DENTAL PRODUCTS PANEL MEETING

VOLUME I

Monday, November 3, 1997
9:05 a.m.
Holiday Inn Bethesda
8120 Wisconsin Avenue
Bethesda, Maryland
PARTICIPANTS

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

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

CONSULTANTS

Gilbert R. Gonzalez, DDS
Leslie Heffez, DMD, MS
Andrea Morgan, DDS
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FDA

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

GUESTS

Peter Bertrand DDS
Allen Moses, DDS
Barry Cooper, DDS, PC
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DR. GENCO: I'd like to welcome everyone, panel members, consultants, and guests. We have a busy three-day agenda.

I'd first like to introduce Ms. Pamela Scott, our Executive Secretary, and she is going to make some introductory remarks.

MS. SCOTT: Good morning and welcome to the Dental Products Panel Meeting. Again, my name is Pamela Scott, and I serve as the Executive Secretary for the Dental Products Panel. I would like to welcome everyone to the meeting today. If you have not signed in, I would please ask you to do so at the sign-in desk just outside of the room. And at the sign-in desk, you will find agenda booklets and information on how you may obtain transcripts of today's meeting.

Meetings of the Dental Products Panel are held only if there are issues or applications that FDA needs to or chooses to bring before the panel. For information regarding meetings, you may call the FDA Medical Advisory Committee hotline. The phone number for the hotline is 1-800-741-8138. Again, that number is 1-800-741-8138. The code for the Dental Products Panel is 12518. Again, the code for the Dental Products Panel is 12518.
At this time, I would now like to introduce the members, consultants, and guests for our panel today.

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

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

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

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

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

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

And we have Dr. Diane Rekow. She is the chairperson of the Department of Orthodontics at the
University of Medicine and Dentistry of New Jersey.

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

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

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

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

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

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

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

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

We have Dr. Barry Cooper, who is also a practicing
clinician in Lawrence, New York.
At this time, I will turn the meeting over to Dr. Genco.

DR. GENCO: Thank you.

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

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

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

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

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

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

DR. GENC0: Any questions about this interesting new innovation, initiative?

[No response.]

DR. GENC0: Thank you very much, Susan.

MR. ULATOWSKI: Good morning. I'm going to bring the panel up-to-date on one activity ongoing in this branch and in every branch in the Office of Device Evaluation--
indeed, across the Center for Devices and Radiological Health.

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

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

What is adoption of a standard? Adoption is recognition of a standard by FDA through an assessment and publication process. The adopted standard pertains to a specified critical regulatory provision. If a person certifies that their device or process meets the adopted standard, in whole or in part, then FDA will accept that the device meets the specified corresponding critical regulatory provision to the extent covered by the certification, and FDA will not require further documentation.
For example, if FDA recognizes a dental material standard, then a person certifying that their device meets the standard in whole will not need to submit supporting data on the material that is addressed by the standard, in a 510(k) or a PMA, whatever the case may be.

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

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

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

Thank you. Any questions on this activity?

[No response.]

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

DR. GENCO: Thank you very much.

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

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

In order to conduct business today, you will discuss current classification regulations, the content of existing labeling for devices, and hear comments between you on the intended use of devices and their description. You should not discuss the safety and effectiveness of any
devices or device types today. You may well discuss the
indications for use or intended use of devices as purported
in labeling, but whether or not they achieve the stated
purpose, the risks involved, or the clinical utility should
not be discussed today by the committee.

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

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

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

Since the topic pertains to classification, I want
to ensure that you have a common baseline of understanding
on classification. This is the supplement, the information that you received this morning during a training session. I will present a very brief primer consisting of seven overheads on how devices are classified and the end product of the classification process.

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

[Slide.]

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

As you've heard this morning in training, the class establishes the degree of control needed to help reasonably ensure the safety and effectiveness of devices in
each generic device type. Class I devices are subject to
so-called general controls. Class II devices are subject to
general and special controls. Class III devices are subject
to pre-market approval.

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

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

We have to take the newly identified generic type
of device through a classification proceeding, which
includes the need for an advisory committee recommendation on the class to assign. One or more of the generic types of devices we are going to discuss today may be one of these pre-1976 generic types of devices that were never classified.

[Slide.]

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

FDA reviews the 510(k). FDA compares the labeling of the candidate device, its technological features, and, when needed, performance data, to the claimed legally marketed device to determine whether the new device is equivalent. The new device may have the same and/or different indications for use from the claimed legally marketed device. The new device may have specific indications related to a general intended use of a legally
marketed device. FDA determines whether the indications stated in labeling create a new intended use different from the legally marketed device. If the new device has a new intended use, then FDA finds the device not equivalent.

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

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

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

A person may claim their new device is equivalent to the pre-1976 device or to any device subsequently found equivalent in the chain. Note device A and B were found
equivalent to the pre-1976 device. Alternatively, although I don't show it on the overhead, device B could have been found equivalent to product A in a chain.

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

[Slide.]

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

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

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

[Slide.]

Entirely new devices first marketed after 1976,
including those found not substantially equivalent per a
510(k), are subject to pre-market approval. These devices
have no link to a pre-1976 device type or associated devices
in a chain. These entirely new devices cannot be marketed
until FDA approves a pre-market approval application for the
specific device. An Advisory Committee may be asked to
review the PMA data and render recommendations to FDA, as
you heard this morning in training. It is not a classification proceeding, the PMA review. The device is already class III.

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

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

A chain for 510(k) equivalence purposes can still
be created for these devices if the device type is
reclassified by FDA into class I or II. Then persons with
claimed equivalent devices may submit 510(k) submissions.
So once class III, not always class III, and once a PMA, not
necessarily always a PMA. It depends on its classification
status.

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

All devices indicated for the treatment and
diagnosis of temporomandibular joint diseases and associated
orofacial pain are covered by one of these methods. The
committee will have to identify and deal with devices in the
former category, not the latter. In other words, FDA in its
review of 510(k)s does its thing with 510(k)s, and we will
classify devices, new devices submitted to us, as submitted
to us in 510(k)s. You're dealing with those unclassified
devices and what still needs to have the original
classification assigned to it.
We are going to ask you some questions that will help us determine what generic device types are unclassified and how to describe these devices. When we send out notice to the public requesting data on the unclassified devices, we hope the list will be comprehensive and clear. I believe you will appreciate the discussion even more if you see a classification regulation and some variations that exist.

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

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

This is my last overhead, and please hold the
applause.

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

In grand summary, we are asking you to discuss devices used in the diagnosis and treatment of temporomandibular joint disease and associated orofacial pain. The desired output of your discussion today will be to help develop a list of the generic device types that are unclassified and to help generally describe these devices. We are not discussing the safety and effectiveness of any of the generic device types or any specific device. This is off the table completely today.
Dr. Betz will now address the table provided to you. Please excuse the slight redundancy in our presentations. Consider those parts, only portions, reinforcement of our message.

Thank you. Any questions?

DR. GENCO: Thank you. Comments, questions?

[No response.]

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

Thank you, Tim.

DR. BETZ: Good morning. My name is Bob Betz, and I'm a periodontist and a reviewer in the Dental Device Branch of the Office of Device Evaluation of the Food and Drug Administration. The FDA is required to classify all medical devices into either class I, class II, or class III, depending upon the level of control necessary to provide reasonable assurance of their safety and effectiveness.

Today's panel meeting is one of several steps by which previously unclassified pre-amendments devices are placed into a regulatory classification. Devices to be discussed today are intended for uses in the diagnosis and treatment of temporomandibular joint disorders and associated orofacial pain.

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

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

The part of the classification process in which you will participate will involve two steps. The first step will be to aid FDA in the process of inventory and grouping. We wish to solicit input from you in the identification of generic types of devices that are reasonably considered to be used in the diagnosis and treatment of temporomandibular joint disorders and associated orofacial pain. The second step, which will occur at a future Dental Products Panel
Meeting, will be for the device industry, the public, and other interested parties, as well as the FDA, to present sufficient information to use so that you will be able to recommend to FDA a class for each generic type of device not presently classified.

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

For each group of generic devices, we would like you to discuss the following: Number one is the physical description of the device; number two, indications for use presented in the labeling; and, number three, the function of the devices placed in the group. We hope to have at the
end of the day a panel-recommended chart which displays all
relevant generic types of devices, their descriptions,
intended uses, and functions of members of that group. We
will also need to know when you feel that consultation with
other device panels may be needed.

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

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

The Dental Branch has undertaken a good-faith
effort to be as complete as possible. If devices were
omitted, they were not intentionally omitted. During the
discussion, device groups may be added, deleted, or
modified. You may identify different sub-groups other than
those proposed. Custom intraoral devices were intentionally
omitted. These devices have been defined within Section 520, Part B of the Federal Food, Drug, and Cosmetic Act and are not subject to pre-market review.

[Slide.]

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

[Slide.]

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

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

[Slide.]

Number one, electromyographic devices, including biofeedback devices, 21 CFR 890.1375 reviewed by the Physical Medicine Panel states that a diagnostic electromyograph is a device intended for medical purposes such as to monitor and display bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor
and display electrical activity produced by nerves for the
diagnosis and prognosis of neuromuscular diseases.

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

Item number 2, sonography devices. 21 CFR
870.1875B, reviewed by the Cardiovascular Panel, states that
an electronic stethoscope is an electronic amplified device
used to project sounds associated with heart, arteries,
veins, and other internal organs. These are class II
devices requiring performance standards. There are no
dental classification regulations under Part 872 of the Code
of Federal Regulations relative to these devices as
sonographic devices designed and intended for the use in the
diagnosis and treatment of temporomandibular joint disorders
and associated orofacial pain. Review of 510(k) submissions
submitted for these devices reveals that they are labeled and are intended for use in the recording and measurement of sounds of joints, the joint components. Some of these devices may also visually represent sounds made by these components.

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

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

TENS devices are used to treat muscular components of temporomandibular joint disorders and associated orofacial pain. Their objective is to obtain muscle relaxation. The use of these devices in electro-anesthesia
is not directly related to temporomandibular joint disorders or associated orofacial pain, and they are not included in this grouping.

[Slide.]

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

However, not reflected in the CFR is the fact that there are more than just this one measurement that may be made with some pantographs currently in clinical use today. In review of 510(k) submissions, we find that these devices are devices that are labeled and are intended for use in the
measurement of joint position or jaw movement. They also
identify the space between the jaws, or freeway space, as
well as mandibular rest position. Some devices in this
group graphically record mandibular position or movement.

Number five, therapeutic ultrasound devices.

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

Number six is thermography devices. Based on
examination of devices submitted for regulatory review,
thermographic devices appear to have no indicated uses or
specific labeling claims related to the temporomandibular
joint. However, 21 CFR 882.1570, reviewed by the Neurology
Panel, describes a powered, direct contact, temperature
measurement device. A powered, direct contact, temperature
measurement device is a device which contains a power source and is used to measure the difference in temperature between two points on the body. These are class II devices that require performance standards. Unless discussion today reveals otherwise, there are no other devices in this group with claims related to the temporomandibular joint disorders and associated orofacial pain. No action is needed at this time.

[Slide.]

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

Tomography devices may be used to image the temporomandibular joint. Reports of the use for diagnosis of these disorders exist in the dental literature and are
presently displayed on Web sites on the Internet. 21 CFR 892.1750 describes a computer tomography device that produces cross-sectional radiographic images of the body, using computer reconstruction. They are class II devices and are reviewed by the Radiology Panel.

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

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

Again, we are not here today to classify any devices used in the diagnosis and treatment of temporomandibular joint disorders and associated orofacial pain. We are here to request your assistance in the grouping of all devices reasonably considered to be devices with these claims. We recognize that there are many devices that may add bits of diagnostic information about
temporomandibular joint disorders and orofacial pain. Unless and until sponsors come forward to the FDA with submissions for these devices and specific TMJ-related claims, the FDA believes that this chart is reasonably complete.

[Slide.]

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

[Slide.]

Question number there, for device groups or categories discussed today, which groups have labeled indication for use or intended use which relate to temporomandibular joint disorders and associated orofacial pain?

[Slide.]

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

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

[Slide.]

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

[Slide.]

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

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

Thank you very much.

DR. GENCO: Thank you, Dr. Betz.

Are there any questions or comments for Dr. Betz?
MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Yes?

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

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

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

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

Any comments from the public?

[No response.]
DR. GENCO: Okay. I take it then--yes?

VOICE: Is there an order of presentations?

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

MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Yes?

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

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

The first presentation will be made by Mr. John Radke from Bioresearch, Incorporated. Mr. Radke?
MR. RADKE: I am the president of Bioresearch, Inc. We're a small company. We've been in business since 1965. I am one of the shareholders in the company. It's a closely held private corporation.

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

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

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

You might be interested to know, if you don't already know, that a company such as Bioresearch could not consider applying for or expect to get a pre-market
approval. So if our products, any of them, suddenly become class III, those products are finished, and whatever benefits society has received from them, that goes out the window.

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

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

We have a device for tracking jaw movements, and sometimes doctors are interested in how the jaw moves when a
patient has a dysfunction. Of course, sometimes they're not sure if it's a dysfunction or maybe it's a disorder or possibly a disease, because under the disorders there's probably a hundred different diseases. Of course, anybody can have a dysfunction, TMJ or otherwise.

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

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

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

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

I guess I'm not exactly sure what the ultimate purpose is here, whether we are charged with coming--or you are charged with coming up with a single category and a single classification for all devices in each one of these groupings, or whether the individual devices would be, in fact, classified individually. But I think what I heard was that this was a generic classification, so anything that falls in the area of sonography would have the same classification regardless of whether it was a stethoscope or something else, I guess.
The thing about TMJ, whatever you call it, is that it's not a single thing, and so it's a lot of different things, and as far as I know, there are no devices for the diagnosis and treatment of temporomandibular disorders and related myofascial pain dysfunction. There are a lot of devices which can provide a little bit of information for the diagnostic process for the clinician, who ultimately is responsible for making the diagnosis.

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

From my point of view, I guess, it seems to me that an electromyograph is best classified as an electromyograph, regardless of whether we're looking at shoulder muscles or leg muscles or facial muscles. It seems
like a TENS device is a TENS device. The fact that somebody
has a sore masseter muscle or temporalis muscle doesn't make
the device any different than if it's the trapezius or
rhomboid or some other muscle. TMJ or TMD patients do have
pain very often, and sometimes they benefit from application
of TENS.

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

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

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

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

MR. RADKE: If there are any questions from the
panel members about anything I've said right now, it would
be real handy—
DR. GENCO: So you're finished with--

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

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

MR. RADKE: Yes.

DR. GENCO: Okay. Thank you very much.

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

DR. MOSES: Thank you.

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

Then the third point would be with regard to electromyographic activity. I believe that there possibly is a difference between surface electrodes and needle electrodes in my mind being that the needle electrodes are
quite a bit more invasive. And I would like to know if we
could draw a clear differentiation there as well in terms of
categorizing these devices.

I would like to know your feeling on these.

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

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

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

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

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

MR. RADKE: Obviously, the needle would be
invasive in the sense, you know, that it goes under the skin. I don't think it's—I mean, it would be comparable in risk, I suppose, to an injection or something like that.

But—

DR. GONZALEZ: Can I make a comment?

DR. GENCO: Yes, go ahead.

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

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

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

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

DR. MOSES: Yes.

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

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

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

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

MR. RADKE: I think it should be considered.
DR. GENCO: Surely.

The other issue you brought up or another issue is--I think Dr. Moses brought it up, too: Should we be considering diagnostic separate from treatment? Does it get confusing to consider the two for each of these categories?

Did you want to further comment on that?

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

DR. GENCO: Thank you.

Dr. Gonzalez, do you want to further comment?

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

DR. GENCO: Dr. Moses?

