SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

ORTHOPAEDIC AND REHABILITATION DEVICES PANEL

September 8, 2020

Via Teleconference

Attendees:

Chairperson

Harvey E. Smith, M.D.
University of Pennsylvania School of Medicine
Philadelphia, PA

Voting Members

Maureen A. Finnegan, M.D.
University of Texas Southwestern Medical Center
Dallas, TX

Lynda J-S Yang, M.D., Ph.D.
University of Michigan
Ann Arbor, MI

Jeremy L. Gilbert, Ph.D.
Clemson University
Charleston, SC

Temporary Non-Voting Members

Carl N. Graf, M.D.
Illinois Spine Institute
Crystal Lake, IL

Karla V. Ballman, Ph.D.
Weill Cornell Medical College
New York, NY

Dirk H. Alander, M.D.
Geisinger Health System
Danville, PA

Benjamin Elder, M.D., Ph.D.
Mayo Clinic College of Medicine and Science
Rochester, MN

Glenn B. Pfeffer, M.D.
Cedars-Sinai Medical Center
Los Angeles, CA

Edward Ebramzadeh Abrams, Ph.D.
UCLA Orthopaedic Institute for Children
Los Angeles, CA

Colonel Patrick M. Osborn, M.D.
San Antonio Military Health System
Fort Sam Houston, TX

Industry Representative

Stacey Bonnell, M.B.A., RAC
DePuy Synthes
West Chester, PA

Patient Representative

Joseph P. O'Brien, M.B.A.
National Scoliosis Foundation
Stoughton, MA

Consumer Representative

Amy Price, D.Phil.
Stanford University
Stanford, CA

Food and Drug Administration

James Swink
Designated Federal Officer

Captain Raquel Peat, Ph.D., M.P.H., USPHS
Director, OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality

CALL TO ORDER

Panel Chairperson Harvey E. Smith, M.D., called the meeting to order at 8:00 a.m. He introduced Captain Raquel Peat, Director of OHT6, who gave introductory remarks. He then noted the presence of a quorum and affirmed that the Panel members had received training in FDA device law and regulations.

He announced that the Panel would be discussing and making recommendations regarding classification of facet screw systems in Session 1 and reclassification of noninvasive bone growth stimulators in Session 2.

PANEL INTRODUCTIONS

Chairperson Smith then asked the Panel members and the FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT AND GENERAL ANNOUNCEMENTS

James P. Swink, Designated Federal Officer, read the Conflict of Interest Statement and reported that no conflict of interest waivers had been issued.

He introduced Stacey Bonnell as the Industry Representative and made general announcements regarding speaker identification and transcripts.

OPEN PUBLIC HEARING

Mr. Swink read the Open Public Hearing Disclosure Process Statement, and **Chairperson Smith** introduced the speakers.

Meg Seymour, Ph.D., spoke on behalf of the National Center for Health Research. She emphasized the need for more scientific evidence regarding medical devices and expressed concern that the panel had not been given sufficient information for making decisions regarding device classification. She also stressed the need for clear, concise labeling information and the importance of providing patients with adequate input for informed consent.

William C. Welch, M.D., spoke on behalf of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons. He stated that the AANS/CNS supports the reclassification of facet screws. He noted that there are decades of published information regarding their use and that clinical results have confirmed their safety, effectiveness, and cost efficiency.

CLASSIFICATION AND RECLASSIFICATION OVERVIEW

Constance Soves, Ph.D., outlined the meeting's objectives. She gave an overview of device classes and classification requirements and specified what the Panel's input and recommendations should include. She then explained what preamendment and unclassified devices are and reviewed the classification process. She also apprised the Panel of further

steps that will be taken after the meeting, noting that all available evidence will be considered before a final rule is issued.

