disorders and associated pain and/or
25 dysfunction." This tells you that there is no exaggeration

1 to the fact that, try as we might, we come up short
2 pinpointing what may be the multiple and complex reasons for
3 the different types of pain and/or breakdown of the joint
4 that forces of millions of patients into dental offices and
5 medical facilities all over this country seeking help.

6 . As the Washington Post concluded in their article
7 covering the NIH Technology Assessment Conference, "You
8 don't know what you are calling TMD, and you don't know what
9 pain in the jaw signifies."

10 The second issue I will touch on is treatments.
11 In 1988, the Director of Scientific Affairs for the American
12 Dental Association, Dr. Enid Neidle, described TMJ as
13 "dentistry's hottest area of out-and-out quackery." In
14 1991, in an editorial entitled, "Above All Else, Do No
15 Harm," Dr. Harold Perry stated, "Our current weekly referral
16 service routinely will see a good 50 percent of the patients
17 presenting with an iatrogenic disturbance because of
18 inappropriate surgery, unwarranted restorations,
19 orthodontics, and most frequently, incorrect splint
20 therapy."

21 In 1996, the Technology Assessment Conference did
22 not find marked improvement in the TMJ research and
23 treatment status since Drs. Neidle and Perry's statements
24 were made, for it concluded: "The efficacy of most treatment
25 approaches for TMD is unknown, because most have not been

1 adequately evaluated in long-term studies, and virtually
2 none in randomized controlled trials."

3 It is said that most patients get better with or
4 without treatment. We don't doubt that. The question we
5 don't have answer to is: how many patients are unaffected,
6 improved or harmed by one of the many treatments they
7 received. We know some patients get better on treatment.
8 But, lacking the science, how ethical is it to put a
9 patient's life at risk without knowing what those risk
10 factors are; that a patient may turn out like the 30,000
11 plus that we have received letters from and personally
12 talked to? One dentist said, "Patient selection criteria
13 are little to none, with the exception of ability to pay.
14 The type of treatment the patient received depended upon the
15 floor they exited in the dental school or office building."

16 The TMJ public has clearly been denied the
17 scientific proof and regulatory protection which would
18 assure them of the safety and efficacy of the 49-plus
19 treatments they are receiving. To again paraphrase the
20 Washington Post, "You don't know what works and what
21 doesn't, because you haven't done randomized clinical
22 trials."

23 The third matter, frequently referred to in the
24 last meeting, is the politics of TMJ. I'd like you to know
25 how we, the patients, have viewed the political and economic

1 dynamics of TMJ over the years.

2 Until recently, TMJ has been referred to in
3 sardonic jest as "The Money Joint." Dental journals touted
4 the treatment of TMJ as a sure way to inflation-proof one's
5 practice, and ensure a financially health retirement.
6 Although the dental community has largely been the care
7 providers to TMJ patients, the American Dental Association
8 has judiciously neglected to adopt TMJ as a specialty, for
9 it lacks any substantial body of scientific knowledge
10 necessary to confer specialty status. This has, in effect,
11 been a policy of malicious neglect, since left to their own
12 devices -- no pun intended -- their members developed
13 numerous methods of treating TMJ. The dental gurus of TMJ
14 passed these methods on to their devotees through what Dr.
15 Perry describes as, "sporadic, single-concept, Hilton
16 University weekend TMD education."

17 The past half century witnessed the formation of
18 numerous professional organizations, based upon their
19 treatment beliefs, some paradoxical to each other, as the
20 equilibration society and the non-equilibration society --
21 or ANTA -- denigrating the other's beliefs to patients,
22 vying with each other in turf battles, and which only unite
23 when they are threatened by actions of the FDA and,
24 recently, the NIH Technology Assessment Conference.

25 Treatment of this joint continues to be largely

1 based on anecdotal information and professional treaters'
2 preferences. The many different treatment preferences
3 yields a field rife with chaos and controversy, and this is
4 certainly obvious to most patients if they have seen more
5 than one treatment professional.

6 . Which brings me to the fourth issue, the harm that
7 has befallen TMJ patients. I could share with you for days
8 the information in our data base, which is filled with
9 information on the patient with 39 splints in two years; the
10 patient whose dentist treated her RMJ by banging her teeth
11 into her gums with a wooden mallet; a few who had their
12 episiotomy scars inject to cure their TMJ; the paralysis,
13 deformity, feeding tubes, morphine pumps, suicides and
14 deaths -- but you know all these stories.

15 Which leads me to the issue of psychogenic
16 etiology, psychological overlay. In the course of TMJ,
17 patients are forced to abandon such dreams as promising
18 careers, marriage, children, committing to anything planned
19 or predictable, eating in a restaurant, having one's faced
20 touched by a child and intimate acts. However, there are
21 additional problems. The media, fed information by the
22 treating professionals, present TMJ as some little problem
23 afflicting crazy, stressed-out women that can be fixed by a
24 little tweaking of the teeth, magic plastic, a new spouse, a
25 jaw exerciser, a new job, some wine or a similar remedy. It

1 is little wonder most TMJ patients are closet bound and
2 refuse to admit they have TMJ, for nobody believes it can be
3 as bad as we know it to be.

4 If the patient's condition worsens as treatment
5 progresses, the patient is usually blamed. We hear, "Your
6 body didn't like that material," or "Why don't you really
7 want to get well?" And your family and friends are told,
8 "Everything is fine. There is no reason she is having
9 pain." The husband of one woman who had 12 surgeries and
10 four different devices told us when they returned from an
11 appointment with the oral surgeon, he said, "The doctor is
12 the expert. Who should I believe, him or you? He says you
13 don't have pain." Upon which, she went into the bedroom and
14 shot herself.

15 The psychological community would say she was
16 depressed. She may have been depressed, but we would say
17 she was desperate; desperate to have everybody stop lying to
18 her and validate the damage that was done to her; desperate
19 to understand that she was indeed in pain and needed help.
20 We would say she felt betrayed; betrayed by doctors who took
21 an oath to do no harm; betrayed by the FDA, whose mission
22 was to protect her; betrayed by the NIH, who funded a
23 negligible amount of research over the years.

24 The TMJ implant disaster is a case study which
25 demonstrates how every entity responsible for protecting the

1 health and safety of the RMJ patients failed in this
2 responsibility. In 1963, John Charnley published an
3 editorial stating that proplast/teflon failed miserably in
4 the hip, a load-bearing joint. Subsequently, the orthopedic
5 community abandoned the use of PTFE in load-bearing joints.
6 Twenty years later, the FDA approved the Vitek
7 proplast/teflon implant in a load-bearing joint, saying it
8 was substantially equivalent to Dow Corning silastic. Dow
9 Corning never conducted studies on silastic for trismus of
10 the jaw joint but labeled their product accordingly. We now
11 know the problems with that material. The oral surgeons
12 implanted these devices with vigor.

13 When the FDA issued a Class I recall on the Vitek
14 because of the damage that was being documented by lawyers,
15 suddenly failure became an orphan. Dr. Homsy, President of
16 Vitek, declared bankruptcy while taking his assets and
17 fleeing the country for Switzerland. The FDA said they
18 weren't to blame; they just 510(k)'d the product. Material
19 scientists and other device manufacturers who strenuously
20 argued with Homsy regarding the utility and safety of his
21 product at meetings years before did nothing to warn the
22 unsuspecting public. The oral surgeons said the FDA
23 approved it, so it must be safe and, besides, we don't have
24 time to read the literature. However, if they did read the
25 dental literature, they would have only read and continued

1 to read good news and nothing much about implant damage.

2 The National Institute of Dental Health said they
3 never funded research on implants because they did not
4 approve of them. Insurance companies who paid to have the
5 implants put in now refused to pay for explanation, citing
6 that procedure is experimental.

7 Animal experiments were only conducted four years
8 being implanted in humans, and to confirm the pathology they
9 were seeing in humans. Since there was no TMJ implant
10 registry, there was no way of knowing how many patients had
11 implants and how to find them. In this scenario, no one has
12 accepted responsibility for any of these actions, and not
13 one of these groups has yet stepped forward to assume
14 responsibility for the RMJ implant patients. To paraphrase
15 the Washington Post, " -- and a lot of people have been
16 harmed."

17 The Vitek situation is a case study, reflective of
18 the whole of TMJ, which demonstrates a system in which each
19 entity functions independently and irresponsibly, lacking
20 any integration of the individual parts, each moving in
21 uncoordinated directions. When all was said and done, it
22 became a "Who us? No. It was them" blame game. And who
23 was left holding the bag? The patients.

24 Today you will be evaluating -- and tomorrow --
25 devices which will have a direct impact on the TMJ patients

1 of this country. If we believe the Tech Conference
2 statement as reported by the Washington Post -- "You don't
3 know what you're calling TMD --" -- then we shouldn't even
4 be here, for the devices are labeled for something we know
5 not what.

6 . But we here. Perhaps you will decide that a
7 device does what it is labeled to do, and then it goes to
8 the practice of dentistry, and they are confused about what
9 they're treating, and they don't file MDR reports, or they
10 do, and the manufacturer doesn't send them to the FDA; or
11 they do send them to the FDA, but what good is that if the
12 FDA has a backlog of 60,000 MedWatch reports, and it takes
13 years to detect the damage. I think you see where I'm going
14 here.

15 The FDA will make decisions -- and you, the Panel
16 -- in these two days. The manufacturers' devices will be
17 decided upon. If we are to change the face of TMJ, every
18 entity, including the TMJ patients, must put the safety of
19 the TMJ patients as their priority in every action taken
20 within the realm of their responsibility. And today the
21 manufacturers and this panel must put the safety of the TMJ
22 patients of this country first and foremost in their
23 deliberations.

24 The FDA and the manufacturers must then excel in
25 their responsibilities as partners in this integrated system

1 of checks and balances, so that harmful treatments are
2 detected and deleted from the standard practice of the TMJ
3 diseases and disorders before thousands or millions of
4 people are harmed.

5 Perhaps the most encouraging and insightful
6 statement made at the November '97 meeting was made by Dr.
7 Barry Cooper. He said, "Maybe what we really have to do is
8 respect the fact there is a bigger illness or bigger
9 possible implication, while acknowledging that the field is
10 still open to discussion and knowledge, and that there will
11 be other things that will be proven to be involved in it."

12 Ask any TMJ patient where they have pain other
13 than the jaw, and most will tell you they have generalized
14 musculoskeletal pain. Ask if they have mitral valve
15 prolapse, hypermobile joints. Over 50 percent will say yes.

16 In the bits and pieces of scientific information
17 drifting out of laboratories recently, we are learning that
18 the TM joint may not be just like other joints in the body;
19 that hormonal influences on pain may be gender
20 differentiated; and what are we to make of nerve growth
21 hormone injected into the arm, producing pain in the jaw?

22 At this time, we do not know where TMJ will shake
23 down. But clearly we are in the infancy of what promises to
24 be a most exciting scientific future for TMJ which will
25 yield improved health care and quality of life for the

1 millions of U.S. TMJ patients. In this, what we hope is not
2 the too distant future, we will have unlocked for us those
3 secrets. What is TMJ? Why mostly women? What works? And
4 what big picture is this a part of?

5 Thank you for the opportunity to present.

6 [Applause.]

7 CHAIRPERSON JANOSKY: Thank you, Ms. Cowley.

8 Do any of the panel members have any questions?

9 [No response.]

10 CHAIRPERSON JANOSKY: At this time -- the next
11 scheduled presenter during the open public meeting is Dr.
12 Garry Wolford. Are you able to present at this time, or
13 would you prefer to wait until after lunch? Is he present?
14 Yes.

15 Would you prefer to present now, or -- are you
16 prepared to present now? Okay. So we'll continue.

17 I ask again that you please state your name and
18 affiliation, and the nature of your financial interests, if
19 any.

20 DR. WOLFORD: My name is Garry Wolford. I'm an
21 oromaxifacial surgeon from St. Clair Shores, Michigan. I do
22 not have -- I'm here at my own expense. I have no financial
23 interest in either Myotronics, Inc., or Bioresearch.

24 In the past ten years my practice has been limited
25 to approximately 90 percent to the diagnosis and treatment

1 of disorders of the temporomandibular joint, and patients
2 with facial pain. I do use Myotronics equipment in the
3 evaluation of my patients.

4 As a bit of a background, I did my oral surgery
5 residency at Parkland Hospital in Dallas, Texas, from 1967
6 through 1970. I was able to train under Dr. Robert Walker,
7 Dr. Jim Bertz, Dr. Bruce Epker, Dr. William -- with which I
8 had the opportunity to perform some of the monkey research
9 for maxillary surgery procedures -- and also Dr. Weldon
10 Bell.

11 From 1970 through 1974 I developed an affiliate
12 program for the Parkland program at the Dallas VA hospital.
13 And in 1974 I was hired by Henry Ford Hospital to
14 reestablish the oral surgery program at that institution.

15 I left there in 1988 to continue my private
16 practice.

17 I wanted to upgrade the equipment that I was using
18 to evaluate and treat patients. They did not have the
19 money, and so like the razor fellow, I went out and bought
20 it myself.

21 I'm currently on the teaching staff at Detroit
22 Receiving Hospital and Detroit Macomb Hospital oral surgery
23 programs, and I have a special interest in jaw dysfunction
24 because I have an internal derangement myself, and have --
25 four times was misdiagnosed.

1 At Henry Ford Hospital, because of our neurology
2 department and neurosurgery department, I was referred
3 numerous patients with facial pain and jaw dysfunction
4 problems. Our initial workup included cephalometric
5 panoramic transcranials, x-rays, models that were mounted to
6 centric relationship. And we surgically corrected the
7 skeletal problems as well as the internal derangements.

8 I found that if I just correct -- repaired the
9 internal derangement the patients developed pain within 12
10 months. We discontinued those procedures.

11 From 1980 to 1986 -- excuse me, in 1980 we
12 developed on arthrography technique, injecting local
13 anesthesia with contrast media into the temporomandibular
14 joint which resulted in a painless -- relatively painless --
15 procedure to diagnose disk positioning. We resurfaced the
16 orthotic appliances, and we noted that all the patients,
17 while they were pain-free and were functioning without any
18 noise -- without any joint noise -- had primary anterior
19 tooth contact.

20 Our therapy then became surgical osteotomies and
21 repositioning the jaws, with disk ligament reattachment.
22 The results with the combination -- surgical orthanathic
23 procedures and the discal surgery were approximately 90
24 percent successful. There were still 10 percent that needed
25 other work. And I was puzzled and I was lost.

1 In 1984, Dr. David Murphy from Merlot, Michigan,
2 introduced me to the Myotronics equipment and came down to
3 Henry Ford and helped me evaluate some of our patients. In
4 1985 I got my first -- the hospital purchased a small
5 portion of the equipment, and we started testing all of our
6 patients for surgical ortho purposes who did not have any
7 joint symptoms, and we also used it for evaluating our
8 temporomandibular joint patients.

9 Our findings were that the surgical orthanathic
10 patients' clenching function improved after their surgery.
11 Their abnormal closing functions, which we identified prior
12 to the surgery, was eliminated; their dyskinesia and
13 bradykinesia were eliminated, and their resting
14 electromyographic values were within-normal-limits.

15 We then started to evaluated our temporomandibular
16 joint patients, and we began constructing their appliances
17 to the myo-trajectory. I could not have the equipment
18 updated and, as I said, in 1988 I left.

19 Our workup now includes, of course, the history,
20 examination, cephalometric, panogramic, submedovertex
21 axially corrected tomograms; I have a fluoroscopy unit, if
22 necessary; electromyographic computerized mandibular
23 scanning and sonography testing on the patients.

24 In my current office, in the last ten years, we
25 have tested 1,028 patients. The protocol for the treatment

1 is very similar to that of -- that has been published -- by
2 that of Dr. Barry Cooper, who I had the privilege of meeting
3 for the first time this morning. I do all of my own
4 testing. I place all of my own electrodes. I do all of the
5 examinations on the patients personally.

6 The results of using the kinesiograph, the
7 electromyographic testing -- since 19 -- well, prior to
8 1988, we operated approximately 100 patients a year for a
9 combination of surgical orthanathic and temporomandibular
10 joint-related problems. Since 1988, using the kinesiograph,
11 the electromyographic evaluation and sonography, I have not
12 operated a single patient with an isolated internal
13 derangement of the temporomandibular joint. I have been
14 able to -- with orthodontists and restorative people, been
15 able to eliminate their symptoms without surgery.

16 The only joints that I have operated on in the
17 past ten years that had not been previously surgerized were
18 those that have had an associated subluxation and
19 dislocation of the mandibular condyles.

20 In preparing for another paper, the last 147
21 patients that were referred to my office with a diagnosis of
22 internal derangement of the temporomandibular joints, there
23 were only 21 that had internal derangements. There were 126
24 that had a subluxation of their condyles. Eleven patients -
25 -a separate 11 patients that had been diagnosed as having a

1 closed lock situation, where the disks were displaced and
2 would not reduce, actually had coronoid -- mandibular
3 coronoid hyperplasia, a mechanical limitation of opening.

4 The results of our analysis -- excuse me, my
5 analysis of patients -- all patients with myofacial pain and
6 internal derangements when tested and evaluated with the
7 kinesiograph, electromyography unit and sonography -- and,
8 as I say, all my myofacial pain patients and patients with
9 internal derangements will close posteriorly to
10 myotrajectory when tested with the kinesiograph.

11 By constructing an orthotic to the myotrajectory,
12 we are able to eliminate the patient's pain and discomfort
13 within a month's time -- with the exception of patients that
14 have a chronic dislocation and subluxation, and patients
15 that have had previous surgical interventions. Their
16 conservative treatment time is prolonged.

17 As I indicated, I had a fluoroscopy unit. I used
18 to perform approximately a hundred arthrography intervention
19 cases a year. It's been two years now since I performed my
20 last one. And, again, it's because I can confirm the
21 diagnosis of internal derangements with the use of the
22 kinesiograph.

23 In the last two years we have operated four cases
24 with subluxation and internal derangements that we could not
25 eliminate their discomfort conservatively. I have also

1 reconstructed successfully 22 cases in the last two years
2 that have had two to nine previous surgical procedures, by
3 mounting the models to a physiological relationship with the
4 use of the kinesiograph and then performing the mock surgery
5 on their study models, and then the surgery on the patients.

6 . In my experience, the use of the myotronics
7 equipment -- the EMG, CMS, myomonitor and sonography -- are
8 safe. They do not harm the patients. It increases the
9 successful treatment time in eliminating the patient's
10 dysfunction and pain, with the exception of those few
11 extraordinary patients that have multiple surgical
12 procedures and have chronic dislocations of their
13 temporomandibular joints.

14 All of the procedures are non-invasive. There
15 have been no adverse reactions from any of my patients that
16 we have used this equipment on. It provides us with a
17 measurement -- the physiological parameters of mandibular
18 function, and it gives us an ability to measure the success
19 of our treatment.

20 If properly used, the number of surgical
21 interventions of the temporomandibular joint will be
22 decreased. And then, lastly, in my opinion these devices
23 provide hard documentation of temporomandibular dysfunction
24 in evaluations or treatment.

25 Thank you.

1 CHAIRPERSON JANOSKY: Thank you, Dr. Wolford.

2 Do any of the panel members have any questions?

3 DR. REKOW: Dr. Wolford, I have a couple of
4 questions. This is Diane Rekow.

5 Can you tell me two things? Could you tell me,
6 please, when you use the splint, what state is the occlusion
7 after the splint therapy? And the second question is: what
8 do you use as your measures of success, both in terms of
9 qualitative and over time?

10 DR. WOLFORD: Measures of success are no pain and
11 no noise.

12 DR. REKOW: No pain with --

13 DR. WOLFORD: No pain and no joint noise.

14 DR. REKOW: Okay.

15 DR. WOLFORD: Ummm --

16 DR. REKOW: For how long?

17 DR. WOLFORD: Okay -- I have to back-track a
18 little bit, because I didn't address the breakdown of the --
19 you know, of all the specific treatment because that's been
20 documented by Dr. Cooper.

21 Basically the patient is seen. They're evaluating
22 the appropriate -- you know, history, clinical exam,
23 etcetera. We utilize the kinesiograph to construct an
24 appliance that is built to the myotrajectory. Again, I
25 don't know if you use -- if you're familiar with that or

1 not. I'm not --

2 DR. REKOW: A little bit.

3 DR. WOLFORD: -- and they're fitted with that
4 appliance. And then they're then followed on a weekly basis
5 for two weeks, with minor adjustments if necessary. They
6 are then followed on two-week intervals for two months, and
7 then after three months they're again re-evaluated and we
8 re-check their electromyographic values and we check their -
9 - making sure that they're still closing along the
10 trajectory.

11 Most all of the patients have relief of pain
12 within a month. And the majority of those patients, when we
13 remove the appliance and we check, every one of them that I
14 have tested has always closed posteriorly to the
15 myotrajectory. And so they will have primary anterior tooth
16 contact with -- and again, in almost all cases -- a slight
17 posterior open bite.

18 At that time, we go to their general dentist with
19 the mounted models and say, "This is the patient's
20 functional jaw closing relationship. They're pain free in
21 this position. Can you fix this restoratively? Can we use
22 orthodontic therapy? " -- and, again, we have several --
23 four orthodontists that we work with. And we have them seen
24 with the closest orthodontist that lives -- you know, to
25 where they live -- and determine whether they can help

1 eliminate some of these problems orthodontically. And if we
2 can, we do that.

3 DR. REKOW: Do you have any sense of what
4 proportion of patients can have that posterior open bite
5 closed and it's stable, over what time, and how many don't?

6 DR. WOLFORD: The majority of the patients that go
7 through the orthodontic work and then if they go through
8 and complete the restorative work have been stable.

9 There are some patients that have elected not to
10 go through the orthodontic treatment and have elected not to
11 have operative or restorative dentistry performed, and we
12 continue those with their appliance.

13 CHAIRPERSON JANOSKY: Additional panel questions?

14 DR. BERTRAND: For your criteria for success, you
15 were mentioning the elimination of pain and jaw sounds.

16 DR. WOLFORD: Yes.

17 DR. BERTRAND: Can you have the elimination of
18 pain without jaw-sound relief, and is the patient stable?

19 DR. WOLFORD: Can the patient still have joint
20 noise?

21 DR. BERTRAND: Right.

22 DR. WOLFORD: And be stable? Umm -- if they're
23 not subluxating and they can -- or subluxate occasionally.
24 Those patients still have been fairly stable. If they have
25 an internal derangement, and when we're completed with the

1 treatment, and they're had -- even with -- or, okay -- even
2 with the splint, if they have an internal derangement click
3 we may be able to keep them comfortable. Those I generally
4 tend to go back and re-treat, because I don't want an
5 internal derangement noise.