DR. MOSES: This becomes an important issue, probably not to the FDA but to the dentists in general,
because in various cases, when people aren't clear on the
differentiation, then insurance companies are rejecting
certain surface electromyography uses such as this one and
saying that it should have been a needle electrode. And I
think the FDA can help by making that distinction for
scientific purposes only. But they would help the
situation, clearly.

DR. GENCO: Okay. Thank you.

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

[No response.]

DR. GENCO: Thank you very much.

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

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

My name is Roland Jankelson. I am the president
of Myo-Tronics, Inc. The company is approximately 25 years
old, I think has the proper distinction of being recognized
as a pioneer in certain technologies that are the subject--
some of the subjects that are being discussed this morning.
I really intended to stay away from any discussion of the 1994 panel because this is a new group. Some of the already insightful questions and comments that I've heard from the panel this morning indicate that this really is a different group. I think, however, some very brief comments since Mr. Radke referred to the previous panel in 1994, and I say this not in any—with any intent to do anything other than to assist the FDA in moving forward with what is their mandate, which is the classification process, which we support.

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

Let me just say that as a result of what happened at that panel, and in connection with some other alleged irregularities in connection with the treatment of Myo-Tronics by the FDA, there was a two-year investigation by the Office of Inspector General for Health and Human Services. There were hearings before the U.S. House Commerce Committee's Subcommittee on Oversight and Investigations. Those of you who think that that background has any relevance to understanding our sensitivity certainly
have access to those findings. I think clearly the FDA has acknowledged some very real problems, for which we are thankful. Four FDA employees--two permanent FDA employees, two temporary government employees--have been disassociated from service with the FDA.

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

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

MR. ULATOWSKI: Through the Executive Secretary.

MR. JANKELESON: For the record, the first letter is a response from Roland Jankelson to Dr. Friedman, dated October 21, 1997. The second is a letter from Roland Jankelson to Dr. Alpert, dated October 24, 1997. The third letter is a letter from Roland Jankelson, dated October 27,
1997, to Secretary Shalala, to Dr. Friedman, to Dr. Alpert, and to Dr. Ulatowski. And the final letter is a letter from Roland Jankelson to Secretary Shalala and Dr. Alpert, dated September 11, 1997.

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

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

Thank you.

DR. GENCO: Thank you, Mr. Jankelson.

Any comments from the panel?

[No response.]
DR. GENCO: Okay. Thank you very much.

MR. JANKELSON: Thank you.

DR. GENCO: Dr. Robert Jankelson?

DR. JANKELSON: Good morning. Mr. Chairman, colleagues, ladies and gentlemen, I'm Dr. Robert Jankelson. I've been in private clinical practice in Seattle, Washington, since 1963, with a particular interest in temporomandibular disorders since about 1970.

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

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

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

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

What is TMD? The FDA Web site characterization of
TMD as "temporo-mandibular joint dysfunction and oral-facial pain" may be misleading, imprecise, and is not consistent with widely accepted models of TMD. This limited definition does not encompass generic musculoskeletal pathologies associated with TMD, does not encompass the cranio-mandibular/cervical model of pathosis, does not encompass the myofascial pain reference model, nor does it include many of the primary and secondary signs and symptoms of TMD. Before advancing to the question of which devices to include in a category of "TMD diagnostic and treatment devices," it is first necessary to adequately define the disease entity.

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

There are two major philosophical paradigms presently being propagated to explain the etiology of TMD signs and symptoms. For the past 60 years, dating from the work of anatomist pioneer Harry Sicher, physiologist Hans Selye, and clinicians such as Nathan Shore, Weldon Bell, and many others, dentists have approached the problem as a primarily physical, or biomechanical, problem, albeit with secondary psychosocial overlays. This has been the reigning clinical paradigm for 60 years. It is only recently that a limited academic group have denied occlusal causality for TMD. In its place, they have attempted to posture TMD as a
psychosocial disease caused by emotional stressors, et cetera. The 1996 NIDR consensus meeting clearly defined the biomechanical versus the psychosocial schism.

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

Often overlooked in the debate is the fact that both—and I stress both—biomechanical and psychosocial stressors can impose stresses that exceed the accommodative capacity of the organism, resulting in clinical dysfunction and/or symptoms. Thus, the pathogenic model for TMD, if it is to conform to the pathogenic model for other
musculoskeletal dysfunctions should logically embrace both
the biomechanical and the psychosocial model. One is not,
and should not, be exclusive to the other.

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

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

Using the biomechanical/psychosocial model,
deVICES to be classified "for the use in the diagnosis and
treatment of temporomandibular joint dysfunction and oral-
facial pain"--TMD, if you will--must logically include
devices that provide data used by the clinician to make
occlusal determinants necessary in fabrication of
therapeutic appliances or to alter the dental occlusion. It
must include devices used to fabricate occlusal therapeutic
appliances, devices used to aid the diagnosis of myogenous
TM dysfunction, devices that aid diagnosis and treatment of
intrinsic temporomandibular joint dysfunction, devices used
for occlusal therapy, physical therapy, and psychometric
testing.

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

One, TMD psychometric tests; two, computerized jaw
tracking devices; three, pantographic tracing devices; four,
axiographic jaw tracking devices; five, occlusal
registration devices used to fabricate TMD appliances; six,
cephalometric analysis software; seven, surface
electromyograph; eight, biofeedback EMG; nine, stethoscopic
and Doppler TMJ sound recording; ten, electrosonography; 11,
thermograph; 12, devices used to fabricate TMD occlusal
appliances or to modify occlusion in TMD patients--example,
Tech Scan, and articulators whose settings will influence the outcome of the occlusal appliance plan; 13, TMD diagnostic software--example, PT Diagnostic Software, Inc.; 14, ultrasound diathermy; 15, galvanic stimulators; 16, high frequency transcutaneous electrical neural stimulators; 17, low frequency transcutaneous electrical neural stimulators; 18, ultra-low frequency muscle relaxation stimulators--there is still a great deal of confusion regarding the distinction of these three categories of TENS devices; 19, iontophoresis devices; 20, mechanical TMD therapy devices, such as the Therabite or Aqualizer; 21, transcranial radiography; 22, pantographic radiography; 23, tomography; 24, computer-assisted tomography; and, 25, magnetic resonance imaging.

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

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

The fourth issue is the misplaced premise during the 1994 Dental Advisory Panel which was advanced by certain anti-instrumentation witnesses giving testimony, testimony which has since been discarded as false and misleading, that
any of these devices, by themselves, make or must make a
diagnosis. A device that record physiologic or anatomic
data does not, in itself, make a diagnosis. The
differential diagnosis is always made by the doctor based
upon patient history, patient evaluation, subjective and
objective data. Anatomic imaging and/or physiologic
monitoring should be pertinent to the particular
patho/physiologic phenomena being considered. When
considering devices that aid in the diagnosis of TMD, or any
disease, three criteria are relevant, and this is most
important:

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

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

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

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

In final summary, if this panel is to perform its
mission, the panel must approach the subject matter with a
full understanding and appreciation of the scope and
complexity of the multi-etiologic, multiple signs and
symptoms complex presently referred to as TMD; it must be aware of the political and scientific history of the two major TMD paradigms; it must consider the broad scope of devices that are used for diagnosis and treatment of TMD; and it must understand the distinction between measurement devices that provide data to assist the clinician in TMD diagnosis and treatment, as opposed to devices that are claimed to independently make a diagnosis.

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

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

Mr. Chairman, thank you.

DR. GENCO: Thank you, Dr. Jankelson.

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

[No response.]

DR. GENCO: Thank you very much.

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

Temporomandibular disorders, also referred to as cranial-mandibular disorders, or simply TMD, encompass a number of musculoskeletal conditions that involve one or both temporomandibular joints, the masticatory muscles, or a combination of both. As part of the ADA Acceptance Program, the Council on Scientific Affairs has established guidelines for evaluating instruments that aid in the treatment of TM disorders as well as for devices that evaluate the TM musculoskeletal complex.
For consideration for acceptance under the ADA Seal Program, comprehensive product information must be submitted. All claims of efficacy must be documented, including all claims in advertising and promotional material, and a detailed product description that explains the principles of design is required.

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

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

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

To demonstrate safety, all electronic instruments must have data to show compliance with specifications set
forth by Underwriters Laboratories. Clinical studies for
efficacy also can be used for safety assessments where
appropriate.

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

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

For TMD treatment devices, the disorder or sub-
category of disorders, as well as those signs and symptoms
the device is reported to treat, must be fully described.

In identifying a particular disorder, companies have to use
a generally accepted classification system based on diagnostic criteria. In addition, all efficacy claims must be supported by documentation that shows the instrument has a specific therapeutic effect in contrast to other possible mechanisms.

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

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

For TMD or a sub-category of TMD, trial populations are identified via defined inclusion and exclusion criteria that are applied to the chief complaint, history, clinical examination, and, when indicated, TMJ imaging of the subject.
Outcome measures must be well accepted and quantifiable and must clearly relate to the patient's condition. Examples include the visual analog scale, the McGill pain questionnaire, and signs and symptoms that are well correlated to TMD conditions, that is, range of motion and tenderness on palpation. Concepts such as achieving muscle balance are not good outcome measures.

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

The fact that these instruments are not to be used alone to diagnose disorders of the masticatory musculoskeletal system is clearly indicated in the guidelines. The association's position on the value and limitation of these instruments is further presented in the statement that accompanies the ADA's seal on accepted products: "This product is accepted as a measurement device..."
for the evaluation of the temporomandibular musculoskeletal complex. Responsibility for proper selection of patients for testing and the interpretation of test results rests with the dentist."

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

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

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

DR. BURRELL: Thank you.

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

Yes?

DR. MOSES: What I guess I'm asking primarily, to
start out, because I have a lot that at some point I'd like
to discuss about this, is relative to what Mr. Ulatowski
said this morning. Are you offering this as a voluntary
consensus standard?

DR. BURRELL: Yes.

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

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

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

MR. ULATOWSKI: They're candidates, yes.

DR. MOSES: Okay.

DR. GENCO: Further comments, questions? Yes?

DR. MOSES: Then I would like to make a few
comments, in that there are several terms that we--either
they're referred to in here--although I will say that I believe that you're fair in that when you're talking about measurement, you're talking about the temporomandibular musculoskeletal complex rather than TMD as a disease.

DR. GENCO: Correct.

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

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

DR. BURRELL: Well, I think there are two parts to the guidelines, and one, if a manufacturer chooses to submit a device that is simply measuring physiological phenomena, then what they have to do is measure good performance in
this area. In other words, if a device is to measure interincisal distance, then data has to be provided to show that it can do this in a reliable manner.

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

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

DR. BURRELL: Yes.

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

DR. GENCO: Further comments, discussion?

[No response.]

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

DR. BURRELL: Thank you, Mr. Chairman.

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

[Recess.]

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

DR. NEFF: Mr. Chairman, panel, presenters, I would like to express my sincere thanks for inviting our
society to this meeting. Dr. Terri-Ross Icyda asked me to represent him to this meeting at kind of the last minute because apparently with the changes we had in the office, he did not receive his information until late. So the standard of our society, the American Equilibration society, is the fact that no instrument or any devices determine the diagnosis of a patient, nor the treatment of a patient. The clinician is the person responsible for. Instrumentation, yes, by all means, you have always accepted, respected the fact that it will aid in our diagnosis, without a question, and will help in our direction for the possible treatment we can render to our patients. But the clinician is the person that is going to do the final diagnosis and the treatment management that this patient may need.

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

Thank you.

DR. GENCO: Comments, questions from the panel?

DR. NEFF: Forgive me, Mr. Chairman. It happened that I was also a person that I was responsible as an advisor in 1982 to the guidelines of the ADA, and I had worked in that capacity then as advisor and author and editor of these guidelines that we still have in this direction and we are still holding to as official
guidelines. So if there are any questions from that time to the present, I would appreciate it and would be happy to answer.

    DR. GENCO: Okay. Thank you.

    Questions, comments?

    [No response.]

    DR. GENCO: Thank you very much.

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

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

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

    Our mission statement is pretty simple. On behalf of the patient's well-being, the American Alliance of TMD Organizations' mission is to support and protect the rights
and freedom of clinicians to practice in the field of TMD within the scope of their care, skill, knowledge, and judgment, and scientific information. The idea of the alliance came about in about 1993 as a result of some things that were going on, but really the thing that crystallized the alliance was the FDA hearing of 1994.

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

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

The problem really goes back to 1996 when the ADA Council on Dental Materials, Instruments, and Equipment...
awarded the seal of recognition to Myo-Tronics, calling
their equipment safe and effectiveness as an aid in the
diagnosis and treatment of muscle tension and pain
associated with TMD and MPD. As a result, some academicians
became concerned that instrumentation would become the
standard of care, and the first time it was in writing that
I know of was when IADR with the Neuroscience Group, the TMD
Subcommittee of the Neuroscience Group of IADR, published in
their newsletter the fact of their concern.

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

Prior to the meeting, this paper was clearly
marked "Draft only, not to be referenced," and despite that
fact, it was submitted pretty widely and was being used by
insurance companies to deny claims prior to that 1988
meeting. As a result of that, the American Academy of Head,
Neck, and Facial Pain filed a lawsuit, and, in fact, got an
injunction which prevented the continued use of this
document. And the publications that came out really gave
them a black eye for that action, and in retrospect, I would think probably it was a wise thing to do.

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

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

During that period, there were 41 positive articles reflecting the successful utilization or the efficacy of jaw tracking. There were 36 positive articles on joint vibration analysis. There were 110 articles, positive articles, on the efficacy of EMG. And yet none of
those were ever considered in the publications that we 
continue to see. A total that I had come up with during 
that period of time, that three-year period, was 46 negative 
articles and 14 presentations that all reflected the 
negative aspect of instrumentation. So it has been 
something that has beat up for quite a while.

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

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

In 1993, I was contacted by CNN to ask me to do an 
interview for them in regard to neuromuscular 
instrumentation, and, in fact, Dr. Mohl and myself were on 
that interview, and there was nothing really bad that came
out of it. They asked a lot of prying questions of over-utilization, were there many false positives, were people treated excessively as a result of instrumentation, and I answered those to the best of my ability.

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

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

To date, there is not a single publication anywhere in the literature that specifically invalidates the
current technology.

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

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

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

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

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

As you know, the FDA hearing, the recommendation was for these instruments to be class III with urgency, and the panel recommendation was dismissed. But immediately after the hearing, there were several publications that said
that FDA was seeking adversely affected patients. This was in the Terrant (?) County Physician, and this is a newsletter from the National Council Against Health Fraud. When asked about where that came from, we were told that one of the panel members requested it, and so they assumed it came from FDA directly.

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

Another affidavit from him regarding some comments from Dr. Seligman, he says that a new policy or plan, the AAOP, is not again to try to influence the policies of
federal agencies with regard to TMJ instrumentation. We will not try to influence and interfere with the FDA classification of instruments. The FDA will eventually have to classify the instruments, and the classification must be class III because the instruments are dangerous. Therefore, all insurance companies will realize that they cannot acknowledge claims that are based on TMJ diagnostic and therapeutic instruments. Logically, we will kill off all TMJ instrument users through non-reimbursement. If a dentist sees that the patient is not reimbursed, then he will not use the instruments. In our new edition of the guidelines, we will point out that all TMJ instruments used for diagnosis and treatment are of no use, that they are dangerous, and the guidelines will then be given to all insurance companies so they can deny reimbursement by referring to these guidelines. That's the way it works in the U.S. You simply starve the dentist who uses TMJ instrumentation.

The next thing that occurred in relation to instrumentation was the NIH pamphlet that was produced, and we never have found out who the author of that is, despite repeated requests, and then the publication packet that was sent along with it, again pointing out the negatives of instrumentation and the problem of its use.
Closely followed by that was the NIH conference on--technology assessment conference. The presenters--I lost my place. I'm sorry. The presenters, several of the presenters were clinicians, one talking about instrumentations, one talking about treatment devices, and one about equilibration. All has presenters to come immediately after them to refute what they had to say, despite the fact that the other people weren't supposed to have information regarding their presentations.