FDA PRESENTATION

Classification of Facet Screw Spinal Device Systems Under Product Code "MRW"

Caroline Moazzam, M.D., provided a device description, outlined the indications for use, and summarized the regulatory history and clinical background of facet screws. She reported findings from a literature review, noting that the adverse events are similar to those of other Class II spinal instrumentation systems and that the clinical evidence supports a reasonable assurance of safety and effectiveness.

She then discussed the uses and limitations of medical device reports. She informed the Panel that the Medical Device Recalls and MAUDE databases were reviewed for additional information regarding risk identification and noted that no new safety concerns have been raised.

Brittany Ferrell, B.S., discussed associated risks and methods of mitigation and gave an overview of the proposed classification and special controls.

Q&A

Maureen A. Finnegan, M.D., asked in what category standard cannulated screws are. She also asked if mechanical studies have been done on the pull load and if extra stabilization is needed. **Dr. Moazzam** replied that she is not aware of any studies that address that particular question. **Ms. Ferrell** informed her that trauma screws have Class II classification.

Lynda J-S Yang, M.D., Ph.D., asked if there is a percentage of neurological injuries or cerebrospinal fluid leaks that contribute to intraspinal nerve root damage. **Dr. Moazzam** replied that the databases do not contain that information.

Edward Ebramzadeh Abrams, Ph.D., remarked that surface texture is an important factor and should be considered.

Dirk H. Alander, M.D., asked if studies were reviewed that regard these devices as an adjunct to fusion. **Dr. Moazzam** informed him that studies analyzed in this context showed similar performance to pedicle screws.

Jeremy L. Gilbert, Ph.D., stated that corrosion is one of the mechanisms that should be considered with respect to allergy and toxicity issues. He asked for clarification regarding the meaning of the biocompatibility statement.

Joseph P. O'Brien, M.B.A., Patient Representative, asked how many of the neurological deficits were attributed to improper use or positioning. He also asked if labeling by itself without the inclusion of device training and navigation systems is adequate for patients. **Dr. Moazzam** replied that the databases do not provide that level of detail with respect to patient-specific outcomes.

Amy Price, D.Phil., Consumer Representative, asked if patient-specific outcomes could be made part of the mitigation strategies. She also asked if the functional status is determined mechanically and if there is available evidence. **Dr. Moazzam** affirmed that all

the available literature has been reviewed and that the databases do not provide specific patient identifiers due to privacy issues. She added that there are no specific studies that focus on patient-reported outcomes other than what was included in the literature review presented.

PANEL DELIBERATIONS AND FDA QUESTIONS

Chairperson Smith read Question 1: FDA has identified the following risks to health for facet screw spinal device systems:

- Loosening or migration
- Tissue injury
- Adverse tissue reactions
- Use error or improper device use
- Pseudarthrosis
- Adverse clinical sequelae

Please comment on whether you agree with inclusion of all the risks in the overall risk assessment of the facet screw spinal device systems under product code "MRW." In addition, please comment on whether you believe that any additional risks should be included in the overall risk assessment of these facet screw spinal device systems.

Dr. Alander emphasized the importance of ensuring that the principles of fusion do not get lost when utilizing the device.

Dr. Finnegan commented that the list is appropriate and suggested consideration of patient-specific outcomes.

Dr. Yang suggested a separate category for neurological injury.

Dr. Ebramdazeh stated that bone fracture should be specifically noted.

Benjamin Elder, M.D., Ph.D., recommended the inclusion of inadequate biomechanical fixation as a specific risk.

Chairperson Smith read Question 2: Please discuss whether the identified special controls appropriately mitigate the identified risks to health and whether additional or different special controls are recommended.

Proposed Special Controls

1. Design characteristics of the device, including engineering schematics, must ensure that the geometry and material composition are consistent with the intended use.
2. Non-clinical performance testing must demonstrate the mechanical function and durability of the implant.
3. Device must be demonstrated to be biocompatible.
4. Validation testing must demonstrate the cleanliness and sterility of, or the ability to clean and sterilize, the device components and device-specific instruments.
5. Labeling must bear all information required for the safe and effective use of the

device, specifically including the following:

- Clear description of the technological features of the device, including identification of device materials and the principles of device operation;
- Intended use and indications for use, including levels of fixation;
- Identification of magnetic resonance (MR) compatibility status;
- Cleaning and sterilization instructions for devices and instruments that are provided non-sterile to the end user; and
- Detailed instructions on each surgical step, including device removal.