6 DR. BERTRAND: So, the end-point of treatment is
7 both pain elimination and, essentially, elimination of joint
8 sound by recapturing the internal derangement?

9 DR. WOLFORD: Yes.

10 CHAIRPERSON JANOSKY: Additional panel questions?

11 [No response.]

12 DR. WOLFORD: Thank you.

13 CHAIRPERSON JANOSKY: Thank you.

14 At this point, we open the floor to anyone else
15 from the public who would like to address the panel.

16 [Pause.]

17 CHAIRPERSON JANOSKY: I ask that you please state
18 your name and affiliation, and state the nature of your
19 financial interest, if any.

20 DR. KULL: My name is Dr. Robert Kull. I'm in
21 private practice in West Seneca, New York, a suburb of
22 Buffalo, New York. And I have no financial interest in
23 either Myotronics or Bioresearch.

24 I'd like to take the opportunity to thank the
25 Dental Devices Branch for an invitation to come as an

1 invited guest to this meeting. I come before you as a
2 practicing clinician, and my intent will be to present to
3 you the clinical efficacy and safety of the
4 electordiagnostic instruments being considered. I'm sure
5 that the technical, scientific and research aspects of these
6 instruments will be handled thoroughly by the manufacturers
7 and other researchers.

8 By way of a brief summary of my curriculum vitae,
9 I was a graduate of Temple University School of Dentistry in
10 1970; complete a residency in General Dentistry at E.J.
11 Meyer Hospital in Buffalo, New York; and have been in
12 private practice since 1971.

13 From 1974 to 1975, I was clinical assistant
14 professor at the State University of New York at Buffalo
15 School of Dental Medicine, as well as the Buffalo General
16 Hospital as a lecturer in Advanced General Dentistry.

17 In 1985, I entered a Masters of Science program at
18 the State University of New York at Buffalo, and in 1988
19 received a master's of science degree with a concentration
20 in neuromuscular function. My area of research was EMG and
21 bite force.

22 Over the past decade, opponents of bioelectric
23 measurement devices have raised valid questions regarding
24 sensitivity, specificity and statistical analysis. The
25 questions have been answered -- as you have undoubtedly

1 found in the literature reviews provided to you. Documented
2 clinical studies, published in refereed journals by multiple
3 authors in multiple, international freestanding
4 institutions, have clearly shown sensitivity and specificity
5 well over the 75 percent level of recommendation. These
6 studies were all backed up by MRI, arthrogram or surgical
7 evaluations. The literature now strongly supports the
8 efficacy, safety and validity of these modalities.

9 I hope to present to you now the importance of
10 these modalities in the life and work of the practicing
11 clinician.

12 I have always treated TMD patients since my early
13 days of practice, but since 1988 when I began to concentrate
14 my practice in the management of TMD and orofacial pain, I
15 have treated over 1,200 cases and evaluated over 3,000
16 cases.

17 Early in 1990, I began treating patients for Dr.
18 Russell Besette, a local physician, dentist and plastic
19 surgeon. His cases came to me with complete copies of
20 diagnostic records including EMG, mandibular jaw tracking
21 and sonography. I quickly noted that these materials
22 greatly enhanced my treatment success through a more
23 thorough knowledge of the functional disturbances presented
24 by the patients and consistency of treatment between the
25 doctors.

1 Through Dr. Bessette, I was introduced to
2 Bioresearch, one of the manufacturers of electrodiagnostic
3 equipment, and spent many hours in training and continuing
4 education in the use of the equipment.

5 The diagnostic equipment being discussed --
6 namely, mandibular jaw tracking and electronathology or
7 joint vibration analysis or electrovibratography -- are
8 simple measurement tools used by the treating practitioner
9 to measure the patient's parameter of function. There are
10 absolutely no invasive or functionally altering aspects to
11 these instruments and the patients tolerate them well.

12 In the present state of the art and science of TMD
13 and orofacial pain management this instrumentation has
14 become hallmark. Solid clinical studies undertaken in
15 freestanding institutions in Buffalo, New York, and Osaka,
16 Japan, have clearly demonstrated extremely high sensitivity
17 and specificity levels of these instruments. Patient
18 management with these diagnostic tools has increased our
19 level of success in my practice to 93 to 95 percent level,
20 as substantiated by two independent, patient self-report
21 surveys conducted in my office of over 1,000 patients.

22 A significant element of this success rate is in
23 patient knowledge and understanding of their dysfunction,
24 which this instrumentation makes possible. More
25 importantly, this instrumentation provides the doctor with

1 objective documentation supporting his diagnosis made
2 subjectively, and provides significant, unalterable,
3 baseline information on which to begin treatment.

4 Prior to the introduction of these modalities,
5 treatment and management of orofacial pain patients and TMD
6 patients was extremely difficult. Diagnosis was based on
7 manual palpation and attempted visual measure, and subject
8 to gross error and subject input. Treatment plans were
9 based upon a compilation of judgment and guesswork.
10 Treatment goals were obscure and arbitrary, depending upon
11 judgments of "I feel better."

12 Today, through electrodiagnostics, I now have
13 clear and objective guides for therapy, measurable treatment
14 goals. Patients have a more thorough understanding of their
15 dysfunction, the goals of therapy and their case completion.
16 These things have been achieved through non-invasive and
17 extremely cost effective diagnostic modalities.

18 Many patients are referred to my office as a
19 result of traumatic injury, either in an automobile or work-
20 related accident. Since the introduction of
21 electrodiagnostic modalities, it is finally possible to
22 present definitive documentation of the existence or non-
23 existence of injury in these types of cases. The legal
24 community has come to rely heavily on the objective, non-
25 invasive nature of these modalities. Furthermore, it is

1 possible to present to insurance companies clear, concise,
2 objective income/outcome criteria, through non-invasive
3 means. Using the results of two independent studies done in
4 my office -- one in 1996 of 800 patients, and one in 1988 of
5 300 patients -- and assessing the objectivity and
6 thoroughness of these modalities without the cost and risk
7 of CT scan, MRI or arthrography, two local insurance
8 companies have accepted our office as the only site for non-
9 surgical management of TMD and orofacial pain.

10 It is my strong contention, with my years of
11 clinical experience, education and research background and
12 success in patient management, that these modalities are
13 indeed safe, effective and an invaluable aid and should be
14 included as part of the current state of the art for
15 management of these dysfunctions.

16 Thank you.

17 CHAIRPERSON JANOSKY: Thank you.

18 Do any of the panel members have any questions?

19 DR. GONZALES: I have a question.

20 CHAIRPERSON JANOSKY: Please.

21 DR. GONZALES: Just -- a question about your
22 outcome measurements, in terms of length of time after: how
23 long have you followed patients after you've done these
24 measurements, and you've completed the studies that you want
25 to do and the treatment. Have you actually followed

1 individuals with these disorders?

2 DR. KULL: Yes. Clinically, I've followed the
3 patient -- once they're stable and no long in active
4 treatment -- for a period of six months to make sure that
5 they stay stable when we've finally finished with them. And
6 through the survey studies that we have, I've followed these
7 patients over the last 11 years, and found them to be --
8 remain stable, on a patient self-reported. It's a
9 questionnaire form that they self-report their own
10 evaluation level. It's not --

11 DR. GONZALES: So, you mean, after six months of
12 following these individuals, the majority, you say, remain
13 stable and are not complaining of -- the parameters that
14 you're measuring.

15 DR. KULL: Correct. The majority --

16 DR. GONZALES: -- without pain.

17 DR. KULL: Yes. The majority are stable during
18 that period of time.

19 DR. BURTON: Pardon me. What treatment modalities
20 do you use. You talked about your diagnostic techniques and
21 evaluation. What are you using for your treatment
22 modalities until you reach a point where you or the patient
23 are satisfied with their condition?

24 DR. KULL: Treatment modalities in the office
25 obviously vary depending on the diagnosis and management,

1 but the number one treatment modality is the removal of the
2 splint therapy. We also use some physical therapy
3 modalities and exercise modality, and in massage therapy and
4 sprain massage therapy.

5 We do some biofeedback and we refer some patients
6 for counseling.

7 DR. BURTON: Thank you.

8 CHAIRPERSON JANOSKY: Additional questions?

9 Dr. Alpert?

10 DR. ALPERT: I just need to make a correction for
11 the record. Although we did contact a number of individuals
12 such as the previous speaker to notify them that the meeting
13 was taking place and that their participation, as with all
14 of the members of the dental community of the public were
15 welcome, they were not "invited" as special guests of the
16 FDA. And I just wanted to make that clear for the record.

17 Thank you.

18 CHAIRPERSON JANOSKY: Okay.

19 At this time we will take our lunch break and
20 reconvene at 1:30. During the lunch time, panel members are
21 not to discuss information that has been presented, and we
22 will return here at 1:30 and continue with the presentations
23 from industry and professional organizations.

24 [Luncheon recess.]

25 CHAIRPERSON JANOSKY: Welcome back.

1 We'd like to continue the open public hearing. At
2 this time is there anyone on the floor who has not already
3 signed up to speak who would like to address the panel?

4 [No response.]

5 CHAIRPERSON JANOSKY: Am I correct, there is no
6 one that would like to address the panel? Okay.

7 Then we will continue.

8 Presentations by industry and professional
9 organizations: the first presentation scheduled is by Dr.
10 Saul Liss. Is he present? And I ask that you state your
11 name and affiliation, and the nature of your financial
12 interest, if any.

13 DR. LISS: Can you hear me?

14 I'm Dr. Saul Liss, and I'm a Ph.D. in biomedical
15 engineering, and I'm proud to say that I got that Ph.D.
16 three years ago at the age of 70. So I am, in fact, the
17 President of Medi-Consultants. I do have a financial
18 interest in my company, and I hope it's more --

19 [Laughter.]

20 DR. LISS: -- but right now it is what it is.

21 I come here to applaud the work that you folks are
22 charged to do. I come here to affirm that the work that you
23 have on TMJ pain control is a Class II status -- oh, I guess
24 I ought to give you the rest of my credentials before I go
25 into that.

1 I am one of the authors of the TENS specification
2 that today is a national standard. My brother and I have
3 our names on 26 patents in the field of electrical
4 stimulation, on both TMJ pain control, restorative
5 procedures without novocaine, cerebral palsy spasticity
6 reduction, depression, anxiety, insomnia management. We
7 have our names on patents related to low-power laser. So
8 we've been in the technology business now for about 24
9 years. And we also have our products described in 23 peer-
10 reviewed published studies. We have over 50,000 people, and
11 a whole bunch of horses that have been benefited from the
12 use of our equipment. We have an equine "happy-halter," for
13 those of you are interested in that, for relaxation of your
14 horse. So that we now, believe it or not, use the same
15 technology for cranial stimulation, whether it's being used
16 for reducing the symptoms of depression, anxiety, insomnia;
17 body stimulation when it's used for chronic, acute and post-
18 operative pain; and dental stimulation when it's used for
19 restorative procedures without novocaine, TMJ pain control,
20 muscle relaxation; relaxation of the spasticity of the
21 cerebral palsy child, etcetera.

22 Now, up until this moment, you in your wisdom have
23 described the pain control device for TMJ as a TENS device.
24 And I urge you to reconsider the name of that device. I
25 think it should be called a "head pain control device,"

1 rather than a TENS device.

2 The reason for that is that, as one of the authors
3 of the TENS specification, they made a big deal about the
4 fact that should you place the contact on the neck, you
5 could start a laryngeal or pharyngeal spasm. And if you put
6 a conventional TENS device on the face, it is not the same
7 as a putting our low-powered micro-current devices on the
8 face.

9 And I urge you to please look at that. And if you
10 want some specifics on that, I'd be happy to be a resource
11 for you.

12 So I urge you to look at the change of the name
13 from "TENS device for dental applications," to "head pain
14 control" and, by all means, do include the indication of
15 headache management, and headache prophylaxis, in the head
16 pain control device. Because you cannot make a big deal of
17 difference in terms of pain control of the section of the
18 anatomy that we call "the head," and separate a headache
19 from a TMJ pain, from an intraoral pain, or a glossodynia,
20 because it's all pain of the head, and it certainly is not
21 the province of a TENS device, which is basically a back
22 pain, foot pain, shoulder pain, tennis elbow.

23 And if you're going to make a separation from a
24 safety point of view -- which I urge you to consider -- you
25 now have a reason to give that your thoughts. So I urge you

1 to consider that.

2 Now, the area that our company has spent a lot of
3 effort - -money, time and whatever -- is to demonstrate that
4 our technology does, in fact, alter the level of
5 biochemicals in order to provide a basis for why does the
6 device work. And we do have evidence that our device --
7 technology -- can increase the level of serotonin, both in
8 the blood plasma and the cerebrospinal fluid. We have
9 evidence that does the same thing for beta endorphin. And
10 in hundreds of cases of measurements, we have recorded
11 reduction in cortisol, representing systemic relaxation, and
12 an increase in ACTH -- which seems like a paradox, but we
13 have a considerable amount of evidence in this area.

14 We even have information that our device can be
15 beneficial in increasing the level of GABBA, as well as,
16 under certain specific conditions, DHEA. And so, for those
17 of you who want to get on track to improve the quality of
18 life, talk to me later about DHEA enhancement.

19 Now, I would like to show you some overhead slides
20 which represent these biochemical changes -- if I don't get
21 strangled by the cord. So far, so good.

22 And I shall make these overhead projector slides
23 available to the committee, and the secretary, or assistant,
24 will process them for everyone.

25 The device that we have is a device that has a

1 carrier frequency of 15,000 cycles. And everyone here knows
2 that a nerve cannot conduct 15,000 cycles. So we use the
3 bulk capacitance of the body to provide a bioactive
4 frequency of 15 Hertz and a halving frequency of 500 Hertz,
5 with a peak current of 4 milliamperes, all of which goes to
6 have a DC equivalent less than 200 microamperes per
7 milliampere of pulse energy.

8 Now, the mechanism by which this works, according
9 to our best insight, is by placing the signal on the bulk
10 capacitance of the body we are now able, when we turn our
11 device off for 33.3 microseconds, expect that charge to leak
12 off into the resistance of the body, forming an internal
13 current that now can do whatever it's going to do. And in
14 this connection we believe that that is the reason why we
15 get the biochemical changes that the other devices do not
16 do. So that we have found a way of converting the energy
17 from a nine volt batter to an internal current that the body
18 can use constructively.

19 Now, this is -- basing our analysis on the fact
20 that for a signal to cross a synapse, it takes anywhere from
21 5 millivolts to 90 millivolts for that signal to cross. And
22 if it doesn't -- if you don't have that level of voltage,
23 the signal will not go part way; it will not go at lower
24 intensity. It will not go. And depending upon where you
25 place the contacts on the head or body will govern which

1 dysfunctional system you can work with.

2 So that the current flowing through its own
3 resistance can now raise that triggering energy level to
4 facilitate the use of subsequent therapy. And in spasticity
5 reduction for cerebral children, as an example -- and this
6 is certainly consistent with spasticity of the muscles in
7 the mouth, as well -- you can see a child that starts off
8 with dysfunctional mechanical position, and in 10 minutes
9 and 20-minute waiting time, you can actually see the child
10 open up like a flower and then you give them the secondary
11 beneficial physical therapy.

12 And, in the same way, you can, in TMJ, use a
13 trans-cranial stimulation to relax spasticity if that's a
14 problem -- and there are cerebral palsy children with
15 spastic problems in the head and face. You then are able to
16 give the physical therapy, and you have a window of
17 opportunity of four hours within which to do that. We
18 believe that has to do with the change in serotonin and also
19 the change in GABBA level.

20 Now, I already indicated, as is shown in this
21 slide, which of the neurochemicals we're involved with
22 altering: and that's the level of serotonin and beta
23 endorphin, both in the plasma and the CSF; tryptophan
24 decreases appropriately; cortisol decreases; ACTH increases;
25 and GABBA and DHEA all increase in the blood plasma.

1 Now, the implications of these biochemicals which,
2 again, I only state for the record, because I know all of
3 you know this -- but serotonin is involved with mood
4 management, pain tolerance, insomnia, symptom reduction,
5 cardiovascular control. And as you listened to the first
6 speaker, who indicated that not only was TMJ a pain-control
7 problem, but there's every other symptom in the body and in
8 the mind that's related thereto. And when you take a
9 fibromyalgia patient, who now suffers from depression,
10 insomnia, malaise, pain sensitivity or pain, an allopathic
11 physician will give things such as Prozac, Ativan, Aproxyn,
12 Darvocet -- and all of a sudden the interaction of all those
13 drugs puts the patient to sleep for seven hours during the
14 day and then nine hours at night. That's not the way to
15 live.

16 But if you now raise the level of serotonin, you
17 can address all those symptoms with energy medicine.

18 And toward that end -- again, you folks know about
19 Prozac being a re-uptake inhibitor, and that's the way they
20 make the serotonin molecule available in the synapse. And
21 then there are MAO inhibitors that still create more
22 serotonin available in the synapse.

23 And there are -- another mechanism, in terms of
24 the initiation of the -- oh, it's summatryptan that can now
25 target a particular sub-receptor, 5HT1D, and you recognize

1 that that's the way they keep more serotonin available in
2 the synapse.

3 What we do is add energy to the body and help the
4 body convert more tryptophan into more serotonin molecules,
5 no matter which sub-receptor site is deficient.

6 Beta endorphin -- the morphine-like biochemical;
7 tryptophan precursor to serotonin; cortisol for systemic
8 relaxation; ACTH is involved with the hypothalamic pituitary
9 adrenal axis in homeostasis. GABBA is one of the two neural
10 inhibitors in the body, and is important in spasticity
11 control. DHEA, as the aging biochemical, can enhance the
12 immune system.

13 And so we now look at the fact that our technology
14 has two different versions: monopolar and bipolar. And now
15 we test it against placebo. And you'll notice that the
16 largest bars indicate, on ACTH, cortisol, beta endorphin and
17 serotonin, that our bipolar version has the maximum benefit
18 of all; the monopolar has less of a benefit. But we
19 monitored an increase in blood flow as a result of the use
20 of the monopolar device, and that's the reason we have a
21 monopolar and a bipolar device. The monopolar can increase
22 blood flow and alter the neurochemical levels; the bipolar
23 does not increase blood flow, but alters the biochemical
24 levels twice that of the monopolar.

25 So you're able now to say: is the pain due to a

1 neurological source, or is it due to a vascular deficiency,
2 like TMJ joint that's suffering from lack of blood flow.
3 You can increase the blood flow there.

4 You can take -- in dental implants, for instance,
5 on smokers who have vascular deficiency, and increase the
6 blood flow to the mandible, selectively, with a 20-minute
7 once a day during the healing cycle, and smokers can now
8 have dental implants. So it all depends what the purpose
9 is; whether it's neurological dysfunction or vascular.

10 Here you see a representation of the CSF
11 measurements and blood plasma in melatonin, serotonin, beta
12 endorphin, norepinephrine and cholinesterase. And there are
13 significant changes in the CSF in serotonin and beta
14 endorphin.

15 Now, the kinetics of the situation are really
16 quite exciting, because cortisol does nothing after a 20-
17 minute transcranial treatment for the first five minutes.
18 And during that time, ACTH, which is synarchic with it,
19 rises 75 percent over baseline, and then continues to go
20 down to 25 percent over baseline at the end of two hours as
21 the cortisol drops to minus-18 percent. So there's a
22 consistency in the parallel action of the cortisol and the
23 ACTH.

24 But it's fascinating to see that it took 20
25 minutes for the serotonin to rise to its peak of

1 approximately 50 percent over baseline and continued to hold
2 for the rest of the two hours of this particular test. And
3 beta endorphin continued to rise for the two-hour period.

4 Now, this is fascinating, because in a dental
5 application -- we did restorative work in testing at Tufts
6 University -- and they had an absolutely wonderful
7 experience showing how transcranial stimulation altered
8 these biochemicals, and then with the contact in the mouth
9 you could drill teeth, and after the restorative process,
10 there was a decrease in the serotonin, decrease in the beta
11 endorphin, but still, at the end of the restoration, there
12 was still the level higher -- at that point -- than it was
13 at the beginning, and so they had another two to four hours
14 where you did not have to give the medication.

15 So what we're doing is recognizing that we're
16 triggering the body's own long-term reactions. And I think
17 that's the important thing.

18 Now, my last bit of slide information here
19 indicates how we tested conventional TENS -- and this is
20 part of the reason I made the presentation before,
21 recommending that the pain-control devices for the head not
22 be considered conventional TENS. If you leave a contact on
23 the face and forget to turn the instrument down to zero, and
24 just take the contact off the patient, that patient will not
25 like to have TENS again on the face -- conventional TENS.

1 Because it's a high voltage that is put there. And I urge
2 you to think about that.

3 But in the biochemical end, you can notice that
4 the first group on this side shows the conventional TENS
5 having very minor effect, if any, on serotonin, tryptophan,
6 cortisol, ACTH, beta endorphin and GABBA, whereas the pain -
7 - "PS" is the pain suppressor, the forerunner to my present
8 machine -- when use on the body, had significantly more
9 change. And when you used it transcranially, had even more
10 of a change.

11 [Pause.]

12 DR. LISS: Would you put the lights on, please?
13 Thank you. Now I can find my way home.

14 So, I want to conclude, right now, and reaffirm
15 that it is our recommendation as professionals in the field
16 of electrical stimulation, that the Panel and the agency
17 maintain a Class II classification for pain control devices
18 on the face and head. And do consider the inclusion of
19 headache, which is certainly one of the sequelae, many
20 times, of TMJ dysfunction.

21 I -- and we do happen to have a 510(k) on
22 headache, so we can discuss that as far as a history on
23 that. And I notice that you have a member of the
24 neurological panel here, as well, so that you're well armed
25 to do what needs to be done.

1 We do recommend that the -- you consider the
2 changing of the name to "head pain device." And I want to
3 Thank you very much for the courtesy you've given me to make
4 my presentation.

5 CHAIRPERSON JANOSKY: Thank you, Dr. Liss.

6 Do any of the panel members have any questions for
7 Dr. Liss?

8 Yes. Please state your name before you address --

9 DR. GONZALES: Hi. I'm Dr. Gilbert Gonzales, and
10 I'm a neurologist, and I'm also a person who works in pain,
11 both malignant and non-malignant pain.

12 It's true that spinal versus supraspinal painful
13 problems are probably modulated by a different form of
14 receptor function; that is to say, we're now recognizing --
15 and I don't want to get into a lecture here, but I want to
16 really comment on some of the things that were presented
17 here.

18 So, there is a background regarding supraspinal
19 head pain, versus spinal pain, in terms of receptor
20 specificity; for instance, Kappa 3, which is an opiate
21 receptor, functions at the supraspinal, and Kappa 1
22 functions at the spinal level. And you'll see some
23 differences in other opiate receptors.