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

If you look at the research, which, according to the Washington letter, has doubled in relation to TMD research, you will find that in the last couple of years $7.3 million has been spent, and most of it has been spent on psychosocial research. Clinicians around the country, clinical academicians, have complained bitterly about the
fact that they have trouble getting grants for clinical research.

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

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

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

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

If you look at clinical examination, you will find that as low as 14 percent in inter-examiner reliability is there, some as high as 50, but very poor inter-relater
reliability. So one of the things we have to address is a
way to improve that.

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

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

He goes on to say, in looking at muscles, he says
that spasm implies a continuous muscle contraction, and it
can only be differentiated with electromyography verification.

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

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

As we continue to look at the problem, I think the best way to sum it up is to read to you what Dr. William Howard said in an editorial in the AGD Impact. He says that electronic instrumentation detractors, who are mostly university-based dentists, would have you to believe that such instrumentation, which includes surface electromyography, sonography, and jaw trackers, force
dentists into making diagnoses based on factors that have very little to do with the patient's condition. They call it machine arrogance. The arrogance in this case is more on the part of the detractors, some of whom either haven't used the devices themselves or who rely on the small body of review articles addressing these devices, who totally ignore studies that indicate these devices have some clinical value. Credibility is lost when they claim that positive articles haven't been published in credible journals. In fact, they have.

Further, I have a hard time believing that electronic instrumentation has no use or else why would the American Dental Association have approved their use? Detractors also claim that instrumentation users are bound to over-treat based on the machine's diagnosis which almost guarantees a bad outcome. More than 1,500 dentists use instrumentation, yet detractors can't show any actual examples of how instrumentation made a dentist over-treat. It's time to stop throwing mud, regardless if the FDA recommends a high risk category or a medium risk category. More studies are needed to help form a consensus regarding electronic instrumentation. The best way to do that is teamwork between manufacturers, instrumentation users, and universities, who have the means to conduct large
double-blind studies and will prove their efficacy once and for all. Conclusive results will take considerable time to achieve.

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

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

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

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

You must realize that signs and symptoms and pain and dysfunction don't always go together. We see
significant signs with few symptoms, significant symptoms with few signs. We see much dysfunction with no pain.

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

Thank you for your time. I appreciate your attention.

DR. GENCO: Thank you, Dr. Tilley.

Any comments, questions from the panel or the guests?

[No response.]

DR. GENCO: Okay. Thank you very much.

DR. TILLEY: Thank you.

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

This afternoon will be spent, however, primarily on open
discussion of the panel.

Thank you.

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

[1:30 p.m.]

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

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

Thank you, sir.

DR. GENCÓ: Okay. Thank you.

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

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

I appreciate the comments presented by the public and by industry and association participants this morning. I think it's been an excellent input to help guide the panel this afternoon in their deliberations. For example, certainly the point raised that we have to have a common base of understanding of definitions to the extent possible.
Perhaps we can't achieve a consensus opinion, perhaps, but at least we need to have a working definition for our purposes for our discussion today. So if there is on anyone's part some lack of clarity on the scope of products that we're talking about today, then we need to bring that up.

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

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

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

What we are discussing today is the regulation of devices and classification of specific device generic types.
That's not to say that the practice and what people do out there is unimportant. It's certainly important in identifying what sorts of devices are on the table here today. But, again, practice does not translate to the need to classify.

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

We talked about generic devices, and there was some appropriate discussion talking about homogeneity, heterogeneity regarding devices. And what we are trying to attempt to do is to find the highest common denominator of generic device that needs to be classified. And in the regulations, 860.3I defines a generic type of device as a means of grouping devices that do not differ significantly
in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

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

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

Well, with that in mind, again, we had some questions before you, and just to reiterate those questions,
to get us to some baseline, we wanted to get your opinion on ultimately the construction of the list that we presented to you and what will come out of this meeting with at the end of today.

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

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

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

No. 4, For the groups or categories discussed today, for which there are existing classifications, any existing classifications, which groups--devices or groups
have 1976, pre-1976 intended uses related to the diagnosis and treatment of TMD and the other conditions discussed this morning? In that chain of devices that I discussed this morning, we have to establish the pre-amendments nature of the product and the chain of equivalents, either of the product was classified in some manner or unclassified in some manner. We have to consider this pre-1976 derivation.

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

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

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

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

Thank you.

DR. GENCO: Thank you, Tim.

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

DR. BETZ: No.

DR. GENCO: Okay. Thank you.
Any questions of the panel or guests for Tim?

Yes/

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

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

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

So it's going to be a range of questions. That list, again, is just a grab bag of possibilities that we could identify. And we heard possibly some others this morning that should fall on the list as well. It didn't state a classification or a status, but we'll discuss that as we move from each class, from each type to type.
DR. GENCO: Tim, maybe I could rephrase that? Are all of those devices pre-'96, those on your list of universe of devices? Were all of those on the market before '96?

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

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

MR. ULATOWSKI: Some have been classified.

Radiological devices, some have been classified, for example, for a particular intended use.

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

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

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

DR. COOPER: Dr. Barry Cooper. I have a question about the fact that the instruments that basically are on
the list within that table all relate in some way to jaw function or masticatory muscle function, but the title of this whole overview is TMD and oral-facial pain. I don't think that we have a working definition of either the easy one, which is TMD, or the very difficult one, which is oral-facial pain.

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

Any further questions on what Tim said?

[No response.]

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

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

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

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

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

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

Should I be more specific?

DR. GENCO: Yes. Help us to understand what you just said.
DR. MOSES: Can I give you a handout?

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

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

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

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

DR. MOSES: If I could speak to this, what I was saying before, what I decided to as part of the way I study a problem, I went to the literature to see how many variables are involved in the diagnosis of oral-facial pain, because I consider myself a diagnostician or oral-facial pain and temporomandibular disorders. The context in which I feel that this is important is, if you'll take a look at the sheet, if I diagnose a patient as having a masticatory disorder, say muscle splinting, I don't want to--I want to
make sure that I've ruled out, say, a malignant lesion so that if, God forbid, it should be a malignant lesion on one of my patients, that I didn't miss that diagnosis. So I feel that we have to be concerned with these diagnoses when we deal with them.

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

So we have to be thoughtful and perceptive, and we have to chunk things together. In reality, the human mind, according to other psychological studies, can contemplate four to six variables in making a complex decision. So I think what we have to do is chunk these things together, and the way that I've chunked them is the way that you see in front of you on the big sheet. Thus and such, I came up
with an organized scheme, and within this scheme, there's various diagnoses of temporomandibular disorder.

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

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

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

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

DR. MOSES: No. Articular--yes, and periarticular. Arthrogenous, non-arthrogenous, myogenous--yes--

DR. GENCO: Everything under those two.

DR. MOSES: That's correct.

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

DR. MOSES: That's my opinion.

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

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

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

DR. MOSES: That is my opinion, yes.
DR. GENCO: So what you said is that if we wanted
to—you're not objecting to that term, "temporomandibular
joint disorder"--

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

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

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

DR. GENCO: Further comments? Dr. Bertrand?

DR. BERTRAND: I'm Peter Bertrand with Navy. I
think what we're talking about is a differential diagnosis
to fill a definition. The trigeminal nerve controls jaw
motion. It also controls the tightness of the eardrum and
eustachian tube, its patency, but that's all it does motor-wise. It's mostly a sensory nerve, and I think if you're talking about pain and dysfunction in the head and neck, you have to look at the full extent of the receptive fields for the trigeminal system. And virtually everything in some studies in cervical nerve 4 or 5 up goes directly into the trigeminal system.

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

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

So I think when we're looking at whatever TMD is and we're trying to decide what type of modalities we are going to use to make a diagnosis, we need to keep in mind the full extent of the trigeminal system.
I think terms like "psychogenic" and "psychosomatic" are incredibly misleading, that they were invented in order to make up for when we don't have the guts to say we don't understand neurogenically what's going on. I think there is a big chasm between the basic science of what a basic scientist can tell you neuroanatomically is happening and what our symptoms are, and I think that chasm is diminishing all the time.

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

DR. GENCO: So just to put that in the context of this definition, temporomandibular joint dysfunction and associated pain, you think that is not sufficient and you would like to add more to that in terms of--
DR. BERTRAND: There is nobody in this room that when they bring their teeth together to swallow particulate food that doesn't utilize their neck musculature, also. If your neck musculature isn't working, then swallowing becomes more difficult. That minimal dysfunction affects the autonomic nervous system, and I think you need to say, hey, what's happening at a neurogenic basis?

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

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

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

Now, I think that's what Dr. Moses was talking
about, but I also know that anxiety refers into the
trigeminal system and affects immediate early gene activity
and will mediate allodynia and hyperalgesia. Those are all
parts of this system.

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

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

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

DR. GENCO: Other comments? Dr. Cooper?

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

DR. GENCO: Yes?

DR. MOSES: I think in putting it, again, in a different perspective, some of us are dealing with the scars of the '94 meeting where they said that some of these things that we're dealing with on a day-to-day basis are life-threatening, and we're saying, wait, please listen carefully and don't restrict us too carefully because some of the
tests at this particular point, while we're dealing with non-threatening, non-invasive instrumentation, we don't want to be so restricted that we can't do these kinds of testing, either. A lot of this testing evolves out of clinical studies, and we are—I think what I am feeling is I don't want to be restricted by a classification that is so oppressive and restrictive that these things can't be easily testing, because we're basically using non-invasive equipment.

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

DR. MOSES: I'm comfortable with it.

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

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

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

DR. MOSES: I think I--
DR. GENCO: There's no condition to be dealt with unless there's pain.

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

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

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

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

Now, if I couple that with clicking and I couple that with, well, their jaw's a little tight in the morning and they're uncomfortable with the tightness in the muscles and they're worried if their teeth are breaking and fracturing, or they're grinding them away to nothing, I want
to be able to make that appliance without feeling that I'm not treating--in other words, I want to treat them for that. If they agree that they need it and I need it but I don't want to be limited that that's not a disease per se, sure, they're going to suffer from muscle splinting. But, in other words, if they come in for treatment and pain, that's a potential diagnosis. But, on the other hand, we're in a vague area. We can't define at this point who's diseased and who's disease-free in terms of controlled studies. That gets back to the basic definition. Who's normal in this?

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

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

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

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

DR. MOSES: It is a very important distinction.
But we also have patients who lie about pain in automobile accidents.

DR. GENCO: Well, you know--

DR. MOSES: It's a complicated question.

DR. GENCO: Exactly. Yes?

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

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

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

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

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

DR. COOPER: Pain or dysfunction.

DR. GENCO: Okay.

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

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

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

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

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

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

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

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

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

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

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

DR. GENCO: No, but it defines--

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

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

DR. HEFFEZ: Yes, I think it's--I agree with it.
DR. GENCO: Unfortunately, it's not diabetes, which is—you know, one word defines it. Well, that gets complicated too, doesn't it?

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

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

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

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

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

MR. LARSON: If we accept the part that the diagnosis has been made already and that it has been
narrowed down to associated pain, then these devices are brought into function.

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

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

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

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

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

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

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

DR. GENC0: Comments? Yes?

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

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

DR. HEFFEZ: Because if we have such a global
definition, then we have to include a tremendous number of
devices that are not listed here.

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

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

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

    DR. BERTRAND: That's true.

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

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

DR. GENCO: Yes, Dr. Moses?

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

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

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

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

DR. GENCORE: Would you agree with that?

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

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

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

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

[Dr. Bertrand nodding.]

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

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

DR. HEFFEZ: Right.

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

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

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

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

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

DR. COOPER: If I may, we could define the
disorders as abnormalities in form or function of the parts
involved. That makes it structural. That means a click is
a disorder because a quiet joint is healthy, is normal, is
ideal, is wonderful, whatever. But it doesn't mean that—I
think that we have to define our role as opposed to the role
of others involved in the field. Our role is to classify
devices, or your role, to classify devices used. It's not to fully—to find out this ill-defined structure. It's to give some form to a presence. As you've said, there is stuff that has to be used, that is used, has to be classified, and we may not in this panel be able to solve all the problems that an entire NIDR conference couldn't solve in terms of what is it, what's it called, how does it go, what's the best treatment and everything else.

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

DR. GENCO: I'm not taking a stand. I just want to see if this is clear what's being presented. If we use the temporomandibular disorder as the definition, the devices are going to be categorized against what they can do for temporomandibular disorder. That would seem to me to
contain a very large number of conditions, including--

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

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

DR. COOPER: I'm comfortable with--

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

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

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

DR. GENCO: I think your hierarchy starts out with pain.
DR. MOSES: Absolutely.

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

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

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

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

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

DR. BERTRAND: That's acceptable.

DR. GENCO: Clearer. Yes?

DR. COOPER: If we eliminate the word "oral-facial" and just have temporomandibular disorders and associated pain or dysfunction," or "pain and dysfunction,"
then I think we've gotten as global as we have to be, and
whatever proves out to be associated in the future, whether
it's cervical sources, central nervous system sources, if
they ultimately affect this unit of the body, it's the
dentist who is going to be dealing with it, at least on a
diagnostic basis first order, and, therefore, it's the
Dental Panel that should be giving some guidance as to
classification.

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

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

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

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

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

DR. GENCO: But how do you feel about leaving
oral-facial pain--"oral-facial" out?

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

DR. GENCO: Okay, good.

Dr. Heffez? Others?

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

[Laughter.]

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

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

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

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

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

DR. NEFF: My name is Peter Neff. The reason I am saying that is because we started to do the TMD in 1982 when we made the guidelines with the ADA. And it stuck there,
and it stayed there. And at that time we were limited in
our knowledge as we called it TMD. As we realized, and
since then, and expanded more on it, TMD is no longer
limited to TMD. We are not dealing with the temporal bone.
We are dealing actually with the cranial structures. As we
already know, we are dealing more structures within the
cranium.

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

Thank you.

DR. GENCO: Thank you.

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

DR. NEFF: As I said, I realize where it came
from. It came from our, you know, again, limited
understanding in 1982. And what I'm saying today, it's
1997, and we have been wrestling with this term. In 1988
there was another conference held, and at that time nothing
even happened because they were to update the TMD to a
different direction, and nothing happened because of what
happened those two days.

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

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

MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Yes?

MR. ULATOWSKI: Just to concur with Dr. Runner,
we're trying to classify devices that are pre-1976 devices
that were labeled for specific indications for use and
functional purposes pre-1976. We're not trying to create
today any new characterizations. If someone wished to claim
cranio-mandibular disorders, whatever, in a 510(k), we'd certainly entertain that, but only under the broad classification--indication--only under the indications we've seen in labeling to date are we really entertaining that.

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

[No response.]

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

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

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

For example, there have been discussions of software being an exposition of information on the one hand or software being an iterative program of some sort that leads to diagnosis or treatment with or without the inclusion of the physician or dentist. And those are
different situations, but I don't believe we've established
a situation as to what constitutes a device or not.

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

DR. GENCO: Okay. Thank you.

Yes?

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

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

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

Any further comments either to definition or to
issue of what is a device? Reasonably clear? Yes?
DR. REKOW: Tim, did I hear you say that the
custom intraoral devices would not be called a device?

MR. ULATOWSKI: That's mentioned, yes.

DR. REKOW: Those are not devices.

DR. BETZ: Yes, that's correct.

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

DR. BERTRAND: Mr. Chairman, one question.

Psychometric inventories are not being considered devices
for temporomandibular disorders and associated pain and
dysfunction?

DR. GENC: Tim, would you give us some direction,
or Bob?

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

DR. GENC: There are some, for example--I am sure
this is what you're thinking of--patented D'Arrigoto scale,
83 questions in a certain order. That's not--I mean, that's a questionnaire but it's more than just something that the dentist dreams up or puts in his record. It's something you buy, maybe?

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

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

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

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

Yes?

