

# When All Else Fails: Understanding the Medical Devices Dispute Resolution Panel

It is rarely used and carries risks. But for sponsors who disagree with the scientific basis on which their product was rejected by FDA reviewers, the dispute resolution panel may be an effective option.

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Nearly five years ago, Congress directed FDA to set up an advisory panel to help resolve scientific disputes between the agency and industry. The result was the Medical Devices Dispute Resolution Panel. Operating under FDA's Medical Devices Advisory Committee, the panel helps resolve product-specific scientific disputes between FDA and product sponsors. It then makes recommendations to the CDRH director, who makes the final decision on the matter.

Established by the Food and Drug Administration Modernization Act of 1997 (FDAMA), the panel procedure has been little used. In fact, it has been convened to resolve only a single dispute. That case involved a product known as Intergel. Made by Lifecore Biomedical Inc. (Chaska, MN), it is intended to prevent surgical adhesions. Lifecore had received an unfavorable review of its pivotal study from a PMA panel, followed by a "not approvable" letter from FDA.

Lifecore requested review under the panel procedure. The dispute resolution panel disagreed with the original



PMA panel and recommended approval. The CDRH director agreed, and ruled that Intergel was approvable. Within a short time, FDA granted PMA approval.

A second dispute resolution panel meeting is reportedly imminent. In February 2003, Cardiogenesis announced that it has been granted such a review for a pending PMA supplement application. The product in question is a percutaneous myocardial revascularization system. FDA's Office of Device Evaluation (ODE) has said that the pivotal clinical trials for this device do not show reasonable assur-

ance of safety and effectiveness. This conclusion was based at least in part on concerns raised by the original PMA panel. That group felt that the studies did not show safety equivalence between the treatment and the control. This issue apparently will soon be revisited by the dispute resolution panel.

Though little used, the dispute resolution procedure offers companies a useful tool. It is a valuable way to obtain an independent second opinion if a scientific disagreement with FDA or a PMA panel leads to an adverse regulatory decision. It is appropriate, however, only in certain circumstances.

## **Legal Background**

The dispute resolution procedure is based on section 404 of FDAMA. (It is now section 562 of the Federal Food, Drug, and Cosmetic Act.) It is intended to help ensure that FDA has effective ways to resolve scientific disputes between itself and sponsors, applicants, and manufacturers.

The concept behind section 404 is that independent expertise will help FDA conduct its business more fairly and objectively. Thus, it directs FDA to use the expertise of clinicians and scientists from outside the agency for guidance on subjects of scientific disagreement with industry.

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To implement section 404, FDA revised 21 CFR 10.75, the regulation covering internal supervisory review of agency decisions. The rule now offers the following option: “A sponsor, applicant, or manufacturer of a drug or device regulated under the [Federal Food, Drug, and Cosmetic Act] or the Public Health Service Act . . . may request review of a scientific controversy by an appropriate scientific advisory panel.”

FDA’s regulation did not mandate specific procedures for section 404 review. Rather, the agency left it to each center to develop its own procedures. CDRH issued its final guidance on July 2, 2001 (hereinafter referred to as “the guidance”).

### Panel Composition

CDRH implemented section 404 by creating a dispute resolution panel that consists of eight people. Five are standing members. Three of these are voting members with broad scientific and medical backgrounds. The fourth is a nonvoting industry representative, and the fifth, a nonvoting consumer representative. These members serve staggered four-year terms. In addition, each time the panel hears a dispute, three temporary voting members with expertise related to the particular issue in dispute will be selected.

### Eligibility for Review

FDA may choose whether to grant a request for panel review. The agency’s view is that its current procedures already provide methods to obtain review of most disputes. It therefore sees the panel as an additional, more focused body for the timely review of scientific disputes.

The guidance defines the term *scientific dispute* as “a disagreement with an FDA science-based decision or action, which bears on a regulatory matter pending before FDA, or an appeal arising from an FDA science-based decision that served as the basis for a regulatory decision.” The definition excludes “matters relating to potential criminal activity, allegations of intellectual or regulatory bias, FDA’s designation of a lead Center to regulate a combination product, and legal issues.”

