

SUMMARY MINUTES OF THE
MEDICAL DEVICES DISPUTE RESOLUTION PANEL
MEDICAL DEVICES ADVISORY COMMITTEE

OPEN PUBLIC MEETING

OCTOBER 31, 2000

Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd., Room 20-B
Rockville, MD

MEDICAL DEVICES DISPUTE RESOLUTION PANEL ROSTER
October 31, 2000

Harold C. Sox, M.D.
Chair

Mark D. Carlson, M.D., M.A.
Voting Member

Scott D. Ramsey, M.D., Ph.D.
Voting Member

Hector H. Gonzales, Ph.D., R.N.
Consumer Representative

Judy F. Gordon, D.V.M.
Industry Representative

FDA Personnel

Les Weinstein, Esq.
CDRH Ombudsman and Executive Secretary

David Feigal, M.D., M.P.H.
Director of Center for Devices and Radiological Health

Phil Phillips
Deputy Director for Science and Regulatory Policy, Office of Device Evaluation

Lillian Gill
Acting Deputy Center Director for Science

OPEN PUBLIC MEETING

Mr. Weinstein opened the meeting at 1:10 p.m. and introduced himself as the CDRH Ombudsman and Executive Secretary of the newly formed Medical Devices Dispute Resolution Panel. He remarked that the purpose of this meeting was to introduce the panel members and to allow them to hear views from the FDA and the public on the resolution of scientific disputes concerning medical devices. He acknowledged the five standing members and thanked them for serving on the panel. In addition, three temporary voting members will be selected to participate in the review of a particular dispute. No Conflict of Interest Statement was required today since the panel would not be hearing and voting on a dispute at this meeting.

Chair Dr. Sox called the Open Public Meeting to order and asked the panel members to introduce themselves, which they did.

Dr. Feigal, CDRH Center Director, stated that this panel is one of the mechanisms to have medical device disputes addressed in public. The FDA values the work of all advisory panels and takes very seriously overruling panel recommendations. He emphasized the importance of problem solving and speed in the dispute resolution process stating that this philosophy can be seen in the work of the various CDRH offices including in the newly created Ombudsman office. He said that the first draft of a guidance on dispute resolution may have been perceived as saying that there were many steps to get a dispute to this panel, but that was not the intent. The intent was to identify the different ways to appeal up the chain of command, but steps can be skipped and mechanisms collapsed. He discussed the kinds of appeals/disputes the panel would be

called upon to hear. He hoped the panel would help in areas of new technology and thanked the panel members for their participation in this endeavor.

Mr. Weinstein remarked that the FDA has both formal and informal processes to resolve scientific disputes. In April 1999 CDRH issued a draft guidance document to resolve scientific disputes by forming a panel whose duties would include reviewing 1) performance standards, 2) appeals of premarket approval applications (PMA) and product development protocols (PDP), 3) post market surveillance of more than 36 months and 4) scientific disputes for which the law and regulations do not already provide a right of review.

With a submission to the CDRH Ombudsman within 30 days of a decision, a sponsor, applicant or manufacturer can request review by this panel. The request should include a summary of the scientific dispute, results of efforts to resolve the issue, and a summary of arguments and information concerning the dispute. The FDA itself can initiate a panel review if parties could be adversely affected by a Center decision. After the Ombudsman receives a request and consults with the Panel Chair and a Deputy Center Director, he will decide whether or not to grant a panel review or offer mediation as an alternative.

The panel will 1) hear arguments from the requesting party, FDA and other interested parties, 2) ask questions and 3) vote on the proposal. The Ombudsman will send the CDRH Director a statement of findings and conclusions that have been reviewed by panel members and signed by the Chair. The CDRH Director will either accept, accept with recommendations or reject the panel recommendations.