DR. COOPER: There are a host of psychometric tests that have nothing to do with TMD. They're just
psychological profiling. But one that comes to mind is the
TMJ scale, which is a specific TMJ-oriented psychological
test that has an evaluating program to interpret the
results, and it gives a weighted scale of the amount of
psychological versus somatic component of a patient, at
least in their response to a questionnaire. So in that
regard, it is used as a differential diagnostic tool, maybe-
—I'm sure, not free-standing and, you know, not
independently diagnostic. But it is used as a diagnostic
aid specifically in TMD, and I don't know that it really
should not be included in some classification schema,
because the implications are that its outcome affects one's
decision to treat.

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

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

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

DR. GENCO: That's what I understand.

MR. ULATOWSKI: Mr. Chairman, it is a medical
device, but custom devices as defined are not subject to
pre-market clearance so, therefore, do not need to be
classified into one of three categories. It's off the table
for discussion purposes. That's not say it's not a device.

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

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

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

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

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

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

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

MR. ULATOWSKI: Well, Mr. Chairman, I'm not quite sure if the gentleman heard what I said. I'm not excluding any medical devices from this discussion. I think all that was said was we're uncertain whether certain products or whatever are medical devices--and we're going to explore
that and have them on the table if they are medical devices.
That's simply all I said.

DR. GENC: Yes?

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

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

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

Thank you.
DR. GENCO: Thank you.

Any further comments?

MR. ULATOWSKI: Yes, Mr. Chairman.

DR. GENCO: Yes.

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

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

When I spoke of psychological instruments, I was speaking of Rast tests and within that context of
information, but I'm not excluding any product. Let me make
that perfectly clear.

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

[No response.]

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

Okay. Let's proceed now with the nitty-gritty.

Do you concur with the basic construct of this grouping of
devices as presented? Again, Tim and Bob and their staff
have put together--it's always an act of courage to do this--
a straw man for us to look at, and that's this table. Are
there any comments about the items in the table with respect
to grouping, this universe of devices? Yes?

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

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

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

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

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

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

MR. ULATOWSKI: Mr. Chairman, it's simply a
display, if you will, of information that we gathered with
no connotation of subcategorization or any other implication
here, and as a first shot—as you said, the straw man.

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

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

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

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

There's a heterogeneity. I think to be evaluated
together would be counterproductive, that they should be evaluated separately.

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

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

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

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

    DR. REKOW: Thank you.
DR. GENCO: Yes?

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

So I think my suggestion is we keep the general category and then specify within it, in the appropriate places, where there is a potential dual function of the same named instrument, but really different instrument, that it can be EMG instruments for diagnosis, that would be one line, and EMG instruments for therapy; and the same thing may go into many other things that will come up. We'll give it a subdivision. Rather than having EMG appear as two separate complete boxes in two separate places on a larger chart, just designate two separate—and then an instrument manufacturer or device manufacturer would say I want to qualify it as an EMG for the purpose of one or two.
DR. GENCO: Dr. Gonzalez, do you agree with that? You had some discussion this morning about--these are all surface electrode devices--about the needle electrode. You had a third category here.

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

Again, that's not really the discussion here. It's really classification. But I do think that since needle electrodes can be used for the same purpose, that is to say, could be used for temporomandibular disorders, it may be that classification that utilizes or puts into it the fact that needle electrodes are different, separate--because of the risks, because of the infections, and because of other aspects of doing needle electrodes, it may be
worthwhile categorizing that separately such that surface electrodes, because they are far safer--again, not commenting on efficacy or the utility of this, because there are different statements regarding that, and I think we're going to get to that in a future meeting.

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

Both the surface electrode and the needle electrode could be used--theoretically, the needle electrode could be used for biofeedback. I think it's rarely used. I don't think anybody would want to use it for that. But, again, I think that because of that--and I don't think anyone is using it for that purpose--I would not break biofeedback into two categories, unlike the measurement of
electrical activity. I think I would shy away from making a
separate surface and needle electrode for biofeedback. I
would stick with the surface.

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

DR. GONZALEZ: Yes.

DR. GENCÖ: Is everybody happy with that?

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

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

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

MR. ULATOWSKI: I think, Mr. Chairman, as we look
at each category, electromyographic devices, for example,
perhaps--so we don't have to keep coming back around and
around and around as we approach each question--it might be
helpful to run through the questions for each group so that
we understand the existing status of electromyographic
devices, classification status, and once we're all done with
that category, we can then move on and look at the next
section comprehensively, the sonography devices, for
example.

DR. GENCO: Okay.

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

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

DR. BETZ: Yes.

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

DR. BETZ: Yes.

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

MR. ULATOWSKI: Right.

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

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

DR. BETZ: Oh, okay.

DR. GENCO: All right. So your Question 3: For
the group that we just discussed, electromyographic devices, what are the labeled indications, intended uses, which related to TMD and associated pain/dysfunction? You've presented two of them: to measure masticatory muscle activity, so that's diagnostic—or am I adding a concept that's not necessary to that? Just measure activity. That's the intended use.

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

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

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

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

DR. GENCO: Okay. Label indications for use.

DR. COOPER: May I go on? Then the example that's
used in parentheses is only an example—to quantify the
amount of tension in muscles of mastication? I have used
EMG for many, many years. I don't think that I measure
tension in muscles. I measure electrical activity in
muscles. That has to be incorrect.

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

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

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

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

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

MR. ULATOWSKI: That's fine.

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

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

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

DR. COOPER: I just fear that we try to do
something that's very specific, and it's not all inclusive,
and it may--you know, it may disenfranchise somebody else
who has a very legitimate purpose which is a variant of measuring activity, but it's not specifically tension. So I think if we're being generic at this point, let's be generic in terms of usage also, at least at today's level.

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

DR. GENC0: Okay. The next one, to aid in biofeedback and muscle reeducation. Any comments with respect to that?

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

DR. GENC0: Further comments? Yes?

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

DR. GENC0: Yes, I guess--what are we doing? You're giving us what the companies have said, and we're reacting to it. And it's like advance notice that when the companies come back in, this is the way the panel feels about certain terms used in the labeling.
DR. BETZ: Yes. This whole column basically is the distillation of what has come from 510(k)s.

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

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

DR. GENCO: Okay.

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

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

MR. ULATOWSKI: An electromyographic device is
intended to...what?

DR. GENC0: And then the companies can make more specific claims or labeling.

MR. ULatowski: Right. May have in the past or in the future.

DR. GENC0: Okay, I'm clear. I didn't understand.

MR. ULatowski: Related to that intended use.

DR. GENC0: Dr. Cooper, would that change anything that you've said so far?

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

DR. GENC0: Thank you.

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

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

DR. Genco: Dr. Cooper, are you in agreement with
that?

DR. Cooper: Yes.

DR. Genco: Any further comments to that? Dr.
Heffez--

DR. Cooper: It's to aid through biofeedback, not
to aid in biofeedback; right? To aid through biofeedback
in--

MR. Ulatowski: Through biofeedback, yes.

DR. Heffez: What is the definition of
biofeedback?

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

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

DR. Heffez: Yes, it can, but--it can be used for
that also.

DR. Genco: So you think the more general term is
to aid biofeedback, whatever it does.
DR. HEFFEZ: I think it's just a generic term.

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

DR. GENCO: Okay. Yes?

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

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

DR. MOSES: Muscle—lower muscle activity.

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

DR. MOSES: Particularly relevant to the electromyographic use, which is what they're testing here, not the blood pressure or the galvanic skin response, which
are other biofeedback instruments.

DR. GENCO: Okay. Yes?

DR. BETZ: Would it be helpful to read back the

definition under 882.5050, biofeedback device?

DR. GENCO: Yes, please do.

DR. BETZ: A biofeedback device is an instrument

that provides a visual or auditory signal corresponding to

the status of one or more of a patient's physiological

parameters such as brain alpha wave activity, muscle

activity, skin temperature, et cetera, so that the patient

can control voluntarily these physiological parameters,

classification 2 performance standards.

DR. GENCO: Are there devices other than

electromyographic devices that are used or that have been

classified or are used for TMD, other biofeedback devices

other than the electromyographic? In other words, do we

need a category of biofeedback?

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

DR. GENCO: Do we?

DR. MOSES: Is that what you think? Cut it from

electromyographic and just have electromyographic for

measurement and biofeedback for everything else. You're

right.

DR. GENCO: So then you'd have a generic
classification of biofeedback, which could be various
devices, some electromyographic, some--what are the others?

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

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

DR. GENCO: So go back to the electromyographic
biofeedback device. You would leave it in this category as
subcategory 2 and--but its use or description would include
to aid through biofeedback in reducing muscle activity. Is
that where we are with that now? Is everybody happy with
that?
DR. COOPER: For the time being, subject to maybe another classification later on of biofeedback devices themselves, then it can refer to Section 1, No. 2.

DR. GENCO: Okay. Good. Now, with respect to electromyographic devices, are there any comments from the observers with respect to the subcategorization and the indications for use? Yes, Dr. Jankelson first, and then--

why don't you come up to the microphone?

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

Clinicians will tell you this has been an area of contention. Despite all the logic behind the foregoing statement, it has been a contention in standard of care, insurance coverage, and I think that it behooves this panel
to very clearly make that distinction so that during the
review process there is no confusion.

Thank you.

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

DR. JANKELSON: I would not--

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

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

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

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

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

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

[Laughter.]
DR. GENCO: I've tried it.

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

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

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

DR. REKOW: Yes.

DR. GENCO: Okay. Thank you. So the suggestion here is that under the current indication for electromyographic device to measure masticatory and
associated muscle electrical activity. Further comments?

[No response.]

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

DR. RUNNER: Yes.

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

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

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

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

DR. GENCO: Or equivalent to something that was unclassified, legally on the market before 1976.
MR. ULATOWSKI: By that we have said that there was a pre-1976 electromyographic device for this use.

DR. GENCO: Right.

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

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

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

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

DR. GENCO: Please.

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

DR. GENCO: Okay. Thank you.

What would you like from us now with respect to
MR. ULATOWSKI: In our historical evaluation, what tells me is that when a 510(k) came in, the applicant identified--perhaps might have identified one of the physical medicine devices that were classified, perhaps, or another pre-1976 device with the same indications and the FDA made a determination per its classification process per 510(k)s, as I mentioned early on in the day, through that classification process determined if it compared to the physical medicine device, we in all likelihood determined the product to be not equivalent or a separate product altogether, as classified as a separate product altogether.

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

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

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

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

DR. HEFFEZ: Just a question. Is it possible that
eventually a different classification can come out from the
panel and be in conflict with the classification that has
been defined previously for physical rehabilitation?

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

DR. RUNNER: Yes.

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

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

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

DR. HEFFEZ: Thank you.

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

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

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

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

So I would like the FDA to make available to the panel the results of any adverse reaction reports on these appliances so that it's not just a mystery. They say, well, I have what I think might be no adverse reaction reports, because I think that would significantly impact the panel in
making a decision. If there are no adverse reaction reports for a period of 20 years, I think it would be very hard to find that appliance, if it's not invasive, to be a class III, and that should impact on the decision.

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

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

DR. MOSES: Will you make that available?

MR. ULATOWSKI: Yes.

DR. MOSES: Thank you.

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

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

DR. MOSES: I'd like to see the appropriate literature reports.
DR. GENCO: More specifically, what kind--

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

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

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

Again, we're not dealing with equipment that just
got off the counter, that's just come off the racks. This is stuff that's been around.

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

DR. MOSES: Safety and efficacy, yes.

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

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

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

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

DR. GENCeO: Okay. What about relationship to this associated oral-facial pain and dysfunction, the muscle activity, electrical activity associated with oral-facial
pain and/or dysfunction?

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

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

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

DR. HEFFEZ: No. It's an instrument that can measure electrical activity, and people who have spasm in their muscles or pain in their muscles, obviously electrical activity will be higher. But it's—I mean, that would be the same regardless of what part of the body that you deal with.

DR. GENCO: Further comments about the kind of evidence you'd like to see? Is this a question of predictive versus aid in diagnosis of existing condition relevant here? Would anyone like to see that kind of data?
In other words, if you have an alteration, will it predict
disease? Or if you have an alteration, will it aid in the
diagnosis of existing disease? Is that relevant here? Yes?

DR. COOPER: From my experience, I think the
latter not the former. I think that my experience with EMG
is that it's relative a person to that person and many times
more so than a person to another person. So your evaluation
of a person at the time you're making a diagnosis and how
that implements on diagnosis and treatment is more
appropriate than it would be as I'm going to examine this
patient as a routine scan type of thing to decide whether or
not they're predisposed to a problem for the future. I
don't think that really is apropos with EMG and TMD.

DR. GENCO: Okay. So the evidence that you'd like
to see would be that it measures muscle activity and that
relates somehow to current diagnosis.

DR. COOPER: Safety and efficacy in current
diagnosis.

DR. GENCO: In terms of efficacy. Safety is a
whole other issue.

DR. COOPER: Okay. Efficacy in terms of diagnosis
and treatment. That's the two things that we are
evaluating.

DR. GENCO: In terms of diagnosis--
DR. COOPER: I guess diagnosis. EMG is only diagnostic at this point.

DR. GENCO: Okay. Does everybody agree? I think that gives some direction to the kinds of data and if it's out there, it's summary and it's interpretation, and we could have a good discussion based upon seeing the actual studies.

Dr. Bertrand, do you want to make any comments about the kinds of data that you'd like to see?

DR. BERTRAND: Anything that can show predictive value would be great, but I'm not sure we have that with EMG data. I think if you can show a difference in EMG activity baseline in an asymptomatic patient versus a symptomatic patient, and then show the difference after, that would be wonderful data. Does that exist? I think that's part of what the debate is.

DR. GENCO: Well, that's why I bring it up.

Now, comments? Yes? Please, go up to the microphone.

MR. JANKESELON: Roland Jankelson with Myo-Tronics.

Under the category of information that I think might be helpful to the panel, I alluded earlier in my opening statements about a letter that I had directed to Dr. Alpert as well as to Secretary Shalala. It referred to earlier
activities of the FDA, specifically to solicit information
about harmed patients with respect to the various categories
of instrumentation manufactured by Myo-Tronics.

In my letter, I simply asked for a response as to
whether there was any such information, which, of course, we
believe to not be true—not to exist. The nature of that
information, some clarification as to how it was gathered.
I think if, in fact, any such information exists, it
certainly should be made available to the panel, but also to
Myo-Tronics, and we have asked for it in this letter, again
asked for it. As we suspect, it doesn't exist, but simply
the fact that the FDA made a concerted effort to dig it out
I think suggests something about—is relevant. If it
doesn't exist, I think that's relevant information for the
panel. If there is something that the FDA has that has not
been disclosed to us, I think that should also be disclosed
to the panel.

Thank you.

DR. GENCO: Thank you.

Dr. Tilley, did you want to make a comment?

DR. TILLEY: No.

DR. GENCO: Thank you. Okay, I think the next
issue is--

DR. REKOW: Can I say one more thing? One of the
things that frustrates me as a panel member when I review
literature--and it's not peculiar to this body of
literature; it's literature in general--is case reports are
interesting and valuable, but it's very hard to make
scientific decisions on case reports. And so the literature
that gets brought to the panel needs to be on studies that
are carefully controlled, have statistical analysis, and are
more than just patient one and patient two and patient
three. And that's a criticism in general of literature, not
of this specific body of literature.

DR. GENCO: So you're arguing for, as much as
possible, randomized controlled trials?

DR. REKOW: If that's possible, but certainly--

DR. GENCO: How are calculations done so they're
adequate size, all the principles of good quality clinical
trials.

DR. MOSES: I'm sorry, Doctor, but I take issue
with that in the field of temporomandibular disorders
because basically there's no general agreement on the
definition, there's no general agreement on who has the
disease and who doesn't, there's no general agreement on
what is normal and what is abnormal. And so to do a
controlled study for these variables, like the psychosocial
variables, it's virtually impossible. It's also virtually
impossible for a doctor to not know if he's adjusting the occlusion in a study, and so to do this double-blind study on some of these things becomes a physical impossibility as well as technical.

