

MEETING OF THE DENTAL PRODUCTS PANEL

November 3-5, 1997

OPEN SESSION

**Bethesda Holiday Inn
8120 Wisconsin Avenue
Bethesda, Maryland**

Panel Participants
November 3, 1997

Acting Chair

Dr. Robert J. Genco

Executive Secretary

Ms. Pamela Scott

Panel Members

Dr. Janine E. Janosky

Panel Consultants

Dr. Gilbert Gonzalez

Dr. Leslie Heffez

Dr. Andrea Morgan

Dr. Elizabeth Diane Rekow

Consumer Representative

Dr. Donald S. Altman

Industry Representative

Mr. Floyd Larson

Guests

Dr. Peter Bertrand

Dr. Barry Cooper

Dr. Allen Moses

FDA Participants

Dr. Robert Betz
Dental Officer
Dental Devices Branch

Ms. Angela Blackwell
Biomedical Engineer/Dental Reviewer
Dental Devices Branch

Dr. Susan Runner
Branch Chief
Dental Devices Branch

Dr. Sandra Shire
Dental Officer
Dental Devices Branch

Mr. Timothy A. Ulatowski
Division Director
Division of Dental, Infection Control, and General Hospital Devices

OPEN SESSION--NOVEMBER 3, 1997

Dr. Robert Genco, Acting Chair, opened the session at 9:05 a.m. Executive Secretary Pamela Scott introduced the panel members and read the conflict of interest statement, noting that there were no conflict of interest matters to be declared concerning the panel. She also read the appointment to acting panel chair for Dr. Genco and introduced Drs. Peter Bertrand, Barry Cooper, and Allen Moses as invited guests. Dr. Genco introduced Mr. Timothy A. Ulatowski, Director of the Division of Dental, Infection Control, and General Hospital Devices, and Dr. Susan Runner, Chief of the Dental Devices Branch.

Dr. Runner updated the panel on two developments since the last meeting in February. The Panel recommended that the mandibular condyle implants for temporary reconstruction of the mandibular condyle in patients who have undergone surgical procedures to remove malignant or benign tumors, requiring the removal of the mandibular condyle be reclassified to class II. Dr. stated that the proposed reclassification notice will be published in the Federal Register. The FDA had also signed a recent Memo of Understanding with the National Institute for Dental Research concerning collaborative activities such as trading panel members and residents and assisting with product evaluation. This memo marks one of the first such ventures; activities will begin next year.

Mr. Ulatowski updated the panel on an initiative underway in both the Dental Devices Branch and the Center for Devices and Radiological Health to identify international and domestic voluntary consensus standards to assist the FDA in evaluating products. The FDA is working with standard-based organizations to develop a list of such standards for assessment and possible acceptance. FDA acceptance of a standard means that devices certified as meeting that standard would not be required to

produce further data or information for FDA consideration regarding the particular aspect of the device that meets the standard. He noted a publication already on the Internet concerning FDA acceptance of electrical standards and predicted others as efforts continue to make the FDA a more standard-based organization.

Mr. Ulatowski introduced the first panel topic: a discussion of how to categorize devices for use in the diagnosis and/or treatment of temporomandibular joint dysfunction and oral-facial pain. He noted that the FDA was required by the 1976 Medical Devices Amendments Act to classify all medical devices into class I, II, or III, depending on the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness. The discussion was to focus on preamendments devices heretofore unclassified and to identify a comprehensive listing of generic types of devices used for temporomandibular joint dysfunction and oral-facial pain. Actual classification of each generic type would occur at a future panel meeting, during which safety and effectiveness for each type of generic device would also be evaluated.

Mr. Ulatowski explained that post-1976 new devices can enter the market through various regulatory paths. Many class I devices are exempt from the 510 (k) process, and there is a trend toward exempting all class I devices from that process. Class III devices require premarket approval applications (PMAs). New devices can also enter the market via a 510 (k) application using the claim of substantial equivalence to a legally marketed device, either one that is already classified or a pre-1976 unclassified device. If FDA review of the 510 (k) determines equivalence and the new device enters the market, a chain of equivalence can thus be established. (Those devices not deemed equivalent become class III devices subject to the PMA or product development protocol process.) Mr.

Ulatowski listed some questions that could be used to determine generic types of classifications. He also showed examples of regulatory classifications and variations in classifications even within the same device type depending on varying risk factors and intended use.

FDA PRESENTATION

Dr. Robert Betz, Dental Officer from the Dental Devices Branch, began the FDA presentation by noting disagreement in the dental literature over temporomandibular joint (TMJ) related terminology and over terms such as “myofacial” and “orofacial.” He stated that the Dental Branch considered myofacial pain to be a subset of orofacial pain. He reiterated that the focus of the meeting was on the inventory and grouping of generic types of devices used for the diagnosis and/or treatment of temporomandibular joint dysfunction and oral-facial pain. He urged the panel to let the FDA know what information or data would facilitate future device classification. Dr. Betz asked panel members to discuss the existing physical description of the device group, the indications for use in the labeling, and the function of devices for each group of generic type of device in order to produce a panel-recommended chart. The FDA would then review the chart and use it to identify devices to be classified at future panel meetings.