24 There's also a literature that dates back quite a
25 while, regarding some of the peptides and other analgesic-

1 related substances that have been measured early on, in
2 spinal fluid as well as plasma. And to make the correlation
3 between elevation or decline in various peptides or
4 analgesic-related or associated compounds, and to make the
5 jump between an elevation or a decrease in your measurement,
6 in terms of clinical response -- that has been very
7 difficult to make. And, in fact, there are very few
8 associations that are strong. There are some behavioral
9 things, like thyroid and depression, but looking at the
10 opiate receptors, looking at the peptides -- serotonin, some
11 of the newer peptides that you didn't mention here, that are
12 actually pain contributing; that is to say, for instance,
13 opioid receptor, what's called nociceptin, which was only
14 discovered a year-and-a-half ago -- pardon me, the ligo-
15 nociceptin and its receptor, orcon-opioid receptor -- some
16 of the newer ones that actually cause pain, as opposed to
17 some of the substances that seem to be related in tissue
18 preparations physiologically in animals and in humans at the
19 cellular level, don't correlate very well with what's
20 measured. And that's been looked at for a number of years.
21 And it's well established that looking at substances -- for
22 instance, serotonin levels in spinal fluid, or serotonin
23 levels in plasma -- don't necessarily correlate with pain
24 improvement, or pain enhancement.

25 The other thing is that when -- I'm assuming that

1 the information that you've presented here was information
2 on humans, because when you talk about substances, you have
3 to identify the species, because you could have
4 diametrically opposed functions. Morphine, for instance,
5 causes constriction of the pupil in humans, but causes
6 dilation of the pupil in chimpanzees. Morphine causes
7 sedation in humans; it causes agitation and activation in
8 horses.

9 So you have to be very, very careful. So I'm
10 assuming that this was all human --

11 DR. LISS: All human.

12 DR. GONZALES: -- material that you've presented -

13 - DR. LISS: That's correct.

14 DR. GONZALES: -- and there's a statement
15 regarding -- you know, what you measure coming out of the
16 spigot doesn't really tell you what's going on in the
17 brewery -- that is to say, the activity -- the biochemical
18 activity. There can be a variety of different biochemical
19 activities and the end result may be very similar, in terms
20 of what you're measuring.

21 So I have to just bring up that caution, that
22 you're measuring various substances and peptides, and making
23 the jump to clinical applicability. And I'm not sure that
24 that's -- that that can be done.

25 DR. LISS: May I respond?

1 DR. GONZALES: Yes.

2 DR. LISS: Dr. Gonzales, I really appreciate your
3 comments, and I chose this track of thinking and performance
4 because in the device field -- unfortunately, in the TENS
5 field in particular -- the attitude of so many of the
6 manufacturers had been "Oh, boy. We can make a little
7 electronic gadget that we can make a lot of money on." That
8 is not -- has not been my history; it has not been my
9 perspective. Because just as we're all here trying to help
10 the patient, we too are trying to help the patient.

11 And I'm offering the idea that to be able -- for a
12 physician, or dentist, a professional to selectively be able
13 to now enhance some of these neurochemical functions at his
14 or her own desire with a device rather than, necessarily,
15 with drugs, can be another useful tool. I don't claim this
16 is a magic black box. I claim this only as a tool -- as
17 another tool in your armamentarium.

18 I say very frequently from the podium, because I
19 lecture internationally on this particular topic that I
20 believe so keenly on, that if you can do the job with a
21 pill, by all means do it. But for the 50 percent of the
22 people for whom the pill doesn't work, or is interactive
23 with other pills that makes it dysfunction for the patient,
24 the other 50 percent need an opportunity as well.

25 So all I'm saying to you is that many of these

1 products will work on 50 to 75 percent of the people.
2 What's going to happen with the other 50 to 25 percent of
3 the people? They need some help, too. So this is just
4 another tool.

5 I posed -- given the opportunity, I could bring
6 together data on over a thousand patients, showing clinical
7 results. And we don't have the funds to correlate, on the
8 patients themselves, because this work was done mainly on --
9 well, some was done on MS patients; normals were used with
10 dental pain problems, and they were all honest dental
11 problems. The Journal of the American Dental Association
12 had an article by Dr. Hochman on 600 patients -- 600
13 procedures. So we have considerable amount of information
14 on over a thousand patients, and I'd be thrilled to make a
15 presentation with all the clinical data as well. In 20
16 minutes, you can't give 24 years of history.

17 DR. GONZALES: Can I ask -- or just make another
18 brief statement?

19 Certainly I'm not questioning the utility of TENS
20 unit for cranial stimulation for pain. That, I think, is
21 fairly well established. But looking at it in terms of the
22 classification, and trying to focus on that, there are a
23 number of devices out there that are very different from
24 TENS unit, but, you know, are being used for similar
25 purposes -- some things that have been around for many, many

1 decades that some people are calling TENS unit for a variety
2 of different purposes.

3 For instance, again, at the turn of the century,
4 the Limogies -- the transcranial stimulation for pain and
5 anxiety, and a number of other devices --

6 DR. LISS: Open heart surgery in France.

7 DR. GONZALES: So -- and they continue to use it
8 in France. But trying to focus in terms of -- and I'm
9 posing this as a question to you -- why do you feel that the
10 TENS unit, the way you apply it or have it or develop it --
11 is different from TENS units, other than some of the
12 frequency differences -- TENS unit that's used in other
13 parts of the body.

14 DR. LISS: Oh, I can tell you precisely on that
15 one.

16 As a member of that panel that developed the TENS
17 specification, there happened to be two paragraphs for
18 safety and two paragraphs for efficacy in that document.
19 And it took me eight years to write those two paragraphs,
20 because I write very slowly. But that was the origin of
21 microcurrent in this country.

22 My two paragraphs on safety and efficacy for
23 microcurrent devices facilitated microcurrent to be on the
24 market today. Okay? So that's where it comes from. And
25 that recognized -- that was the first recognition that there

1 was a difference in the waveform, and in the intensity. And
2 I'm merely adding to the store of information, showing that,
3 in fact, I took the best conventional TENS device on the
4 marketplace -- to my knowledge -- and compared that on these
5 15 people. The TENS device was used on Monday, the pain
6 suppressor was used on Wednesday peripherally, and then
7 transcranially on Friday. So that we had normalized the
8 information; both time of time, as well as placement of the
9 contacts and so forth. I think it was a well controlled
10 study.

11 And we demonstrated that there was, in fact, a
12 biochemical result and outcome from the use of conventional
13 TENS on the same people as using the low current device,
14 that actually had more of an effect on the neurochemistry.
15 Because I'm posing to you that a conventional TENS device
16 will work, according to the Wall-Melzac theory, but it is a
17 substitution technique. You would substitute an electrical
18 signal, an electrical sensation, for a pain sensation. And
19 the amount of carryover benefit that you have when you take
20 the device off is minimal, unless you've gotten rid the
21 reason for the pain. But that is minimal carryover as
22 compared to our technology which does have a carryover
23 because we are now triggering the serotonin and beta
24 endorphin reactions which are four hour or more reactions in
25 the body. And that is the key issue, in my opinion. And

1 that's a difference. And that's why I urge you to consider
2 that.

3 The way you have to use a conventional TENS device
4 for TMJ pain, you're putting a device on the face, which the
5 TENS standard says you should not do on a transcranial
6 basis. And there are times when you need to put it across
7 the head. And if you say "This is transcranial but on the
8 jaws is not transcranial," that's not something that we can
9 really wax poetic about. The face is the face, the face is
10 the head, the head is the face. It all is a melange.

11 And so I pose for you that there's a conflict and
12 a paradox being set up by continuing the name
13 "transcutaneous electrical nerve stimulator" for a dental
14 device that, by the standard, does not permit its total use
15 over the whole head and face. Whereas if you go at it from
16 the cranial stimulation, and just make the statement that a
17 cranial stimulator is used for the purposes of reducing
18 symptoms of depression, anxiety and insomnia, so it takes
19 another name completely different -- "Head pain control
20 device" -- to fit into that and solve that problem. That's
21 the only suggesting I'm making.

22 CHAIRPERSON JANOSKY: Are there additional
23 questions from the panel members?

24 [No response.]

25 DR. LISS: I thank you for the questions, by the

1 way.

2 CHAIRPERSON JANOSKY: Okay. Continuing with the
3 presentations by industry, the next presentation is by Dr.
4 Robert Jankelson. Again, please state your name and
5 affiliation, and also the nature of your financial interest.

6 [Pause.]

7 MR. JANKELSON: Actually, my name is Roland
8 Jankelson, and I'm going to take a few moments before Dr.
9 Jankelson assumes his portion of the 20 minutes.

10 I am associated with Myotronics and, in that sense
11 -- in some sense of the word, I think if one fully
12 understood the economics of operating most medical device
13 companies, the term "financial interest" -- you'd probably
14 find a better word. But, nonetheless, certainly we do have
15 a commercial interest in Myotronics.

16 I would like to address several issues. And I'm
17 going to ask you to indulge my motivation here. I assure
18 you my motivation is not to dredge up old history for the
19 sake of doing that, but rather to make sure that this panel
20 has a firm grasp of the context in which this classification
21 process is occurring.

22 As I believe everybody knows, this process started
23 in 1994. Four years later we're here -- we're still here.

24 In 1994 some things happened in connection with
25 this panel. Dr. Alpert, this morning, described them as

1 "procedural irregularities." I would submit, respectfully,
2 to CDH staff that they were not procedural irregularities.
3 They were irregularities of substantial magnitude. And they
4 were irregularities that, for the most part, were disclosed
5 after investigation was superimposed onto the CDRH process.
6 That investigation occurred primarily by the Office of
7 Inspector General for Health and Human Services.

8 The irregularities were not procedural, they were
9 egregious. And they were the result -- and this is the
10 relevance of bringing forth this history -- they were the
11 result of an agenda on the part of a small group of
12 individuals who saw their interests being threatened by
13 emerging new technologies, some of which are the subject of
14 the discussion by this panel.

15 As a result of what were obviously more than
16 procedural irregularities, a number of individuals -- FDA
17 employees -- associated with that panel had their service
18 with FDA terminated. The consultant, the executive
19 secretary, the panel chairman, and a 23-year-long FDA
20 employee who was a product reviewer and advisor the staff
21 and to the panel had their service with FDA terminated.

22 I simply want to keep the Panel aware of the
23 importance of understanding who you're hearing input from,
24 and that you make your evaluation as scientists and as
25 researchers, which you all are. But it is important that

1 you understand the context within which some material is
2 inputted into this process, and what the motivation is on
3 the part of some individuals who would continue the agenda
4 that was played out in 1994.

5 Let me briefly review -- and we're now talking
6 about two device categories, which in and of itself raises
7 some real questions. But I don't think, at this point,
8 there's any real point in discussing why two devices, out of
9 some 26 devices that were identified in November, narrowed
10 down to 12 devices by CDRH staff after the November meeting,
11 now narrowed down to 2. But let's just talk about the two,
12 because that's really what we're here for.

13 We're talking about sonography, we're talking
14 about jaw tracking. What do the devices do?

15 We have a tendency sometimes to overcomplicate
16 subjects. Let's talk about what they don't do.

17 They don't diagnose. They don't make treatment
18 decisions. They don't dictate treatment philosophy.

19 Let's talk about what they aren't. They're not
20 independently diagnostic. and they're not treatment
21 modalities.

22 What are they?

23 Sonography -- and I'm going to draw a distinction
24 in two types of sonography modalities, but for the moment
25 let me say that sonography and jaw tracking are simply

1 computer capabilities that record; that provide information
2 -- one type of information to be used by the clinician,
3 together with all other information the clinician's
4 background, training, skill, instincts.

5 That's what these two devices do. They do it
6 objectively. They do it accurately. But they only provide
7 information.

8 The Panel has to deal -- as I understand the
9 process -- with two issues. One is efficacy, and one is
10 safety.

11 On the issue of efficacy, I think by the time --
12 you have heard some clinicians speak, and I assume you'll
13 hear more, and I know that the Panel is very familiar with
14 these subjects -- but on the issue of efficacy, I do want to
15 point out that there is in the literature more than 300
16 articles that are primary articles, that are research
17 articles -- as distinguished from opinion articles. So when
18 one looks at the literature in this field -- and I must say
19 there are people at both tables, and Dr. Robert Jankelson
20 and other people in this room who are certainly, from the
21 standpoint of scientific and clinical qualifications, much
22 more able to deal with this subject than I am.

23 But I want to make a point that when one looks at
24 the literature, it's not a matter of weighing this amount of
25 literature against this amount of literature. The

1 literature in this area, if one excludes certain opinion
2 articles that were circulated by a small group beginning in
3 1990 -- when one -- which, unfortunately became a primary
4 part of the original literature package that you've received
5 from CDRH -- if you eliminate that, the literature is
6 incredibly unbalanced. And it's unbalanced in support of
7 these capabilities.

8 I think an informed evaluation of these
9 capabilities leads to the conclusion that they offer the
10 clinician the opportunity for more conservative, for less
11 treatment, not overtreatment.

12 One of the areas that I would describe as outright
13 pollution of information received by the panel in 1994, was
14 the argument by three well-credentialed, respected academic
15 clinicians who stood before that panel and said, "In our
16 institutions hundreds of patients present to us as having
17 been mis-treated as a result of this instrumentation."

18 We thought it was reasonable, after hearing that
19 kind of information inputted into a Federal panel, to obtain
20 from those institutions either confirmation or rejection of
21 the validity of that information. And we did that --
22 through our attorneys. We said to each of those
23 institutions, number one, "Are these individuals who
24 appeared and made those statements -- are they representing
25 your institution?" The answer in each case was "No."

1 The second question we asked was: "Can you give us
2 any evidence that would support the statements that they
3 made?" And the answer was "No."

4 If anybody stands before this Panel and makes
5 statements about over-treatment, or mis-diagnosis as a
6 result of these capabilities, they need to be challenged.

7 On the issue of safety -- what am I doing on time?
8 I'm probably taking everything from my --

9 CHAIRPERSON JANOSKY: You've been, probably, about
10 11 or 12 minutes into it --

11 MR. JANKELSON: Okay. I'm going to try to do
12 this--

13 CHAIRPERSON JANOSKY: -- 20 minutes total.

14 MR. JANKELSON: -- very, very quickly.

15 On the issue of safety, jaw tracking -- our jaw
16 tracking instrumentation has been in the marketplace, I
17 think, for 28 years; maybe a few more -- at least 28 years.
18 I know of no adverse reaction report ever. I also know, in
19 the case of sonography, the instrumentation has been in the
20 marketplace, I think, for about eight years. I also know
21 that the evaluation that the American Dental Association
22 does on the issue of safety and efficacy, the same matters
23 that you folks are dealing with here, with respect to the
24 awarding of ADA seals, which this instrumentation has -- is,
25 by its nature -- and this is not a criticism of this Panel

1 or the panel process -- but it is much more rigorous than
2 anything that could occur here in a couple of days. So it
3 is very relevant to look at what the ADA has to say about
4 the safety of these devices.

5 The last thing I want to say is on the issue of
6 sonography. The sonography device that I'm assuming is the
7 subject of classification here is a device that records and
8 displays joint sounds, unlike the table -- the website table
9 -- which says "to classify and interpret specific joint
10 sounds," Myotronic's sonography device does not interpret
11 joint sounds.

12 It goes on to say "-- as means of assessing TMJ
13 status." As long as one understands that what the device is
14 doing is recording and displaying data, then that statement
15 is correct. But if the statement suggests that it is doing
16 more than that, and that somehow the clinician is being
17 relieved of what a clinician does, which is to use
18 information, together with other information, to arrive at
19 whatever conclusions are appropriate, then that statement is
20 misleading.

21 In the next to the last column over, it uses the
22 word "interpreting specific joint sounds." Again, what the
23 Myotronics device does is it records and displays joint
24 sounds. It does not interpret.

25 Now, we're drawing a distinction here between

1 another device that happens to be marketed by a competitor,
2 which has claimed to do more than that. But if that device
3 is going to be the subject evaluation it needs to be looked
4 at for what it is, and distinguished from what we are, which
5 is a device that records only.

6 I would submit that on the issue of safety, on the
7 issue of these two devices being non-invasive, on the basis
8 of their being recording devices only -- non-treatment
9 devices -- that a Class I, which is the class presently
10 assigned to the pantograph, would be appropriate.

11 Thank you.

12 CHAIRPERSON JANOSKY: Thank you.

13 Do any of the Panel members have any questions
14 they'd like to address?

15 [No response.]

16 CHAIRPERSON JANOSKY: Okay. We will continue with
17 the presentations by industry. The next scheduled is Dr.
18 Michael Singer.

19 DR. JANKELSON: Can we --

20 CHAIRPERSON JANOSKY: Oh -- okay. My apologies.
21 Yes.

22 Dr. Robert Jankelson. Again, I ask you to state
23 name and affiliation, and any financial interest.

24 DR. JANKELSON: Yes. My name is Dr. Robert
25 Jankelson. I have a financial interest in Myotronics. I

1 have also a clinical practitioner for 35 years in the field
2 of TMD.

3 I think we've made some progress. In October of
4 1994 many of us here came to a panel meeting expecting to
5 explore the categorization of two categories of devices. At
6 the end of that day, of course, as is now well documented,
7 we explored and disposed of four categories of devices.

8 The progress, of course, is we came here today
9 thinking we would have four categories, and now we're only
10 discussing two. So, for that, I think we can be grateful.

11 I would like to point out that, I think with my
12 background, I am eminently capable of reading and critiquing
13 the literature. And my function, following my brother, I
14 think, is to bring to your attention some of the historical
15 significance of the literature that was provided to you.

16 The first package that you received contained, I
17 believe, 31 or 32 articles, of which 10 were negative
18 opinion literature reviews. Now, that's significant. And
19 that is not a representative display of the overwhelming
20 scientific literature.

21 An opinion article is not a scientific paper. A
22 literature review is not a scientific paper.

23 These 10 articles, with the specific authors of
24 Mole, Greene, Rulund that were in your first literature
25 packet, all have their origins in a single document. I have

1 in my possession that original document, when in 1988 Dr.
2 Mole was commissioned by the American Dental Association
3 Council on Scientific Affairs to review the literature
4 regarding these devices.

5 Subsequently, a draft status report was given by
6 Dr. Mole to the American Dental Association Council on
7 Scientific Affairs. I would encourage you, if you have time
8 this evening, to reference the specific articles in the
9 original Mole draft report, and also in eight of the
10 articles that have been passed out in your original
11 literature review. They all have one of those four names,
12 and they come to very negative conclusions regarding the use
13 of the devices.

14 I can assure you that if you carefully review that
15 literature, over 87 percent of the scientific articles
16 referenced in that literature review are supportive of the
17 instrumentation.

18 And remember there is a three-step yardstick that
19 we use to determine whether any measurement device is safe
20 and efficacious. One: is there a physiologic parameter that
21 can be measured. Two: does that physiologic parameter have
22 diagnostic significance somewhere in the overall diagnostic
23 equation? And number three: can that device safely and
24 accurately record that physiologic event or parameter?
25 Those are the three questions that you have to ask regarding

1 any measurement device.

2 Now, the negative conclusions in the original Mole
3 draft report are the verbatim conclusions that you read in
4 those articles that were included in your first literature
5 handout. It is important to point out that that draft
6 status was not for release outside of the Scientific
7 Council. However, within a year it had wide dissemination
8 in the dental literature.

9 The Scientific Council, after extensive review of
10 this draft status report -- a review that we cannot in the
11 two days that we have duplicate -- came to the conclusion
12 that this draft status report was to be rejected,
13 culminating in the ultimate granting of the American Dental
14 Association's seal of acceptance. And I should point out
15 that when it comes to the issues of safety and efficacy,
16 these issues have been explored and been found safe and
17 effective by the American Dental Association Council on
18 Scientific Affairs.

19 Ultimately, if you look at the dates on the
20 literature with authors entitled Mole, Green, Rulund, you
21 will see that, with one exception, that literature was
22 published between 1989 and 1994. I would like you to put
23 that within the context of the politics that occurred within
24 that period. Having lost the ability to influence, via the
25 American Dental Association, we then culminated in the

1 events of, unfortunately, October 1994 -- just trying to
2 give you a perspective of the literature as it exists.

3 Now, the second mailing that you received only
4 last week is only a small sample of the scientific
5 literature. I presented to the -- to Dr. Alpert, a stack of
6 literature -- scientific studies supporting the use of
7 sonography, jaw tracking, TENS, surface electromyography --
8 that was approximately three feet tall. There are 300
9 primary articles -- scientific articles, original research.
10 There are over 500 secondary articles that support the
11 particular use to identify particular parameters of
12 physiologic events.

13 As my brother said, the literature is
14 overwhelming. We often wonder what the issues and the
15 arguments are.

16 But I can assure you that if you explore this
17 subject in depth, you will find that these devices become
18 invaluable to assist the doctor in making a non-invasive
19 more accurate diagnosis. The more information that we have,
20 the more objective data that we have, the more conservative
21 will be our therapy. And I cannot emphasize this enough.

22 Because most temporomandibular disorders have
23 origin in the myogenous component of the stomatognathic
24 system. The more data we have about the physiologic events
25 of the neuromuscular system, the more conservative, the less

1 invasive will be our final therapy.

2 And, finally, I'd like to point out that to my
3 knowledge there were 28 to 30 thousand joints operated with
4 the Proplast procedure. We all know the history. I would
5 like to point out that if those patients had been
6 appropriately worked up by a number of the doctors here that
7 use the instrumentation, that not one in 50 of those
8 patients would have been operated. Instead, of 30,000
9 surgically invaded joints, we'd probably have less than a
10 few hundred.

11 So my point is that the more information you have,
12 the more precise your diagnosis, the less invasive and the
13 more reversible.

14 Thank you. If you have any questions, I'll be
15 happy to entertain them.

16 CHAIRPERSON JANOSKY: Are there any questions from
17 Panel members?

18 [No response.]

19 DR. JANKELSON: Okay. Thank you very much for
20 your attention.

21 CHAIRPERSON JANOSKY: Okay. The next presentation
22 is from Dr. Michael Singer.

23 DR. SINGER: My name is Dr. Singer. I have no
24 financial interests. I'm here purely as a clinician only.
25 I have not done any research.

1 CHAIRPERSON JANOSKY: Excuse me.

2 DR. SINGER: Yes?

3 CHAIRPERSON JANOSKY: Would you please adjust the
4 microphone.

5 DR. SINGER: Oh, the microphone? Okay.

6 I have not done clinical research myself, nor
7 would I consider myself an expert in the technology. But I
8 can talk about, you know, what it does for patients.

9 I was first introduced to the TENS in 1978 by Dr.
10 Joel Councilman, and some might recognize that name. And as
11 was mentioned previously by another speaker, the current of
12 the TENS unit at that time was approximately 60 milliamps.
13 And, of course, we were cautioned against using that
14 transcranially, or across the face.