And so a case study relative to my case, that represents to me evidence, whereas what you're looking at in a controlled study is inference. And I think that it's stronger to relate as a clinician an evidentiary study than it is an inferential study, in many cases, if it's the same disease.

DR. REKOW: Then I would propose that at least the studies be in sequential patients and all of them get reported and the dropouts get reported for why they dropped out. You know that there are many cases where you start with 50 patients and you end up with the 25 that worked or you chose 25. Not you, but you know that those--

DR. MOSES: I understand what you're saying. I think those things--what I fear is that these kinds of studies that you're looking for here are simply not available. They simply haven't been done at the quality that you're looking for. That's the point I'm making.

And so to ask for quality studies when there are none is an unfair standard to put upon these manufacturers to produce. That's my point.
MR. ULATOWSKI: Mr. Chairman, under the definition of valid scientific evidence in Part 860 for classification, there's a range of information that's eligible to be presented, and it includes controlled or uncontrolled studies or various types of other data. And it defines only a few instances that data is really not valid scientific evidence, random case reports, for example. So there is an allowance for quite a range of information.

Of course, the quality of the information provided gives you more or less better information that you can deal with, but there is the opportunity to present, for the people to present to you a range of information.

DR. GONZALEZ: I think that regarding literature, rather than try to reinvent the wheel for each one of these categories, it's true that there's not a lot of literature in some of these areas, but in other areas there are. And there have been groups of people, academies, associations, who have gone through and have at least come up with a statement saying there isn't sufficient evidence or have made a statement about safety of some of these, even though they may not necessarily be effective. And I'm referring to the American Academy of Physical Medicine and Rehabilitation, American Academy of Electrodiagnostic Medicine, American Academy of Neurology with its physical
treatment of chronic pain, and a number of others, where
they've gone through the world's literature on this,
including case reports, and categorized all of the
literature all the way up to double-blind controlled
studies, and at least for some of these--at least three that
I see here, I know that those statements exist that are
fairly recent in the last couple of years.

So I think we should get at least that, the
Academy statements, where this work has already been done
for some of these areas, and then we can take off from that
point, accept or reject it.

DR. GENCO: So your suggestion is that the panel
also be given the summary statements for--not the TMD use
but the other medical uses of these devices for a context.

DR. GONZALEZ: Yes, and which also includes some
statements, I believe for TMJ as well.

DR. GENCO: Thank you.

Further comments about the type of evidence?

[No response.]

DR. GENCO: Okay. The FDA wants to know from us
with what priority should they pursue classification, and we
will talk about specifically the electromyographic devices.

Anybody want to start the discussion? Yes?

DR. MOSES: Are you looking at me?
DR. GENCO: I just thought you wanted to make a comment.

DR. MOSES: I'll be happy to make a comment. I think that the priority is not very high. I don't know that we've seen--again, Tim, you could answer this question better in terms of have there been adverse reaction reports between 1994 and 1997, the significant numbers on this, because if we're talking about devices that are, frankly, 20 years old in use already, I don't know that they're so dangerous that they need an immediate classification, that this is the highest priority item for the FDA.

MR. ULATOWSKI: I'm not familiar with the database on the MDRs and other information right now. But your point is well taken. It's something for the panel to consider in view of your comment.

DR. GENCO: Further comments about priority?

[No response.]

DR. GENCO: Okay. Thank you.

Let's take a break. We've got a lot to do in the next hour and a half or so. We've got to go through the other devices because we have a schedule for tomorrow. So get your thoughts together, have a cup of coffee, and meet you back here in 10 minutes.

[Recess.]
DR. GENCO: Let's proceed now to the sonography devices. Does anybody want to discuss whether that is a generic category? Yes?

Excuse me. Actually, someone has to leave and has requested that we talk about TENS next. So if there's no objection, let's go to the TENS devices. Is that a generic classification?

DR. COOPER: There are variations in that theme. There are high-frequency TENS, low-frequency, and ultra-low-frequency. I think we should differentiate. They have different therapeutic purposes.

DR. GENCO: Similar to electromyographies, single generic classification with 1, 2, 3 subcategories?

DR. COOPER: Right, I would think so.

DR. GENCO: And there's a rationale for each?

DR. COOPER: Right.

DR. GENCO: Could you give them again?

DR. COOPER: High-frequency TENS is used as a pain suppressor; low-frequency and ultra-low-frequency are used as stimulators for muscle relaxation. That is my understanding, but we have a neurologist on board.

DR. GONZALEZ: It's more complex than that when we're talking about pain. I can get off on Y dynamic neurons and Y—you know, low-frequency with a very high
internal frequency is better, and central pain, where a
high-frequency TENS is probably better than low-frequency
with an internal high frequency, and the classification by
Clifford Wolf and other classifications. And I'm not sure
that ultimately the frequency that's being used—the
classification or categorizing the frequency as opposed to,
let's say, how the TENS unit is being used in terms of which
patient may benefit. So I think that the general
classification, if you did want to break it down into high
and low frequency, my question would be: Does that mean
that the machinery that's being asked to go through FDA for
categorization and approval will limit a machine like that?

And I even bring that up because when I was
hearing the discussion about the hierarchy regarding the
types of disorders, I started thinking about, for instance,
central pain, which is not listed on this very elegant
diagram, or phantom region or phantom limb or phantom
structure pain, which are not listed there either. And
those different diagnoses that are centrally mediated and
centrally generated conditions, depending on who you read,
the frequency is going to be different.

So I think a general—and I'm going right back to
agreeing with you, Dr. Cooper, that I think that having low
and high frequency is useful, because we think in that way;
but, in fact, a TENS unit, depending on, again, who you read
and who you believe, is much more complex. And the pundits
of, you know, low frequency--you know, tell you, no, that's
the Y dynamic neurons, and others will tell you that it's
the lateral, thalamic, ventral basal nuclei--you know, on
and on and on.

So basically what I'm saying, just to try to put
this aside, when the details come out, I'm not sure it's
going to be very clear. I think it's going to be, you know,
just really quite difficult to make heads or tails of it.
And I think knowing that in the background, you can still
categorize--and I'm coming right back to what you said, and
I'm agreeing with you; that you can come right back to high-
and low-frequency TENS, but let's just be aware that just as
in the categorization--the very first thing that we talked
about in that is how we're going to classify, what title are
we giving this. Well, you know, the titles, the names of
everything are changing so rapidly. On your list here, the
reflex sympathetic dystrophy that Dr. Moses put together,
you know, it's changed in the last three years to
sympathetically mediated pain, in the last year and a half
to complex regional pain disorder. And it's about to change
again.

So in the same way, if this categorization can
reflect that, that is to say, that we understand--if we can put some sort of notation that we understand that it's much more complex than that, but for the time being understand that most people really who are giving therapy in terms of a TENS unit think of high and low frequency, but there are low frequency with an internalized high frequency, and all sorts of variations to that, according to Clifford Wolf and others that I've mentioned.

So I think it's technically useful right now to say high and low frequency, but understanding that further classification may become important in the future.

DR. COOPER: Can we then further--your addendum is fine. It may have to have an asterisk, again. Can we further generalize and say the TENS is used for pain amelioration and/or muscle relaxation, and will it be then the responsibility of a manufacturer of a device to then specify, A, which type of TENS they're manufacturing, and, B, what its intended use is? In other words, can we be doubled in terms of the whole thing: A, the type of TENS, and, B, its usage, and then permit within that box a manufacturer then to submit an application for an evaluation, classification based on that specific instrument that's on the table? It's either a high or a low and it's supposed to do this or that, and then the obligation on the
manufacturer is then to specify I can prove that it does
this or that?

DR. GONZALEZ: My understanding right now is TENS
is used for pain control and not for muscle relaxation.
Just the opposition, it produces muscle contraction. The
risk—and we'll talk about this in future meetings. The
risk, of course, is that frequencies can produce sustained
muscle contraction which can produce necrosis or at least
over-contraction, fatigue, and injury to muscles. So I
think that first of all I would say that the TENS unit in
this context should be for pain—specified as for pain
control, not for muscle relaxation, not for any other
purpose. Although TENS and electrical stimulation may have
other utilities, my understanding is that it would be
specifically for pain. Is that--

DR. COOPER: No. In TMD, not so. The reverse.
In TMD it's used more for muscle relaxation, as monitored by
EMG, lowers EMG activity. So for chronic pain, TENS high
frequency is used as pain relief.

DR. GONZALEZ: My comments are strictly for pain
control in terms of high and low frequency.

DR. COOPER: But in TMD, the other is the
dominant. So I would acknowledge that both are uses, maybe
not of the same machine, but both are uses. So we have to
list them both.

DR. GENCO: So are you comfortable, then, the panel, with that subdivision into high and low frequency? And then further comment with use, to treat by application of electrical energy for muscle relaxation and pain control?

DR. COOPER: And/or pain control.

DR. GENCO: And/or. Further comments?

DR. HEFFEZ: I have a question for Dr. Gonzalez. In the body of literature, what does it state about TENS as far as muscle relaxation is concerned?

DR. GONZALEZ: This is getting into efficacy. If we want to get into efficacy, I sure can. But I was a facilitator on the American Academy of Neurology, the physical treatments of chronic pain, and we came up with some statements regarding TENS unit for chronic pain.

But I'm not sure it's relevant to the temporomandibular. We had very specific types of pain that we were addressing, and it did not address, to my knowledge, temporomandibular--it would be my--it was specifically not included, but it was one of those that would be included later.

DR. HEFFEZ: For example, has TENS unit been used for lower back pain with lower back muscle spasm?

DR. GONZALEZ: It has, yes.
DR. HEFFEZ: Okay. It is used for muscle relaxation or pain modulation in those cases?

DR. GONZALEZ: We're looking at the outcome, not in the physiological effects necessarily. Just the outcome in terms of studies that were looking at outcome, how patients did after.

DR. HEFFEZ: So, therefore, we're looking at just pain modulation as an outcome.

DR. GONZALEZ: Yes.

DR. HEFFEZ: Because it's one thing, I think, to separate out and say TMD is a separate sort of category and we have to treat that differently, and then on the other hand try to embrace TMD saying it's very close to other pathological conditions. So we can't have it both ways. There are muscles in the head, and there are muscles somewhere else in the body.

I could maybe make the argument that if you reduce pain, patients will indirectly have less muscle spasm or less tension in their muscles, and, therefore, the biofeedback or the EMG will indicate less muscle electrical activity. It's very hard for me to detect whether it actually is causing muscle relaxation or is just pain modulation and indirectly giving me my effect on the muscles.
It will go down to Question 7, which is essentially provide me the scientific evidence--

DR. GENC0: Right, the kinds of evidence that you'd like to see. I think we've gone into that.

Further comments then about the use statement? Does anybody--is everybody happy with the TENS designation? Dr. Gonzalez, you said the nomenclature is changing? Is this the term that's being used?

DR. GONZALEZ: TENS?

DR. GENC0: Yes.

DR. GONZALEZ: Yes, transcutaneous electrical nerve stimulation.

DR. GENC0: Okay, so we're happy with that, then.

Further comments about this as a generic classification, two subcategories, high and low, and pain and muscle relaxation, electrical stimulation for pain and muscle relaxation.

Yes?

DR. TILLEY: Larry Tilley. I just have to wonder if this isn't where iontophorential therapy, iontophorential stimulation, micro current, high volt, things like that, would not be classified in that section also.

DR. GENC0: Can anybody on the panel comment to that? No? Okay. Dr. Tilley has brought up another group
of instruments that could be categorized in with the TENS.
And iontophoresis. So you're expanding this as a generic
group of any device that delivers electrical current to the
body. Yes?

DR. MOSES: Well, the category there says
stimulatory devices, things like the alpha stim. There's a
lot of them.

DR. GENCO: Does TENS include iontophoresis? I
guess that--so do we need another name for this generic
category?

DR. MOSES: The generic category it says there is
stimulatory devices on my sheet.

DR. GENCO: Okay. So the TENS is an example.

DR. MOSES: Is an example of a stimulatory device.

DR. GENCO: All right.

DR. MOSES: As is the alpha stim, as is
iontophoresis, as is high voltage.

DR. GENCO: Okay. I misread that. I'm sorry.

DR. COOPER: If we do that, which is fine, that
would broaden the category of electrical stimulating
devices. Then you also have to broaden the characteristics
of what they do. Iontophoresis delivers analgesics or anti-
inflammatories. So there has to be an increase in the list
of the possible therapeutic applications. So it can't be
just muscle relaxation or pain relief. It also could be
anti--I don't know how we want to word it. Somebody else
help. But it can be--

DR. GONZALEZ: Anti-inflammatory or--

DR. COOPER: Anti-inflammatory or pain--well, pain
we've dealt with, so if it's an anesthetic being applied--
it's probably--somebody can help us. It's probably the--
there's probably no other function of an electric
stimulator, is there? In this usage. I don't mean to grow
nerves.

DR. GONZALEZ: Actually, yes. I mean, anti-
nociception by electrical stimulation, I think the way it's
being used, or TENS unit, would be the gate control theory
of pain to reduce pain, whereas other cranial stimulation,
like limoges (?) transcranial stimulation, which is used for
pain control, also it's been used in the past as an anti-
anxiety method, which is literally low-amplitude, low-
frequency transcranial electrical stimulation of the head
used in France and Russia, as an analgesic method.

I don't believe--and there's very little
literature on this--it works in the same way as TENS is used
peripherally. No one knows how limoges works, if it works
at all.

My concern with this classification of stimulatory
devices is exactly that, throwing in devices like limoges, transcranial stimulation, and others. I'm not sure I'm resolving this at all. I think, you know, I'm just trying to think about other problems that could develop if we say in a global way, well, this includes all stimulatory devices, because I would be very concerned. In fact, that's up for a lot of discussion right now. In fact, it's the subject of a lot of discussion in a number of groups, things like transcranial electrical stimulation, galvanic stimulation, and others.

So maybe stimulatory devices should be more specific to state TENS and then maybe be very specific for other devices, and to state those devices up front. Again, maybe it could be added on to later. Maybe, you know, it needs to be refined more. But I'm concerned about the term "stimulatory devices."

Dr. COOPER: Can we be site specific again? Can we say electrical stimulatory devices to the masticatory and associated muscles and temporomandibular joints? That keeps you closer into home. That means you can apply something to the TMJ capsule. You can apply something to masticatory muscles. You can apply something to the posterior cervical muscles. I'm trying to keep it home to you, trying to keep it narrowed for the sake of--the brain is--this is a Dental
Products Panel. We shouldn't be stimulating brains. I mean, we should be stimulating each other's, but not outside this room.

DR. GENCO: So what is your feeling about that? In other words, leave it as stimulatory devices, and then make it site specific, to treat by application of electrical energy to masticatory and associated muscles.

DR. COOPER: And temporomandibular joints.

DR. GENCO: Okay, and joint.

DR. COOPER: Because iontophoresis is applied to a joint.

DR. GONZALEZ: And trigeminal nerve. I mean, isn't that what TENS does? It works through peripheral nerves for central activation of the gate control theory of pain. So it would be structures in the temporomandibular joint region, including muscle, trigeminal nerve, and--

DR. COOPER: And joint, temporomandibular joint.

DR. GENCO: Okay. Then to just finish this, used for relief of pain and for muscle relaxation.

DR. COOPER: And delivery of medication.

DR. GENCO: And delivery of medication.

DR. COOPER: I hope that would be--would that be describing iontophoresis.

DR. GENCO: The iontophoresis.
DR. COOPER: We can then subset—that TENS can be categorized as high or low frequency.

DR. GENCO: Right.