The Dental Branch had previously generated a draft list of generic device groups for discussion purposes, which Dr. Betz presented. He noted the intentional omission of custom intra-oral devices, which are not subject to premarket review, and listed seven device groupings: electromyography, sonography, stimulatory (including TENS), kinesiology (including pantographic tracing), ultrasound, thermography, and imaging (including radiographic, tomography, magnetic resonance, and diagnostic ultrasound). For each category he gave a device description, intended use, and indications for use as

related to the diagnosis and/or treatment of TMJ disorders and associated orofacial pain. Dr. Betz then listed questions for the panel to consider in discussing the chart.

Dr. Genco thanked Mr. Ulatowski and Dr. Betz for their presentations and opened the floor for the public hearing.

OPEN PUBLIC HEARING

There were no new requests to address the panel during the Open Public Hearing.

INDUSTRY PRESENTATIONS

Dr Genco then proceeded to the next agenda item, the industry presentations.

Mr. John Radke of Bioresearch, Inc., began the industry presentations. He stated that he had been present for the panel meeting three years previously during which the Panel had recommended classification of muscle monitoring devices as class III devices subject to PMA, despite the lack of real evidence of any public harm over the previous 20 years of use. He pointed out that small firms such as Bioresearch could not underwrite the costs involved in submitted a PMA application and that their products, if classified as class III, would be “finished” and of no help to the public or the industry. Mr. Radke described the four basic devices marketed by his company. These devices include an electromyograph, a TENS device, a device for tracking jaw movements, and a device for recording joint sounds. He noted that TMJ dysfunction is not a single, simple entity and that no single device can diagnose it on its own. He argued that devices should be classified by device type rather than the anatomical site on which they are used. For example, an electromyograph should be classified with other electromyograph devices whether the site of application is a shoulder muscle or facial muscle.

Panel comments after Mr. Radke’s remarks suggested differentiating devices within categories

on the basis of treatment versus diagnosis and on the basis of invasive versus noninvasive procedures.

Mr. Roland Jankelson of Myo-Tronics, Inc. recapped the history of this issue as it related to his firm since the 1994 panel meeting. He stated that as a result of which there was a two-year investigation by the Office of the Inspector General and hearings in the House of Representatives. The FDA had since acknowledged problems during this time, and Mr. Jankelson expressed his pleasure at seeing new faces on the 1997 panel. He noted that he had submitted four letters to the panel's Executive Secretary raising issues relevant to the day's agenda but had not yet received a reply. He suggested that the issue of a generic classification versus a finite classification was a significant question to be addressed.

Mr. Robert Jankelson, a private specialist in TMJ disorders and a stockholder in Myo-Tronics, listed four major areas of discussion specific to classification of devices used for temporomandibular joint dysfunction and orofacial pain. First, the panel must have a full understanding of the scope and complexity of the multi-etilogic TMD complex and a clear definition of it. Second, it must be aware of the political and scientific history of the two major TMD paradigms, the biomechanical and the psychosocial, both of which should be included in the pathogenic model for TMD. The panel must also understand the broad scope of diagnostic, therapeutic, and psychometric devices that must be considered for use in the diagnosis and/or treatment of TMD, of which he listed 25 types. Finally, the panel must understand the distinction between measurement devices that provide data to assist the clinician in TMD diagnosis and treatment and those that are claimed to independently make a diagnosis. Dr. Jankelson listed three criteria relevant in considering devices that aid in the diagnosis of TMD: whether the device measures a known physiologic phenomenon, whether the data measurement is

accurate, and whether the data provide additional relevant information for the diagnosis.

Dr. Kenneth Burrell of the **American Dental Association (ADA)** discussed the criteria used by the ADA's Council on Scientific Affairs to evaluate TMD diagnostic and treatment devices for possible acceptance under the ADA seal program. He defined temporomandibular disorders or TMD as encompassing a number of musculoskeletal conditions that involve one or both temporomandibular joints, the masticatory muscles, or a combination of both. He outlined product information that must be submitted such as efficacy claims, product description, design principles, packaging and instructional materials, limitations and sources of errors, precautions, contraindications, and calibration procedures. He specified what must be provided for TMD diagnostic aids, treatment devices, or both types, and stated that measurement devices are evaluated by performance standards, whereas diagnostic devices require clinical trial data. He outlined examples of safety and performance standards and assessments such as reliability and validity studies and sensitivity and specificity data for TMD diagnostic aids. Dr. Burrell reviewed the information and documentation required for TMD treatment devices as well as ADA's classification system. He discussed the criteria involved in the two required, independent, randomized clinical efficacy trials. He noted that the Association considers instruments only as aids in diagnosis of TMD and that seven devices for evaluation of TMD carry the ADA seal. The ADA Council determines a statement that accepted TMD treatment devices carry upon approval of each product, but there are no products on the ADA's list of accepted products that have been shown to be useful in the treatment of TMD.

Panel discussion after Dr. Burrell's presentation noted that the ADA standards could be considered as voluntary consensus standards for the FDA to consider adopting.

Dr. Peter Neff spoke on behalf of Dr. Terri-Ross Icyda of the **Equilibration Society**, stating that the Society's position is that the clinician, not the instrument, makes the diagnosis of TMD and determines the treatment.