15 There are units now that deliver far less current,
16 such as an AlphaStim 100, and I believe these folks have
17 been before the panel before in the past. But this unit
18 delivers only .6 milliamps, and when used transcranially I
19 have never had an adverse reaction.

20 However, in their reports to the Panel, out of 106
21 human studies encompassing 5,500 patients, approximately,
22 only nine cases of headaches and five cases of skin
23 irritation have been noted.

24 Because of the difficulty of patients that I see
25 at Walter Reed, and the problems with polypharmacy, as a

1 clinician and a dentist, when these patients come down to
2 the hospital dental clinic, in trying to treat these
3 patients, I'm faced with many problems.

4 I found that it's most reassuring not to have to
5 add another drug, such as Klonopin or Valium to a complex
6 problem that already exists for the patient. And I have
7 found -- and I believe that the AlphaStim 100 has been
8 already approved for anxiety -- and I have found this, you
9 know, to be a great help in that respect.

10 In patients who are sensitive or allergic to local
11 anesthetics -- for instance, for trigger-point injections,
12 other than using saline -- I have found that in using this
13 AlphaStim in conjunction acupuncture trigger-points -- with
14 acupuncture points -- that the efficacy of this instrument,
15 you know, has been greatly improved.

16 So when patients are given a choice between
17 trigger-point injections or acupuncture needles, or any type
18 of TENS-like unit, the choice, in my experience, has always
19 been the electrostimulation or TENS unit.

20 And I'm just simply here to make the statement
21 that I feel that this unit, in my hands, is, again, as the
22 last speaker had said, is a non-invasive and very
23 conservative in treatment. And have just some literature
24 that I would like to present to the panel. And that's
25 simply the end of my statement.

1 CHAIRPERSON JANOSKY: Dr. Singer, will you please,
2 again, state your affiliation and whether you have any
3 financial interest?

4 DR. SINGER: Oh, no. I have no financial
5 interest. I was first introduced to this unit at Walter
6 Reed Army Medical Center, and I have since retired but
7 continue to use this in my practice.

8 CHAIRPERSON JANOSKY: Thank you.

9 Do any of the Panel members have any questions for
10 Dr. Singer?

11 [No response.]

12 CHAIRPERSON JANOSKY: Thank you.

13 [Pause.]

14 CHAIRPERSON JANOSKY: Our next presentation will
15 be by Dr. Barry Cooper.

16 [Pause.]

17 DR. COOPER: Could someone set these up, please?

18 [Pause.]

19 My name is Barry Cooper. I am a general
20 practicing dentist in New York City. I have no financial
21 interest in the manufacture of electronic instruments.

22 Madame Chairman, members of the Panel, consultants
23 and guests, I'm here as the International President of the
24 International College of Craniomandibular orthopedics --
25 ICCMO -- representing our members in the United States and

1 throughout the world. Our membership overwhelmingly
2 utilizes the devices being classified here in their
3 practices and universities, in the management of
4 temporomandibular disorders -- TMD -- and in restorative
5 dentistry, as well as in research.

6 I've come here today to present the results of my
7 personal clinical research over an 18-year period, involving
8 the diagnosis and treatment of almost 1,200 patients
9 suffering from TMD. The treatment I provided involved the
10 use of low frequency, low amperage TENS, surface
11 electromyography, computerized mandibular tracking, and
12 sonography.

13 The actual research paper about which I will speak
14 this afternoon, supported, in part, by ICCMO, contains no
15 data on electrosonography. Sonographic data was not
16 included in this study because my database for sonographic
17 recording of TMJ joints did not begin until many years after
18 the beginning to the study, and many of the patients had
19 already been treated and concluded.

20 I've provided to Ms. Scott a copy of this NIH
21 paper which I will be discussing in the next 20 minutes, and
22 you will have all the details from that because the data
23 goes by fairly quickly.

24 I feel the classification process for devices used
25 in the management of temporomandibular disorders is

1 valuable. I have been involved in this process since 1994
2 regarding the FDA. I appreciate the FDA administration's
3 provision of time for me now to present my research findings
4 in order to demonstrate the clinical utility, safety,
5 precision and therapeutic effectiveness of these devices in
6 the successful treatment of temporomandibular disorders.

7 This paper was presented at the NIH NIDR Consensus
8 Conference.

9 This left projector is not moving. Could you
10 check it, please? Thank you.

11 [Pause.]

12 It was published in excerpt form in JADA in
13 November of 1996, and you have the full paper from triple O.

14 The left one is not moving. It should be on
15 number two.

16 [Pause.]

17 DR. COOPER: TMD arises from an imbalance in the
18 relationship of the mandible and skull with the muscles that
19 posture and move the mandible into dental occlusion and
20 interrelationships within adjacent structures. TMD effects
21 alterations in the structure or form of the
22 temporomandibular joint, the dentition and its supporting
23 structures and its neuromuscular system.

24 The initial diagnosis of TMD and the decision to
25 begin treatment must be based on history, clinical

1 examination and a clinician's judgment. Bioelectronic
2 instrumentation provides objective documentation of physical
3 parameters of TMD before, during and after treatment.

4 Neuromuscular occlusion -- you've heard that term
5 used. Its definition: it's a stable, maxillo-mandibular
6 position at occlusion, arrived at by isotonic contraction of
7 relaxed masticatory muscles, achieved by stimulation of
8 muscles on a trajectory from a rested mandibular position.
9 The proposition of this research paper was to demonstrate
10 that neuromuscular occlusal position is a stable physiologic
11 position; muscle resting activity is low; muscle functioning
12 activity is high and symmetrical; rest position of the
13 mandible is stable over time; occlusion is stable over time;
14 the occlusal position is repeatable and reproducible.

15 A study population -- a first -- a large study
16 population of clinically examined patients -- these are
17 people who completed questionnaires and were examined but
18 not necessarily treated -- were a study group of 3,681
19 subjects in my private practice and in a clinic in New York
20 City. The details of the population are not critical at
21 this point.

22 Of those, 1,182 patients were actually treated.
23 This was not a selective process, other than these are
24 patients in the private practice who elected to undergo
25 treatment.

1 The first few slides are just to demonstrate that
2 just by an analysis of the population that by age group,
3 clinical evidence -- clinical exam -- and symptoms, it was
4 actually a typical group of the same findings in the larger
5 group. So the age sequences were similar and so were the
6 others. All patients filled out a questionnaire. All
7 patients were interviewed by a single person -- me. All
8 patients had an intra-oral and extra-oral examination by me,
9 including palpation, auscultation of TMJs, intra-oral dental
10 examination and observation of mandibular movement.

11 So the population in general: 3,681 were examined
12 and interviewed. Of those, 1,182 were treated with jaw
13 tracking -- and you'll understand the history of the
14 evolution of additional instruments. Of those, 823 had
15 their initial testing to include EMG, which was invented
16 later. And at three months we re-tested each of the
17 patients. And of those initial patients, 606 returned for a
18 retest; and, of those, 403 had re-testing including EMG.
19 And then, finally, those who decided to go for long-term
20 treatment -- and there was a question this morning about
21 what you do after initial treatment -- all of my patients do
22 not undergo long-term treatment; only those who elect to and
23 who have experimented with discontinuance of the use of an
24 orthotic with a resurgence of symptoms then go into some
25 sort of a long-term treatment. If they can wean themselves

1 off it and become adaptive, they do. If they have partial
2 use of an appliance part time, they do.

3 So only 313 of the original 1,200 elected to go
4 under long-term treatment.

5 Okay -- you're not going to be able to read this
6 here, but you will read it all in the chart. It's just to
7 show you the symptom occurrences, and I won't be able to
8 read it from here, either. But the symptom occurrences were
9 matched in the smaller group and the larger group --
10 predominantly joint sounds, headaches, ear pain and so on.

11 And the same thing on a clinical examination
12 basis. The same parallel populations, with small
13 exceptions, of the same kinds of muscle tenderness; the same
14 kinds of joint sounds and joint problems; the same kinds of
15 ear problems, neck problems and so on.

16 Okay. The devices that were used: the names
17 evolved -- and you've heard a lot of them today, or you will
18 over two days, because the naming system changed.
19 Originally called a mandibular kinesiograph before
20 computers, then it was an Apple Computer as a K-6 diagnostic
21 system, and finally it was an IBM compatible computer which
22 is now called a computerized mandibular scan. And basically
23 what it's recording three-dimensionally is the movements of
24 that small magnet attached to my daughter's lower incisors,
25 or just below them, and that magnet is the only artifact in

1 the testing system. That sensor array is held on her nose
2 and her face, or her forehead, and as she opens and closes
3 and moves laterally or protrusively, or any curvilinear
4 motion, that magnet is being traced, and that magnet is
5 what's recording the movement of the center point of the
6 mandible.

7 EMG evolved as well. The first EMG was called EMG
8 1-R and it was not a computerized instrument, and it was a
9 series of bar graphs that floated up and down; a series of
10 piled up LEDs. It's data was not included in the study
11 because it was not compatible for study. EM-2 was a
12 freestanding adding machine-like -- looking -- machine which
13 produced a paper tape. Its data was computerized and it
14 could be added into this. And, finally, with the
15 computerized mandibular scan in a computer, there was a
16 capability of adjoining data as you'll see.

17 And we tested, for this study, three sets of
18 muscles. We tested masseter muscles, middle masseter,
19 anterior temporalis and digastric. These two muscles --
20 temporalis and masseter -- were considered as elevator
21 muscles. They lift the jaw. Digastric is part of the
22 mechanism of opening the jaw. We cannot use surface EMG on
23 lateral pterygoids, which are a very important muscle. But
24 these are the muscles accessible to us for study. So these
25 are the muscles that were used for the study.

1 TENS stimulation -- we've heard a lot about it
2 this afternoon. I'm glad I have an opportunity just to
3 clarify one thing: the TENS we are using is not the
4 instruments that you've heard described. This is a
5 neuromuscular stimulator. It is an on-off pulse, mostly
6 off, as you'll see -- not so much on. It is a gentle
7 stimulator that enervates the mandibular division of the
8 fifth to move all the muscles that move the mandible in a
9 pulsatile on-off swing kind of an arc. It relaxes the
10 muscles and ultimately is used to swing the jaw on that
11 neuromuscular trajectory I mentioned before.

12 And the electrodes are placed bilaterally over the
13 notch between the condyle and the coronoid process because
14 we have access to the mandibular division of the trigeminal
15 nerve at that point, from the outside.

16 The testing protocol: initially freeway space was
17 measured before and after TENS. Trajectory of movement from
18 rest to natural occlusion and to a therapeutic bite
19 registration was tested. Resting muscle activity before and
20 after TENS; muscle clenching activity -- meaning maximum
21 voluntary clenching -- in natural dentition and then later
22 on in a neuromuscular bite registration.

23 And then at three months the same testing was
24 done, however, the orthosis was in the mouth at the time of
25 the testing because patients wearing an orthosis or a splint

1 full time do not clench their teeth into the natural
2 occlusion -- not unless they re-train muscles to find the
3 old occlusion. So we used the orthosis before the test --
4 before TENS -- and after TENS we actually placed the
5 original bite registration obtained three months before --
6 it's an acrylic material -- back in the mouth and we
7 compared it.

8 So, pre-TENS freeway space and after -- and at
9 long term for this study we only used jaw tracking. We did
10 not use EMG. So you'll see the accuracy of the bite
11 position as checked by jaw tracking.

12 Okay. This is a before and after TENS. The
13 colored illustrations appear, actually, in an article in the
14 New York State Dental Journal, which I understand you did in
15 the second packet of information. It's not in color because
16 it's been xeroxed, but you'll see the data.

17 Basically, what EMG tells us is two things. It
18 tells us how muscles rest and how they work. This is the
19 resting activity. Big squiggles means lots of activity;
20 small ones means quieter activity, more return to normalcy.
21 And you see before and after TENS there is a reduction.

22 The actual statistical analysis of this large
23 population showed that temporalis activity just from using
24 TENS was reduced by 40 percent; masseter activity by another
25 -- this is going to be difficult -- 40 percent; digastric

1 less so. But overall, there's a 36.7 percent relaxation or
2 lowering of activity with TENS.

3 Patients returned for testing at three months and
4 the same protocol was done. And you'll see that these
5 numbers are slightly less than the optimum we achieved at
6 TENS the first day, but these people had been wearing an
7 appliance for three months. They come in cold-turkey at
8 presentation three months later. Whatever way they go there
9 -- in traffic, out of traffic -- that is how they presented.
10 But it is less than they were when they first came in for
11 first treatment with the same traffic patterns, and after
12 TENS they were still further reduced.

13 And, overall, muscles tended to stay more relaxed
14 than they were prior to treatment, which is a good sign. It
15 means that part of the effectiveness of therapy is to
16 maintain lower muscle activity, which was one of our
17 propositions.

18 These are functional recordings -- higher numbers
19 at this point of good things, because it means you have more
20 effective activity. These are electrical activity, not
21 force. But research has shown that there's a parallel line
22 between electro-activity in muscles and the force generated
23 by them, or work.

24 So this happens to be a patient -- a presentation
25 in a reconstruction of his dentition made non-

1 neuromuscularly. He had all kinds of aches and pains, which
2 I won't burden you with, and this was a reconstruction after
3 inter neuromuscular position and he has significantly
4 stronger muscle function, balanced muscle function. So if
5 muscles work better and rest better, they are considered
6 signs of a successful outcome.

7 And this is just another graph, which you'll see
8 better in the article, but it basically showed that muscle
9 strength increased significantly in each of the muscles and,
10 quite interestingly, there became a dominance of masseter
11 muscle function in the therapeutic position versus a
12 temporalis dominance in the natural position. Masseter
13 muscles are angled forward; temporalis muscles are angled
14 backwards. The normal swing of the jaw, like your arm, is
15 up and forward. So you've created a more natural, a more
16 physiological occlusal position and, indeed, the correct
17 muscles work better.

18 At re-test we have, again, a slight drop in the
19 effectiveness of the occlusion versus testing the original
20 bite registration. However, when the bite registration was
21 put back in the mouth that was made three months before, it
22 turns out that function has improved even more than it was
23 at the first test. Therefore, wearing an appliance in a
24 neuromuscular occlusal position generated more muscle
25 strength and lower resting activities.

1 We also wanted to analyze the amount of change in
2 jaw position after TENS relaxed muscles. So we measured --
3 and this is just tracing across the screen, breaking up the
4 movement of the jaw at rest from its vertical component, its
5 forward-backwards component, and its lateral components;
6 taking a curved movement and breaking it into vectors.
7 After TENS, the vertical space increased.

8 That has been a criticism of the system, is that
9 everybody opens their mouth more when their muscles are more
10 relaxed. Indeed they do. But as we've seen -- or you'll
11 see in a moment, the amount of change is quite subtle;
12 usually within a millimeter or two. So it's not grotesque,
13 gargantuan changes, it is subtlety. But there's also a
14 subtle change in AP and sometimes lateral.

15 At the bottom of the screen you will also see
16 simultaneous recordings of EMG. So while the jaw's relaxing
17 at various verticals, we can actually see whether elevator
18 or depressor muscles are becoming more activated or less
19 activated; in other words, we can zero in on a quiet zone,
20 which we'll call rest position of the mandible.

21 And this is the data -- or these are the data --
22 and the increase in freeway space from before and after
23 TENS, as you can see, is about one-and-a-half. And that
24 pretty well holds true. AP, we have .61 to 1.29, so you've
25 gone a half a millimeter forward. So, as one of the

1 speakers said this morning, the neuromuscular position tends
2 to be slightly more forward. But what I'm showing you
3 numerically, on 1,200 people, it's slightly more forward.
4 But it is precise.

5 Overall, comparing vertical, the largest vertical
6 change was made before and after TENS at the first visit.
7 Once a patient returned, there's really stability of that
8 rest position before and after TENS, and even at three
9 months -- even at long term, which is the last column, you
10 have basically almost the same vertical freeway space, and
11 the same changes happened AP and laterally. So the position
12 you get a person into is very often very reliable and stays
13 the same over long periods of time.

14 This is just a sagittal side view of the jaw.
15 That's the person nose, back of the head; side view. The
16 TENS instrument causes an artificial pulsing, a stimulus.
17 That's the swing of the jaw by a stimulation of the muscles.
18 We turn off the pulse and ask the person to close naturally,
19 and that's the position of natural occlusion above, and
20 sometimes behind, the neuromuscular or the idealized
21 position which would be on that swing path.

22 This is a frontal tracing of the exact same thing.
23 That's the TEN stim. It's turned off. The person
24 voluntarily closes. The natural occlusion is slightly
25 displaced to the right side. This is their face. Okay?

1 When we re-test them at three months, we're
2 testing the bite registration for accuracy, and whether we
3 use the TENS or we shut it off and let them close
4 voluntarily, they are accurate within one-tenth of a
5 millimeter on a sagittal plane and the vertical plane. The
6 occlusion position you set up stays there. It doesn't float
7 all around the mouth.

8 Before treatment, only 20 percent of our patients
9 were on that idealized neuromuscular trajectory. At three
10 months, 67 percent -- and remember, this is an appliance
11 worn 24 hours a day in my office, therefore these do wear
12 down. Testing the neuromuscular bite registration position
13 at long term, almost 94 percent were right on trajectory.
14 Most were over-closed, or too much vertical freeway space
15 before. Almost none were at the end. Posterior
16 displacement is rampant, though subtle; almost nonexistent
17 lateral displacement again. It is not over-closure, it's
18 posterior displacement and lateral displacement that causes
19 people symptoms -- I find.

20 Again, on trajectory, they got better over our
21 treatment period; over-closed, they got better; posterior
22 displaced they get better; lateral displaced they got
23 better.

24 The most important thing is did they get better.
25 In other words, did my patient feel better? Did I solve

1 their problem, or did I only solve my problem? And, indeed,
2 at one month, at least 70 percent of our patients said that
3 their headaches were better; almost 80 percent at three
4 months. Joint symptoms went away by 60 percent, up to 70
5 percent; ear symptoms, 60 and -- that looks like it's higher
6 than 70 percent. So it does work. Symptoms get better,
7 which is the bottom line.

8 Okay. Rest position of the mandible: patients
9 with TMD typically have elevated muscle resting activity;
10 hyperactivity associated with muscle posturing in an
11 accommodative rest position. TENS effectively relaxes
12 muscles; relaxation of muscles is associated with alteration
13 of mandibular rest position in all three dimensions.

14 The treatment position: TMJ and jaw tracking can
15 aid in the determination of rest position of the mandible.
16 TENS stimulation causes mandibular movement on a
17 neuromuscular trajectory. Selection of a therapeutic
18 occlusal position on that trajectory can be made. A bite
19 registration obtained at that neuromuscular occlusal
20 position can be tested.

21 The therapeutic effect: muscle function and net
22 occlusion is significantly greater, with masseter dominance
23 compared to natural occlusion. An occlusion so created
24 requires less muscle accommodation, with improved rest,
25 stability of rest position and occlusion. A neuromuscular

1 occlusion is associated with a significant reduction in
2 subjective symptoms.

3 Conclusions: electromyography and electronic
4 mandibular tracking are clinically useful methods of
5 quantifying TMD in patients being screened for treatment.
6 Electronic measurements create objective milestones in
7 planning treatment and evaluating treatment outcome.
8 Improved relaxation and function through occlusal alteration
9 can reduce the predisposition to future TMD.

10 The goal of treatment is the elimination of pain
11 and dysfunction. The immediate and long-term goals of
12 treatment are to establish a healthy, functioning
13 relationship among the teeth, TMJ and neuromusculature. The
14 creation of a neuromuscular occlusion accomplishes these
15 immediate and long-term goals.

16 The specific therapeutic philosophy of
17 intervention remains the decision of the clinician. It is
18 now based on history, clinical examination findings, and can
19 be based on objective test measurements which can confirm
20 and redefine clinical impressions. The ability to measure
21 transcends treatment philosophies and becomes the common
22 language for clinicians to evaluate and compare different
23 patient outcomes and strategies. Successful treatment
24 incorporates physiological improvement and patient
25 subjective improvement.

1 The data proves that occlusion plays a primary
2 role in the etiology and management of TMD. The data proves
3 that establishment of a neuromuscular occlusion using
4 electronic instruments overwhelmingly resolved symptoms in a
5 very large TMD population. The data proves that clinical
6 dentists -- me -- can provide a major source of
7 scientifically valuable knowledge concerning the cause and
8 treatment of TMD.

9 If you can measure something, it's a fact. If
10 not, it's an opinion. That was said by U.S. Supreme Court
11 Justice Benjamin Cardozo. Bioelectronic instruments permit
12 objective measurements of mandibular function, masticatory
13 muscle function, dental occlusion, and TMJ sounds. These
14 are facts.

15 Based on my 20 years of experience with these
16 devices, I would like to recommend the following
17 classifications. As devices which passively measure and
18 record physiological components of temporomandibular
19 disorders, computerized mandibular scan Class I; surface
20 electromyograph, Class I; electrosonography, Class I.

21 Based on its active role which causes a
22 physiological change in muscle activity associated with no
23 risk to the patient, low-frequency, low-amplitude TENS,
24 Class II.

25 Thank you for giving me this opportunity of

1 addressing the panel.

2 CHAIRPERSON JANOSKY: Thank you, Dr. Cooper.

3 Panel members have questions for Dr. Cooper?

4 DR. BURTON: Yes, Dr. Cooper.

5 CHAIRPERSON JANOSKY: Would you please state your
6 name?

7 DR. BURTON: It's Dr. Richard Burton, University
8 of Iowa.

9 What treatment modalities are you using, both
10 short and long term? And are you using any other
11 pharmacological management in these patients while they're -
12 -

13 DR. COOPER: Okay. I don't use any
14 pharmacological management. If a patient gets
15 pharmacological management, they get it from their
16 physician, not from me. But, by and large, my patients do
17 not.

18 My treatment, initially, for all patients that I
19 treat with this protocol, is an acrylic orthosis; a
20 mandibular, anatomically perfect carved orthosis which
21 alters occlusion. It's worn 24 hours a day, except for
22 brushing the teeth. It's worn for a period of three months.
23 A patient sees me once a week for the first four weeks --
24 five weeks. After that I don't see them for two months
25 unless it's an emergency, or unless they want to come in for

1 extra TENS therapy. And at three months I re-test them.

2 At three months patients are told -- actually,
3 they're told for a second time, because they're told before
4 treatment -- that they are at a crossroads. I do not
5 believe that any irreversible changes happen from wearing an
6 appliance full time for three months. But if they're going
7 to wear an appliance for more than three months, there are
8 possibilities of tooth changes; tooth positional changes.
9 So they're told at that time that they're at a crossroads.
10 They don't make a decision that day, but we make a decision
11 as to whether the appliance in their mouth is as accurate as
12 I can make one. If it isn't, it's remade. If it's right on
13 target, and it hasn't worn, then I will tell them that they
14 can still continue to wear it.