Dr. Finnegan observed that there is no mention of the possible need for additional stability in the first two points regarding design characteristics and non-clinical performance.

Dr. Alander opined that compression alone is not going to guarantee a fusion.

Dr. Gilbert remarked that biocompatibility does not mean the same thing to everybody, and its meaning in this context is unclear. **Captain Raquel Peat, Ph.D., M.P.H., USPHS,** replied that there are a number of detailed standards and guidance documents on biocompatibility and that these specific areas are looked at for all cleared or approved devices.

Stacey Bonnell, M.B.A., RAC, Industry Representative, commented that the controls are appropriate and consistent with other Class II systems.

Dr. Price stated that she is concerned about making a decision on predicates and biocompatibility without having direct evidence.

Ms. Bonnell pointed out that substantial equivalence to biocompatibility would not be a precursor within the premarket notification, unlike validating similarities to the intended use and technological parameters of a predicate device.

Chairperson Smith summarized the Panel's response:

- There is concern regarding the aspects of these devices as adjuncts.
- There is a need for a fusion technique and principles.
- Patient-reported outcomes should be included in risk assessment.
- Neurological deficit, implant failure and/or fracture, and bone fracture should be listed as separate categories.
- Biocompatibility should be designated as a separate risk factor or complication.
- There is concern regarding the assumption of biocompatibility from previously approved devices.

Chairperson Smith read Question 3: Please discuss whether you agree with FDA's proposed classification of Class II with special controls for facet screw spinal devices. If you do not agree with FDA's proposed classification, please provide your rationale for recommending a different classification.

The Panel members agreed unanimously on Class II classification.

FDA PRESENTATION

Proposed Reclassification of Noninvasive Bone Growth Stimulators

Shumaya Ali, M.P.H., informed the Panel that FDA is proposing to reclassify noninvasive bone growth stimulators from Class III to Class II. She gave a device description, reviewed the intended use and indications for use, and explained the rationale for the proposed reclassification. She advised the Panel that FDA believes there is sufficient information to establish special controls that can, along with general controls, provide a reasonable assurance of safety and effectiveness.

Philip Belmont, M.D., discussed the regulatory history. He reviewed clinical data from three prior premarket application Summary of Safety and Effectiveness Documents, noting that noninvasive bone growth stimulators demonstrated a clinical benefit and that adverse event rates were low.

Jesse Muir, Ph.D., gave an overview of available postmarket data. He disclosed that no significant safety concerns were found during the literature review and that the rate of reported events is low. He recapped the regulatory history, summarized safety and effectiveness data, and provided information on health risks and methods of mitigation. He then briefed the Panel on proposed special controls and highlighted FDA's comments. He indicated that FDA has recommended the inclusion of clinical and nonclinical performance testing, software testing, and labeling as mitigation methods in the special controls.

Q&A

In response to questions posed by Dr. Yang, **Dr. Belmont** informed the Panel that there was no statistical difference with respect to radiographic fusion at 12 months for the CervicalStim device.

He also clarified that the reviewers used clinical judgment rather than actual clinical surveys in their assessment of the SpinalPak and SpinaLogic devices.

Dr. Finnegan asked if patients put the electrodes on themselves. **Dr. Muir** replied that the patients treat themselves at home and would be applying the electrodes on their own.

Dr. Belmont also specified that radiographs were used in the spinal fusion studies.