Dr. Larry Tilley of the American Academy of Head, Neck, and Facial Pain spoke on behalf of the **American Alliance of TMD Organizations**, a group that he said crystallized in response to the 1994 panel hearing. He noted the divisive and emotional nature of TMD, and he outlined the chronology of events and publications concerning TMD since 1986. He underlined the need to address interobserver reliability, range of motion, quality and symmetry of jaw movements, and joint sounds through clinical studies and research. He stated that the detractors of electronic instrumentation forced dentists into making diagnoses without the benefit of instrumentation and that more studies were needed to get consensus on instrumentation regardless of classification. He commented that clinicians rather than devices determine diagnoses and he asked for a thoughtful approach and a committee of integrity.

OPEN COMMITTEE DISCUSSION

Dr. Ulatowski thanked the speakers for their comments, particularly on the need for a working definition of TMD and on the scope of products involved. He reminded the panel that the FDA exists to regulate devices, not the practice of dentistry, and that dentists can use legally marketed devices as they see fit. He also noted that some products and devices mentioned are not medical devices as defined in the classification regulations. The task of the panel was to classify devices as defined and labeled by finding the highest common denominator of devices to be regulated and selecting groups that do not differ significantly in major ways. He repeated the questions posed earlier to the panel.

Panel discussion focused first on the question of how to define the disease or disorder of TMD

or TMJ. Dr. Moses suggested considering it a subset of myogenous periarticular masticatory orofacial pain rather than psychogenic pain. Dr. Bertrand felt that it was important to look at the full extent of muscles and functions involved in the trigeminal system and that to consider TMD psychogenic was misleading because it could be neurogenic. Dr. Genco acknowledged the complexity of the diagnosis but suggested that orofacial pain and/or jaw dysfunction were the key characteristics under consideration. After discussion, the panel consensus was to consider devices used in the diagnosis and/or treatment of temporomandibular disorders and/or associated pain and/or dysfunction.

The panel then focused on what constituted a device and whether software could be considered a device. It was noted that many psychometric tests are software that attribute the TM disorder to physical or mental causes; some of the industry spokespeople present felt that such products should not be excluded from discussion. Mr. Ulatowski stated that the FDA was not excluding any product a priori but would not classify such products until they are ruled devices. Information is forthcoming on whether freestanding software constitutes a device.

The panel considered all eight questions for each proposed device grouping. It was agreed to consider **electromyograph devices** as a generic group with two main categories: (1) to measure masticatory and associated muscle electrical activity and (2) to aid through biofeedback in reducing muscle activity. All 510 (k)s in this group were unclassified or equivalent to unclassified devices except for a biofeedback physical medical device, which would be subject to classification, possibly as class II, later. Information needed prior to classification included adverse reaction reports on any product mentioned here and appropriate literature reports on clinical efficacy results relating to muscle activity measurement. The need for randomized, controlled, good quality clinical trials or at least the use of

sequential patients was noted, as was the need for reports and literature from professionals and associations relating to TMD. This category was assigned low priority.

It was agreed to limit the **stimulatory devices category** to **TENS devices**, to treat by application of electrical energy to the temporomandibular region for pain control and muscle relaxation. TENS devices would be subdivided into two subcategories of high and low frequency devices. There is one 510 (k) application for TMJ use based on substantial equivalence to an unclassified predicate device. It was noted that blinded studies will not be possible for high frequency devices. This category was assigned low priority.

The panel agreed on the category of **sonography devices** to measure and graphically display or represent sounds made by TMJ components. There are class II devices in this area but the dental predicate device was unclassified. This category was assigned low priority.

The **jaw kinesiology category** was renamed **jaw tracking devices**, with subcategories of jaw kinesiology and pantographic tracing devices, because the common denominator is measurement of jaw movement and position but the dynamics are different. The indications for use remain to measure and graphically record jaw movement in three dimensions. It was noted that there are class I or class I exempt pantographic devices for prosthetic dental uses but not specifically for TMD, and that there are unclassified pre-1976 predicate devices in kinesiology that will probably be reclassified. This category was assigned low priority.

It was noted that in the categories of **ultrasound, thermography, and imaging devices**, there are no devices with claims related to TMD or orofacial pain. Panel members debated whether devices in these areas should be classified by site or disease-specific indications and whether these categories

should be included if there are no devices with related claims in these areas. FDA representatives pointed out that once products are cleared, they can be used as practitioners see fit and that devices may be used for TMD off -label and should still be addressed

It was suggested that other categories be added such as **occlusal evaluating devices; occlusal therapy implementing devices; free standing software; and iontophoresis.**

A representative from Myo-Tronics asked hypothetically whether his company's devices could avoid reclassification by removing all references to TMD uses and whether other device manufacturers who avoid TMD claims are avoiding reclassification by being less forthright. It was suggested that if the panel has a new perspective on safety and efficacy relative to the 1994 panel, the burden of proof should be shifted to assume substantial equivalence in favor of the manufacturer. Mr. Ulatowski replied that the FDA needed to take stock of the position and have more information before any reclassification decisions were made. Mr. Jankelson of Myotronics observed that the conclusion of the panel was four categories of instrumentation, as the 1994 panel had concluded, with no disposition of any other categories. Dr. Genco replied that he hoped new guidelines had been established in regard to classification but that more information is needed before classification begins. He adjourned the meeting at 4:30 p.m.

