HPSGROUP LLC

Research on Advisory Committee Members as Part of FDA Advisory Committee Preparation

Our approach to researching the backgrounds, intellectual interests and style of advisory committee members is based on four observations:

- Research on panel members is a useful and necessary task, but rarely has more than a marginal impact on the company's presentation. It creates familiarity and reduces surprise and suggests lines of questioning for which preparation should be made. In the end, your advisory committee will be successful (or not) based on the quality of the science and the clarity of your presentation and answers.

- Research on the backgrounds and credentials of individual panel members should be supplemented by reviewing the tapes of past advisory committee meetings of the same panel. Depending on what is available, the following might be useful:
  --tapes of similar drugs or similar issues reviewed by the same committee, regardless of whether current panel members were present, and
  --tapes of recent panel meetings at which some of the current members participated.
  Tapes of current members help to assess both individual styles and panel member interaction. The latter is often quite different and more instructive than static portraits.

- While all panel members are important, focus should be placed on the three individuals most likely to lead the committee in a particular (good or bad) direction: the chairman, the statistician, and anyone who has a tendency to be forceful in expressing their views.

- The panel you prepare for may be quite different than the one to which you present. In most cases, three or four members rotate off annually, but may be asked to participate as voting consultants. In addition, FDA will add other consultants to reflect different expertise or perspectives. This will add another one to five individuals, possibly very late in the process.

Based on past successful experiences, we recommend the development of the following products:

Traditional Profiles of Panel Members and Consultants—Through database searches, phone calls and other means, a notebook should be created with tabs for each member. It should include traditional CV or bio, list of publications, selected articles from this list, photograph (if available), and any public statements they may have made about their academic interests (e.g. often on university websites) or on current issues. Also included might be selected pages of transcript from prior advisory panels on which they participated and any published articles about them.

A brief factual thumbnail sketch on each panel member, their academic interests and publications should be created and put in the front of each tab. Because the addition of new members and the naming of consultants will take place over several months and may not be announced until just before panel, this notebook will change over time. Note: these searches should only include information available in the public record. No contact should occur with the panel members. Even calling their offices for a CV should be avoided, if possible.

Qualitative assessments of panel members. These brief stylistic analyses should be compiled based on review of the notebook and review of advisory committee tapes in which the individual appeared. Companies that have recently presented to the panel may also be contacted. If possible, the team putting the analysis together should attend meetings of the advisory committee, along with the company, to see the members in action.

Assessments should cover both individuals and interactions among committee members. As a matter of prudence, this should be presented to the team orally and not circulated in any written form. The oral briefing may also include brief segments from the tapes that illustrate the points being made. Particular attention should be paid to the chairman, the statistician, and any panel member with a tendency to be forceful.

Analysis of committee handling of past similar drugs or issues. Depending on whether there are appropriate instances and they are available on tape, an analysis should be done of how the committee and its members handled similar drugs or issues (e.g. an otherwise different drug, but sharing concerns about Qt intervals or the reliability of a statistical methodology or evaluation tool). This is important regardless of whether current panel members were on the committee, since patterns of response are likely to recur. In fact, if there are reasons to draw parallels, FDA is likely to make panel members aware of the earlier committee hearing.

The appropriate type of analysis could be a page or two….all the way up to a technical analysis done by a medical or scientific expert. Among the variables is the strength of the analogy and the way the committee handled the earlier instance.

Identification of advisory committee tapes that should be viewed by the entire team. Given the time and other pressures on presentation team members, they should not be reviewing tapes unless the tape has already been identified as being relevant to their preparation needs. Even then, the availability of transcripts may shorten the time to absorb critical information. Therefore, the initial review of tapes and transcripts from key advisory committee meetings should be delegated, if possible, and recommendations brought back to the presentation team.