



Case Study

Project Description: Facing an FDA Advisory Committee Hearing

Challenge: A medical device company needed to present its PMA application in front of an FDA advisory committee. They had a decade of research and 400 volumes of data, but only 60 minutes to tell their story. They then faced questions from the committee that might cover any aspect of the product, as well as related medical, scientific, public health and ethical issues. They wanted their presentation to be understandable and persuasive, without being inaccurate or incomplete.

Action: As we have done for a number of companies that needed to present to FDA advisory committees, we focused on the science and the endpoints that had been set with FDA. **Our philosophy in these matters is: Good communications cannot save bad science. However, good science often fails because it is poorly communicated.** Accordingly, we made sure their presentation fully reflected the key points about the safety and effectiveness of their product in a balanced, credible, and ultimately persuasive way.

Results: The company presentation was smooth and well-understood and did not exceed the allotted time. Company representatives and outside experts did an excellent job of handling more than an hour's worth of questions ranging from biomechanical testing to informed consent. The company's product was recommended for approval with conditions, the best outcome that the company had hoped for.

The services we provided for this client and to other clients preparing for an FDA advisory committee include:

Briefing books. Based on our knowledge of persuasive communications, messaging and regulatory process and our ability to understand science, medicine, and statistics, we review and suggest revisions to any briefing books that are to be submitted to FDA and the advisory committee.

Committee presentation. As we did for the briefing books, we reviewed and suggested revisions to the presentation to FDA....not only for clarity of message, but also slide content and appearance, as well as flow of the presentation. Typically, companies have 60 to 90 minutes to present what was in an 80 page briefing book, which in turn represents tens of thousands of pages of data and years of preclinical and clinical studies.

Training. We train presenters to be understandable, credible and professional and we train the entire team on the best way to handle Q&A.

Mock panels. An FDA advisory committee operates in real time and it is impossible to know what their concerns are going to be. To prepare our clients for whatever may come, we typically organize and run two mock panels. At these, the company rehearses in front of, and gets feedback from, a group of scientific, medical and regulatory experts who have been at FDA or sat on advisory committees. Our services include recruitment of the mock panelists, in consultation with the company.

Logistical support. We provide logistical support for the company in planning rehearsals, week of event accommodations, and setting up an on-site command center with proper equipment and staffing.

Third party development. We often work with supportive third parties (individuals and groups) to help them be ready for the advisory panel.....and also monitor other third parties that may be critical of the company's position.

Media and financial and employee communications. We provide media support before, during and after the hearing, including training spokespersons. This often includes communications with analysts, employees and other specialized audiences.

Research. We research the backgrounds of the advisory committee panelists so that the company has the benefit of information about their expertise and likely area of questions.

On-site counsel and staffing. We provide on-site staffing of rehearsals and at the advisory committee meeting. We stay with you to provide feedback and help the company communicate well.