Panel Participants
November 4, 1997

Acting Chair

Dr. Robert J. Genco

Executive Secretary

Ms. Pamela Scott

Panel Members

Dr. Janine E. Janosky

Dr. Mark D. Patters

Dr. Willie L. Stephens

Panel Consultants

Dr. John Brunski

Dr. James Drummond

Dr. Leslie Heffez

Dr. George McCarthy

Dr. Andrea Morgan

Dr. Elizabeth Diane Rekow

Consumer Representative

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Guests

Dr. Glenn Clark

Dr. Eric Furst

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OPEN SESSION--November 4, 1997

Acting Panel Chair Dr. Robert Genco opened the meeting at 8:35 a.m. and introduced Executive Secretary Pamela Scott. Ms. Scott introduced the panel members and read the conflict of interest statement for the November 4 and 5 sessions, noting that matters pertaining to Drs. Genco, Rekow, Heffez, Morgan, and Drummond had been considered but deemed to pose no conflict of interest. Waivers for Drs. Janosky and McCarthy had also been granted, allowing their full participation. Ms. Scott also read an appointment to temporary voting status for Drs. Rekow, Morgan, Drummond, and Heffez.

OPEN PUBLIC HEARING

Dr. Genco opened the floor for the open public hearing on reclassification of endosseous dental implants. There were no new requests to speak.

FDA PRESENTATION

Dr. Susan Runner, Chief of the Dental Devices Branch, gave a brief regulatory history of endosseous dental implants, which were originally recommended as class III devices in 1976 and thus classified in 1987 on the basis on insufficient evidence of safety and efficacy. Subsequently a petition was lodged for down-classification to class II, which caused a panel decision more than five years ago to classify the uncoated screw type implants in the anterior mandible as class II devices and all others as class III. Since then, as such implants have become the acceptable standard of care, the FDA is reconsidering the classification of some subgroups and asked the panel to consider the information, ask questions, and state what levels of scientific evidence are necessary to allow a reclassification of various subtypes of endosseous implants.

Dr. Angela Blackwell, a biomedical engineer in the Dental Devices Branch, presented two versions of a grid showing implant types and indications. She listed the 15 different types of implants and described their physical characteristics and discussed the six indications to be considered. She noted that not all implant types are for all indications and that some would not be addressed at the panel meeting, such as use of implants with other devices. She asked the panel to mention any specific indications that should be added for future consideration.

Dr. Blackwell listed four questions for the panel to consider in its deliberations. She noted that dental implant accessories would not be considered because the FDA is proposing to reclassify all dental implant accessories used in the mouth for less than one hour as class I exempt devices.

INDUSTRY PRESENTATIONS

Dr. Alan Balfour of **Balfour Medical Consulting** discussed the mechanical aspects of dental implants. He outlined the standards for functional and structural testing in the 510 (k) process and the questions such standards are designed to answer. He compared the mechanical properties of bone versus titanium and how standards are set by determining the normal maximum occlusal force and adding a defined safety factor. Dr. Balfour described what structural tests should be done to evaluate a new implant design, such as compressive bending, torsional loading, compressive fatigue, and bending moments, and discussed how testing standards have been developed.

Dr. Charles Babbush of the **Dental Implant Manufacturers Association** spoke on the basis of his 20 years of experience with implant reconstruction, as well as consultation with other clinicians, to strongly urge recommendation of class II status for all endosteal osseo-integrated implants: blades, cylinder, and threaded. He based his recommendation on their wide acceptance and use,

favorable risk/benefit ratio, and substantiation with life table analysis. Dr. Babbush observed that if there is a divergence in reclassification of these systems, a number of practitioners and patients will be put at risk because threaded implants cannot and will not produce acceptable levels of success in some patients. He added that one-half of the edentulous population cannot function with conventional removable prosthetic appliances and that those with severe advanced atrophy would be helpless. While recognizing the professional responsibility to protect the public, he also noted the professional responsibility to demonstrate proven efficacy and sufficient benefit/risk ratios so that such procedures can be used when other routine dental procedures are not acceptable forms of treatment.

Mr. Bill Knox and **Dr. Freimut Vizathum** of **Friatec** described their company and outlined the process that occurs after tooth extraction in which bone atrophy can lead to a cascade of pathologies. Dr. Vizathum described implant materials used by his company such as titanium and ceramics, as well as factors to be considered in the procedure such as implant surface, surgical concept, application system, and load protection. In conclusion, he recommended down-classification for endosseous implants because of the high potential benefits to a large patient population.

Dr. Gerald Marlin of **Universal Implant Systems, Inc.** asked the panel to address implant abutments from a regulatory perspective, saying that they are over-regulated with far-reaching effects on the profession, the industry, and the public. He discussed problems with the current regulatory classifications of abutments and their potential ramifications and summarized clinical and industry experience that justify reclassification on the basis of proven safety and efficacy. Dr. Marlin proposed that dental implant abutments be expeditiously classified as separate devices in class I or class II or be left alone as preamendment devices. He urged consideration be given to making these products class I

exempt on the basis of the extensive positive clinical experience of the last 14 years. In reply to panel questioning, he stated that an abutment could hypothetically cause an implant to fail, but it would be very rare.

Dr. Victor Sendax of **MDIC Management, Inc.** discussed a different approach to implants, focusing on one-stage with immediate loading implants. These are ultra-small, biocompatible titanium transitional devices or mini-implants to support a replacement bridge or prosthesis while conventional implants are being integrated. He stated that data show that these mini-implants are doing what they are supposed to do safely and effectively, and he recommended that the devices, well functioning on a limited basis, be cleared. In reply to panel questioning on whether placement and/or loss of a mini-implant could prevent a permanent implant, he replied that he had never encountered such in his experience.