Glenn Pfeffer, M.D., asked if the same rigor of academic work that is needed for prospective randomized studies will be done for Class II devices. **Dr. Muir** replied that the same level of data is expected to demonstrate efficacy. He explained that all U.S. clinical studies require IDE submissions, which are reviewed with the same rigor regardless of the marketing pathway. He added that clinical evidence with respect to efficacy would be required, especially in the case of new technologies.

Dr. Gilbert asked if a postmarket surveillance study could be a potential mitigation method. **Dr. Muir** replied that it could be. He specified that postmarket data is considered when there are uncertainties or questions that cannot be answered in clinical trials.

Dr. Alander commented that his primary concern is ensuring that efficacy will be upheld to the fullest extent if the devices are downgraded to Class II.

Chairperson Smith asked for opinions on how a fusion should be defined. He

queried whether there would be higher standards for new devices as a result of those definitions or if the same standards would still apply.

Dr. Alander remarked that it would have been helpful to have CT scans in the studies.

Dr. Muir acknowledged that the difficulty of assessing fusion rates is an ongoing, evolving process. He pointed out that most of the studies under discussion are older and that they did provide clean radiographs. He added that IDEs under the current standards would most likely have CT data, and assessments would be made using the most modern techniques.

OPEN PUBLIC HEARING

Charles Sansur, M.D., spoke on behalf of the AANS/CNS. He gave an overview of the three main types of bone growth stimulators. He related that neither he nor his patients have encountered any major complications with the external devices. He also noted that potential complications with the internal devices are fairly minimal, that he has found implementation to be straightforward and safe, and that removal of the generators is very easy. He affirmed that AANS supports the reclassification of these devices to Class II.

Robert Muratore, Ph.D., spoke on behalf of Acoustic Sciences Associates in support of the proposed reclassification of LIPUS noninvasive bone growth stimulators as Class II devices. He pointed out that low-intensity pulse ultrasound BGS devices have a 26-year record of safe and effective use and that there is an increasing understanding of the biological mechanisms. He stated that ASA believes that a set of special controls in addition to general controls will entirely mitigate any risks to safety or efficacy.

BGS Coalition presentation

James T. Ryaby, Ph.D., discussed regulatory considerations that preclude BGS reclassification. He stated that findings from the 2006 panel meeting are still applicable and that Class III continues to be the right classification. He pointed out that BGS devices are not a generic type due to differences in waveforms, modalities, and dosimetries. He also noted that there is no new knowledge or preclinical methods that would enable reclassification.

Mohit Bhandari, M.D., Ph.D., FRCSC, discussed evidence-based medicine and the need for continued high-quality clinical trials for the regulation of BGS devices and trauma applications. He emphasized that clinical studies require a number of bias-reducing measures to assure valid, scientific results and that introduction of BGS without that assurance will put patients at risk of harm. He cautioned that preclinical studies do not replace well-designed clinical trials, that risks increase with fewer methodological safeguards, and that effective treatment is critical.

Chi Lim, M.D., discussed his experiences with BGS devices in spinal applications. He stated that inadequate devices have poor clinical outcomes and that unsafe devices have the potential for injury. He pointed out that structured, high-quality trials are necessary to

ensure safety and effectiveness and that deregulation and elimination of the PMA pathway will lead to ineffectual devices. He further noted that BGS devices for high-risk patients are vital to the success of spine fusions, that inferior devices lead to catastrophic failures, and that high-quality information is needed to support clinical decisions.

Dr. Ryaby summarized the presentation. He reiterated that Class III status for bone growth stimulators is consistent with FDA's mission and that reasonable assurance of safety and effectiveness can only be provided in Class III.

Q&A

Dr. Pfeffer asked what the rationale would be for classifying BGS devices under Class III when total joints are Class II and pose more of a potential risk.

Dr. Ryaby asserted that any new application of these devices should be based on Level I and II clinical evidence and that manufacturing should require FDA review of all premarketing proposals and inspections.

Dr. Lim pointed out that effective studies cannot be done on bone growth stimulators until after surgery, whereas mechanical studies can be done on implantable devices like total joints or pedicle screws before they are implanted.