15 If they wear it full time, then they're really
16 committing themselves to making a decision to do something
17 long term, which I'll talk about in a moment. But they're
18 also invited to experiment with wearing it part time at that
19 point, and see whether the symptoms that went away stay
20 away. If they return, they're encouraged to go back to
21 full-time usage. If they don't return, then they're
22 encouraged to go to less usage. The only exception to that
23 suggested pathway is somebody with a bona fide joint
24 problem, rather than a myalgic problem, in which case I
25 would encourage them much more strongly to maintain the

1 support that the splint is giving them on a long-term basis.

2 If they want to go for long-term treatment then
3 their options are to continually wear a series of acrylic
4 appliances but replaced when they get unhygienic; to make a
5 metal overlay partial-denture-type appliance, which I happen
6 to make with gold teeth on the molars and acrylic on
7 bicuspid and that, they're told, will last them anywhere
8 from three to five years.

9 Some patients want to choose reconstruction of
10 teeth, which is either done with some sort of an artificial
11 material; a buccal occlusal only, if the teeth are basically
12 natural, or if they're heavily restored teeth, with crowns
13 or bridges if they're needed.

14 Orthodontics is a option to me. I don't have vast
15 experience with orthodontists erupting to my vertical
16 position, so I will defer to my friends who have had better
17 success with orthodontics. That's not a knock. I think you
18 know what I'm talking about. It's not always achievable,
19 verticalizing teeth.

20 So I do offer a restorative solution. One of my
21 patients in the last 20 years has had arthronathic surgery
22 very successfully, with orthodontic finish-up.

23 So those are some of the ways -- I have done
24 passive eruption, where I've eliminated the coverage on the
25 final tooth. I can't call it terminal -- but the most

1 distal tooth. When the vertical change that I'm hoping for
2 is within a millimeter or so -- and, remember, I'm working
3 on very subtle differences -- then with the patient's
4 understanding that they're committing themselves to an
5 occlusal change, I will uncover the second molars; make sure
6 the contacts are free, and give it, easy, a half a dozen
7 months to see if those teeth erupt and their partners above
8 come down. If that does -- even if it takes a year, then
9 I'll remove the covering on the first molar and eventually
10 walk myself out of their mouth. And we've done that
11 successfully. We do it with young people very often. We do
12 it with adults less often.

13 DR. BURTON: Thank you.

14 DR. MOSES: My name is Allen Moses, and I'm from
15 Chicago.

16 Dr. Cooper, would you mind explaining the basis
17 for your changed -- recommending that the FDA change the
18 classification from what's on the grid?

19 DR. COOPER: The only classification I recommended
20 changing was EMG. I'm not quite sure, from Dr. Alpert's
21 remarks this morning -- I think it's probably not on the
22 table to accomplish, but this Panel might recommend that the
23 FDA consider it.

24 I think that EMG should not be lumped between two
25 totally different kinds of EMG: needle or fine-wire EMG and

1 surface EMG. They are two totally different modalities. We
2 have all kinds of problems in insurance because everything
3 is judged by the same ruler and it's not the same.

4 Surface EMG doesn't do anything to a patient.
5 It's an observational device, just like jaw tracking
6 sonography. You're looking at -- I put bandaids on, as you
7 saw. We record things that are happening. We ask people to
8 relax, close their eyes, and we take measurements.

9 If you put a needle into somebody, you are setting
10 up a cause and effect. Some say that any time you talk to a
11 patient you've made a cause and effect, and that's probably
12 true. But we certainly, by putting a needle into somebody,
13 you have done something that has absolutely made the
14 potential of a change.

15 I think, from the standpoint of usage -- and that
16 is part of the process of classification, surface EMG should
17 be considered by itself, and needle EMG or wire EMG should
18 be a separate classification. And if that be the case, then
19 this measurement-only device, which has no analytical power
20 and no active component -- there is no electricity being
21 brought to that patient. This is coming out. The only
22 electricity is the computer that's running the pictures.

23 I think that Class I is a better classification.
24 It think it's more accurate.

25 DR. MOSES: Are you saying about sonography also,

1 I believe?

2 DR. COOPER: Yes -- sonography. It's not classed
3 yet. I'm suggesting that it be Class I.

4 I'm suggesting that any non-invasive, measurement-
5 only device be considered Class I. Any doing-device, like
6 TENS -- even muscle stimulating TENS -- has an active role,
7 and that be considered as Class II. It becomes something to
8 the body.

9 DR. MOSES: Thank you.

10 DR. BERTRAND: Question -- Peter Bertrand.

11 Dr. Cooper, your data didn't talk about patients
12 who have used sonography diagnostically. And with the
13 advent of sonography, how has that changed what you do
14 therapeutically --

15 DR. COOPER: Very --

16 DR. BERTRAND: -- and have you applied it to any
17 of the previous patients with the protocol?

18 DR. COOPER: As -- probably Dr. Jankelson said,
19 sonography has been on the market probably for about eight
20 years or so, compared to the 20 years that we've been doing
21 this.

22 Yes, I do do sonography. I find that sonography
23 is valuable to me because it gives me an idea of what the
24 joint components of my patient's problem are. And it may
25 not have immediate direct implications on the therapy I'm

1 going to institute, because if I'm going to change a bite to
2 improve the jaw function, I'm going to change it from the
3 jaw position, and the joint is going to, hopefully, come
4 along with me.

5 Whether it re-positions a disk or not, I'm not
6 sure. And, truly, the only way to know would be if somebody
7 did MRI's before and after and see what I really
8 accomplished. I doubt that any self-paying or any
9 insurance-covered patient is ever going to have a double MRI
10 to be able to prove that we did what we did.

11 But I think a very valuable thing is that it lets
12 us know, at least by the frequencies that are being
13 displayed and the size of the sound -- the amplitude of the
14 sound -- what kinds of situations are going on in an area
15 that is invisible to me. Radiographs can tell me something.

16 I don't believe that every patient that comes in
17 for TMD treatment needs to have an MRI. I think that's
18 extremely costly. I mean, in my burg, that's \$2,000 worth
19 of stuff, and it's not necessary. But I do want to know
20 that there is a serious -- let's say, high frequency -- kind
21 of sound coming out of those joints, so that when a patient
22 tells me after a month -- and it doesn't have to go three
23 months -- that they are feeling terrible pain in their joint
24 that's not getting better at all from what I'm doing -- the
25 headaches are getting better but their joint pain is

1 terrible, that's the person I'm going to send to an oral
2 surgeon competent to deal with the joint, who will order an
3 MRI him or herself, I'm sure, and that's fine, because
4 they'll use it -- the organization of their choosing. But
5 at least I have a screen.

6 I think that there is another value in diagnostic
7 information, and that is to evaluate your failures. No one
8 ever talks -- we have great success, and I'm very happy.
9 I'm a successful TMJ patient treated neuromuscularly. My
10 wife is -- that's how I got into this. I think we all got
11 into this 20 years ago because we all had a problem that
12 somebody very close that had to be treated.

13 But when you have somebody that does not say they
14 get better -- they don't all come back, and anybody who
15 treats knows that they don't all get better; anybody who
16 takes out teeth knows that you don't never get a dry socket.
17 When they don't get better and you can test them with
18 electrodiagnostics, and you can prove that everything that
19 you can do has been done as well as it can be done, then you
20 don't mess around with more splints and filing down teeth,
21 and putting orthodontic brackets on. You know it's time to
22 bail out and get in the marines.

23 So that's when, depending on the symptoms, I know
24 who I have to call: it's a neurologist, it's an
25 otolaryngologist; it's an oral surgeon -- it's somebody else

1 that has to give me -- it may be concurrent care; a physical
2 therapist. It may not be that my treatment is a failure,
3 but I'm not getting to the heart of it.

4 So being able to evaluate is treatment
5 conservative and health conservative, because you know when
6 to get out of the problem. So I think that's a tremendous
7 value, too. When you're working blind, you just keep making
8 more pieces of plastic, or doing more things, or trying more
9 techniques that are in your skill base, but they may be all
10 the wrong techniques because you may not be treating the
11 problem that the person has.

12 DR. BERTRAND: May I ask another question?

13 DR. COOPER: Sure.

14 DR. BERTRAND: Thank you.

15 If I'm looking at your data correctly, I
16 understand that if a patient comes to the crossroads and has
17 to go to the restoration of the position of their mandible,
18 is this only a 1.25 millimeter on the average or mean change
19 in the relative protrusive position of the jaw?

20 DR. COOPER: A -- protrusive, it's even less.
21 It's about a half.

22 The average vertical change is about a millimeter-
23 and-a-half, two millimeters. I mean, I just restored
24 somebody with a four millimeter change in vertical, so
25 there's -- you know, there's a range, obviously. And this

1 case, this person needed double arches of posterior build-
2 ups of occlusion. It's a very extreme case. It's not
3 usually done.

4 My mouth was such a situation 19 years ago, and
5 it's stable and I get about a headache a year now, instead
6 of about four a week. So there is durability.

7 Yes, it's very -- it's a very small change on an
8 average, but an average means that there are zeros -- there
9 are people for whom I make a neuromuscular orthotic
10 appliance and there are holes in it to start. I mean, it is
11 that subtle. But I would rather make that than file -- do a
12 coronoplasty and file enamel, because I don't know whether
13 that's their ultimate relaxed position. So I'll make them
14 an appliance that's like lace, and I'll tell them that it's
15 not a mistake; you didn't get a cheap one. This is what
16 it's supposed to be like, and we're just going to watch it
17 and see what happens.

18 And it may be, as they relax more, things will
19 increase vertically. Or that may be just where they belong,
20 in which case they can be -- their occlusion can be
21 adjusted.

22 DR. BERTRAND: And one last question, please: you
23 have the surface EMG data with digastrics, and temporalis
24 and masseter. Do you have any baseline neck EMG data,
25 before and after?

1 DR. COOPER: Neck?

2 DR. BERTRAND: Yes.

3 DR. COOPER: No, I don't test. I'm not saying you
4 can't. The machinery is capable of more than I originally
5 did. The machinery -- probably both manufacturers have
6 created -- can measure eight muscles, not six. So certainly
7 you can do posterior temporalis. I originally did not,
8 because I found that people did not like having hair trimmed
9 behind their ears, and I'm very sensitive about trimming
10 hair, as you can see. So I don't want to take away from
11 anybody.

12 But that can be done. And you can take any
13 muscles. You can use SEMs and you can use traps and
14 everything else. It's just a recording device.

15 I tend to stay with the ones that I did
16 originally. And, certainly, for the study I wanted the
17 longest run of patients. And I had to eliminate the
18 earliest EMGs just because it was non-compatible. But I
19 tried to have the longest base. But, yes you can. You
20 certainly can, and I think it's valuable.

21 DR. BERTRAND: Thank you.

22 DR. COOPER: Thank you.

23 CHAIRPERSON JANOSKY: I'd like to -- I have a
24 question for you, also.

25 DR. COOPER: Sure.

1 CHAIRPERSON JANOSKY: We've been talking about the
2 treatment of TMD. I'd like to return to the diagnoses. And
3 within your article you list a -- well not a hierarchy, a
4 listing of -- an iteration of what were used to make the
5 diagnosis of TMD. And one of these were jaw tracking.

6 Can you tell me whether there was a hierarchy?
7 And, if so, where did jaw tracking fit within that, in terms
8 of diagnosing a patient with TMD?

9 DR. COOPER: The diagnosis of a patient is done a
10 week before they ever have an instrument put on them. The
11 diagnosis is a clinical judgment based on an exam and a
12 history. That's when I decide that this person is somebody
13 that I feel that I could help and I want to have the
14 opportunity to treat. That's the diagnosis.

15 Once that commitment is made, then all of the
16 testing is really just to design my treatment. It's to tell
17 me what's going on on a critical level, on a measured level,
18 so that if I decide that I want to improve muscle function I
19 better find out that muscle function wasn't good before. If
20 I decide that I want to use TENS to relax muscles -- I
21 typically will use TENS for one hour, but very often it will
22 be much longer, because at the end of an hour we go on EMG
23 and see if the muscle levels really got low. If they
24 didn't, they go back on TENS for another hour or another
25 half hour.

1 So, the instruments are giving me numericals. The
2 decision is totally out of my head. That's my 35 years of
3 experience in dentistry is doing that.

4 CHAIRPERSON JANOSKY: Our charge is the diagnosis.
5 That's why --

6 DR. COOPER: I think it's a diagnostic aid. I
7 would have to say it's definitely not free-standing, because
8 I don't think that -- I don't think that anybody -- no, I
9 can't say "anybody" -- you probably could not find somebody
10 who comes in and has a perfect occlusion, God-given or
11 orthodontist-derived, that has perfect muscle function,
12 that's in a perfect trajectory, and I don't have to treat
13 that person if they also don't have any symptoms.

14 So, all of these diagnostic aids are really to be
15 put into place with a person who clinically has a problem,
16 who presents with symptoms demanding treatment, and now I'm
17 going to use these instruments to quantify it.

18 CHAIRPERSON JANOSKY: Okay. So, again, these
19 instruments, for this particular research study, were not
20 used for diagnoses. Is that correct?

21 DR. COOPER: They were used as a second level of
22 diagnosis, okay? Diagnosis is an ongoing triage --

23 CHAIRPERSON JANOSKY: Uh-huh.

24 DR. COOPER: -- not just at that point.
25 Throughout the whole treatment period there's a constant

1 reevaluation of what you've accomplished by what you've
2 done. And if you haven't accomplished it, the person still
3 has this, this problem, I go back and I test again. I mean,
4 this is my own personal protocol. I'll go back and re-test
5 the whole thing and see if I did it right. I mean, I don't
6 charge for that -- quality control.

7 CHAIRPERSON JANOSKY: Uh-huh.

8 DR. COOPER: But at least I have quality controls.
9 I have qualities that I can evaluate and see if they're
10 good.

11 CHAIRPERSON JANOSKY: Well, that's really where
12 I'm getting -- whether there was a companion study or a
13 study yet to be -- in press, yet to be released, looking at
14 --

15 DR. COOPER: No, no, no. That is -- that was --
16 at long-term treatment, that was the last time these people
17 were tested. We have some of these patients who have --
18 there's a problem in a TMD patient population, and that is
19 that they're not all my dental patients. Many remain so,
20 and therefore I have the access to follow them up. Many are
21 from other places and they go back to their own dentists and
22 I never see them again.

23 You all know, from a clinical practice situation,
24 it's not absolute and sterile. You send out questionnaires,
25 they don't send them back. So you can only follow the

1 people that you have access to. And, obviously, the ones
2 who keep coming back to me for their dentistry or for
3 another appliance ten years later are people who are
4 satisfied and they're happy, and you can keep that little
5 line going.

6 And what we do do on those is if they're going to
7 have a new appliance made -- we just had somebody ten years
8 later -- they're re-tested. And it's a small group, and
9 when they're re-tested, we take a new bite registration and
10 keep them right on target, because what they have is worn
11 down.

12 So you don't have the opportunities in private
13 practice of doing tremendous follow-up, as you can see by
14 the shrinking population. Even at three months they had to
15 spend money to come in for that test. If they were feeling
16 well, they may not want to spend the money. If they weren't
17 feeling well, they definitely weren't going to spend the
18 money. But you can't make a conclusion on the people who
19 don't come in. You can only evaluate the people that do.

20 CHAIRPERSON JANOSKY: Additional questions from
21 the Panel?

22 DR. BURTON: Just a couple of brief questions --
23 it's Richard Burton.

24 Are you -- I've just been looking through the
25 article -- but are you administering all the TENS treatment

1 in your office, or is the patient administering it in his
2 home?

3 DR. COOPER: Almost universally in the office.
4 Years ago we used to loan out machines, and on very, very
5 uncomfortable patients who did not have a great deal of
6 access to the office, we would give them a home TENS and let
7 them -- there's a miniature of that -- of a big box. It's
8 as big as one of these little lavalieres, and we would send
9 them home and let them use it.

10 But 95 percent of them are getting TENS in my
11 office so that I have a chance to see them each time that
12 they're there, which I do do. I mean, I do -- I don't do a
13 full examination, but I interview them, measure range of
14 motion, see how they're doing.

15 DR. BURTON: So you're monitoring the therapy
16 yourself.

17 DR. COOPER: I'm not putting it on. I mean, it's
18 put on by --

19 DR. BURTON: And also, in clarification, so you
20 would really consider the diagnostic battery that you've
21 used here, again, as a secondary diagnostic follow-up,
22 beyond your clinical exam.

23 DR. COOPER: Correct.

24 DR. BURTON: Thank you.

25 DR. TALLEY: Bob Talley, Norman, Oklahoma.

1 Perhaps I'm suffering from heat exhaustion from
2 the heat in Oklahoma, but I've lost something here.

3 I want a point of clarification. Dr. Cooper, you
4 discussed the three elements here: TENS, a kinesiograph --
5 jaw tracking -- and sonography. And TENS obviously is a
6 treatment modality, and the other two --

7 DR. COOPER: And EMG. And EMG.

8 DR. TALLEY: And EMG -- excuse me.

9 Those three -- EMG, jaw tracking and sonography --
10 are classified as diagnostic tools. Yet, in your
11 presentation there is at least some confusion for me as to
12 whether you were using them as diagnostic data-gathering,
13 informational pieces, or are they used in the direction and
14 focus of actual treatment. Are they treatment devices?
15 Could you clarify that for me, please?

16 DR. COOPER: Okay.

17 No, I thought I did just a moment ago. They are
18 diagnostic devices. They're not free-standing diagnostic.
19 The only treatment device is TENS and the orthotic appliance
20 I put in the mouth. So they are all diagnostic. They are
21 telling me where the jaw is, when the muscles are relaxed
22 and, in the case of sonography, what kind of sounds are
23 being produced at various parts of opening and closing in
24 somebody's open-close cycle.

25 So they are all diagnostic input things. Yes,

1 they are used to help me design my therapeutic position,
2 because based on where I see that jaw, and what those
3 muscles are doing, and clinically what the mouth looks like
4 at the same time -- in other words, am I making a great big
5 opening in the mouth for letters to be mailed, or am I doing
6 something which is prudent and cautious, I will find out
7 what the implications of my selected treatment position on
8 what the muscle resting activity is.

9 If I close the person down, am I blowing my muscle
10 cool, and a temporalis muscle is starting to fire up; or if
11 the patient is protruding their jaw, the digastric muscle is
12 starting to fire up. So I am making a treatment decision
13 and evaluating that data that's coming in at the same time.

14 CHAIRPERSON JANOSKY: Okay. Thank you, Dr.
15 Cooper.

16 DR. COOPER: You're welcome. Thank you.

17 CHAIRPERSON JANOSKY: At this time we'll take a 15
18 minute break, returning at 3:50 to continue the
19 presentations by industry.

20 [Recess.]

21 CHAIRPERSON JANOSKY: We're continuing with the
22 industry presentations. The next presentation is by Mr.
23 John Radke.

24 Again, I ask that you state your name and
25 affiliation and the nature of your financial interest.

1 MR. RADKE: My name is John Radke. I'm the
2 president of BioResearch, Inc., and a principal thereof. A
3 little confusion here, though. I thought it was 200
4 minutes, but I guess -- it's just 20 minutes --

5 [Laughter.]

6 MR. RADKE: -- is that right?

7 Well, fortunately, a lot of what I could have said
8 has already been said, so maybe I can cut this down to 20
9 minutes. Yes, maybe even less.

10 In the opinion of BioResearch -- and I believe
11 that's what we've been asked for here -- we believe that
12 magnetic jaw trackers and sonographic devices should be
13 classified Class I for the following reasons.

14 The first reason is that we believe that these
15 devices are inherently safe. That is, they are non-
16 invasive; there's no electrical contact to the patient or
17 the dentist; there is no energy applied to the patient; no
18 physiologic change is induced by either of these devices; no
19 life-support function is involved with either of these
20 devices; and no diagnosis is made by either of these devices
21 -- the dentist makes the diagnosis.

22 It's also evident that these devices are
23 predicated on pre-amendment devices, which means that these
24 devices have been in the marketplace for at least the last
25 22 years, and they have been regulated, then, by general

1 controls for the last 22 years. General controls seem to be
2 very effective in regulating these devices.

3 I don't know how knowledgeable the Panel members
4 are of what the general controls are, but, for instance, the
5 Good Manufacturing Practices are applied to these devices
6 and have been since they were passed. And, as a
7 manufacturer, that's not a trivial fact. There's a good
8 deal of activity that goes on at BioResearch as a result of
9 complying with Good Manufacturing Practices.

10 More recently, the ante has been upped to
11 something equivalent to the 9001 ISO protocols. So now,
12 even though these devices are unclassified, I can tell you
13 that we're real busy jumping through hoops all the time,
14 making sure that the quality is there, that we keep track of
15 these devices, that we keep track of who we sell them to.
16 We keep track of anything that goes wrong; any repairs that
17 we do are tracked. We spend a great deal of effort just to
18 comply with the regulations that are currently applied to us
19 with respect to these unclassified devices.

20 If for any reason the Panel should find that these
21 devices -- or conclude, or recommend, or the FDA should
22 determine that these devices ought to be in Class III, then
23 I think it's very predictable that these devices will be no
24 longer manufactured. And that's an economic factor, because
25 that then raises the bar to another level which is

1 unachievable for this type of device in the current
2 marketplace.

3 The other factor that I think is pretty evident is
4 that these devices are efficacious. And, specifically, if
5 you look at indirect evidence, there are about 3,000 --
6 roughly -- practitioners for whom TMD is a major or
7 significant part of their practice. And our best guess is
8 that about 2,000 of those people use this instrumentation.
9 That may surprise you, but we're actually facing market
10 saturation here in the U.S.

11 I realize that's indirect, but it would suggest
12 that these people find something useful, in spite of the
13 fact that very often they can't get reimbursed from
14 insurance plans for the use of this instrumentation, and
15 they continue to use it anyway.

16 The fact that the ADA has accepted these devices
17 after several years of investigating them would suggest that
18 in their eyes the devices are efficacious and also safe.

19 The direct evidence of efficacy is simply the
20 literature. And we obviously can't discuss the entire bulk
21 of the literature at this meeting, but I think that if you
22 look at, you know, a few of the articles that have been
23 submitted you will see in the original articles -- the
24 original studies -- you'll see a very one-sided theme, and
25 that is that the studies show usefulness, efficacy

1 correlations; different levels, some more, some less, but
2 it's a recurring theme that's very widely distributed
3 throughout the literature.