Dr. Hessam Nowzari of **Sargon Dental Implants** gave an overview of the Sargon immediate load implant, which he described. He summarized clinical, histological, immunological, and microbiological features of the implant and concluded that the Sargon tooth replacement system seems to be the most advanced treatment modality available at present and that this implant constitutes a valuable treatment modality in optimizing the potential for healing.

Dr. Charles Weiss of **Oratronics, Inc.** compared the root form and blade implants, noting that if the panel chooses to reclassify root forms because they have been proven safe and effective for intended use, they should also reclassify blade forms that have produced equal and often superior data. He cited clinical trials that show good results in helping prevent the serial loss of natural teeth often associated with removable partial dentures and in being remarkably free of long-term harmful effects.

He noted that blade implants were suitable for use in 100% of patients with available bone suitable for root form implants and in 90% of those not suitable for root forms. Dr. Weiss supported reclassification for both root form and uncoated blade implants (with or without impressed interface textures) based on their record of safety, effectiveness, and quality. **Dr. Irene Hermann** of **Nobel Biocare**

discussed variables such as implant material, design, surface, patient site, prosthesis, and surgery. She discussed permanent and temporary implants made of titanium and non-titanium materials for long or short-term placement. She gave statistics on the Brandemark System Implant and its success rates for various indications and techniques. She recommended down-classification to class II for all screw-shaped temporary and zygomatic implants, based on their promising patient benefits. Dr. Hermann noted a special training program for implant placement, saying such could be a special condition for reclassification.

Mr. Mike Keehoe of **Innova Corporation** described the company's Endopore Dental Implant System and gave its clinical history. **Dr. Pilliar** described the geometry of its system design, noting its porous and textured metal surface. **Dr. Paul Armstrong** gave clinical results from various studies and summarized reported cumulative success rates to support reclassification to class II based on the shape, material, size, surgical technique, clinical experience and reasonable assurance of safety and effectiveness. He strongly recommended that coated cylinder porous metallic implants be reclassified to class II. In reply to panel questioning, he did not specify a classification for abutments.

Mr. Kermit Stott of **Sulzer/Calcitek** urged that endosseous HA coated cylinders and screws be reclassified as class II, noting that special controls can help ensure safety and efficacy of class II devices. He thought the design features were well known and safety and efficacy demonstrated

sufficiently to warrant such reclassification. **Dr. Bill Wagner** noted that the manufacturing technique can help determine the quality of HA coating, and that the coated hip implants that are classified as class II use the same coating as dental implants. He recommended at least three special controls on the HA coating content and characteristics for class II categorization and suggested that other HA coatings be classified as class III. In reply to panel questioning on when failures occur, he said those that happen generally occur within the first year.

Dr. Don Kennard of **Steri-Oss, Inc.** cited the extensive history of safety and efficacy of endosseous dental implants and said that manufacturers need additional time to provide data arguing for fewer controls. He suggested that the panel review ongoing studies since its 1991 meeting, including the American Dental Association acceptance of various types. He encouraged the FDA to allow time for manufacturers to submit the same data as that presented to the ADA in the reclassification consideration and suggested that the recommendations be as broad as possible. In reply to panel questions on abutments as a separate subcategory, he suggested that material type and application be considered and that abutments be given separate consideration but perhaps not separate classification.

Mr. Bill Ryan and **Dr. David Cochran** of **Straumann USA** described the company's ITI Dental Implant System. They described their products' features and ITI implant types, as well as the surface characteristics. They provided in vitro testing results, fracture rate analysis, scientific support, peer reviewed studies, and clinical results for the ITI dental implant system and concluded that it has a consistently high success rate over all anatomical locations, that the safe and effective use of the ITI hollow and solid titanium plasma sprayed implants has been confirmed by scientific literature, and that the FDA has sufficient general and special controls to provide reasonable assurance of safety and

efficacy. They recommended on the basis of clinical and nonclinical results of their implant system that uncoated and titanium plasma sprayed root form titanium dental implants be reclassified as class II devices. In reply to panel questioning, they acknowledged differences between the nonsubmerged and submerged dental implants but thought them not different enough to require separate classification. They also argued against subcategorizing solid cylinders from solid screws and against using labeling restrictions based on anatomical location.

Dr. Richard Caudill of **Implant Innovations, Inc.**, reported clinical data from ongoing PMA trials on his company's threaded cylinder implants. After reviewing statistics and demographics from the multicenter, multisite trial and listing implantation criteria, he summarized safety and efficacy results, saying that no medical events indicate biocompatibility problems and that there is adequate indication of success in all locations. He suggested that anatomical location restrictions be made on the merit of the individual device and that the panel should require adequate research data for future implant systems. In response to panel questioning, he noted that all of his company's implants are solid implants.