Dr. Finnegan asked why there has been no improvement information for the past 14 years. **Dr. Ryaby** disagreed that there is no new information. He noted that there has been a lot of new peer-reviewed publications, including data from randomized clinical trials, that continue to show the applicability of these technologies. He acknowledged that efforts are under way to expand the usefulness of these devices, but Level I clinical data must first be made available.

Dr. Gilbert emphasized the need for more information on what is effective and ineffective in terms of waveforms and how to determine what is valid in terms of treatment.

Dr. Ebramzadeh pointed out that Type 2 errors must also be taken into account. He observed that a good study would optimize both Type 1 and Type 2 errors. **Dr. Bhandari** agreed that the two must be balanced. He recognized that the big challenge for FDA is to have that balance in mind and to look at what the greater harm is from the patient's point of view. He observed that the more egregious risk is putting a device out on the market that is purported to have benefit, but yet has none. He emphasized that focusing on Type 1 false positives has the greater potential risk.

PANEL DELIBERATIONS

Mr. O'Brien stated that he is uncertain as to how many revision surgery patients with pseudarthrosis used bone growth stimulators.

Dr. Muir specified that the literature search was narrowed down to clinical studies using cleared devices for on-label use, that much of the patient-level data is not available, and that it can likely be assumed that there was some follow-up on patients who did not achieve a union.

Dr. Yang asked what the strongest argument is that there is now enough new information to establish Class II special controls. **Dr. Muir** replied that the evidence from 40 years of clinical experience supports it.

Dr. Yang pointed out that, that information would have been available in 2006. She asked what has changed between then and now with respect to new data. **Dr. Muir** responded that there is additional internal data that was not previously available supplemented by another 14 years of use data, MDR analysis, and follow-up studies. We do have additional data that we looked at when we did this presentation. One group of information that wasn't really available in the last Panel was the prior SSED data from utilizing the 6-year rule. That was a fairly recent available dataset that was available while -- this data is internal, we were not able to use this in our recommendation for the establishment of special controls in the prior Panel.

In addition, we have an additional 14 years of use data, MDR analysis, and follow-up studies for the devices that have been marketed including devices that had just come on the market at that time. The CMF device, I believe, the CervicalStim device had just been marketed right around the Panel and was not part of that discussion. We now have the SSED and postmarket data on that, as well.

Mr. O'Brien asked why FDA believes that bone growth stimulators are not of substantial importance in preventing impairment of human health, especially as it relates to pseudarthrosis.

Dr. Muir identified specific components that are analyzed in risk assessment and emphasized that efficacy studies would address the possibility of device ineffectiveness which could lead to pseudarthrosis or nonunion. He added that this is where special controls are being looked at as a method of mitigation. He further noted that, even though pain is the most common adverse event, the overall rate of reported events is extremely low.

Dr. Ebramzadeh pointed out that making too much of an effort to ensure that substandard devices are not introduced could decrease the probability of developing devices that may work better.

Chairperson Smith asked if it would be possible to require demonstration of certain performance parameters if the devices were to be classified as Class II. **Dr. Muir** replied that it would. He verified that this is considered for any device regardless of the pathway. He further explained that, if a company were to come in with a new signal, it would have to demonstrate that it generates an effective and safe treatment.

Ms. Bonnell related that a poll taken by the Orthopaedic Surgical Manufacturers Association of its 35 member companies revealed split consensus regarding appropriate classification of noninvasive bone growth stimulators. She emphasized that there is a potential for the development of standards for the different technological parameters and that the special controls are needed.

Dr. Price observed that there will be postmarket surveillance of new products and that clinical data is going to be asked for. She remarked that if a device is not effective, it will not likely stay on the market. She pointed out that even products that have been through clinical trials can have issues. She also endorsed the idea of requiring demonstration of performance parameters.