DR. GONZALEZ: Well, iontophoresis, my understanding is that it transcutaneously delivers medicine, but it's not necessarily site specific. It diffuses once it's delivered. Are we really treating deep structures such as the temporomandibular muscles, the joint, the bone, the periosteum, using iontophoresis? I don't believe that that's been looked at. The companies that have iontophoresis devices, one English and I think Alza in California, and a couple of others that are working on this, make statements about diffusion subcutaneously into fatty and other tissues. I don't believe that they're stating they're delivering it to muscle. I don't believe they're making that kind of a statement. So wouldn't that fall out of this categorization?

DR. COOPER: I'm not sure.

MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Yes.

MR. ULATOWSKI: I think that point is well taken, that we are trying to consider devices that are pre-amendments or are substantially unclassified devices and not devices that have garnered some new uses along the way or
something post-1976. And in regard to the stimulatory
device category, it was a construct that we did at FDA, but
I think FDA would tend to be splitters and not lumpers in
terms of this particular category in terms of the definition
of a generic device type, where you have different purposes
and designs and functions in amongst this group that
differentiate one from another.

DR. GENCO: So you're suggesting we ought to
consider leaving iontophoresis out of this category?

MR. ULATOWSKI: Defining the category, the generic
type in a manner that's succinct and doesn't capture or
garner a bunch of things that really fall outside or is an
entirely different function from a TENS device.

DR. COOPER: In other words, stay with TENS for
the moment and we have enough subdivision and with this the
possibility of then setting up a category for other
electrical stimulators as more knowledge comes in.

MR. ULATOWSKI: Exactly, yes.

DR. GENCO: So presently you have no 510(k)
related to iontophoresis devices, so there's no need to
reclassify them?

MR. ULATOWSKI: We do have an iontophoresis device
classification.

DR. GENCO: Okay.
DR. RUNNER: But not in relation to TMD.

DR. GENCO: Okay.

MR. ULATOWSKI: There's no claims for TMD. No pre-amendments claims for TMD whatsoever.

DR. GENCO: Okay. Yes?

DR. TILLEY: Larry Tilley. There is a company that makes claims about iontophoresis for the use and treatment of TMD.

MR. ULATOWSKI: Well, we'd have to understand what that device is and when it entered the market and what it was claimed equivalent to if it was found equivalent.

DR. TILLEY: It is not a stimulatory device. Iontophoresis by the characteristics—rather, make it not a stimulatory device. I'd also ask you about infrared diodes, helium, neon, infrared lasers, things like that that we're seeing used more and more. There obviously needs to be another category because they don't necessarily fit into stimulatory devices.

MR. ULATOWSKI: If I could ask, as before, if you have information on those specific devices that we could research and list appropriately.

DR. GENCO: Further discussion of the stimulatory devices?

[No response.]
DR. GENCO: I think we have come to the suggestion that we limit that to TENS type, high and low frequency, and then to treat by application of electrical energy to the temporomandibular region for reducing pain—for pain control and reducing muscle—relaxing muscle.

Okay. With respect to—what is the status? These are like the EMG? There's a chain of evidence, a chain of devices based upon a non-classified device for dental, but the TENS is classified category 2 for medical, just like electromyographic.

MR. ULATOWSKI: Yes, Bob—Mr. Chairman?

DR. GENCO: Yes.

MR. ULATOWSKI: To ask Dr. Betz—

DR. BETZ: Can you ask that again?

MR. ULATOWSKI: To ask you, Bob, this indication for use for this TENS device was gathered in from a 510(k). Correct?

DR. RUNNER: Yes.

MR. ULATOWSKI: And what was the status of that 510(k) as far as its claimed equivalence? What was the predicate, a classified device or an unclassified device?

DR. BETZ: It's my recollection—I don't want to sound like a lawyer, but it's my recollection that it was unclassified.
MR. ULATOWSKI: For that claim, for that intended use?

DR. BETZ: To the best of my knowledge, yes.

MR. ULATOWSKI: Well, we'll have to research it just to make certain one way or the other. If it was found equivalent to the classified TENS devices, and there are classified TENS devices, then the panel doesn't have to take any action. It's already classified per that 510(k).

DR. GENCO: I thought in your opening comments, Bob, you said it had no dental classification.

DR. BETZ: That's correct, specifically.

DR. GENCO: But the question now is was it-- devices that have been approved by a 510(k) with the predicate device a classified medical device. If so, then we don't have to deal with it. If not, if it's unclassified, then we have to deal with it. That's the issue. What is the predicate device, pre-1976?

DR. RUNNER: I believe the one with the TMJ uses is unclassified.

DR. GENCO: Okay. What about evidence? Any different lines of evidence for this group of devices than for the electromyographic? Any unique kinds of information? I think for the electromyographic, we've agreed, of course, with the FDA that the kinds of evidence that can be
presented can be anywhere along the hierarchy. Of course, it's more convincing the more close you get to randomized controlled trials. Is there anything different about this group, any unique feature of this group, any pitfalls in the experiments, the evidence?

DR. GONZALEZ: One comment about that. With TENS unit, it is very difficult to do controlled studies. The outcome of utility of TENS is the induction of paresthesias, a feeling. You use that to measure the fact that you have a proper amount of energy being delivered. If you have a control, you have to deliver less energy. In other words, not induce paresthesias. So it is--some people feel it is impossible to ever do controlled studies on patients for TENS because of that fact.

The same goes for spinal cord stimulator, but for TENS you do need the induction of paresthesias, and people who have tried TENS before know when you give them not enough energy, not enough electrical stimulation to produce activity and pain reduction. So just a caveat is that when we look at the information regarding TENS, the information which we've done already, the American Academy of Neurology, is not going to be studies that are double-blind, or at least believable double-blind studies. And so the level, if you will, of type of studies that we're going to look at
will be less convincing. Just for those of us who are sticklers for academics, we're just not going to achieve that. So we have to be cautious in saying that it doesn't work and disregarding it because studies have not been done. You may not be able to do those studies. It may depend more on large numbers of reports.

DR. GENCO: Are there alternate designs, like intractable pain treated longitudinally, baseline, or treat with a placebo?

DR. GONZALEZ: There have been trials of on and off and in varying limbs for patients with bilateral lower extremity or upper extremity pain, but the bottom line is the criticism of all of those that have tried very hard to be objective is always the same criticism—that is, you don't have truly double-blind studies. And we just need to keep that in mind and try to be objective in that respect and not discount it because they haven't done a double-blind study yet, because it may not be achievable.

DR. GENCO: Okay. Thank you very much.

Any further comments about the order of—or the level of science, the types of design?

[No response.]

DR. GENCO: Okay. What about the priority for these? What is your opinion as to the priority to classify
the TENS type devices? Yes?

        DR. COOPER: I would consider it low priority. I can't say--I've been using TENS for 18 years, so I can't see any potential harm. You either relax people or you eliminate pain, or you don't. You can't do too much of it, at least in the instruments that I'm familiar with. So I don't think that there's any great imminent danger. So it can go into the group of low priority.

        DR. GENCO: Any other comments? Yes?

        DR. GONZALEZ: I definitely agree with that, that it should be given a low priority.

        DR. GENCO: Okay. Any other comments about TENS and stimulatory devices? Yes, go ahead, Dr. Jankelson.

        DR. JANKELSON: Again, this is not unusual that there is confusion regarding TENS. I don't know whether I'll add or detract from the subject, but it's one that I'm very, very familiar with, working in the area and publishing in the area for the last 25 years.

                There are really three types of TENS, exclusive of variable wavelengths and forms. The high-frequency TENS typically have a frequency between 80 and 100 hertz, work, as Dr. Gonzalez said, through some gate mechanism, Melzak wall, probably some issue of C fibers versus A fibers, loading up the alpha fibers, and it's a pain blocker. It is
in most, I believe, 510(k)s defined as effective for blocking pain.

We then have the low-frequency TENS. Low-frequency TENS in the literature is defined as having a frequency of between 1 and 4 hertz. This isn't complicated. And the early Swedish literature, Scandinavian literature, you often refer to it as acupuncture-like TENS. Specifically, it was designed for muscle relaxation. The mediation is very different. With high-frequency TENS you do not get visible muscle contracture until you have an amplitude sufficient to provide tetany, and Dr. Gonzalez addressed that issue.

The low-frequency TENS, it is impossible to achieve a state of tetany. The characteristic of low-frequency TENS is involuntary muscle contraction coordinate with the number of stimuli per second.

There's actually--and I believe the FDA--correct me if I'm wrong--prefers a third category that has not been mentioned, and that is what we call the ultra-low-frequency TENS, below 1 hertz. And, again, I believe that is presently and recently being referred to as muscle stimulators. So we really have three categories. That also is based upon initiating involuntary muscle contraction and the subsequent relaxation due to circulatory lymphatic
changes. And to my knowledge, there are no claims specific
to pain blockage, only amelioration of pain that is a result
of muscle relaxation.

So I hope that clarifies more clearly the status
of actually the three categories of TENS.

Now, I'm somewhat confused because it appears that
we again summarily dismissed the physical therapy devices
which were alliterated by Dr. Tilley. And the reasoning was
that these devices, such as iontophoresis, have 510(k)s--

DR. GENCO: Excuse me, Doctor. We have not
dismissed them. They're going to be discussed.

DR. JANKELSON: Okay. They will be?

DR. GENCO: Oh, sure.

DR. JANKELSON: Very good. But there was this
issue of will they be considered outside the general 510(k)
classification presently or specific to either site or
disease? I think this is a very important issue. If, in
fact, we do not consider them site or disease specific, then
we must go back and revisit the issue of TENS as site or
disease specific, i.e., we must consider whether we should
be considering the TENS categories because they are site or
disease specific--something I think for the panel to
consider.

Thank you.
DR. GENCO: Thank you. I think we're discussing all of these as site specific, and, in fact, in the stimulatory device use, the suggestion was made to specifically talk about temporomandibular joint application of the TENS.

DR. HEFFEZ: I was going to suggest that maybe the TENS be separated out as a separate category, not used as stimulatory device as it prefix. I think it would work; it would be more appropriate just to call it TENS unit.

DR. GENCO: It looks like that's where we're headed. Any objection to that? Okay. So Tim has advised us that they would prefer, for many reasons, I'm sure, to split these rather than lump. So that's a generic group. It sounds like it's a complex group, and in enough complexity that we shouldn't add other things to it. Okay. Thank you. Dr. Gonzalez? Okay.

Let's proceed now to sonography devices. Anyone want to--does everybody agree that this is a generic category? How about the use, to measure and graphically display or represent sounds made by the TMJ components? Does that encapsulate the use? Yes?

DR. COOPER: I think we can also add not just measure but analyze. I think the present usage approves spectral analysis of sound coming out of the joint from some
of the devices. It may not from a stethoscope, but it does
from some of the more highly technological ones.

DR. GENCOR: It says measure and graphically
display or represent. How would you--to measure and analyze
sounds made by TMJ components?

DR. COOPER: Right.

DR. GENCOR: To measure and analyze sounds made by
the temporomandibular joint components.

DR. COOPER: Correct.

MR. ULATOWSKI: Mr. Chairman?

DR. GENCOR: Yes?

MR. ULATOWSKI: Once again, in terms of products
that are legally marketed and what they've been cleared for,
we don't want in this exercise to add uses that have not ben
through a clearance process. We're classifying things on
the market right now that have been through a clearance
process and identifying whether they're classified or
unclassified. So they may well--was the analysis a part of
labeling of a marketed device?

DR. COOPER: Let's ask the manufacturer. I don't
know.

DR. GENCOR: We need some direction here with
respect to the term "analyze."

DR. JANKELSON: I would say the representation
that analyze is not correct in our present 510(k). Recent
510(k) changes expanded the way that you can look at data,
but it would not be correct to categorize it as a change in
the analysis program.

DR. GENCO: So to graphically display or represent
sounds, to measure and graphically display or represent
sounds made by TMJ--it's a reasonable description of what
these devices do today.

DR. JANKELSON: I think the FDA representation is
quite reasonable here, yes.

DR. GENCO: So that also would account for the
future, reasonable--

DR. JANKELSON: I think so.

DR. GENCO: Okay.

MR. ULATOWSKI: Again, Mr. Chairman, if someone
wanted to add that aspect to labeling, they'd submit a
510(k) and get that in their labeling.

DR. GENCO: Okay. Fine.

Dr. Cooper, are you comfortable with that?

DR. COOPER: That's fine. I'd defer to the people
who are manufacturing. Sonography is also used as Doppler.

Now, is Doppler a separate classification of device, or is
Doppler considered a kind of sound recording? That's a two-
part question. The first is as Doppler is used to record
sound from a joint. The other is that Doppler is used to
measure blood flow in temporal arteries, for instance, which
I have seen dentists doing. So that now takes the recording
of sound away from the joint, but it's recording of the
sound just the same.

DR. GENCO: Does anybody want to comment to that?

Yes?

DR. RUNNER: If Doppler's are being used in the
TMD area, that's within the practice of medicine at this
point. We have no specific applications requesting that as
a claim on a Doppler device at this point in time.

DR. GENCO: All right. Now, this is, again, a
class II, if I remember your comments, medical device but no
dental classification; therefore, it's unclassified. The
predicate devices are unclassified, so, therefore, there's a
requirement or a need to classify for dental application or
the TMD application.

MR. ULATOWSKI: Mr. Chairman, let me rephrase
that. And, again, Dr. Betz, this 510(k) that you culled the
indications from, it was found substantially equivalent to
something.

DR. RUNNER: Those were found substantially
equivalent to pre-amendments devices--

MR. ULATOWSKI: Unclassified.
DR. RUNNER: Unclassified.

DR. GENCO: All right. Then we get right to the question of what kind—is there any unique aspect—and the intent is to be helpful to industry for the submission. Is there any unique aspect of the data that should be emphasized that you'd like to see? We can go through the whole discussion of hierarchy of evidence. I think we understand that. But are there any unique aspects of the design of testing of these devices that should be emphasized, you'd like to see expanded?

[No response.]

DR. GENCO: Okay. How about priority for classification of the sonographic devices? Does anybody have an opinion on that? Yes, Dr. Moses?

DR. MOSES: Again, I feel that having been around for such a long time, and with a tremendous safety factor, that the priority ought to be low.

DR. HEFFEZ: I would concur.

DR. GENCO: All right. Let's now go to the jaw kinesiology and pantagraphic tracing devices. Is this one generic group, in your mind? Any objection to them being in one generic group?

DR. COOPER: I think they're all one group. Just one I think is—kinesiology probably is more dynamic;
therefore, it probably relates to the electronic type of devices, the other the more mechanical type of devices. But as a big group, they measure jaw movement or position.

DR. GENCO: So the common denominator here is the measurement of jaw movement and jaw position. They vary in how they do that. But that's not an essential attribute of their safety and efficacy.

DR. COOPER: Right. You added in a word that isn't on the descriptor, and that is jaw movement and position, which is—you're accurate, so it should say jaw movement and position.

DR. GENCO: I remember my occlusion lectures. Okay. So then we get into the indication for use: to measure and graphically record (trace) jaw movement and position in three dimensions. Any comments on that? Does that adequately describe these instruments?

[No response.]

DR. GENCO: Okay. Again, are these in that same category—oh, no, these are already classified as category 1, the pantagraphics tracing devices, category 1.

DR. RUNNER: Class I.

DR. GENCO: According to your discussion this morning.

DR. RUNNER: There is a classification for a
pantagraph that is class I, yes.

DR. GENCO: All right. If the recommendation is to put all of these in one category, does that mean they're all class I, category I?

DR. RUNNER: I think we would like you to decide whether these devices fit with this classification as it is defined. If you would like me to read it, I will. The definition in the CFR does not specifically mention TMD uses. It's a more general--

DR. GENCO: Oh, I see. Dental uses rather than TMD.

DR. RUNNER: Correct.

DR. GENCO: Do you understand that? In other words--okay. This is used for construction of prostheses, for studying mandibular movement, position, but not specifically for diagnosis or treatment of TMD.

DR. BETZ: That's correct. Restorative and prosthetic versus TMD.