Dr. Kenneth Burrell of the **American Dental Association (ADA)** invited the panel to use the ADA's Acceptance Guidelines on Endosseous Implants. He listed in detail what the ADA required for product information, quality controls on manufacturing processes, details on physical properties, and proof of safety and efficacy through data from two independent prospective clinical studies. He stated that major ADA concern centered on the design of clinical trials and the specificity of clinical data. Instead of using various categories and subgroups, the ADA chose to define the study population so that the subjects would have implants in less favorable locations; thus, clinical success could be extrapolated to more favorable locations. He discussed the model for the clinical studies, evaluation

techniques and standards, and criteria. Manufacturers must describe restorative components used, but acceptance is issued only to implant and placement technique. Companies can petition for acceptance of similar product types, but significantly different implants must have separate clinical trials. Recognition of national and international materials standards for dental implants would lessen the need for clinical trials, but until such recognition each implant system must be evaluated separately to ensure safety and efficacy. In reply to panel questioning, Dr. Burrell said that some 20% of the 20 million totally edentulous patients in the United States have lost so much bone they cannot be served by dental implants.

OPEN COMMITTEE DISCUSSION

In discussing the categories or groups of devices, the panel first suggested dividing endosseous implants into root form and blade subgroupings, with root forms further subdivided into porous for biological fixations, other coatings, and noncoated types, and blade form divided into coated (porous and nonporous) and noncoated types. Dr. Runner suggested that another perspective would be to look at types of implants and indications and decide what degree of regulatory control is necessary, pulling out any other categories needing other degrees of control. From that perspective, the panel suggested four subcategories with clear differences for indications: root form, blade, special retention features, and temporary.

The panel recommended that the FDA should not continue to consider implant location in the oral cavity as a component of the device's indication for use.

The panel recommended that the FDA should classify abutments separately from the implant fixture because of practical concerns such as the number of combinations and the different array of

problems. There was disagreement from the manufacturing representatives present about whether abutments should or should not be used with implants produced by other companies.

The panel asked for additional information before the next panel meeting on the rationale and justification data for special indications or uses like bone ingrowth or healing. Panel members also wanted more data on when failures occur and what kinds of failure occur at particular stages. Life table analyses and safety and efficacy data were requested on the four subgroups, as well as a comparison of coated versus uncoated implants and a study of ceramic versus metal implants.

Executive Secretary Pamela Scott noted that the next panel dates would be January 12, 13 and possibly 14, 1998.

OPEN PUBLIC HEARING

Dr. Genco opened the session on classification of intra-oral appliances for the treatment of obstructive sleep apnea and snoring by introducing the invited guests, Drs. Barry Hendler, Eric Furst, and Glen Clark. He opened the floor for presentations by professional organizations.

Dr. Martin Scharf of the **Tri-State Sleep Disorder Center** stated that snoring is not the same as sleep apnea, but that snoring is still a problem in that the sleep of snorers requires greater effort and is not as refreshing as regular sleep. He noted problems with many of the medically approved cures for snoring and commented on the number of commercially available devices for snoring. He reported some success his patients had experienced using a commercial device called SnoreBan but also some reports of side effects and associated problems. He asked for clinical data on the device. FDA representatives noted that SnoreBan is an illegally marketed device subject to seizure.

Dr. Sandra Shire, Dental Officer of the FDA Dental Devices Branch, noted that this

category of products is designed to treat snoring and mild-to-moderate obstructive sleep apnea by increasing the amount of space in the patient's airway, thereby decreasing air turbulence. She noted that apnea may occur in 35% of snorers. This group of products includes mandibular repositioners, tongue retaining devices, and palatal lifting devices, all of which are currently unclassified. Prescription labeling is required for all intra-oral devices in this category. FDA review of these appliances is required prior to marketing; during this review, the FDA examines the extent of claims. The Agency has recommended that products that claim to treat obstructive sleep apnea include clinical data demonstrating effectiveness. She asked the panel to consider whether prescription labeling is appropriate and what labeling considerations should apply if over-the-counter use is deemed appropriate, and she read questions for the panel to consider.

Dr. Charles Berman spoke on behalf of **Dr. Hillerson**, a maker of anti-snoring devices. He suggested that snoring devices be down-classified to class I and labeled only for anti-snoring use. He thought the panel should view this as a decision of conscience, to make it easy for makers to bring devices for snoring relief to the market and to make it easy for snorers to obtain relief.

Dr. Daniel Loube of the **American Sleep Disorders Association (ASDA)** spoke about the medical sequelae of obstructive sleep apnea, which include hypertension, coronary artery disease, hyperglycemia, and stroke. He discussed the treatment options and responses of patients with various respiratory distress indexes (RDIs) and the practice parameters for using oral appliances for snoring and sleep apnea. He noted that the use of oral appliances is not perfected for sleep apnea and that side effects such as gagging, salivation, or TMJ symptoms occur in as much as 25% of all users. He recommended that use of oral appliances be considered with respect, that dentists and doctors should

be involved in the decision, and that subjective responses and analyses are inadequate.

The open meeting was adjourned for the day at 4:40 p.m.

Panel Participants
November 5, 1997

Acting Chair

Dr. Robert J. Genco

Executive Secretary

Ms. Pamela Scott

Panel Members

Dr. Janine E. Janosky

Dr. Mark D. Patters

Dr. Willie L. Stephens

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FDA Participants

Dr. Robert Betz
Dental Officer
Dental Devices Branch

Ms. Angela Blackwell
Biomedical Engineer/Dental Reviewer
Dental Devices Branch

Dr. Susan Runner
Branch Chief
Dental Devices Branch

Dr. Sandra Shire
Dental Officer
Dental Devices Branch

Mr. Timothy A. Ulatowski
Division Director
Division of Dental, Infection Control, and General Hospital Devices

OPEN SESSION--November 5, 1997

Acting Panel Chair Dr. Genco opened the meeting at 8:10 a.m. Executive Secretary Pamela Scott reiterated the conflict of interest statement from the preceding day's session.