Mr. Phillips reported that his Office of Device Evaluation will have to provide the panel with the necessary regulations pertaining to the evidence required for a particular device submission. Only valid scientific evidence can be used in determination of the safety and effectiveness of a particular device. At this time there are several avenues within the agency for review of appeals, before coming to the panel for dispute resolution. He referred the panel members to the agency web site for a document on resolving least burdensome issues and discussed some of those issues. In response to questions from Dr. Sox, he reviewed the definition of “effectiveness” and talked about scientific evidence from clinical investigations.

Ms. Gill stated that the panel would probably not have to deal often with enforcement and compliance issues from the Center. The very small percentage of these kinds of disputes would probably involve the manufacturing process and quality control of companies, as well as issues regarding the data submitted to FDA supporting marketing applications. Formal enforcement actions include seizures, injunctions and civil penalties. The informal channels feature an appeal process. She also discussed warning letters and other kinds of correspondence with firms as follow up to investigations conducted by district offices. In response to a question from Dr. Sox as to the level of evidence involved in compliance disputes, she said it is the reasonable likelihood that a manufacturer’s practices would produce a poor product that might cause harm or injury.

James Benson, Executive Vice President, Technology and Regulatory Affairs, Advanced Medical Technology Association (AdvaMed), noted that since legitimate disputes arise between the FDA and industry, it is critically important that this panel

exists though he hopes that disputes could be resolved without the necessity of convening the panel. The panel not only brings order to the dispute resolution process, but its existence gives permission to have a dispute. Dr. Feigal's philosophy and Les Weinstein's attendance at meetings of the industry to learn of its issues and at meetings between CDRH and sponsors indicate that the Center is going in the right direction to better implement the dispute resolution process which is encouraging. With the enactment of FDAMA, CDRH has initiated a least burdensome process, which includes dispute resolution, and which will help bring good science to the table.

Charles H. Swanson, Ph.D., Vice President and Chief Quality and Regulatory Officer, Medtronic, Inc., felt that the Ombudsman and panel provide additional mechanisms for dispute resolution that can be used as a safety valve as needed. FDAMA has allowed the FDA and industry to arrive at binding agreements at early meetings. With regard to the panel, industry needs 1) predictability, 2) reasonable requirements and 3) timely submission review, especially in regard to break-through products. In deciding whether to initiate dispute resolution, a company must weigh the cost and time for product testing with the cost and time for an appeal and the likelihood of success. In response to a question from Dr. Ramsey, he stated that timeliness is the most important attribute the panel can have at this time. In response to a question from Dr. Sox, he stated that the product development protocol (PDP) is a good route to follow for known products, but is a very difficult process for break-through products.

Mary-Lacey Reuther, Deputy Director, Medical Device Manufacturers Association (MDMA), encouraged the FDA to finalize its April 1999 guidance document entitled Resolving Scientific Disputes Concerning the Regulation of Medical

Devices. She reiterated MDMA's concerns about the document: 1) the panel not be limited to review of formal agency decisions and actions, 2) the need for swift time line of review by the panel, and 3) the CDRH Director's authority to overturn the panel's recommendations.

Dr. Swanson added that a reasonable time line for resolution of disputes would be 60 days.

Dr. Feigal was pleased not to hear that entering into a dispute resolution process would create a bias or negative feelings on the part of the agency or that initiating this procedure would have adverse consequences for the firm. He reassured everyone that the agency strives to make decisions based on scientific evidence, and it is legitimate for industry to ask how and why a decision is made and whether there is another way to look at the same evidence. In the future the panel will meet on an unpredictable schedule and he thanked the panel members for their willingness to be called upon on an as-needed basis.

Mr. Weinstein thanked the various offices for making the meeting possible: Systems and Management, Center Director, Device Evaluation and Compliance.

Dr. Sox thanked the various speakers and adjourned the meeting at 2:45 p.m.

I certify that I attended the Open Session of the Medical Devices Dispute Resolution Panel Meeting on October 31, 2000 and that this summary accurately reflects what transpired.

Les Weinstein
Executive Secretary

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

Harold C. Sox, M.D.
Panel Chair

Summary minutes prepared by:
Lynne Blei
8916 Burdette Rd.
Bethesda, MD 20817—2112
(301) 365-4031