DR. GENCO: Okay.

DR. HEFFEZ: The information that you obtain, though, is not different than whether you would be using it for TMD reasons. It's the same information, but you can choose to apply it any way you want. So I'm not clear on whether it should have to be reclassified or relooked at.
DR. RUNNER: Correct, although the--go ahead.

MR. ULATOWSKI: Mr. Chairman, we listed jaw kinesiology and pantographic tracing devices for a particular use, and, again, you know the drill: What 510(k)s were there and how do we classify it?

DR. RUNNER: The 510(k)s that we saw had specific claims for TMD and were pre-1976 claims and were claimed to be unclass--and were unclassified as saw them in the--

MR. ULATOWSKI: Both types of devices? Both?

DR. BETZ: No. The pantagraph is a separate classification that had been approved by the Dental Products Panel under 18 872.3730, I believe, and that is a class I, I think maybe even exempt. It's either a class I or a class I exempt device. The ones related to TMJ have no predicate devices as such in dental.

DR. GENCO: Okay. So it's an appropriate topic, and industry should present data to the panel. The panel will consider that classification in due course.

DR. BETZ: For the jaw kinesiology and not the pantagraph. The pantagraph is already a done deal, if you will.

DR. GENCO: Okay. Is that clear? Yes?

DR. COOPER: It's clear, but it's not logical. If the pantagraph is approved in the fabrication of dentures
and oral reconstruction and, as Dr. Heffez said, in the
treatment of a different person who walks into the room and
the same appliance is put on to record mandibular position
to produce an orthotic appliance, it's the exact same usage.
One's a temporary occlusion; one's a durable occlusion. If
somebody does phase 2 TMJ therapy, they are going to use the
same thing to make dentures or to make reconstruction or
long-term orthoses.

My feeling is that they're all the same thing and
we're splitting hairs; and if the pantagraph has one usage
and it's the same usage, so does any kind of jaw tracking.
All you're doing is recording where's the jaw and space.
Your uses of it probably are going to be the same. The
patient complaint to you walking in the door may be
different, but if the use is the same, then the
classification should be the same. And it's quite possible
that the whole thing should be class I. It's all the same--
one may be higher technology, but it's the same--you're
doing it for the same ultimate reasons.

DR. GENCO: Yes, Susan?

DR. RUNNER: So you're saying that that should be
a subpart of the existing classification. That's one of the
questions we're asking.

DR. GENCO: Other panel members have any opinion
on this? Agreed?

DR. ALTMAN: I agree.

DR. GENCO: Okay. So the opinion of the panel is

that this should be a sub-classification. And, of course,

the rest of the other questions wouldn't be relevant, then.

Let's go on to ultrasound--

MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Yes?

MR. ULATOWSKI: I guess I'm not real clear there,

just to come back to it. The jaw kinesiology devices, we

have 510(k)s for such devices, for those claims you stated,

Bob.

DR. BETZ: That's correct.

MR. ULATOWSKI: And they have been found

equivalent to pre-1976 devices that were classified.

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

No, these things were--the jaw kinesiology devices

were not--they did not use the pantagraph as a predicate

device. Did I answer the question?

DR. RUNNER: So, in other words, they were found

equivalent to pre-1976 devices, but they were unclassified.

DR. GENCO: Therefore, they should be looked at.

MR. ULATOWSKI: Then they need to be classified.

DR. RUNNER: Correct.
MR. ULATOWSKI: The pantagrophic devices.

DR. BETZ: Pantagrophic devices are already cleared under 872.3730.

DR. GENCO: For TMD?

DR. BETZ: Not for TMD. For prosthetic and restorative. No mention of TMD that I've been able to pick up.

DR. GENCO: So neither have been cleared for TMD.

MR. ULATOWSKI: Is there a claim for TMD in labeling for pantagrophic devices?

DR. BETZ: No, not for pantagrophic devices that I'm aware of.

MR. ULATOWSKI: Well, then, how one would be classified would be to submit a 510(k) with a TMD claim and to be found substantially equivalent to a classified pantagrophic device. We're not creating uses. We're talking about existing labeling in classifications.

DR. GENCO: I guess we're going to need some help here in terms of sorting that out. Would the opinion be that if these devices were claiming to diagnose or treat TMD, that there's no classification--no prior device that's classified pre-1976, pre-predicate device for that claim?

DR. RUNNER: Correct.

DR. GENCO: Okay. For both.
DR. BETZ: Not the pantagraph.

DR. RUNNER: For the pantagraph there is a classification. For the jaw kinesiology devices, there is no classification.

DR. GENCO: Okay. Does that change your opinion?

DR. COOPER: No, but I think we probably have to go through the process of classifying it.

DR. GENCO: Okay. Dr. Tilley?

DR. TILLEY: Just a point of information. The Danar pantagraph and its reproducibility index was advertised by them to be able to be used to diagnose TMD.

DR. GENCO: I think that's what Bob has said, but not the jaw kinesiology devices.

DR. TILLEY: No. He said that it wasn't advertised and it wasn't approved for TMD, the pantagraph. And, in fact, it was advertised that way with that reproducibility index.

DR. GENCO: Maybe I misheard you. I'm sorry.

DR. RUNNER: No, I don't think you misheard us. We have no cleared any devices--the pantagraph is a separate classification for the rehabilitation, reconstructive aspects. If we saw a device that came in with a TMD claim, that would be--could be looked at under that same classification with supporting data.
MR. ULATOWSKI: Mr. Chairman, the 510(k) process being the classification process would classify that new claim for that pantagographic device, and the panel doesn't have to get involved in that.

DR. GENCO: Okay. And that's happened?

MR. ULATOWSKI: Unless there's one on the market already that has claimed--

DR. GENCO: That's what Dr. Tilley said.

MR. ULATOWSKI: Then the question, as before with the other products, is: When was it cleared? We'd have to research what it was found equivalent to, blah, blah, blah.

DR. GENCO: Okay. Good.

MR. ULATOWSKI: So we'll need information there as well to research that.

DR. GENCO: All right. So there's the possibility of reclassifying.

MR. ULATOWSKI: There's a possibility.

DR. GENCO: And also jaw kinesiology, a greater--there's a probability, a high probability of that being--

MR. ULATOWSKI: Yes, yes.

DR. GENCO: Now, what is the panel's opinion as to unique data here? Any unique features of the studies?

[No response.]

DR. GENCO: Okay. What about priority for
classification of this group?

DR. COOPER: I would say low priority.

DR. GENCO: Okay. Let's go to ultrasound, then.

DR. HEFFEZ: Can I make one point?

DR. GENCO: Yes.

DR. HEFFEZ: Maybe the category should not be jaw
kinesiology and pantagographic tracing devices, but jaw
tracking devices and then have sub-categories of each of
them. It seems it would be easier to classify them, and
then as other jaw tracking devices were developed, they
would fit easier into the system.

DR. GENCO: Any objection to that? So we're
suggesting jaw tracking devices as the name for this
category.

Further comments on this category?

[No response.]

DR. GENCO: Let's proceed, then, to ultrasound.

Before we go on, there's at least three other groups, maybe
a fourth, and that is ultrasound, thermography, imaging
devices, and then the physical therapy devices like
iontophoresis. What is our responsibility--what would you
like from us about those? Are TMJ claims being made for the
ultrasound, thermography, and imaging? It says no specific
TMJ claims. So what is our role here?
MR. ULATOWSKI: Mr. Chairman, we're trying to identify devices that are unclassified for products to use in the area defined by the panel and guests. If one has not--a manufacturer has not presented a device with a claim, then it may not be a candidate for classification. There are classified ultrasound devices which have intended uses in their classification, and within the practice of dentistry and medicine, one may well use products, as I said, however they feel fit for their patients. But that doesn't translate to a labeling claim for the product. That needs to be classified, for example, with X-ray devices where an image is taken of a particular anatomical structure, that's essentially the intended use, and we haven't cut it any other way to say you take a picture of this or a picture of that or a picture of whatever. It's imaging sites. So very general and all encompassing and would include imaging of the TMJ and any other structures, in our estimation, if one so wishes to use it for that purpose.

DR. GENCO: So we should go through each one of these as if there were claims, or there may be claims, or they're used off-label, so to speak?

MR. ULATOWSKI: Well, no. If there's no claims or no claims are revealed to us by anyone now or later, they're
really not eligible for classification.

DR. GENCO: Okay. So that takes care of those three categories. Yes?

DR. RUNNER: One of the reasons that we included those categories was to be all inclusive of all devices that could possibly be used so that the discussion was as broad as possible.

DR. GENCO: Okay. So the question to the panel is: Do you agree that these are out of the domain of the devices to be classified, from what the FDA has told us, from what your experience is, what your expertise is? Yes?

DR. COOPER: I don't think that that's what our experience is. Our experience is that some of these devices are very specifically used for TMD, and I think that the problem we're all facing with it is we don't know what's in the advertised claim in writing. The FDA doesn't necessarily know what's in the advertised claim or in the teaching of the uses of these things.

If you have a TMJ MRI, that's a specific surface coil used to image the TMJ or the middle-ear bones. That's a specific usage. And I think that the issue we'll have to all deal with, next time, probably, is whether or not we will generalize or site-specific-ize what we're doing.

Because if we're being site specific, then each of these
things has a specific usage in TMJ. If we're going to
accept that radiography is radiography whether it's a knee
or a TMJ, so is EMG, so is TENS, so is all these things.
And I won't even accept on that light level jaw tracking
because that's no different than arm tracking and all of the
other goniometers that are used.

So it's a major issue we'll all have to address as
to whether the fact that an instrument is used in our
specific area makes it a specific use, or are we being
prejudicial and it really should be thought of in its more
general sense. We'll have to visit this issue sometime
before the end of the next session.

DR. GENCO: And, similarly, for the physical
devices like iontophoresis.

MR. ULATOWSKI: Correct. Every one of them.

DR. GENCO: Okay. Yes, I think there was a
gentleman—you first, and then Dr. Jankelson.

MR. RADKE: John Radke with Biorresearch. There
are specific radiographic devices, obviously, for the
imaging of the TM joint that are used only for that
particular image. There are also or have been thermography
devices that are specifically for imaging of the side of the
face as a TMJ-type device that I'm aware of. I don't know
what the manufacturing claims are just offhand because we
don't make them, but those devices do exist, and I think
that they need to be looked at.

DR. GENCO: So the issue is the claim. Obviously,
TMJ X-ray, radiograph, would be used for many things,
including dealing with temporomandibular joint dysfunction
and associated pain.

MR. RADKE: I think most people would agree, if
they're involved in TMJ treatment, that they're going to
take an X-ray of the joint. That's a pretty--you know, as
part of your diagnostic work, you're taking a joint X-ray of
some kind.

DR. GENCO: The issue is maybe the claim that if
you don't do this--or if you do this, you are better able to
diagnose or treat. I mean, is there some implicit claim
that this is a necessary or very useful device? I guess, is
that the issue?

MR. RADKE: Well, if there's a suspected internal
derangement, then a lot of times they will, you know, even
do an MRI or something to try to image it before they get
involved in therapy to really be certain of the
appropriateness of the therapy.

DR. GENCO: Does that help you in terms of whether
or not we should deal with these in classification? I'm
asking the FDA.
MR. ULATOWSKI: Mr. Chairman, I think it's certainly appropriate, as mentioned, if there's some advertising or some pronouncements by a manufacturer or a training session by a manufacturer that alludes to a specific use condition within the realm of what we're discussing today, and I think that may produce a condition for a classification effort. But without such information, we can only conclude what we see in the 510(k)s and in the historical record when these products were classified, which is it's everything and anything with these products, with imaging, and there's no linkage in the classification history that we read, and the classification regulations, no linkage to any specific condition or use.

DR. JANKELSON: Once again, I get the amazing feeling of deja-vu, October 13, 1994. I look at your groupings, your classifications. I was at this same podium a few moments ago when we were discussing the four products that deal with Myo-Tronics and Bioresearch product line. I asked the question: Are these products subject to site or disease specificity? And I think, Mr. Chairman, it was made very, very clear, and I think you did a very excellent job in moderating this: Yes, they are.

Then we get to the rest of the categories, and
once again there seems to be a summary dismissal of the
previous statement that we must be site and disease
specific. We as clinicians know that all of these devices
have been and are being used specifically for diagnosis and
treatment of TMD, and what we are told, it is already
classified under a different category.

I think that the time has arrived that we have an
explanation for this position because it's now 5 o'clock and
I'm beginning to have the same feeling I did October 13,
1994, that we basically are back to the same four categories
that are going to be subject to the classification process,
and rightfully so.

However, we also have the appearance of a vast
category of devices that have been given, if not
differential, differential treatment. So I think that we can
expect as a panel at this time an explanation from the FDA
regarding this dichotomy.

          Thank you.

DR. GENCO: Thank you. And we certainly have
asked for that.

MR. ULATOWSKI: Mr. Chairman, can I respond?

DR. GENCO: Yes.

MR. ULATOWSKI: The major difference in terms of
these product groupings for classification purposes, as
stated up front by me and during discussion, is existing labeling and claims made for products. We're not trying to create something out of the blue, but to reflect upon current labeling and existing classifications in pre-amendment status to come to a decision whether or not certain products needs to be classified. And as I said, in terms of the three products, to our knowledge, unless comments or whatever is revealed to us otherwise, now or later, we're not aware of any specific TMJ claims for the latter three categories. But if there is some information in this regard, then we certainly would consider that and add those products to the list for consideration for classification.

DR. GENCO: Further comments to this question?

DR. HEFFEZ: So it is possible to have a device in use with application to the temporomandibular joint, et cetera, region, and the company not making a statement to that effect that it is specifically doing it for the temporomandibular joint, and, therefore, they don't have to alter their 510(k)?

MR. ULATOWSKI: A product, once cleared and legally on the market, can be used as you feel fit for your patient.

DR. HEFFEZ: So as long as they do not make a
specific statement that it is used for temporomandibular
joint--

MR. ULATOWSKI: No labeling claims, no stated
intended uses, through such vehicles as statements in
labeling, labels or labeling, advertising material,
pronouncements by sales staff that can be documented,
training, those sorts of things, we can't--we're not going
to regulate the practice of dentistry inasmuch as people use
products.

DR. HEFFEZ: So I think that's an important
statement for everybody to understand.

DR. GENCO: Yes, Dr. Moses?

DR. MOSES: I'm still--I try and hear everything
you say, and yet I can't grasp why, if these manufacturers
fill out a 510(k) saying it's equivalent to a product in
function that performs a similar function elsewhere, and now
it's doing it for the TMD, that it has to get a complete
panel review and that that classification can't be
arbitrarily applied to that product as part of this
classification system. Or is that just going to be a rubber
stamp by the panel? Why this uniqueness here, that they
file the form appropriately explaining that similarity to
the other appliance, why are we--why is this procedure
taking place over more than one day?
MR. ULATOWSKI: I think Dr. Runner perhaps wants to respond.

DR. RUNNER: I think that initially when the 510(k)s came into the agency, equivalence was claimed to the pre-amendment device with that same claim, and not specifically to the other panel classifications. They were claiming pre-amendment status as a device that had a specific TMD claim.

DR. MOSES: So it may be no more complex for these manufacturers than to refile their 510(k) equivalent--equivocating it to an appliance that's currently classified, and then be a paper procedure; is that correct?

DR. GENCO: Maybe the FDA would like to address that.

MR. ULATOWSKI: Well, they've already been subject to a process, a 510(k) process, or were already pre-1976 and, therefore, legally marketed until classified, if considered unclassified. There's always the opportunity for a reconsideration on the part of FDA of its 510(k) determination. There's a process after a determination, a process of appeal. But there is an established history for these products. There's an established history of filings by manufacturers stating their unclassified status and any subsequent "me too" device being unclassified. 510(k)s, in
our examination of 510(k)s, there have been determinations that products were not equivalent to those other products, to other classified devices for reasons that include a number of things as we go through an equivalence determination. It may have the same uses. It may have different technological characteristics, or the particular use may pose different types of questions compared to the other product legally on the market.