4 The devices provide measurements of magnitude,
5 duration, frequency and spatial relationships. The
6 sonography devices are pretty focused on just the joints.
7 The jaw tracking devices, however -- the movement of the jaw
8 represents the sum total of the muscle activity and the bone
9 movement and the joint function, and so some of the people
10 who use jaw tracking find that they can get enough
11 information from that that they choose not to use
12 sonography, and may not use electromyography, may not use
13 TENS, and will focus on just getting the information they
14 need from the jaw tracking. Those people have, in most
15 cases, looked at a lot of jaw tracings on a lot of normal
16 and abnormal and dysfunctional patients, and they've learned
17 to distinguish various factors from the appearance of the
18 jaw tracings.

19 Other practitioners may find that they're more
20 interested in the sonography to just give them an idea of
21 whether or not there's a problem in the joint, and if
22 there's not, then they will assume that whatever problem a
23 patient has, then, is in the musculature or the occlusion or
24 somewhere else. So the sonography can help them make a
25 determination in that direction.

1 If you look at the alternatives to sonography,
2 palpation and auscultation have been shown in the literature
3 to be about as efficacious as flipping a coin. And that's
4 not by us -- that's by other independent people.

5 MRIs have been touted as sort of the gold standard
6 by some people, but that's a pretty expensive alternative.
7 So -- and the various forms of computer aided tomography,
8 and so on. But that's an economic question.

9 The devices actually, as we view them, are
10 complementary, in terms of what they offer to the clinician.
11 They don't replace the history or the clinical examination.
12 They don't substitute for normal radiographs. They provide
13 an indication of dynamic function, since the recordings are
14 made with the patient moving -- opening and closing and
15 moving and chewing and talking and so on -- you get an
16 indication of how the patient is moving, whereas most of the
17 other diagnostic aids are providing static information. If
18 you're looking at the models, you have a static indication
19 of the morphology of the occlusion; the x-rays are static
20 images of the joint at various positions. So we view this
21 information as complementary and contributing to the
22 information the doctor has to enable him to arrive at a
23 diagnosis.

24 I think you could make an analogy to other types
25 of equipment, perhaps; you know, measuring an instrument

1 such as a microscope that allows a laboratory technician to
2 view blood cells and determine if there's low count or a
3 high count, but doesn't necessarily make the count by
4 itself. The technician is making the count.

5 Likewise, the jaw tracker makes a recording of the
6 motion, then the dentist looks at that motion with an
7 understanding that he has developed by looking at a lot of
8 these same motions on a lot of different patients, and then
9 makes an interpretation of the significance or
10 insignificance of a particular motion that's recorded.

11 Just for your information -- and this may or may
12 not be relevant -- the European Economic Community also has
13 Class I and II and III categories for devices, and they're
14 not exactly the same. But I can tell you that they have
15 classified jaw tracking and sonography as Class I
16 measurement devices.

17 So, in general, the devices that we're talking
18 about today can help the clinician visualize data that may
19 not be apparent to the naked eye; that is, you may see --
20 you think you see a deviation when the patient opens, but
21 you're not sure, and with the jaw tracker you can see
22 precisely that there is a deviation, how much of a
23 deviation, and how consistent the deviation is. It's
24 essentially giving you some magnification and a little
25 better view of things.

1 And the other thing that it does is it allows jaw
2 movement and joint sounds to be interfaced to a computer and
3 manipulated with software. So the power of the personal
4 computer now can be utilized in the analysis of this
5 information -- of this data, whereas if you're looking at
6 somebody, you can't exactly take what you saw and put it
7 into a computer and somehow manipulate it. Or if you're
8 listening with a stethoscope to the joint, you can't exactly
9 take that -- what you heard -- type it into a computer and
10 somehow analyze that.

11 In the process of arriving at your -- the Panel's
12 recommendation, you're going to be asked to answer some
13 questions, and I would like to kind of anticipate this. I
14 hope this isn't out of order, but I would like to just
15 comment on these questions.

16 The first one -- question you will be asked is: is
17 the device life-sustaining or life-supporting. And I think
18 that we could all agree -- it seems to me it's obvious that
19 it's not.

20 Is the device for a use which is of substantial
21 importance in preventing impairment of human health? And I
22 would say that neither of these devices can prevent
23 impairment of human health. That's not the purpose of the
24 device. It may help you detect that there's an impairment.
25 It may help the clinician to decide what the impairment is.

1 But it's not going to prevent an impairment of human health.

2 Does the device present a potential unreasonable
3 risk of illness or injury? And I think if we look at the
4 last 22 years -- more than 22 years -- that these devices
5 have been in the marketplace, we'd have to say no, there's
6 not an unreasonable risk of illness or injury.

7 And then: is there sufficient information to
8 determine that general controls are sufficient to provide
9 reasonable assurance of safety and effectiveness. And my
10 point here is that for the last 22 years general controls
11 have been doing exactly that. So if general controls can do
12 it for the last 22 years, it would seem to me they ought to
13 be able to do it for the next 22 years.

14 I would like to just make one other comment
15 relating to the indications for use. And this relates to my
16 observations over the last 26 years that I've been in the
17 business of developing jaw trackers, and that is that it
18 seems quite remarkable to me that when a dentist graduates
19 from dental school, typically he has almost no idea of how
20 the jaw functions. And if there's one thing that jaw
21 tracking does, more than anything else, is that people who
22 have the fortune to be around the jaw tracker and get to use
23 it a little bit realize how the jaw functions. And if they
24 get around an electromyograph, pretty soon they know how
25 muscles function. And using a sonograph can be very

1 beneficial in their education about learning how joints
2 function and what sort of dysfunctions can occur in a jaw
3 joint.

4 So I think one of the -- maybe one of the primary
5 indications for use is for a dentist who needs to learn
6 about stomatonathic function, it would be good to prescribe
7 some jaw tracking exercises or studies or what have you.

8 The truth is, in my experience, that after some
9 number of years that doctors used this instrumentation, they
10 actually end up using it a little bit less and a little bit
11 less, and more selectively, because they become more astute
12 in recognizing clinically problems and the nature of
13 problems, and they end up using this more often just to
14 verify what they've already suspected from a clinical
15 examination.

16 So I hope I've made a couple of points, and I hope
17 I haven't bored you with too much redundancy over the past
18 speakers. And thank you.

19 CHAIRPERSON JANOSKY: Are there questions from the
20 Panel members for Mr. Radke?

21 [No response.]

22 CHAIRPERSON JANOSKY: Thank you.

23 Our next speaker is Dr. Ray Dionne.

24 DR. DIONNE: Thank you. My name is Ray Dionne.

25 I'm at the National Institute of Dental Research in the Pain

1 and Neurosensory Mechanisms Branch, where I've done clinical
2 research evaluating therapeutic modalities for acute and
3 chronic pain for approximately 20 years. I have no
4 financial interest in any of these devices that have been
5 discussed.

6 The interest of the NIDR in these devices is based
7 on, in part, the controversy that has existed in the dental
8 profession concerning temporomandibular disorders and, in
9 part, based on the public health concern over the use of
10 anything for treating patients for a disease process which
11 can be, in general, characterized as having unknown
12 etiology, poorly characterized diagnostic criteria, and
13 using largely non-validated therapeutic modalities.

14 I'd like to show a few slides here which
15 illustrate some of those comments.

16 This is a very simplified illustration of the
17 pathway that exists between the site of injury in the
18 temporomandibular joint and the eventual perception of pain
19 in the central nervous system. In this very simplified
20 illustration you can still see that there are many factors
21 occurring in the periphery that are associated with the
22 actual development of the nociceptive impulse.

23 There are also processes that occur in the
24 peripheral nerve which result in -- at the level of the
25 first synapse in the spinal cord, or its trigeminal

1 equivalent in the medulla, and then various points along the
2 way where these messages can be modified, even at the level
3 of the cortex, where effect and other types of motivational
4 factors can alter the perception of pain.

5 As a consequence, while many people have focused
6 in on factors such as the occlusion, the position of the
7 disk in the joint, or the relationships of the muscles and
8 their various levels of activity, and other people have
9 focused in on factors in the central nervous system such as
10 depression or anxiety, at this point many of the conferences
11 that have been sponsored have yet to develop a clear
12 consensus on what the etiology of these processes are and
13 what the various factors are that are important.

14 As a consequence it makes it very difficult to
15 diagnose and manage them, and that is, in large part, the
16 basis of this meeting today.

17 This is reinforced by a review of the current
18 literature on TMD therapies that was done on the NIDR
19 contract that covered the period from 1980 to 1992. And
20 more than 4,000 references were reviewed at that time. Only
21 15 percent of these were actually found to be clinical
22 studies, and a mere 1 percent were found to be randomized
23 controlled trials. And as I'll try to describe to you, this
24 represents the minimum type of information you need to
25 actually be able to make statements about therapeutic

1 modalities.

2 Based on this, the author of this study, who was
3 affiliated with the Harvard School of Public Health at the
4 time, and a relative expert on how meta-analysis is done.
5 So it was not clear whether these therapies provide any
6 benefit over placebo along. And despite the fact that this
7 was done -- based on through 1992, subsequent meetings such
8 as the NIDR workshop in '95, the NIDR Consensus Conference,
9 and other bodies have not come up with any conclusion that
10 suggests that many of the therapies are much better than
11 placebo at this time.

12 As a consequence, the current management of
13 temporomandibular disorders is often based on unverified
14 hypotheses. The treatments are based on something that
15 hasn't been actually proven. They're often using non-
16 validated practices and, in fact, some studies such as the
17 splints, when have been subjected to fairly well-controlled
18 clinical trials, often do no better than an inactive splint
19 or one that's not even given to the patient.

20 Most treatments are very ineffective when
21 subjected to this criteria of randomized controlled trials.
22 But there is a potential for iatrogenic injury, which is
23 often very significant. So we have a situation where many
24 of the treatments are being based on hypotheses that haven't
25 been -- etiologies that haven't been identified, using

1 treatments that don't work, and have the potential for
2 iatrogenic injury.

3 And, finally, these problems are somewhat
4 perpetuated by the inability to transfer this generally
5 accepted scientific knowledge to clinicians.

6 Part of the process lies in how we evaluate
7 clinical success, and there's been a great deal of
8 discussion today about people making observations and coming
9 to the conclusion that they have had a great deal of success
10 in their hands. The problem is that if you have a
11 therapeutic modality and you apply it to a patient and it
12 works, you naturally develop the perception of clinical
13 success, especially if this occurs repeatedly in your hands.

14 Unfortunately, this is a very complex process.
15 You're actually conducting an uncontrolled trial in a
16 situation like that, which places greater emphasis on
17 success and tends to ignore failures. People don't get far
18 in their careers publishing spectacular failures. They'll
19 usually only document their successes.

20 There's very often biased patient selection. I
21 know, from the kind of studies that I do, that I could very
22 easily make morphine look like saline, and saline look like
23 morphine, depending on how I select subjects for my studies.
24 Fortunately, they don't let me get away with it due to the
25 blinding and randomization process. But it's easy to

1 identify, very often, who's going to be a responder and who
2 isn't.

3 The response rates in uncontrolled trials vary
4 greatly among investigators. As a consequence, people have
5 recognized for a long time that uncontrolled studies are
6 more likely to lead to positive results which are fallacious
7 than controlled trials.

8 The actual process of evaluate clinical success
9 for a therapeutic modality aimed at pain is very complex,
10 and is described on this slide here.

11 The therapeutic process involves a number of
12 things which can mimic clinical success in the absence of an
13 actual genuine therapeutic response. For the treatment of
14 pain, it's been long recognized that the placebo response
15 results in about 35 to 50 percent of the efficacy of any
16 modality that we use. A positive doctor-patient
17 interaction, as well as fluctuations in remissions of
18 symptoms can also mimic clinical success. A good example of
19 that is a study we did a number of years ago where we
20 selected patients on the basis of near daily pain for three
21 months' duration; gave them a diary to fill out to record
22 their baseline pain, and then when they came back, we found
23 that approximately 25 percent of these patients no longer
24 fit the inclusion criteria we had for near daily pain. If
25 we had done something at the first visit, and saw them at

1 the second visit, we would have assumed that whatever we did
2 was responsible for this improvement when, in reality, it
3 just represented some sort of fluctuation in their
4 symptomatology. Obviously there are treatments that should
5 have a therapeutic effect.

6 On the other side of the equation there are even
7 stronger factors, such as the bias of the clinician, chance
8 occurrences, the type of control group or, in many studies,
9 no control group is used, which doesn't allow you to control
10 for all these factors; and, finally, the evaluation criteria
11 that is used.

12 As a consequence, randomized controlled trials for
13 the evaluation of a diagnostic or a therapeutic modality are
14 based on the fact that, by and large, they avoid the biases
15 that are inherent in the uncontrolled evaluations. They
16 also provide a basis for statistical analysis. Virtually
17 every test that's used to evaluate an outcome assumes that
18 the treatments have been randomly allocated, or the subjects
19 have been placed in the treatment groups randomly. So any
20 elaborate statistical analysis at any level which doesn't
21 involve using some degree of randomization probably doesn't
22 meet the minimum criteria for this test having any meaning.

23 So as a consequence, randomized controlled trials
24 are an essential tool for evaluating the efficacy and the
25 toxicity of therapeutic innovations.

1 It's not generally recognized, but much of the
2 evidence I've heard thrown around today -- the -- which has
3 been characterized as "the scientific literature," doesn't
4 really fulfill the criteria of having been a hypothesis --
5 an idea -- which has been actually -- becomes clinical
6 knowledge by passing through this difficult and time-
7 consuming process of being testing by properly controlled
8 studies and patients. It doesn't make any difference how
9 many poor studies have been done; how many subjects have
10 been observed in an uncontrolled fashion; or how prominent
11 the people are that make the assertions -- the outcome is
12 still pretty much a hypothesis until it's been validated in
13 some kind of a controlled clinical trial.

14 The hierarchy for evaluating evidence from
15 clinical trials has been pretty much generally accepted in
16 the literature. Case reports are the least valuable form of
17 information, and they usually just form the basis for more
18 evaluation later on. Series of cases without controls,
19 which actually constitute much of the information that
20 exists in the temporomandibular literature, is actually
21 considered to be only slightly better -- and usually just
22 forms the basis for more well controlled trials.

23 An example of that might be the use of
24 amitriptyline 20 years ago for the treatment of chronic
25 pain. This was an anti-depressant drug, and based on a

1 series of cases that eventually underwent rigorous
2 scientific studies, and it was determined that, in fact,
3 amitriptyline and anti-depressants in general, at low doses
4 had analgesic effects which could be separated from their
5 analgesic effects [sic] and now, in fact, it forms a
6 mainstay for treatment of chronic pain.

7 So this process of going from a series of cases to
8 a randomized control trial gave us some knowledge which was
9 useful.

10 Conversely, many of the treatments which have been
11 around for treatment of chronic pain for decades have not
12 been subjected to this rigorous type of evaluation and still
13 can only be considered to have low levels of evidence to
14 support them, such as series of cases with literature
15 controls, historical controls. Even one single randomized
16 clinical trial in the hands of one investigator is usually
17 considered to be inadequate, and the usual criteria is you'd
18 like to see replication by two separate investigators.

19 As a consequence, there's sort of a natural
20 history of therapeutic innovation in the treatment of
21 chronic orofacial pain. Initially, the initial case reports
22 are very positive or they wouldn't be published, but we
23 still would have to consider them to be un-validated
24 clinical practices at that early time point. Case series
25 would still fall into this gray area. Ultimately, poorly

1 controlled clinical trials are done, and this gives us a
2 basis for either going forward to well-controlled clinical
3 trials, or possibly considering this to be not worth
4 pursuing.

5 If there are several well-controlled clinical
6 trials then we have a validated clinical process.
7 Conversely, if we fail to meet that criteria, then we have
8 something that, if it persists, would maybe be considered an
9 un-validated clinical practice or, in an ideal world, would
10 be removed from the market or somehow or other restricted.
11 Unfortunately, sometimes these things persist and are
12 actually considered to be irrational clinical practices,
13 despite the weight of evidence.

14 I'd like to just cite one example to you which
15 comes from outside of the TMD area, and this involves a
16 well-validated hypothesis in animals that was subjected to
17 testing in man. This involves stimulation of the
18 periventricular gray matter which was demonstrated in
19 animals to unequivocally produce analgesia and release beta
20 endorphin into the cerebrospinal fluid, coming up on
21 attractive mechanism for why it would work. And, in fact,
22 the first clinical trial, which was just actually a case
23 series of three subjects, showed very robust clinical effect
24 and the release of beta endorphin into the cerebrospinal
25 fluid over the time period associated with the stimulation.

1 And this was published in Science.

2 The paper published right after that in the
3 proceedings of the National Academy of Science again showed
4 a dramatic clinical effect and the release of beta endorphin
5 into the cerebrospinal fluid. However, a subsequent study
6 that was done was able to indicate two things. First of
7 all, the release of this -- apparent release of beta
8 endorphin into the cerebrospinal fluid was apparently an
9 artifact associated with the use of the radiopaque dye that
10 was administered as part of the surgical procedure and
11 actually after the electrode was placed and turned on, the
12 levels continued to drop as the dye washed out of the
13 cerebrospinal fluid. All the data showed that on the day
14 after surgery there was actually no changes in beta
15 endorphin -- double-blind methodology using masking the
16 active stimulator versus a passive stimulator, using drugs
17 to obscure the effect and whatever were never able to
18 demonstrate that this treatment actually worked in man and,
19 by and large, this was abandoned -- but not before there
20 were deaths in each of the two series of studies that
21 evaluated this, due the fact that this was a very risky
22 placement, indicating that the use of these types -- in
23 general, that the use of non-validated clinical practices,
24 even based on well-founded animal hypotheses is not without
25 risk.

1 This may seem like all of academic interest and
2 totally unrelated to the question that is at hand today, but
3 I'd like to just point out the impact you can have of using
4 unverified clinical practices on patients. And this is just
5 one example of someone at the time of one of the early
6 hearings associated with the proplast implant problem
7 described her case series and actually testified. And this
8 was a female physician who had been actually very successful
9 in practice, had a dental problem and had a series of
10 procedures done, and the one that would probably be
11 considered to be pivotal was the placement of this
12 teflon/proplast implant which had never actually been
13 probably indicated for this procedure. It had a
14 catastrophic process and eventually she went on to, at the
15 point of letter was suffering from symptomatic pain
16 management and was considering suicide as the only way out.

17 I'd like to just show you one overhead -- and if
18 we could have the lights on --

19 [Pause.]

20 And I picked this out just on the basis of the
21 fact that it was presented earlier in the presentation as
22 illustrating the fact that these methods which are used for
23 diagnosis are effective an result in conclusions which were
24 described as facts.

25 This was a paper that was published in the

1 proceedings of the TMD Technology Assessment Conference in
2 journal that's indicated, and actually the type of research
3 was a case series, as was indicated, of 1,182 patients out
4 of 3,681. You can gather right away, based on what I've
5 already asserted, that this represents either one-third of
6 the patients who had clinical success, or it could be two-
7 thirds of the patients did not have clinical success, based
8 on the fact they were never evaluated or followed up on. We
9 don't know that on the basis of that. I'm not making any
10 accusations. I'm just pointing out that only evaluating
11 one-third of the patients only gives you that information on
12 one-third and, obviously, two-thirds, if they failed, that
13 would be a very inadequate treatment.

14 It's also in the paper that this was a
15 retrospective study with no parallel control group. So this
16 represents strictly a case series -- the lowest form of
17 evidence we would have for documenting the effectiveness of
18 a certain treatment or a diagnostic method.

19 Another thing that was mentioned in the paper --
20 the purpose for doing this was to demonstrate the utility of
21 these particular devices for both evaluating and treating
22 the patients with TMD. I think it's an artificial
23 distinction to say that the devices that are under
24 consideration are only used in some abstract way to evaluate
25 the patients and arrive at a diagnosis when, in fact, the

1 treatment that follows from this is almost always based on
2 the outcome of this diagnosis and, in fact, the speaker
3 indicated that he used this electromyography repeatedly
4 during the treatment to assess the effectiveness of it.

5 Finally, it should be pointed out that the
6 rationale for this whole thing was based on what is
7 considered to be a postulate -- it was something that does
8 not represent a scientific fact. And I suspect if we were
9 to have a hearing on the basis of this -- electrophysiology
10 or the evidence supporting this particular assertion we
11 would have a room full of neuroscientists who would have
12 very active opinions on this.

13 So as a basis, this conclusion -- which was many -
14 - that the data from this clinical study supports the
15 hypothesis that occlusion has a role in the cause and
16 management of TMD, I think illustrates the problem rather
17 than forms a basis for assertion that this is a fact. And,
18 in fact, this type of thing is really just an unverified
19 opinion based on uncontrolled clinical observations.

20 As a consequence of those considerations, I'd like
21 to urge the committee to only consider evidence from well-
22 controlled, randomized trials in evaluating the
23 effectiveness of the devices being considered, and to
24 recognize the potential risk to patients being treated on
25 the basis of the diagnosis provided by these devices.

1 Thank you.

2 CHAIRPERSON JANOSKY: Questions from the Panel
3 members?

4 DR. MOSES: Yes. I was wondering -- you've been
5 talking about TMD and the conference on TMD, and yet you're
6 saying they failed to define TMD.

7 So I would like to elaborate on how you would
8 define TMD, and the purpose of your presentation, please?

9 DR. DIONNE: Well, the actual definition of what
10 constitutes temporomandibular disorders is very complex
11 because it's assumed to have an origin in the structures of
12 the orofacial region, but obviously result in pain
13 perception at the higher levels. So part of the reason that
14 the term "TMD" has been selected is there's at least 20
15 different terms that have been used to describe it, all
16 based on some facet of it. But "temporomandibular disorder"
17 just is a very general term that describes pain and
18 dysfunction originating in the orofacial region.

19 DR. MOSES: So you're really -- you're asking for
20 an epidemiological, double-blind controlled study on
21 something you haven't defined. You haven't even defined
22 "normal" for that. You haven't defined abnormal for that
23 condition called TMD.

24 Now, if you stand up here and you tell me that you
25 expect a study on any one of those 20 disorders that you've

1 named, I say that's probably reasonable. But when you're
2 talking to me about TMD and giving me this stuff, you're
3 talking about an ethereal concept that you can't even
4 define.

5 I mean, I agreeing with you on that. But I just
6 fail to understand how you could ask for a double-blind
7 study on a condition where normal hasn't been defined, where
8 abnormal hasn't been defined, where the patient group hasn't
9 been defined.

10 DR. DIONNE: I'm not so much asking for that as
11 I'm saying any assertion that one can treat and diagnose
12 this nebulous disorder using a device that only focuses in
13 on one facet of it ignores the fact that there's a very
14 complex process of pain perception going on, and that just
15 looking at one thing may be looking at something that's
16 related to the etiology or the outcome or may be looking at
17 an unrelated --

18 DR. MOSES: Are you saying, then, the joint sounds
19 are irrelevant?

20 DR. DIONNE: They may be.

21 DR. MOSES: Are you saying that electromyographic
22 activity is irrelevant to the function of the joint?

23 DR. DIONNE: I'm saying it hasn't been
24 demonstrated based on the usual rules of evidence for
25 evaluating things in clinical trials.