A request for panel review must be submitted to the CDRH ombudsman. The ombudsman and the panel chair review each request for eligibility. To be eligible, a request for panel review must primarily concern a scientific dispute as defined in the guidance. It must show sound scientific grounds to support reconsideration of information, data, evidence, or views in the administrative record.

Finally, the dispute must be at an appropriate stage. This requirement is flexible, but the requestor must make sufficient effort to resolve the dispute through less-formal dispute resolution

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mechanisms, especially review up the supervisory chain, pursuant to 21 CFR 10.75. FDA believes that such internal supervisory review is enough in most cases to help clarify the issues. It also helps ensure that additional FDA perspectives and experience are involved, and creates a record for meaningful panel review, if still needed.

The paradigm case for a dispute resolution panel appeal would resemble the following: A sponsor believes it has submitted sufficient data to establish that its device should be marketed. FDA, however, has disagreed for scientific reasons. It has then issued either a “not approvable” letter for a PMA application or a “not substantially equivalent” (NSE) determination for a 510(k) premarket notification.

Additional scenarios for dispute resolution panel review are nonetheless possible:

- CDRH orders a five-year post-market surveillance study. The manufacturer believes that there is no scientific reason to collect data beyond a three-year period.
- With active CDRH involvement, FDA issues a warning letter. New

scientific information indicates a potentially serious, unforeseen health hazard with a product. The agency threatens enforcement action if the manufacturer continues to market its product as originally labeled. The manufacturer disagrees. (Note: Even if panel review is granted, such review will not stay enforcement action in the interim if FDA believes it is necessary to protect the public health.)

- The lead CDRH reviewer tells a PMA applicant that an additional clinical study is needed. The applicant believes such a study is scientifically unnecessary. Furthermore, similar requirements have not been imposed upon competitors. While appeal up the supervisory chain may be an appropriate first course, it may not be a prerequisite for panel review.

A request for review may be denied if the CDRH director has substantially participated in the disputed decision or action. The reason for this is simple. The panel makes its recommendation to the director, who makes the final decision. The director’s involvement in the original decision could raise questions about the fairness and objectivity of the panel review process. To keep that option open, therefore, informal appeals up the supervisory chain should go no higher than the deputy director. In all events, before submitting a request, it would be wise to contact the CDRH ombudsman and discuss informally whether the dispute would be appropriate for panel review.

### Request for Review

The guidance document sets forth the information that should be provided in a request for panel review. First, the request must explain “why the requesting party believes it has standing to request review of the particular matter.” Though not spelled out further, this requirement seems to mean that the requestor must show that he or she is either a sponsor, applicant, or manufacturer of the product. No other parties are permitted to request dispute resolution panel review.

The request should concisely summarize the scientific dispute. The sum-

mary should include an overview of the FDA action or decision appealed, any prior advisory panel action, and the results of any efforts made to resolve the dispute. The request must also clearly outline the arguments and relevant data and information.

Panel review is best reserved for complex scientific disagreements that warrant specialized expertise and independent review. The requestor may not rely upon information not in the official administrative record at the time FDA made its decision or took action. A new interpretation of data already in the record, however, is allowed.

Finally, the request should provide a clear statement of the action requested of FDA. Generally, the request would be that the center accept a favorable panel recommendation and reverse or revise its regulatory decision or action.

### Panel Proceeding

Meetings of the dispute resolution panel are open to the public. As per FDA's normal procedure, however, parts of the meeting could be closed for such reasons as discussion of trade secrets, or disclosure of confidential commercial or financial information. The requestors speak first and present their views. They are followed by FDA representatives and other affected or interested persons. Either side may bring along experts and legal counsel for supplementary testimony or to respond to questions from the panel. Comments from the general public will be taken for at least an hour. After the meeting, the ombudsman will write up the panel's findings and recommendations, including any minority views.