FDA QUESTIONS

Chairperson Smith read Question 1 and 1(a): FDA has identified the following risks to health of non-invasive bone growth stimulators based on available information for these devices:

- Failure or delay of osteogenesis
- Burn
- Electrical Shock
- Electromagnetic Interference (EMI)
- Adverse Tissue Reaction
- Adverse Interaction with Internal/External Fixation Devices
- Adverse Biologic Effects

a. Please comment on whether this list completely and accurately identifies the risks to health presented by non-invasive bone growth stimulators.

Dr. Gilbert asked for clarification regarding what the concern is with interaction. **Dr. Muir** explained that it is in reference to possible cross-effects with other devices or implants.

Carl N. Graf, M.D., remarked that "adverse biologic effects" seems vague. He suggested that it could be better defined or deleted.

Dr. Finnegan proposed the addition of a caveat to specify that the signal itself is not detrimental.

Ms. Bonnell opined that labeling and special controls would greatly allay any concerns.

Chairperson Smith read Question 1(b): Please comment on whether you disagree with inclusion of any of these risks, or whether you believe that any other risks should be included in the overall risk assessment when considering all indications for this device type.

There were no comments from the Panel.

Chairperson Smith read Question 2 and 2(a): Section 513 of the Food, Drug, and Cosmetic Act states a device should be Class III if there's insufficient information that exists to determine that general controls are sufficient to provide a reasonable assurance of its safety and effectiveness, or that application of special controls could provide such assurance, and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

A device should be Class II if general controls by themselves are insufficient to provide a reasonable assurance of the safety and effectiveness, and there is sufficient information to establish special controls to provide such assurance.

A device should be Class I if general controls are sufficient, or if there's insufficient information that exists to determine that general controls are sufficient to provide a reasonable assurance of their safety and effectiveness, or establish special controls to provide such assurance, but it's not purported or represented to be for a use in supporting or sustaining human life, or for a use which is of substantial importance in preventing impairment of human health. Additionally, it does not present a potential unreasonable risk of illness or injury for Class I.

a. FDA believes that general controls alone are not sufficient to provide a reasonable assurance of safety and effectiveness for non-invasive bone growth stimulators. If you disagree, please discuss how general controls alone are sufficient to provide a reasonable assurance of safety and effectiveness for this device type. General controls may include:
    i. Prohibition against adulterated or misbranded devices,
    ii. Good Manufacturing Practices (GMP),
    iii. Registration of manufacturing facilities,
    iv. Listing of device types,
    v. Record keeping, etc.

There was unanimous agreement among the Panel members that general controls are not enough.

Chairperson Smith read Question 2(b): FDA does not believe that non-invasive bone growth stimulators are "life-supporting or life-sustaining, or of substantial importance in preventing impairment of human health." Do you agree with this assessment? If not, please explain why.

Mr. O'Brien noted that the number of surgeries, revisions, and complications is growing worldwide. He asserted that, from a patient perspective, pseudarthrosis cannot be overlooked as an important impairment to health if there are no devices that are good adjuncts to spinal fusion surgery.

Dr. Alandar agreed, but noted that access to newer technologies is also important.

Dr. Gilbert stated that he agrees with FDA.

Ms. Bonnell remarked that the question is more about outcome than it is about what can be mitigated in terms of control.

Chairperson Smith asked the Panel members to indicate whether they agree or disagree with FDA's viewpoint.

All of the panelists with the exception of Mr. O'Brien concurred.

Chairperson Smith read Question 2(c): FDA does not believe that non-invasive bone growth stimulators present a "potential unreasonable risk of illness or injury." Do you agree with this assessment? If not, please explain why.

Dr. Gilbert stated that he would agree based on decades of use and the small amount of reported adverse events.

The rest of the Panel members agreed.

Chairperson Smith read Question 2(d): FDA believes sufficient information exists to establish special controls for non-invasive bone growth stimulators. Based on the information presented today, please discuss whether you believe that sufficient information exists to establish special controls that can provide a reasonable assurance of safety and effectiveness for this device type.