1 DR. MOSES: Well, I think that basically what
2 we're dealing with here is not a research modality because
3 for research modality, the FDA isn't asked to do this
4 approval. I think what we're talking about here, for
5 example, is a clinical modality which I'm going to use in my
6 practice. And I don't think that any of my patients come in
7 wanting to be randomized controlled subjects. They want to
8 ask me how can I do the best to repeat my results of
9 previous treatment. And if I don't have meaningful data, I
10 don't know how to -- and I don't know what I did on past
11 patients, I don't know how to treat them.

12 So I'm trying to relate what you're talking about,
13 because what you're talking about as a result of a double-
14 blind controlled study, to me, that's inference on what's
15 going to happen to my patient. Whereas when I get a result
16 of an electromyograph and it tells me what the electrical
17 activity in the muscle is, that's evidence to me; that by
18 any definition of the word evidence -- you're talking about
19 inference and I'm talking about evidence. I just don't see
20 what the point is.

21 DR. DIONNE: The point is that, as you mentioned,
22 when your patients come in and they ask you to treat them,
23 they don't want to be participating in an uncontrolled trial
24 of something that's not verified. They haven't been given
25 an informed consent that tells them the devices or the

1 treatments that they're about to receive have never been
2 validated using the usual rules of science.

3 And what I'm -- clinical methodology trials -- so
4 what I'm point out is that while there's been assertions
5 that all this stuff has been verified by piles of data that
6 are three feet high, in reality other bodies of people have
7 looked at the same information and found it to be
8 inadequate.

9 DR. MOSES: That's your opinion.

10 DR. DIONNE: That's what we've been hearing all
11 afternoon. I'm just trying to draw a distinction between
12 what's been presented as fact, and what is still considered
13 to be opinion.

14 DR. MOSES: Okay. Thank you.

15 DR. TALLEY: Dr. Dionne, I have just a couple of
16 questions.

17 You've been with the NIDR for 20 years, is that
18 correct?

19 DR. DIONNE: Yes.

20 DR. TALLEY: And the Neuroscience Division for --

21 DR. DIONNE: Pain and Neurosensory Mechanisms.

22 DR. TALLEY: And your background is dentistry and
23 pharmacology, I understand?

24 DR. DIONNE: That's correct. Right.

25 DR. TALLEY: What efforts is the -- what efforts

1 are being extended by the NIDR to establish well-controlled
2 randomized clinical trials for any of the instruments, both
3 in diagnostic or therapeutic regimens that are used in
4 temporomandibular disorders? And what has been done over
5 the 20 years you've been affiliated with the organization to
6 help establish those well-controlled, randomized clinical
7 studies?

8 DR. DIONNE: Well, there's many answers to that.
9 The basic process whereby the NIH works is to, of course,
10 give grants. And that is based on a peer-review process.
11 And the clinical trials, in general, fare very poorly in a
12 study section environment. So as a consequence, it's only
13 been until recently there's been some money that's been set
14 aside for the actual research on temporomandibular disorders
15 and has been allocated within that context, that has been a
16 reasonable amount of money that's been allocated, as far as
17 I know. But that, again, is all from the extramural side of
18 the coin, and I'm not really that intimately involved with
19 that.

20 Intramurally, the assumption has always been made
21 -- and the model for the intramural research program is that
22 if you can do good basic research which sheds light on the
23 mechanisms of any disease process, then this can ultimately
24 lead to new knowledge that can be applied clinically. That
25 can be construed as a logical way of doing things or as an

1 easy way of avoiding the difficult questions, and I suspect
2 it's a little bit of both.

3 DR. TALLEY: Well, I respect your position and
4 your eloquence in your presentation today.

5 I guess my basic concern is that you stand here
6 before us as a scientist representing the NIDR and yet the
7 NIDR, which we as dentists look to as being our research
8 branch and a part of the NIH, is doing -- if I understand
9 you correctly -- virtually nothing to establish well-
10 controlled randomized clinical studies. And yet we are
11 being, as clinicians and practitioners, involved in the
12 daily activities with our patients, doing the best we can
13 with the knowledge available through science, and through
14 clinical practitioners who do present and write in their own
15 rights, to the best of their abilities -- but we're seeing a
16 judgment passed here without a counter to it.

17 I'm not seeing that you're showing me the studies
18 that prove that we are wrong. You may be proving that
19 clinicians are not writing effective scientific papers with
20 the usual methods of science. But I would like to see those
21 usual methods of science used by the institutions that we,
22 hopefully, see better funded. And, again, not being
23 critical of you personally, sir, but that we would see this
24 evidence out there so that we could make judgments
25 clinically and apply those skills appropriately. And we're

1 not seeing that.

2 DR. DIONNE: Well, in fact --

3 DR. TALLEY: We're seeing darts thrown at us as
4 clinicians.

5 DR. DIONNE: The institute organized a workshop in
6 '95 that was designed to develop methods that could be used
7 for just these types of questions. They, of course, the
8 Technology Assessment Conference and the whole product of
9 that was research recommendations -- not necessarily
10 pointing the blame or indicating what was right or wrong
11 with everything. This led to the increased funding,
12 extramurally, for this, and there has been some increased
13 funding intramurally.

14 Despite that seemingly long track record, there
15 have been a number of studies that we have done and, by and
16 large, we found that most of the things we've evaluated
17 which were being used clinically did not stand up to the
18 scrutiny of a well-controlled clinical trial --
19 iontophoresis, for example, was evaluated on double-blind
20 method using active drugs did no better than placebo.
21 Patients got better under both of the regiments. The use of
22 certain benzodiazapenes showed a slight beneficial effect in
23 some contexts and not others and, ironically enough, the use
24 of non-steroidal anti-inflammatory drugs chronically did not
25 demonstrate any activity, and this is somewhat difficult to

1 explain, but there is a possible logical explanation for
2 that. And there are -- right now, an evaluation of TMJ
3 implant patients is being undertaken, which represents a
4 very difficult and large commitment to try to learn
5 something about this, which represents the worst possible
6 group of patients.

7 DR. TALLEY: So -- I'm not trying to draw total
8 conclusions, but basically what you're telling me is the
9 usual methods of science for analysis of all of the
10 treatment modalities that you just went through indicate
11 that there's nothing we do for these people -- that it has
12 any efficacy. Am I extrapolating the wrong information
13 there?

14 DR. DIONNE: I would have to say that the -- you
15 know, the weight of the evidence indicates that many of the
16 treatments that are used haven't been scientifically
17 validated. And maybe I haven't articulated the point
18 clearly yet, but the goal would be to identify those and
19 subject them to trials over time, but in the interim, not to
20 be subjecting -- using these devices or methods or
21 therapeutic modalities on patients in the absence of clear-
22 cut evidence they work, when almost all of them carry some
23 potential for problems.

24 So that if, say, someone offered temporomandibular
25 joint surgery to a patient and said the weight of the

1 evidence is that this doesn't help most people, and it has a
2 lot of iatrogenic complications, and the patient still
3 elects to proceed, that would be a reasonable therapeutic
4 approach. Conversely, if someone came in and was told that
5 this procedure works extremely well and five years later it
6 turned out to be that was teflon/proplast that was put into
7 the temporomandibular joint, then that was not a rational
8 therapeutic situation and probably not even an ethical one.

9 DR. TALLEY: Thank you, sir.

10 DR. MOSES: Excuse me -- Allen Moses, again.

11 I must be missing something here. You said that
12 iontophoresis, when it was compared against benzodiazapene
13 was shown to be no more effective -- is that what --

14 DR. DIONNE: No, I was rattling off a list of
15 studies we had done over the last ten years. Iontophoresis,
16 using dexamethasone and lidocaine, compared to a placebo,
17 under double-blind conditions with in-subject crossover, did
18 not show any efficacy. The patients got better under both
19 sets of conditions.

20 CHAIRPERSON JANOSKY: Any other questions from
21 Panel members?

22 [No response.]

23 CHAIRPERSON JANOSKY: Thank you.

24 At this time, I'll call for any other comments --
25 from industry, from the public, from professional

1 organizations.

2 DR. COOPER: Dr. Barry Cooper. I just have to --
3 I must make a comment on Dr. Dionne's erudite analysis of my
4 paper.

5 First of all, Dr. Dionne, I wanted to thank you
6 for helping with the editorial work on my paper. He truly
7 is a very skilled editor, and he did a lot of work on my
8 manuscript.

9 This is the second time I've been in the audience
10 that Dr. Dionne has chosen to use my paper as a
11 representative of analysis of bad research. I would hope
12 that if he knew I was on the program he would pick somebody
13 else's, even if he has the overhead for this one study.

14 [Laughter.]

15 DR. COOPER: Okay. So please, next time, Ray,
16 pick another study.

17 But I do -- that's on a light note, and I'm
18 serious, and I respect him.

19 On a serious note, I resent his characterizing the
20 research as bad research. It was what I said it was. It is
21 clinical research on real patients in a real practice. He
22 not only implied but stated that his assumption was that I
23 picked 1,200 out of 3,600 patients because these are the
24 ones that got better. And he didn't listen, and he didn't
25 read, because he should have read the paper.

1 Those patients were patients in a private practice
2 who, on an individual decision basis of their own elected to
3 have treatment. I didn't select them as the winners versus
4 the ones I thought to be the losers. So I resent that
5 connotation.

6 When -- I stated in the paper -- when -- he
7 stated to me in his critique of my work that there was no
8 control. I stated that the controls were the patients
9 themselves, because we used the data before we treated them
10 and compared them with the data after we treated them, and
11 there were internal controls.

12 I know we don't have the kind of controlled
13 studies that the true scientists would like to see. That
14 is, to our knowledge as clinicians, with 35 years of
15 experience and more in this room, an impossibility. First
16 of all, we cannot not treat our patients. And these are not
17 research models, these are patients in clinical practices.
18 If they come to you for treatment you have to treat them.
19 You can't make them a mock occlusion change; you can't make
20 them a mock appliance; and you can't give them TENS that
21 doesn't work. If you do, you will be sued up the kazoo. We
22 have to treat our patients.

23 So we are doing the best that we can in the
24 environment in which we are left; meaning that there is no
25 research coming out of any university or NIH which is giving

1 us the support of the knowledge that we really need, yet we
2 on a daily basis are being sent patients by physicians and
3 other dentists who need to be treated.

4 So we have to do the best we can with what we
5 have, and we have a responsibility to our patients to do the
6 best work we can. We are not taking untested things and
7 doing dangerous things to them. The comparison to joint
8 surgery is a very poor one. That is something which can
9 have, as many in this room can attest, horrendous effects.
10 What we are doing is beneficial or it has not effect at all.
11 What we're showing from bioelectronic instruments is that we
12 have a physiological improvement. We are making muscles
13 rest better, work better, stay in the same place get better
14 range of motion -- and, by the way, getting tremendous
15 symptom improvement. If that's anecdotal, so be it. That's
16 our level of science.

17 But I, too, go back to the NIH -- and I went back
18 and visited the NIH after that conference, on a separate
19 trip at my own expense, and told them I would like to get a
20 research grant to do the kind of research that they want.
21 And they said, "You don't stand a chance of getting a first-
22 time research grant even for minuscule money unless you are
23 coming out of a university where somebody who has had a
24 successfully completed NIH project will be your sponsor,
25 because otherwise you can't do it, clinician, they'll never

1 give you the money."

2 So, I'm telling you, as Dr. Talley just did, that
3 if the scientific community demands a certain level of
4 science, then they better define the terms that they can
5 agree on -- that we all can agree on -- carry out the
6 studies, and give us the ammunition with which we can treat
7 our patients on a daily basis.

8 Thank you.

9 DR. LISS: I'm Dr. Saul Liss, from MediConsultants.

10 And nobody can argue with the wisdom of getting
11 the best science possible to accomplish the generation of
12 the information that we all would love to have. But when
13 you're putting nickels and dimes together in order to
14 studies, and getting clinicians who, of their own good will
15 want to do something to give something back to the
16 profession as the only way of getting studies, this is what
17 we're getting. And there's no compromise. This is the real
18 world.

19 And if you want better, join us and give us a
20 means of getting the budgets necessary to do that level of
21 research. The money is there. I went to an SBIR program
22 one time to learn how to write proposals. And when I wrote
23 12 proposals I found out later on that the reviewers all had
24 dinner together. And they said, "Gee, I got a proposal from
25 a guy by the name of Liss on TMJ pain control." Another one

1 said, "I got one on depression." Another one said, "I got
2 one on headache." I wrote a dozen proposals. I didn't get
3 one.

4 Don't make it so damn difficult for us to function
5 to give you the data that you want, that the country needs.
6 Give us a chance to help, please.

7 DR. JANKELSON: Once again, Dr. Robert Jankelson,
8 Myotronics Research. I do have a financial interest in the
9 company.

10 I'd like to respond to several things that have
11 just happened in this committee. Being here in October
12 1994, I have not heard the term "death risk," of using
13 unverified clinical practices carrying potential for serious
14 problem since that time.

15 This is not a venue in which we fear-monger, or
16 should fear-monger. I think you all realize what has just
17 happened.

18 But let me address the scientific methodology,
19 which I think I'm quite familiar with.

20 Now, it's an imperfect world. First of all, as I
21 believe Dr. Moses pointed out, it is impossible to control -
22 -to construct double-blind studies in a syndrome such as TMD
23 where you have at least 60 markers of TMD appearing in any
24 degree of severity, combination, chronology, intensity. You
25 can have a double-blind study for any one of those markers,

1 but not this thing we call TMD.

2 Also, in the formulation of any good scientific
3 study there has to be hypotheses and premise. I'd like to
4 take a little example. One of the common paradigms being
5 expounded at this time is that occlusion has nothing to do
6 with TMD. The studies used to support that premise employ a
7 double-blind study -- a control -- in which a mock
8 equilibration is performed on the control group, and the
9 real equilibration on the subject or other patient group.
10 What's wrong?

11 Two things are wrong. First of all, there had to
12 be a premise that, number one, occlusal equilibration was
13 the correct therapeutic choice. That, in itself, was a
14 tremendous leap of faith, because we know that seldom do we
15 grind tooth structure in the TMD patient.

16 Secondly, was the assumption that the
17 equilibration technique employed was the correct
18 equilibration technique employed. So the study concludes
19 there was no difference between the mock or control group
20 and the equilibration group.

21 Conclusion? Occlusion has nothing to do with TMD.
22 Again, we must be very, very careful in evaluating the basic
23 premise.

24 Now, I'd like to make a point in regards to Dr.
25 Dionne's comments. One of the truly defining advantages of

1 having objective measurement is we are not measuring TMD.
2 We are not measuring pain after it's been processed along
3 the trigeminal pathways through the reticular activating
4 center, the limbic system, the cortex -- and all that
5 integration that comes from the cerebellum and the
6 descending pyramidal and extrapyramidal coordinates of that
7 central nervous system loop. We are measuring specific
8 physiologic responses or phenomena that do, in fact, have a
9 common basis in the scientific literature.

10 This is why I felt it was so important for you as
11 a panel, even though it would impose upon your time, to
12 explore the full 300-plus scientific studies that met
13 different levels of the criteria that Dr. Dionne mentioned.
14 But as an accumulated body of knowledge so definitively
15 defines the applicability, the safety and the efficacy of
16 the measurement instrumentation as it was intended to be
17 used.

18 Do not be deterred by the tyranny of so-called
19 rigid scientific methodology. It comes in many forms. It
20 comes in many ways -- through clinical studies, as
21 mentioned; through controlled studies. But, again, when you
22 see these controlled studies, be very, very critical about
23 what is controlled. Is it a TMD group versus a non-TMD
24 group? That is not a valid control, because we have not
25 defined TMD.

1 Now, if that study is examining a specific
2 physiologic response to a specific intervention, then we can
3 have a scientifically valid controlled study. And within
4 that literature package are dozens and dozens and dozens of
5 scientific articles that do exactly that.

6 You should be leery of any so-called scientific
7 study that is doing controlled studies in which they have a
8 TMD group and a non-TMD group; a control and a subject
9 group. It's like centric relation. There's seven
10 definitions, none of which are reconcilable. If you have 20
11 definitions of TMD, how can you have a patient group and a
12 control group. The answer is: you can't.

13 So, to our Panel members, I want to apologize for
14 taking this time to clarify some of the methodology. I'd
15 like to speak to this subject for hours which, really, I
16 think would be very enlightening. If you have any questions
17 about the 300 specific studies which we submitted regarding
18 this instrumentation I'd be very happy to do exactly that.
19 I think I'm familiar with most of them.

20 Thank you very much.

21 DR. KULL: Dr. Robert Kull from Buffalo, New York.

22 I'd like to make two comments. Number one, the
23 instrumentation that's under consideration today is under
24 consideration for efficacy and safety as a measurement
25 device. And I as a clinician who have to look at the

1 patient, deal with the patient, deal with the insurance
2 company, deal with the lawyer, deal with the court system,
3 that wants to know why did I treat this patient. They want
4 to know. And clear-cut, solid, documented measurable
5 evidence is invaluable.

6 I think the literature that's been published since
7 1993 documents clearly that the measurement devices are
8 accurate.

9 I'd like to make a second comment in corollary to
10 Dr. Talley. I am a graduate of a Master's of Science
11 program in TMD orofacial pain and neuromuscular function.
12 It was the first graduate program funded by the NIDR. And
13 after I graduated from the program and began clinical
14 practice, introduced into my clinical practice measurement
15 technology, the director of my graduate program became more
16 than a little disturbed by such, and there were several
17 exchanges which culminated in my calling him and saying,
18 "Let's just have lunch. Let's not do this. Let's just have
19 lunch and talk."

20 And I put the question to him: "You direct the
21 first NIDR-funded research program. If you don't like this
22 material, bring it into your program, test it and prove that
23 we're wrong." The response was, "No one is interested."
24 And the lunch ended.

25 What can we do? Research out here -- published

1 clinical research -- documents that the instruments do what
2 they claim they do. Clinical evidence of treating patients
3 indicates that we can support and back-up what we do. So we
4 continue to do what we do.

5 Thank you.

6 CHAIRPERSON JANOSKY: Okay. That will end this
7 session of the agenda, and we will now move into the Open
8 Committee Discussion.

9 CHAIRPERSON JANOSKY: First report from Dr.
10 Alpert.

11 DR. ALPERT: I find myself needing to make a
12 couple of comments as -- to refocus the Panel and to provide
13 some assurance, I think, to the process.

14 One is -- someone I know well is fond of saying
15 that reasonable people can disagree. And we also had a
16 comment made earlier that this has been a very contentious
17 area in dentistry. And I think that's what we just
18 experienced. I think there's a lot of controversy, and
19 there a lot of opinions, and there's a lot of strength of
20 idea and issue on many sides of this question. And that's
21 what brings me to say the other things I wanted to say.

22 As you go into the Panel's deliberation,
23 notwithstanding Mr. Roland Jankelson's comments regarding
24 his concerns about the process, I wanted to provide you
25 assurance that we have taken many actions and have taken

1 actions that we don't normally take in preparing for this
2 Panel meeting to assure that it is as unbiased as we can
3 make it; to be sure that you're hearing all of these voices
4 that are, in fact, important to your deliberation, and to
5 provide you access to representative samples of the
6 literature that speaks to all of these issues, so that you
7 have in front of you the context in which the decision that
8 we're asking you to make -- the advice we're asking you to
9 give us -- is made.

10 I want to assure you that we made efforts to see
11 that it was as unbiased a process as we could provide, so
12 that you can understand why we thank you for participating -
13 -recognizing that this was a controversial area, you were
14 still willing to come to the table, and we appreciate that.
15 And we expect that the process will continue in as open and
16 unbiased a fashion as we can make it.

17 I want to come back to something I said this
18 morning; something you have heard in your training, and
19 something that I know we will discuss again tomorrow. And
20 that is that the statute and the regulations regarding
21 initial classification of pre-amendments devices recognized
22 several things. They recognized the hierarchy that Dr.
23 Dionne mentioned, in terms of the scientific hierarchy of
24 different types of research.

25 It also -- or they, the statute and regulations --

1 also recognize that that wasn't the way all the research was
2 done on pre-amendments products, and they were products in
3 use in the marketplace at the time that the regulations were
4 put in place in 1976; and for that reason, recognized all of
5 the types of research as valid scientific evidence for the
6 purpose of classification, and directed us and you to
7 consider all of them -- understanding that they come in a
8 hierarchy, but to consider all of the available information,
9 including your own knowledge and experience with such
10 devices, in order to reach a determination as to whether
11 there's reasonable evidence of safety and effectiveness, and
12 then to put in place -- or to put the products in a category
13 that provides the right level of oversight from a regulatory
14 standpoint regarding the product itself and the claims that
15 are made for those products.

16 And I expect that tomorrow we'll spend a lot more
17 time talking to just that issue: what's the device and
18 what's the claim, so we can make those determinations.

19 But I did want to remind you what the statute and
20 the regulations say as you begin your deliberations, and
21 also to assure you that we've made every effort to keep this
22 as unbiased a process as we can, and anything that we can do
23 to assist you in your deliberations we are here to provide.

24 And, again, thank you for participating.

25 CHAIRPERSON JANOSKY: Thank you, Dr. Alpert.

1 Next we'll here from Dr. Betz about MDR.

2 [Pause.]

3 DR. BETZ: Good afternoon.

4 At the last Panel meeting the FDA was requested to
5 provide data from the Medical Device Reports, or MDRs,
6 regarding devices used in the diagnosis and treatment of
7 temporomandibular disorders and associated orofacial pain.

8 MDRs are described in CFR -- at 21 CFR Sec. 803.

9 Basically, this section states that medical device
10 manufacturers and user facilities are required to report
11 deaths and serious injuries when a device may be a possible
12 cause or contributing factor. Reports by clinicians are
13 voluntary unless the event has occurred in a user facility.
14 Manufacturers are also required to report certain other
15 device malfunctions.

16 These reports are not all-inclusive and should be
17 considered to be a snapshot in time of the use of the device
18 reported upon. It is unknown how many reportable incidents
19 go unreported.

20 MDR reporting is a required reporting under the
21 Code of Federal Regulations and is separate from the more
22 global MedWatch program. As of 17 July, there was no
23 backlog in device MDRs to be entered into this database.
24 The Office of Surveillance and Biometrics constantly
25 monitors this. The review of our MDR database of the

1 devices used in the diagnosis or treatment of
2 temporomandibular joint disorders and associate orofacial
3 pain revealed only two MDR reports, neither report was
4 related to either of the devices under consideration for
5 reclassification at this meeting.