After receiving the statement of findings and the transcript of the meeting, the CDRH director has several options. He may concur with the panel recommendations, with or without specific exceptions. If he does not concur, he has several options. He may direct specified actions, such as the gathering of more evidence, or he may order further panel consideration. He also may conclude that the matter was not appropriate for panel review and begin a separate investigation.

Oddly, the guidance does not expressly state that the director may sim-

ply reject the panel recommendation and reaffirm the original action or decision. It is not clear whether this omission is intentional. Surely the CDRH director has such authority.

### Anticipated Timeline

A company has 30 days following an adverse FDA decision or action to request panel review. FDA may waive the requirement "as long as an unreasonable amount of time has not

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elapsed." CDRH's anticipated timeline for the panel process is as follows:

- Request filed within 30 days of decision or action (FDA may waive this requirement).
- FDA acknowledges filing within five working days.
- The CDRH ombudsman completes eligibility review within 15 days "unless circumstances require more than 15 days."
- FDA may make an offer of mediation in lieu of panel review. The offer must be acted on within 15 days. Mediation "should" be a 90-day process.
- FDA will "attempt" to schedule a panel meeting within 60 days of granting the request. Review packages for panel members will be provided at least 15 days before the meeting.
- The CDRH ombudsman will prepare a draft statement of findings within 15 days of the panel meeting. Panel members will then have 10 days to comment. The ombudsman and the panel chair will prepare the final version within five working days of receiving comments. The chair will approve the final statement within five working days of receiving it.
- The director will "normally" make

a decision within 10 days of receiving the statement of findings and the transcript of the meeting.

### Deciding Whether to Request Review

A decision whether to seek panel review will depend on several factors. First, the dispute with FDA must have a scientific basis. For example, panel review is not meant to resolve legal issues. Therefore, any request for review must carefully frame the scientific issues for the panel to resolve. If they cannot be identified, panel review may not be appropriate.

Second, the process is obviously costly, in both time and resources. If all goes according to the guidance timeline, a decision will take about four months. But the timeline only sets goals. FDA faces no penalties if they are not met. Therefore, the process could take much longer. Furthermore, making the request and briefing the panel will be costly. As a rough guideline, the expense and effort may be comparable to undergoing a typical PMA panel review for a new product. Obviously, the product must be significant enough to warrant this kind of effort. It certainly makes sense to exhaust informal negotiations before considering panel resolution as an option.

Last but not least, some companies may have a concern about FDA retaliation. A request for panel review is inherently a criticism of the original decision makers within FDA. Agency officials may not appreciate the review request, especially if it comes after they have attempted to resolve the disagreement informally.

This concern is real enough that two commenters on the FDA draft regulations establishing section 404 review brought it up, and suggested that FDA permit anonymous proceedings through third-party representatives. FDA rejected the idea as unnecessary:

FDA reiterates and reaffirms its commitment to an environment in which challenges to agency decisions can be raised without fear of adverse consequences. By memo dated June 29, 1995, Commissioner Kessler reminded all FDA employees that companies are free to vigorously challenge agency positions and requirements, and to freely voice their views. By letter of

the same date, Commissioner Kessler assured members of Congress that any act or threat of retaliation by any FDA employee is totally unacceptable and will not be tolerated. . . . FDA believes that its employees are highly sensitive to the need to avoid even the appearance of impropriety, and to strive to make complex clinical, scientific, legal, and factual decisions fairly and evenhandedly. Accordingly, FDA believes that sponsors, manufacturers, and applicants will not be dissuaded from requesting review of issues under section 404 of FDAMA.

Even taking this statement at face value, it makes sense to weigh the risk

of harming one's relationship with FDA before requesting review. This is another reason that panel review

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should only be sought for significant matters involving important products.

If, however, the decision is made to go forward, the relationship risk can be

minimized by proceeding in a professional way. For example, as a courtesy, the FDA officials whose decision will be appealed should be told in advance. A company also should avoid accusations of bias against specific officials. (In fact, such accusations are not eligible for resolution by panel review.)

Deciding to pursue review by the dispute resolution panel is likely to be expensive, and not without risk. However, if an important product has become mired in a significant scientific disagreement with FDA, panel review may be the best way out. ■