Dr. Finnegan asked for clarification as to whether IDEs would be required for any new proposals in Class II. **Dr. Muir** specified that clinical evidence would be requested, but not necessarily an IDE.

Dr. Finnegan asked if this would include clinical efficacy. **Dr. Muir** replied that clinical evidence is part of the special controls.

Chairperson Smith asked the panelists to state whether they agree or disagree with FDA's viewpoint.

The Panel members unanimously agreed.

Chairperson Smith summarized the Panel's response to Question 2:

- There was unanimous agreement on Questions 2(a), 2(c), and 2(d).
- There was general agreement on Question 2(b) with some concern regarding potential prevention of nonunions.

Chairperson Smith read Question 3: FDA proposes the following special controls for non-invasive bone growth stimulators to provide reasonable assurance of their safety and effectiveness:

1) Clinical performance data must support the intended use of the product.
2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.
3) Patient-contacting components of the device must be demonstrated to be biocompatible.
4) Performance data must demonstrate the electrical safety and electromagnetic compatibility of the device.
5) Appropriate software verification, validation, and hazard analysis must be performed.
6) Labeling for the device must include:

    i. Warning against use on compromised skin or when there are known sensitivities;
    ii. Appropriate warnings for patients with implanted medical devices;
    iii. A detailed summary of the clinical testing, which includes the clinical outcomes associated with the use of the device and a summary of adverse events and complications that occurred with the device;
    iv. A clear description of the device;
    v. Instructions on appropriate usage, duration, and frequency of use;
    vi. Instructions for maintenance and safe disposal;
    vii. Instructions for appropriate cleaning of any reusable components;
    viii. Specific warnings regarding user burns, electrical shock, and skin irritation; and
    ix. The risks and benefits associated with use of the device.

Please discuss whether these special controls appropriately mitigate the identified risks to health of this device type and whether you recommend additional or different special controls.

Dr. Gilbert recommended the addition of postmarket surveillance. **Dr. Finnegan** agreed, adding that it might help alleviate concerns regarding efficacy.

Dr. Alandar agreed and voiced his support.

Dr. Price and **Mr. O'Brien** concurred.

Dr. Elder also agreed. He encouraged rigorous collection of clinical data for special controls at a higher standard. He also suggested looking at broad health optimization and consideration of factors that can determine fusion rates.

Dr. Yang recommended giving more attention to interactions with other implanted devices beyond labeling.

Chairperson Smith summarized the Panel's response:

The following areas of concern were identified:

- Postmarket surveillance and the need for at least one-year follow-up.
- Special controls with respect to potential interference with other devices.
- The need for quantifiable performance data and follow-up after postmarketing.

FINAL COMMENTS

Ms. Bonnell commended the Panel for its thorough review of the topics and for reaching an appropriate, least burdensome decision.

Mr. O'Brien expressed appreciation for the efforts put forth by FDA and the panelists and for the consideration that is given to patients.

FDA SUMMATION

Captain Peat affirmed that FDA will take the Panel's recommendations into consideration. She thanked the panelists for their time and active participation in the discussions.

Chairperson Smith thanked the Panel, the Open Public Hearing speakers, and the FDA for their contributions to the meeting.

Captain Peat also acknowledged and thanked Lieutenant Commander Randoshia Miller, who is currently deployed in Hawaii, for her efforts and contributions to the meeting.

FINAL REMARKS

Lieutenant Commander Randoshia Miller, M.S., BSN, RN, thanked the Panel members, presenters, and FDA staff for their efforts in putting the meeting together.

ADJOURNMENT

Chairperson Smith then adjourned the meeting at 2:37 p.m.

I certify that I attended this meeting on September 8, 2020, and that these minutes accurately reflect what transpired.

_____/S/_____
James Swink
Designated Federal Officer

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

_____/S/_____
Harvey E. Smith, M.D.
Chairperson

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September 15, 2020