There are a number of questions that we're presented with that we need to answer in our evaluation, but I guess the long and short of it is, as we examine this list and these preliminary comments, I think we have every intention to look back again and research several of these issues to determine whether or not we can revisit this issue on regrouping or classification status. So I don't think it's an end-all to do all today, but we're going to look back, gathering the comments now and afterwards, now that the public and everyone has heard discussion here. We're certainly going to entertain any comments that anyone has to say about this, as we've discussed it today. But, ultimately, then we'd have to come up with a final list that we believe is appropriate for classification. But we're entertaining discussion today, and your point is well taken.

DR. GENCO: I think that if I could emphasize what
I hear the panel say is that these ultrasound, thermography, imaging devices, iontophoresis, are indeed being used for TMD, and there's a concern that they're not regulated for TMD. So I think that's a very clear statement from this panel of a concern of, as I put it, off-label use, and that's not unusual. I've read statistics where drugs are used off-label 60 percent of the time. So, I mean, it's a big concern, and I think this panel is responsible in addressing that. We're not sweeping anything under the floor. We're saying this should be addressed.

Yes?

DR. COOPER: Could I expand the discussion just because I know that we're getting to a late time? We earlier discussed psychometric testing, which is specific psychometric testing vis-a-vis TMD. Something that has never come on the floor but was mentioned in one of the presentations was occlusion evaluating devices, such as Tech Scan. For your benefit, if you don't know, you clench on something which is a pressure sensor electronic and it maps out occlusion and is used, therefore, to analyze occlusion and to design a treatment to improve occlusion.

So I would like to consider--I don't know how far we'll go today, but not only psychometric testing--occlusion evaluating devices and, finally, devices that are used for
the implementation of occlusal therapy, because that is a significant part of the clinical practice of TMD treatment. So there are devices with which you begin your treatment or help you in the treatment and whatever.

So I just--whatever we accomplish at the end of today, I just wanted to have on the table that there are a few other areas other than electrical stimulating devices that yet have to be talked about.

MR. ULATOWSKI: Mr. Chairman, I'd like to agree with that. I've already listed for my own purposes, after we go away from this discussion, the additional devices discussed today for our research and evaluation, free-standing software, iontophoretic devices and other devices that you've mentioned. But you've got to help us out here. You've got to provide information to us, if you can, so that we can determine its legal status, when it was marketed, and what it was marketed for, so that we can determine whether it's pre-1976 and the panel maybe needs to do something about it, or whether it's post-1976 and we'll have to deal with it in a different manner. So give us a little help here if you can, or anyone reading this transcript or behind you.

DR. GENCO: So the other areas you mentioned are pressure sensors for occlusal--
DR. COOPER: I would just say in general, as a general generic group, occlusal evaluating devices.

DR. GENC0: Okay. And then--

DR. COOPER: Devices for implementing occlusal therapy.

DR. GENC0: Okay. What are those? Are you talking about--are these custom devices or are these--

DR. COOPER: No, no. Off the top of my head, even things like adjustable articulators are used.

DR. GENC0: Okay. If TMJ claims are used--or if they're being used to somehow suggest to a patient that this is important for TMJ.

DR. COOPER: And this is how I'm going to treat you initially or long term or whatever.

DR. GENC0: The implication being this is a important device for your relief of pain, et cetera.

DR. COOPER: Right. And/or dysfunction.

DR. GENC0: And that's our concern. Okay.

Further comments about that issue? I think we've added four possible categories, in addition to the ultrasound, thermography, and imaging devices, so there's seven new categories--four new and three older to be looked at, all in this domain of effectively or in practice being used in the opinion of clinicians here with TMJ claims.
implicit?

DR. COOPER: Some, yes.

DR. GENCO: Or expressed?

DR. COOPER: I would say if you--

DR. GENCO: But maybe not made by the manufacturers.

DR. COOPER: In some cases, yes, made by the manufacturers.

DR. GENCO: Not in the 510(k), possibly.

DR. COOPER: We don't know that. We don't know the technical status, but we know that is--

DR. GENCO: Or maybe not in the advertising.

DR. COOPER: Correct.

DR. GENCO: Okay. So that the public is aware of this, and we are aware of this, and we need this information, as Tim said. Let's get as much of this as possible.

DR. COOPER: Right.

DR. GENCO: Good. Further comments? Yes?

DR. HEFFEZ: Just a question. If research is performed with the support of a company and the clinician then finds that the instrument can be used specifically for temporomandibular joint reasons, is that taken as a need to alter the 510(k)?
DR. GENCO: Tim, do you want to comment?

MR. ULATOWSKI: Could you restate that? I think I understand what you're getting at.

DR. HEFFEZ: If research is performed by a clinician with the support of the company and that research is geared toward applying the device toward temporomandibular joint specificity, does that mean that the company then needs to alter its 510(k)?

MR. ULATOWSKI: Well, if you want to promote and advertise the product for a new intended use, a new indication for use, you have to take stock of what you already say and whether that use falls within the cleared indications. If it is a new indication for use, you need to submit a 510(k).

DR. HEFFEZ: But it would be the clinician who would be promoting--

MR. ULATOWSKI: The clinician is doing the research to support--

DR. HEFFEZ: But he would be promoting it as well.

MR. ULATOWSKI: The clinician is promoting it?

Well, that's not the manufacturer. I'm sure clinicians say a lot of things out there about a lot of devices, but that's not promotion by a manufacturer.

DR. GENCO: So promotion by manufacturers, 510(k)
statements, labeling statements, statements by the
manufacturer's representatives, the salespersons,
representations of--

MR. ULATOWSKI: Of course, that's always tough to
get. Anything in writing--

DR. GENCO: But not what clinicians doing the
research say.

Yes?

DR. TILLEY: I just wanted to say I was surprised
at what you said, too, about the FDA not being familiar with
these. Every iontophoresis company, every high-voltage
company, everybody that makes any of this instrumentation
shows clearly in their training manuals, they teach people
in their classes to use it for TMD or for jaw and face
muscles. The other thing that really floors me is the
radiographic implications. There are units, like the
transcranial radiographic unit, that can be used for nothing
except TMD X-rays, and it went through--

DR. GENCO: We went through that. TMD X-rays are
not specifically for relief of pain. You take them for a
hundred reasons, including relief of TMD problems.

DR. TILLEY: Okay. I'm sorry.

DR. GENCO: I mean, that's a subtle point, but you
have to also understand what the FDA's role is and what
their job is.

    DR. TILLEY: I'm sorry.

    DR. GENCO: Okay. Thank you.

    DR. MOSES: I've got to go back to that. Isn't this for the diagnosis and treatment of these diseases? Our charge is diagnosis and treatment, not just treatment. The radiograph is diagnostic.

    DR. GENCO: Well, it's on the list.

    DR. MOSES: Yes, well, I don't want to see it off the list.

    MR. ULATOWSKI: Mr. Chairman, the point is in regard to what's being said out there--well, I don't want to seem like we have our head in the sand as far as what's being said out there, but sometimes the only information we get on what's being said out there is from people who supply us information. The information we have in hand is what's in 510(k)s, from meetings we attend with our limited budgets, what we can read in the press. So as I said, any help is wonderful.

    DR. GENCO: Yes?

    DR. HEFFEZ: The title that we gave to this was--could you repeat it, the title for this universe of devices?

    What is the--

    DR. GENCO: Let me go back to my notes.
Temporomandibular disorders and associated pain and/or dysfunction.

DR. HEFFEZ: So it has to be associated with pain and dysfunction?

DR. GENCO: I think this is what the panel felt.

DR. HEFFEZ: I'm just trying to address Dr. Moses' point concerning the radiographs.

DR. GENCO: Yes?

MR. JANKELSON: I'm still a little confused, and maybe some people on the panel are, too. Roland Jankelson with Myo-Tronics. I would like to address a couple of questions to Mr. Ulatowski.

Hypothetically, if Myo-Tronics were to remove in its labeling any reference to TMD, and recognizing that its instrumentation is utilized for a broad spectrum of dental activity, and that TMD is only one, and if we were to substitute in its place only claims that the instrumentation was for the purpose of tracking jaw motion, measuring joint sounds, measuring muscle electrical activity, and in the case of the TENS product for relaxing muscle, would then we have--would this particular classification process have no jurisdiction over our product? And are we, in fact, as a consequence of our simply being forthright with respect to the claim that one application of these devices manufactured
by Myo-Tronics is in the field of TMD, whereas the other
device manufacturers in this category that I believe is
being dismissed, even though Mr. Ulatowski makes it clear
that somehow in the process this whole issue will be
revisited, I think the purpose of the panel today was to
provide some clarification, not only for FDA staff but for
the manufacturers so the manufacturers have some sense of
structure with respect to going back and operating their
businesses, investing in research and development, et

cetera. And these gray areas that are going to somehow be
revisited by FDA staff at some future time I believe fall,
should fall under the purview of this panel.

I would be much more comfortable in the process
knowing that the panel was providing direction to FDA staff,
given our experience in the past, than that FDA staff was
making these determinations after this panel had disbanded
and each of you have done your separate ways.

So that was a long question, but I think the point
is obvious. Are these other device manufacturers escaping
the same classification process simply because they avoid
specifically—if they do in some cases, and I think we've
heard enough testimony to suggest that people here have
knowledge that in other cases there are specific claims made
that should clearly obligate this panel to include those
devices in the TMD category. But are they simply avoiding
the classification process by being less forthright than
perhaps Myo-Tronics and BioResearch?

That's my question, because we can solve this
problem for our two companies I think fairly easily: by
making specific claims regarding what the instrumentation
does without specifically claiming their use in the area of
TMD, because that's what we're seeing—that's the
circumstance that's been described with a whole range of
other devices. So I leave that as a question, not a
statement.

Thank you.

DR. GENCO: Yes, do you want to answer that?

MR. ULATOWSKI: Yes, I'll be happy to answer it,
perhaps with a general answer in one regard.

A product is what a product says it does, and by
that I mean a product may or may not be a device, for
example, based on its labeling. A pillow is a pillow, but a
pillow that makes a claim that it serves to support the
spine for post-op whatever makes it a medical device.

Inasmuch as people get more and more specific in
regard to labeling claims, it becomes possibly a situation
where you get into another avenue for classification
purposes. We look at the existing classification. The
manufacturer, when they submit the 510(k)s, for example, make a claim for equivalence to some product, legally marketed product, be it classified or unclassified. And we examine the labeling, the claims for the product, the candidate product, to the legally marketed device that they claim equivalence to. And we make a determination whether it's the same intended use or a different intended use.

If you make a specific indication for use that's not in the predicate, it may render the product as having a new intended use and, therefore, not equivalent.

So the answer to your question is there is a possibility that changing uses could get you into a classified situation. Intended use is defined very specifically in the regulations, so you have to be cautious in that if you say a product is generally for this or that, then you cannot by your actions as a manufacturer present it in another light, for example, present it at training sessions or make statements about it, or whatever, that go beyond what labeling says so that you create a new intended use for it by those statements. So it's not just what's in labeling. It's what you say about the product as a manufacturer.

But there's a possibility—and we have people every day with 510(k)s where we say, look, you've listed all
this stuff about your product, the wonderful things it does, but half this stuff isn't in the predicate. And if you're going to keep half this stuff, all this stuff in there, we're going to have to find you non-equivalent. Change your labeling, look at the predicate, line it up, and you're out of here. So it works that way.

There was another aspect to your question.

MR. JANKELSON: The other aspect has to do with the fact that there's many, many devices than those four that we've narrowed down today. Basically we're back to where we were in October 1994 looking at four devices that just happen to be manufactured by two companies. I'm addressing these remarks to FDA staff and not to the panel.

MR. ULATOWSKI: Okay. Well--

MR. JANKELSON: But the other half of the question, Mr. Ulatowski, was: Are you suggesting that those devices that are clearly being marketed without specific claims being put under the nose of the FDA that are clearly intended for use in this field are not subject to classification simply because the manufacturers are being less forthright than we are?

MR. ULATOWSKI: Well, I can only react per our procedures to what manufacturers state for their product by those means that I mentioned. And we will act on that
basis.

If what you say is the case—and it may well be
the case that they have used those in conditions—then you
have to provide us that information and we can act on it. I
can't act on no information.

DR. GENCO: Further comments, discussion? Yes?

DR. MOSES: Let me rephrase this perhaps another
way. If, in fact, we have all stated here—and perhaps
we've convinced the panel. Maybe we haven't. But let's
assume for a second that the panel now has a new perspective
on perhaps the safety and efficacy of these devices relative
to what the FDA had in 1994. Couldn't the burden of proof
then be—rather than to prove—to do this—wouldn't it be—
in other words, lacking substantial evidence that these
devices are substantially different or that the
temporomandibular condition or the problem for which they're
being used in this instance is substantially different from
the others, that they just go according to the equivalency?

In other words, yes, it's temporomandibular
disorder, but in lieu of substantial evidence that this
condition is substantially different than the other
conditions, there's a different burden of proof and
substantiation involved. Couldn't it be considered on that
basis?
MR. ULATOWSKI: Well, I'm not ruling out that possibility, and I think to provide some reassurance, as we examine discussion today and your position and others', as we believe we need to come back to the table for further discussion before classification proceedings, we'll do that. But I think we do need to take stock of what was mentioned here today and to get additional information to take the next step to fine-tuning the list and seeing where we stand with it. I think there's been a lot of information stated here today, and I think it's going to help clarify issues in some way. But we'll provide further information after this meeting to the public in regard to what we believe is the case with these particular devices discussed today.

DR. MOSES: I would like to thank the panel and the FDA representatives for their tolerance, for their understanding, and for their patience in listening to these issues. I thank you personally.

MR. ULATOWSKI: Well, I thank you for your input.

DR. GENCO: Further comments? Panel, FDA representatives, the audience? Yes?

DR. JANKELESON: Dr. Robert Jankelson. Once again for the record, I would like to make note that at the conclusion of this hearing, we have arrived at a disposition of four categories of instrumentation, clearly understood.
These are the same four categories that were considered in the 1994 panel. There has been no disposition in the same manner of any of the other categories. And if you would please enter that into the record, it would be much appreciated.

Thank you.

DR. GENCO: Everything that's said is in the record. That's why you give your name.

Okay. Any further comments or discussion?

[No response.]

DR. GENCO: I also would like to thank the panel and the guests and the FDA for being particularly helpful, and also those from industry. Hopefully what we've done is established some guidelines, some sense of where the experts on the panel feel the data should be, where the field is, as a continuing process in terms of classification of these devices. I don't say it's easy. It's difficult. But I feel personally we've made major progress today. Read the transcript carefully. There's a lot of good information that has come from this panel and from our guests.

Yes?

DR. COOPER: Thank you. I, too, would like to thank you all and the FDA for giving us the opportunity to participate. It is a very different panel than the last one
I spoke before. And I would also like to just agree with
Tim's last comment, that I think at least there was a
possibility there is so much unanswered at this juncture,
this may not take a day to do because everybody has become
familiar with the subject, which took a while today; but I
think that before the process finalizes to a point of
actually assigning classifications, we should try to
collectively gather all the information on all of the
question marks on seven other classes of devices, even if it
means that we all have to get together another time. But by
the time we get to classifying, we'll know everything that's
on the table, and then we just have the simple task--I hope--
of just assigning it a classification, but at least we
won't have to revisit what should be classified.

MR. ULATOWSKI: Mr. Chairman, I absolutely agree.

DR. GENCO: Okay. Thank you all. I'd like to
invite the panel back at 7:30 tomorrow morning for the
training session.

[Laughter.]

DR. GENCO: Enjoy the evening, and thank you
again.

[Whereupon, at 5:25 p.m., the meeting was
recessed, to reconvene at 7:30 a.m., Tuesday, November 4,
1997.]