FDA PRESENTATION

Dr. Sandy Shire, Dental Officer in the Dental Devices Branch, gave an overview of the issue of classifying intra-oral appliances for the treatment of obstructive sleep apnea and snoring. She noted that snoring is a social and medical problem and that 35% of snorers have sleep apnea. Almost all patients with obstructive sleep apnea snore unless they have had surgery. Apnea that lasts more than 10 seconds or occurs more than seven to ten times per hour is considered pathological. She noted that there are surgical and medical approaches to treatment of snoring and that intra-oral devices are reviewed under the 510 (k) and PMA processes, depending upon the extent of claims. One question for panel consideration was whether these devices should continue to be sold by prescription only or should be made available for over-the-counter (OTC) use. She reported three main types of devices cleared for the market: the tongue retaining devices that increase airway patency, the palatal lifting devices that lift the soft palate, and the mandibular repositioning devices that move the mandible forward. Dangers or side effects include musculoskeletal problems with the mandible and TMJ complications. She noted that 25-50% of snorers have at least some measure of apnea and 99% of those with apnea also snore, unless they have had surgery to correct it. Some snorers have upper airway resistance syndrome, in which they do not sleep well but they do not have apnea.

Executive Secretary Pamela Scott introduced the panel and guests Drs. Glenn Clark, Eric Furst, and Barry Hendler.

Guest speaker **Dr. Barry Hendler** of the **University of Pennsylvania Medical Center** opened his presentation by noting two issues: primary snoring and obstructive sleep apnea. He remarked that people who snore can be relatively healthy but those with obstructive sleep apnea have complications and a potentially life-threatening disease. Mild sleep apnea is defined as a respiratory distress index (RDI) of less than 20; moderate as an RDI of 20 to 40, and severe as an RDI of 40 or more, showing oxygen desaturation in varying degrees. He reviewed the practice parameters presented by the American Sleep Disorders Association and the American Board of Sleep Medicine clinical guidelines, emphasizing that while the objective of treating snoring without apnea is just to eliminate snoring, for obstructive sleep apnea the objective is to resolve the symptoms and normalize the apnea and oxygen saturation. Moderate to severe OSA should be treated with a trial of continuous positive airway pressure (CPAP), which can cure most moderate apnea, but patients often refuse to comply with the treatment. Oral appliances are recommended for those with mild to moderate apnea who refuse CPAP; surgery is also successful. The side effects of oral appliances, however, make it important for the fitting to be done by professionals. He noted the lack of randomized clinical studies on sleep appliances and warned that the mere removal of snoring has the potential for danger for those with undiagnosed sleep apnea.

Dr. Dennis Bailey spoke on behalf of the **Sleep Disorders Dental Society (SDDS)**, saying that SDDS feels strongly that they should work together with the ADA on the issue of oral appliances. He outlined the architecture of NREM and REM sleep, noting that delta slow wave sleep during NREM, which is lost during sleep apnea, is critical to health. He said that apnea is a medical, not a dental disorder, with clinical signs and physiologic sequelae. He noted the variability of effectiveness of oral

appliances and CPAP and reviewed the ASDA clinical guidelines for treatment. He discussed the types of appliances, showed pictures, and explained how they function. He concluded that oral appliances are effective, based on changes in patients' apnea index and RDI. They are more effective for snoring than for apnea, which they do not eliminate but they do improve. He discussed contraindications such as central sleep apnea, TMJ disorder, inadequate dental status, and lack of motivation, and he listed possible side effects, such as excessive salivation, dry mouth, soft tissue irritation, or TMJ discomfort. He noted the importance of dentists working with doctors to ascertain those patients with optimal outcomes. The mission of SDDS is to develop a certification process for dentists using and making these appliances. He noted that soft palate lifters are no longer considered effective and suggested splitting the temporomandibular appliances into fixed, mobile, and adjustable.

Dr. Steven Burton and **Mr. Robert Hezlep** of **EPM Systems** stated that snoring and apnea are related but separate problems. They are producers of an FDA-accepted device for snoring. They noted that the vast majority of snorers just snore, and that restricting avenues for relief affects some 50 million people. They stated that snoring is improved and often eliminated in almost all patients who use oral appliances, which are the first-line therapy for primary snoring from the ASDA position. Mr. Hezlep stated that snoring alone does not have high enough diagnostic accuracy to serve as a useful screening test for apnea. They proposed a classification of class II devices for apnea and class I over-the-counter devices for snoring or class II custom-made devices for snoring. They suggested that patients should be cautioned about danger signs such as excessive daytime sleepiness, episodes of holding breath during sleep, high blood pressure, stroke, dentures, and history of TMJ or jaw pain and should be advised to consult their doctor about using the device.. Symptoms suggesting the need for

medical care would include excessive daytime sleeping, waking one's self from a snore, sweating while sleeping, and morning headaches. They suggested a continuum of problems that ranged from no snoring, to periodic snoring affecting 28 million, to chronic snoring affecting 35 million, to upper airway resistance syndrome, to mild sleep apnea affecting 5 million, to moderate or severe sleep apnea affecting 10 million, to hypoventilation.