6 Both reports were related to electroanesthesia
7 devices. One report stated that the machine did not work.
8 The other one stated that the patient's injuries were not
9 permanent, lasting approximately 6 weeks. Neither report
10 constitutes a trend, and therefore should be considered to
11 be isolated malfunction incidents.

12 CHAIRPERSON JANOSKY: Thank you.

13 Dr. Runner, do you have some additional comments
14 you would like to make?

15 DR. RUNNER: I don't think so. I think you could
16 either choose to begin your discussion this evening until
17 the beginning of the closed session, or you could wait until
18 tomorrow.

19 CHAIRPERSON JANOSKY: Well, we were going to have
20 a short presentation by Dr. Moses.

21 DR. RUNNER: Okay.

22 CHAIRPERSON JANOSKY: Oh -- excuse me -- comments.

23 DR. MOSES: Pardon?

24 CHAIRPERSON JANOSKY: You were going to give us
25 some comments?

1 DR. MOSES: The comments being that I was --

2 CHAIRPERSON JANOSKY: Yes.

3 DR. MOSES: -- yes -- a problem?

4 CHAIRPERSON JANOSKY: Yes.

5 DR. MOSES: Basically, I think we all agree that
6 there was some contentious arguing going on, and I really
7 wasn't sure that everyone here has an idea of what this
8 equipment looks like that, you know --

9 CHAIRPERSON JANOSKY: Excuse me, Dr. Moses. Can
10 you please speak into the microphone a little?

11 DR. MOSES: Okay.

12 I really wasn't sure that everyone had a
13 conception, coming in today, as to what this equipment
14 really looked like. So I thought that I would bring
15 pictures of this so that you could just take a look and see
16 -- and maybe, perhaps, have a better conception of what it
17 is that this instrumentation actually looks like and a brief
18 explanation, perhaps, of what it does.

19 So if you would help me to pass these.

20 [Pause.]

21 DR. MOSES: By now, I assume that we are familiar
22 with the fact that there are essentially about four devices
23 that we're talking about: sonography. This is the -- the
24 first picture is just the way it looks on the cart in my
25 office. And that's all.

1 The next picture -- and I think you've seen a
2 similar picture from Dr. Cooper. It shows the
3 electrokinetic jaw tracker. What I would choose to point
4 out, again, is that you can see the magnet. The magnet goes
5 on the lower lip -- in the lower vestibule. It's held in
6 place with a non-toxic, non-allergenic adhesive. And the
7 sensor array that's anchored on -- it's called a "pair of
8 glasses" or a "glass frame," for lack of a better word --
9 picks up the movement of the jaw tracker and puts it into
10 the computer, which breaks it up into the various functions
11 that we ask of it -- that we ask it to examine.

12 The next page is the electromyography. In fact,
13 with these systems we're using skin electrodes, as you have
14 been told, placed over the anterior temporalis. There is
15 one there which you can't see -- again, on posterior
16 temporalis; medial -- mid-masseter, and anterior digastrics.
17 The one on the neck is the indifferent electrode. And, as
18 he said, this instrumentation is taking information from the
19 patient. There is no input.

20 The next picture with the two people -- again --
21 shows sonography in place. The lightweight headset contains
22 a vibration-sensitive transducers and the patient's
23 instructions are, with this sitting over the TMJ, is "Open,
24 close. Open, close. Open, close. And open, close."

25 The next picture shows the TENS unit in place.

1 This is used for muscle relaxation; one impulse every
2 second-and-a-half; very low amplitude, low frequency. The
3 net effect is to relax -- it is hoped that the effect is to
4 relax the muscles.

5 Sonography is used simultaneously with jaw
6 tracking, so that we can see where the sound event occurs in
7 real time. When you're using a metronome you may think you
8 know where it is, but if you do it in conjunction with jaw
9 tracking, you know exactly where it happens.

10 The EMG can be used in conjunction with the TENS,
11 so that when I say to you that it relaxes muscles, we
12 actually have a means of validating the relaxation of the
13 muscles by simply checking after the patient has been on the
14 unit for an hour, or an hour-and-a-half.

15 Last of all, the jaw track can be used with the
16 electromyography to register the bite. When we're
17 registering a neuromuscular bite using the TENS unit we can
18 check the activity of the muscle in the bite, and we can see
19 exactly, in three dimensions in space, where that bite
20 occurs.

21 That's it.

22 I put on the front of this a little device which
23 we use before we do sonography by itself. And it's simply a
24 device which we use to measure the vertical opening, and
25 measure lateral movement. And this is objective

1 measurement. And I'm really -- my personal belief is that
2 this is actually no more -- the instrumentation, with the
3 exception, perhaps, of the TENS which puts electrical
4 impulse in, is not more invasive than this wafer.

5 Thank you.

6 Any questions?

7 [No response.]

8 DR. MOSES: Thanks.

9 CHAIRPERSON JANOSKY: Let's continue with an open
10 committee discussion.

11 Are there any comments on the table? Any of the
12 Panel members like to make some comments about some of the
13 presentations they heard today, or some issues that --

14 DR. GONZALES: We're discussing the table now, is
15 that correct?

16 CHAIRPERSON JANOSKY: Please state your name.

17 DR. GONZALES: Gilbert Gonzales.

18 Under "sonography," and under "classification
19 regulation" it states here that it's presently classified as
20 a Class II, "an electrically amplified device used to
21 project the sounds associated with heart veins and other
22 internal organs," and that it's the -- the CFR citation, is
23 that of an electronic stethoscope.

24 Now, thinking back to other uses for the
25 stethoscope, whether it's electronic or auscultation just

1 because of the tympanic effect and amplification that way,
2 sonography has been used in the distant, distant past for
3 amplifying sounds from various structures besides the heart
4 and vein. For instance, even at the century the cracked-pot
5 sign for auscultating over the surgical head of the femur
6 and tapping on the knee to amplify sounds, looking for hip -
7 - joint and hip, itself, fractures, was a standard
8 procedure.

9 Pleural rubs, for instance, or even auscultating
10 the neck in neck rotation -- listening to crepitus and other
11 sounds -- has been used for a long time.

12 If we were to extrapolate the fact that cracked-
13 pot sign, for instance, that the orthopedic surgeons use for
14 the joint measurement -- if you can extrapolate that to the
15 joint being the jaw in this case, it would seem to me that
16 that's not very different in that you're measuring
17 abnormalities within a joint -- the hip in this case --
18 looking for fractures or any problem in terms of
19 interruption of the integrity of the joint or the bone
20 itself. It would seem to me that if auscultation, either by
21 electronic stethoscope or by standard auscultation non-
22 electrically -- my question from this is: right now, is
23 auscultation considered a Class II? It would seem to me
24 that that's a Class -- just intuitively, it would seem to me
25 a Class I.

1 And if, in fact, auscultation is a Class I, using
2 those same extrapolations, wouldn't a device such as this
3 also be a Class I?

4 I'm just asking the question right now about
5 auscultation and, specifically, heart auscultation -- or
6 auscultation, in this case, of other joints.

7 DR. RUNNER: The classification that was placed on
8 this grid -- electronic stethoscope -- is presently a Class
9 II device. The regular stethoscope, I'm assuming, is a
10 Class I exempt device. The electronic stethoscope, which
11 seemed to be the closest, in terms of our review of present
12 classifications, to the sonographic device, is a Class II
13 device.

14 But that was not to say that it should be the
15 same.

16 DR. GONZALES: All right.

17 DR. RUNNER: We're just giving you a similar
18 classification regulation of a similar type of device.

19 DR. GONZALES: Looking at the classification
20 requirements, that's how I take it. That is to say that
21 auscultation with a stethoscope would be a Class I --

22 DR. RUNNER: Mm-hmm.

23 DR. GONZALES: -- based on, historically, the pre-
24 amendment, on and on and on; the non-invasiveness.

25 So, then, the next step would be why wouldn't

1 electronic enhancement of what can be heard without
2 electronic enhancement not be also a Class I? What does --

3 DR. RUNNER: I can't answer that question for that
4 particular device, which is in the cardiovascular panel. I
5 can answer the question in terms of our bringing the
6 question to you, in that some of the devices that we have
7 seen in this area with TMD-related claims have claims
8 associated with interpreting and classifying joint sounds,
9 given particular sounds.

10 That's not all of the devices. There are some
11 that are labeled with those indications. And that was
12 primarily what we were asking the Panel to evaluate, in
13 terms of classification -- as well as the whole group. But
14 that was an indication that we found to be outside of any
15 previous classifications that we could relate to.

16 DR. GONZALES: But I'm bringing up the point, now,
17 that maybe it's not outside of prior classification.

18 DR. RUNNER: Okay.

19 DR. GONZALES: That is to say, if you look at the
20 use of auscultation through the orthopedics application --

21 DR. RUNNER: Mm-hmm.

22 DR. GONZALES: -- again, another joint in the
23 body -- the hip -- and this cracked-pot sign, that -- and
24 it's called that because when you tap and you listen at the
25 area of the hip while you're tapping the knee it sounds like

1 a cracked pot.

2 DR. RUNNER: That's why I want you to discuss it.

3 DR. GONZALES: So, to me it sounds awfully
4 similar. I mean, it happens to be a bit bigger joint, a
5 different joint, but it's doing the same thing, in terms of
6 measuring its structural integrity; measuring sounds that
7 may indicate that there could be pathology in the joint.

8 And so then if there would be an agreement -- if
9 there would be an agreement that, in fact, it's doing the
10 same thing, then the only difference would be the fact that
11 it's electronic as opposed to non-electronic. And the
12 electronic stethoscope, as I understand it, does nothing
13 more -- you get no other information from the electronic
14 stethoscope except enhancing the sound. You don't hear
15 different sounds, you enhance the sound.

16 DR. RUNNER: I think that the differentiation that
17 we were making in the labeling that we saw on certain
18 devices was that if you had a certain type of sound, you had
19 a certain diagnosis. And whether there was data relative to
20 that determination to substantiate that certain specific
21 sounds made by the TM joint could be correlated with
22 specific disorders, dysfunction -- not to say that they all
23 were labeled in that way, but this is some of the labeling
24 that we saw.

25 DR. GONZALES: But I'm having a little difficulty,

1 then, in terms of what we're doing right now. Since we're
2 not looking at safety and efficacy of an individual device
3 per se, we're looking at just the classification, and
4 therefore utilizing the things that we have available to us,
5 and past history of things that exist, this would -- again,
6 intuitively -- go in that direction.

7 DR. ALPERT: I think the question that you're
8 asking, if I may, is speaking to the heart of the
9 classification process and maybe I can help clarify for you.

10 We have a lot of products in the device arena that
11 are used in many different medical disciplines. When we
12 look at them, we look at them -- we look at the product and
13 the claim in the discipline as a set. So we can have a
14 product -- the exact same product -- in a Class I claim in
15 neurology, a Class II claim in urology, and a Class III
16 claim in cardiovascular. Same exact product, depending on
17 what the claim is, and the evidence to support the safety
18 and effectiveness and the third piece: how much oversight.
19 Because classification really asks: how much information,
20 what kind of information, how much oversight does there need
21 to be to assure the safety and effectiveness?

22 So, you're right, the first question is: as a
23 category, are the devices safe and effective? And I think
24 your comment is: a device recording sound either records
25 sound or it doesn't. Here's -- you know, is able to assess

1 sound or not. But there are other aspects. And that is,
2 when technology changes, when you go from a manual to an
3 electronic, the question then is: do you need additional
4 testing that ought to be part of a guidance. Do you need
5 additional testing that ought to be part of a standard? Do
6 you need additional labelling that is very specific to the
7 claim that everyone needs to say about the use of the
8 product to assure the safety and effectiveness of the
9 product.

10 All of those aspects come into play when we talk
11 about classification. The basic assumption is, if we're
12 classifying it, it's safe and effective. Then the question
13 is: how much oversight. How much do we need to continue to
14 know about new devices entering the marketplace in those
15 same classifications in order to assure that the new ones
16 will remain safe and effective.

17 And it's a complicated question. So, as I said,
18 if we're going to classify, you have to be safe and
19 effective to get classified, unless you're automatically in
20 III because you're not safe or there's no data to show
21 safety and effectiveness.

22 But in Classes I and II, there's an assumption
23 that, based on data, it's been established that the product
24 is safe and effective, and then the difference between I and
25 II is: what do we need to know about incoming product to

1 assure that that incoming product is as safe and effective
2 as the things that are already out there.

3 It's complicated. So we might need to talk about
4 that before we talk about the specific devices.

5 DR. GONZALES: We know that auscultation is safe
6 and it's effective, because it's used in an effective way.
7 Now, the auscultation that I was talking about was of the
8 hip. It's very effective for determining that.

9 Now, we've all been discussing, now, effectiveness
10 in terms of its use right now. And that's what we're
11 supposed to base our classification, in that you will then
12 follow up, in terms of the amount of regulation in that
13 class that we give it.

14 DR. ALPERT: No, the class actually determines
15 what the regulatory oversight is.

16 DR. GONZALES: Right.

17 DR. ALPERT: So if you have determined, for
18 example, that the product in the category is not only safe
19 and effective, but that general controls, as described --
20 basically, if they're manufactured properly and they have
21 the claim on them that you classify -- and that's what Dr.
22 Runner was speaking to: what is the claim? If the claim is
23 simply to record and present sound, is that in the same
24 classification, does it need the same amount of oversight as
25 a claim to distinguish on the basis of that sound one group

1 of patients from another, one diagnosis from another. That
2 was the point that Dr. Runner was making; that you may have
3 the same product, you may say certain claims -- the same
4 product, one claim in Class I -- a claim for thresholds
5 having been established may need evidence of a different
6 sort, testing of a different sort, that might place it into
7 a different class.

8 It may not. You may determine that there's so
9 much evidence that it's all in the same class.

10 But that's the question we're asking you to
11 discuss tomorrow about each of the devices as you walk
12 through the questionnaire on the products that we're asking
13 you to make recommendations on.

14 I think what you're talking to is what's the
15 process? What's classification. And I know you've had some
16 discussion this morning, and then tomorrow we expect to have
17 some additional discussion, because I think it will bear
18 repeating once you've had a chance to absorb today's
19 discussions and ask questions about what do we know, what do
20 we know is needed about these new products?

21 For example, there are products where we think --
22 and this is just an example, and I don't want anybody to get
23 -- to take this as an outcome. This is an example.

24 There are devices where we have determined that it
25 is appropriate for the next devices coming in to have to

1 follow a guidance in terms of what's in a submission;
2 address six types of information in a 510(k) submission;
3 pre-market notification. And based on that data we will
4 determine if the device is substantially equivalent to the
5 other ones and whether or not it can move into the
6 marketplace.

7 There are others where we have guidance and we say
8 that there's a voluntary recognized standard; that we've
9 recognized the voluntary standard that's been developed by a
10 standard development organization that we think the product
11 also needs to meet in order to establish -- in order for us
12 to be sure that these products will remain safe and
13 effective.

14 There are other products where we also say there
15 are certain labelling warnings, or contraindications that
16 must be on every product in a class in order for us to
17 assure that it's safe and effective. That's a labelling
18 special control.

19 And in other cases we say not only do we need
20 things like that, but we may need a small clinical
21 experience -- or a full-blown clinical trial -- even in
22 Class II, in order to be assured that it's as safe and as
23 effective as the other products in its category.

24 So, the issues that want you to discuss is what's
25 -- establish the safety and effectiveness of the product for

1 the claim being made for it; the category of products, the
2 claims being made. And then what kind of information ought
3 to be available to assure that the next product in that same
4 category is going to be as safe and as effective --
5 substantially equivalent -- to products already in the
6 marketplace with that same kind of claim.

7 I mean, that's the -- we struggle with this. I
8 can understand why it's confusing. We struggle with this on
9 a daily basis in looking at changes in technology and creep
10 of claim, and determining whether -- are there new
11 questions, new types of questions? Is it a variation on a
12 theme? If you have a general claim for something, does a
13 specific claim in a specific body system -- is that as safe
14 and as effective as the general claim? Does it raise new
15 types of question? Or is it just a more specific claim and
16 we just need a little more data on that specific use, and
17 once we see that, it's as safe and as effective as making
18 the general claim.

19 Those are the kinds of things we struggle with on
20 a daily basis, and we're happy to have you here struggling
21 with us. But it really is a struggle.

22 DR. BERTRAND: I have a question -- Peter
23 Bertrand.

24 We're talking about Class I and Class II, and the
25 economic realities of the world. And maybe this isn't a

1 place I should go.

2 How much more difficult is it for a small company
3 to justify a Class II versus Class I -- does that affect the
4 economic reality of patients in an arena where we're not
5 even really sure what we're applying clinically?

6 DR. ALPERT: Well, there are two aspects to what
7 you asked. One is that the economic issues are not on the
8 table -- only the scientific. We are very specifically
9 directed to deal with the science and not to deal with the
10 economics, whether that's reimbursement or charging -- those
11 are not in our purview, except the regulations that deal
12 with what a sponsor of an investigational product -- what
13 the manufacturer of an investigational product may or may
14 not charge for that product.

15 Other than that, we are not empowered to address
16 the economic issues. Our job is to address the science.

17 In terms of your second question as to the
18 difficulties between Class I and Class II for a device
19 manufacturer, it depends on what the special controls are,
20 very honestly. What was pointed out earlier is that these
21 products have been moving into the marketplace under what we
22 call "unclassified" -- in an unclassified status, which
23 means not that they have not been regulated. They actually
24 have. They have -- if a new product came forward -- the old
25 product's the same thing that was in the marketplace prior

1 to '76; didn't need to come in. But if a device was
2 significantly modified or if a new company came forward with
3 the same product, they came in to us through the pre-market
4 notification, or 510(k) process, as if they were in Class I
5 or II, because that was the determination that was made as
6 the appropriate level of oversight for unclassified
7 products. They move into the marketplace through pre-market
8 notification.

9 So there was, in fact, oversight. It just wasn't
10 in a category, and therefore it was predominantly general
11 controls, but with specific questions or data being
12 addressed toward the use of the product. Some were sort of
13 in between -- not special controls, but not only
14 manufacturing and a statement of what the label was, but
15 some data to support the equivalence between this product
16 and the one already in the market -- the pre-amendment
17 product already in the market; usually established on some
18 type of testing, bench testing, 95, 98 percent of the time,
19 comparing the modified or new product at the bench to the
20 product already legally marketed.

21 DR. MOSES: Could we perhaps think analogously in
22 that I was wondering if you could tell us what the special
23 controls are that exist for the electronic stethoscope,
24 either used for cardiac or orthopedic use, so that we could
25 back into it?

1 DR. ALPERT: We'd love to. There's only one little
2 kink in that, and that is that in the original
3 classifications, when most of these products were originally
4 classified, special controls did not exist as a category.

5 The classifications -- products were placed in a
6 classification because they needed additional testing, but
7 the specific type of testing was not specified. It was only
8 with the Safe Medical Device Amendments of 1990 that
9 Congress specified the need for the agency, in placing
10 things into Class II, to define the special controls, and
11 what those special controls were. Prior to that, the issue
12 was one of additional specific testing -- sort of global --
13 and if a performance standard, which is different than a
14 voluntary conformance standard -- but if there was a
15 performance, a device-specific performance standard that
16 could be developed, then we were directed, in time to
17 develop it.

18 When that never happened for the Class II products
19 that were originally classified in the late '70s an early
20 '80s and into the '80s, Congress changed the statute to
21 reflect that that was not being done and provide us the
22 opportunity to identify special controls, the statutory term
23 for the kinds of testing and requirements that we put in
24 place for Class II products.

25 DR. MOSES: What I'm saying --

1 DR. ALPERT: It's an evolving process.

2 DR. MOSES: What I'm sensing then, is that if an
3 electronic stethoscope manufacturer came and asked to be --
4 that it be lowered to a Class I, that you'd probably say,
5 "Sure."

6 DR. ALPERT: No, and I'm glad you asked that.
7 Actually, there's a process involved. I'm very glad you
8 asked that, because it give me a chance to comment on two
9 more things.

10 It is a complicated process.

11 Down-classification can, in fact, be proposed by a
12 petition. A manufacturer or someone from the general public
13 can petition us to down-classify a product: from III to II,
14 from III to I from II to I, from I to exempt.

15 That petition is generally referred to a
16 classification panel for its consideration, based on the
17 available evidence. Again, it needs to be publicly
18 available evidence, in the forms of all the kinds of
19 evidence we talked about earlier today. So there's a
20 process. And then we propose the regulation.

21 In some cases -- it gets a little complicated --
22 and, again, the regulatory environment is process driven.
23 There are processes coming in in a certain way -- a petition
24 can be answered by us, by the FDA absent a panel
25 recommendation. In other cases we are required to go to a

1 panel for an opinion as well. But it's process, and then
2 there's an announcement of the proposal for the change or
3 the change itself.

4 So we don't just say yes. We have a procedure
5 that we need to go through in order to move products from
6 one category to another.

7 I mentioned earlier today that there was -- the
8 FDA Modernization Act of 1997 was signed in November. FDAMA
9 also complicated things yet one more step by the following.

10 Up until this year, in order for a product to go
11 to market absent a pre-market notification -- so without a
12 510(k), without us saying "Yes, you may enter the market,"
13 they had to be exempted by regulation. And in order to do
14 that, they had to be in Class I, and then exempted from
15 510(k). So at the time that a panel like yourselves
16 recommended that a product be placed in Class I -- as you
17 will be asked -- they were then asked, "Does this product
18 need to have a 510(k), or can it be exempt from pre-market
19 notification?"

20 FDAMA said that there are products, appropriately
21 in Class II, needing special controls for their testing to
22 assure that they're safe and effective, but they don't
23 necessarily need pre-market notification. So it allows the
24 process to identify a Class II product with special
25 controls, but determine that that product can be exempt from

1 510(k) -- from pre-market notification, from FDA review --
2 prior to entering the marketplace.

3 So there are lots of options for how products get
4 oversight, and that's why this is a difficult and rather
5 complicated process, and why all of the questions on the
6 questionnaire are there, so that all of these issues get
7 addressed in an organized way for all products consistently,
8 and then decisions are made.

9 [Pause.]

10 CHAIRPERSON JANOSKY: Before moving into the
11 closed session, let me remind everyone that if anyone from
12 public or industry would like to comment tomorrow morning
13 there is a sign-up sheet at a sign-in table out in the hall.

14 And for today we will close our open committee
15 discussion. We'll continue it tomorrow, and move into
16 closed session.

17 [Whereupon, at 5:38 p.m., the meeting was
18 adjourned to reconvene at 8:00 a.m the following day.]

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CERTIFICATE

I, **THOMAS C. BITSKO**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

A handwritten signature in black ink, appearing to read 'T. C. Bitsko', is written over a horizontal line.

THOMAS C. BITSKO