In response to panel questions, Dr. Shire of the FDA replied that the FDA could make a regulatory suggestion such as class II with OTC or prescription distribution so that the Agency could review the labeling. A video and or education pamphlet and money back guarantee were also suggested. It was also noted in reply to panel questions that sleep apnea is very rare in children but snoring is not.

Mr. Gary Meade and **Mr. Stephen Brown** of **DISTAR, Inc.**, discussed the Snore Guard and TheraSnore oral appliances made by Mr. Brown's father. These are adjustable prefabricated mandibular positioning devices. Their experience has been that this device is safe and effective in the treatment of snoring with only minor side effects and that such devices do not require special controls. They recommended a classification of class I for OTC or at most class II OTC use to permit Agency review of device labeling.

There was some concern expressed by the panel about the potential for lower anterior flaring with long-term use of oral devices.

Mr. Bob Lezia of **Great Lakes Orthodontics** spoke about his company's experience with the ClearWay device. He suggested that the three types of oral appliances be kept separate, and he noted that mandibular repositioning devices differ among themselves. He recommended that each

appliance supply studies to show results, and he thought OTC availability could be dangerous. He suggested TMJ, periodontia and edentulism be contraindications for use and suggested randomized clinical trials of two groups with pre-use and post-use polysomnographs, a quality of life assessment questionnaire, and compliance data. He cited study results on the ClearWay device, noting that these appliances are FDA approved and custom-made from a mold but manufactured en masse.

In discussing the questions presented by the FDA, the panel suggested three subclasses of oral appliances: mandibular repositioners, tongue retaining devices, and palatal lifters. They had significant concern about designs not permitting oral breathing and recommended that design features should include adequate space for oral breathing and should prevent incisor flaring in those under orthodontic care. Recommended warnings included not using the device (1) in patients with edentulism, (2) with removable dentures, (3) in patients with periodontal disease, (4) with loose teeth or tooth mobility, (5) in growing or not fully grown individuals, (6) with previous TMJ disease or discomfort, such as jaw clicking, crepitation, tooth pain or jaw pain, (7) in patients under orthodontic care, and (8) if there are signs of incisor or periodontal flaring. Use should be discontinued if pain develops in the jaw muscles.

The panel considered discussing prescription use versus over-the-counter use strictly for snoring claims. **Dan Loube** of the **ASDA** objected to splitting the indications, saying that snoring should be treated as a medical problem and that all treatments for snoring are applied for sleep apnea and patients cannot assess the outcome. The panel decided to discuss the devices for prescription use only.

The panel then filled out the general device classification questionnaire for the generic group of removable intra-oral devices for the treatment of snoring and obstructive sleep apnea. The panel agreed that the devices were not life-sustaining or supporting. After some discussion and clarification, they

agreed that the devices are not of substantial importance in preventive impairment of human health and that they do not present a potential unreasonable risk of illness or injury. They felt that general controls were not sufficient to provide reasonable assurance of safety and effectiveness and that special controls were required. They agreed there was sufficient information to establish special controls, which included testing guidelines and the specific warnings listed above. They restricted sale, distribution, or use to prescription use only. As supplemental data, they identified the following risks to health: sore teeth and gums, TMD pain and dysfunction syndrome, flaring of the lower anteriors, and obstruction of breathing. As specific hazards to health, they identified painful gingival sores and long-term orthodontic effects such as generalized tooth loosening from the pressure induced by the device; TMD from poor adjustment and the orthopedic effect; oral obstruction from the lack of airspace, and interference with normal orthopedic development from the rigidity of the appliance. The panel recommended class II classification on the basis of presentations to the panel by industry and professional associations, of information received, of clinical experience, and judgment. The appropriate materials standards should be applied to the devices.

It was clarified that a reclassification petition would be required to obtain over-the-counter availability for the devices. Pamela Scott announced that the voting members of the panel were Drs. Rekow, Morgan, Drummond, and Heffez. A motion was made and seconded to classify the devices as class II. It was unanimously approved.

The panel asked to see studies on snoring that would present randomized, controlled trials comparing devices or at least blind scoring of the data. Snoring should be measured by microphone and oximetry and by sleepiness questionnaires. The panel recognized that the FDA is not the National

Institutes of Health and that some studies are already done, but members would like clinical data on snoring and obstructive sleep apnea showing reasonable outcomes, power calculations, and reasonable controls.

The panel was asked to comment on the possibility of OTC use for snoring indications only. Some panel members thought it reasonable to consider OTC use for snoring if devices were properly labeled and presented with sufficient studies. Other members remained concerned about masking cases of apnea. Still others had concerns but felt the matter should be looked into with more information available, such as long-term data on tooth movement over time. They also suggested adding patient educational methods such as a phone-in information line as backup.

Dr. Genco thanked the FDA staff and panel members, as well as invited guests and adjourned the panel at 1:00 p.m. On behalf of the FDA, Pamela Scott thanked Dr. Genco for serving as acting chair.

I certify that I attended the Open Session of the Dental Products Panel Meeting on November 3-5, 1997, and that this summary accurately reflects what transpired.

Pamela Scott
Executive Secretary

I approve the minutes of the meeting as recorded in this summary.

Robert J. Genco, M.D.
Acting Chair

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