

JULY 2008

THE BUSINESS MAGAZINE OF PHARMA

Pharmaceutical Executive

Public Relations

Get Ready for Your Premiere at Ad Comm

As an Advisory Committee meeting debuts, the public is formulating its views on your drug. Here's how to make the most of your performance

Last year, an amendment to the Federal Food, Drug, and Cosmetic Act placed FDA Advisory Committee meetings, or "Ad Comms," in the script for nearly all pharma and biotech companies with late-stage products. Before FDA will consider granting final marketing approval, products that include an active ingredient not previously cleared by the agency face the inevitable spotlight of an Ad Comm.

This performance may seem like a formality compared to the lengthy and complicated paths some products travel to get to this point. Ad Comm meetings are important, however, as FDA often considers the committee's guidance when reviewing a drug application. Prior meetings and conversations with FDA usually take place behind closed doors. But with Ad Comm, the doors are opened, and proceedings play out among the agency, the sponsor, and a panel with varied expertise, personalities, and perspectives. The product's merits are debated, leading up to a final act—when the committee votes.



Sponsors spend many hours and dollars preparing for an Ad Comm. These well-choreographed efforts are keenly focused on FDA and the committee; however, media and financial analysts should not be overlooked. They will be in the audience, making their own judgments about the value of the product, the ability of the company to get it approved, and the drug's commercial potential. And they will make those views public to a variety of stakeholders, including physicians, patients, advocacy groups, the financial community, and employees. Therefore, it's essential that corporate communications and public relations teams participate throughout the planning process to build, protect, and manage company and brand reputations.

Here are some tips and considerations for ensuring these important audiences hear your voice.

Study Your Lines and Rehearse

When striving for a perfect performance at Ad Comm, no company should "wing" the communications component. Prepare extensively, beginning with a communications strategy that includes credible, consistent, effective messages and positions on critical issues. These messages should be clear, balanced, compelling, and informative—not to mention controlled and rehearsed. The day of the Ad Comm is no time for surprises.

Speakers should train in the same way Presidential candidates do when preparing for a debate: Mock panels should be conducted early and often, with a final dress rehearsal held in front of a relevant external audience of experts. These rehearsals are critical not only for increasing the confidence and comfort level of the presenters, but also to gain additional insights about and prepare for tough questions.

The public relations team should prepare for three potential outcome scenarios (favorable, neutral, and negative), so the team can move quickly to issue a prepared statement following the committee's final vote. All company and external spokespeople should be trained for each potential outcome and prepared to answer questions from the media and analysts—a key step to ensuring accuracy and maintaining the brand and corporate image.

Know Your Audience

Companies spend significant time and effort trying to understand committee members—their background and medical expertise, training, positions on issues at previous meetings, etc. Yet it is essential to know the other audiences in the room, including journalists, financial analysts, and competitors.



Laura M. Liotta is President of Sam Brown, a healthcare public relations agency. She can be reached at 610-353-4545 or laura@sambrown.com. For more information, visit www.sambrown.com.

To ensure accurate coverage, conduct media and analyst briefings in advance, providing background information so writers can move quickly to file stories following a decision. Reporters from newswires such as AP, Dow Jones, Reuters, and Bloomberg report on hundreds of new products each year and appreciate the opportunity to gain greater context on clinical data and other relevant disease background information prior to the meeting. Of course, the briefing information must be public and non-material to the sponsor.

Beware the Early Reviews

You only get one chance to make a first impression—and in the case of an Ad Comm, the media and financial community can make your product's first impression for you. A few days prior to the meeting, FDA posts its own briefing, as well as company briefing documents online, triggering the first round of media calls and coverage. These initial inquiries can set the tone for the day of the Ad Comm meeting. Therefore, it is important to ensure that the contents of the company briefing document and the communications strategy are aligned to convey consistent messaging.

The situation is complicated by the fact that many companies impose a "quiet period" during this time. On a case-by-case basis, companies should decide whether to comment on briefing documents. Celgene, Gilead, Adolor, and DOR BioPharma, have issued press releases announcing the availability of FDA and company briefing documents at www.fda.gov, so investors have fair and full access to data and product information. Others prefer to wait for the public forum to offer comments.

Set the Stage

Whether working with an event management firm or handling the meeting logistics in-house, all participating parties must be "in the loop" to ensure the show goes off without a hitch. Final rehearsals should be held off-site, in a confidential location to ensure that the presentation information remains confidential from investors and competitors prior to the Ad Comm.

An on-site communications headquarters must be established prior to the meeting, and should be equipped with computers, Internet access, printers, copiers, and a live satellite feed from the meeting room. This "communications war room" will provide a secure area from which the communications and extended team can come to listen to the presentation and hold confidential discussions on messaging, strategies, and outreach. Prior to the meeting, establish a process and chain of command for managing on-site/real-time decision making for final communications following a committee vote.

Also consider setting up a separate room for media to conduct interviews, gain Internet access to write and file

Post-Show Wrap Up

Journalists are writing and filing stories as the meeting progresses, but the final vote of the Ad Comm is the big story of the day. The better prepared you are, the faster the company can issue its final statement, and more effectively shape the stories being written. Delay may result in official statements that are irrelevant or seem reactive or defensive.

Grab the appropriate draft from your scenario planning, revise the release to reflect the day's events, gain approval from your review team, and issue it as quickly as possible. Depending on the materiality of the news, the release may need to cross BusinessWire or PRNewswire before you can conduct any interviews. This process may not be cut and

You only get one chance to make a first impression—ensure that your briefing document and communication strategy convey consistent messaging

stories, and take a break from the meeting. Your communications team should reach out to them during breaks to ensure they have access to materials and post-meeting interviews.

The Curtain Rises

When the curtain rises on the big day, it's everyone's job to give their best performance. Remember, it is a performance—but the stage extends beyond just the Ad Comm meeting.

Reporters—and competitors—will be watching and listening, so avoid discussing confidential information about the product or company, or making any outcome predictions in the meeting room, hallways, or even when traveling to and from the Ad Comm. Don't react in public to events from the meeting (including facial expressions). Instead, take reactions and private discussions to the war room. All company personnel, whether they are presenters or spectators, should be cautioned to avoid unofficial "hallway conversations" that can be easily overheard. Only company spokespersons should talk to the media.

dried, especially when the panel decision is mixed or unclear, and the race against the clock is on because FDA may issue a press release or host a press conference of its own. Without the company perspective, that information will drive the way the story is told.

Once the release has been issued, follow up with media and update key stakeholders. Monitor for media coverage, distribute coverage reports, and continue to build overall momentum for your product as it travels the last leg of the journey toward a final FDA decision.

Take a Bow

An FDA Ad Comm is a major opportunity for companies to communicate key messages about investigational products; making effective, consistent communication during and after the meeting critically important. With ample preparation and consistent communications, you will have done everything you possibly can to ensure that fans and critics alike leave with an accurate interpretation of the clinical benefit of your star product—which will hopefully achieve blockbuster status and enjoy a long, successful run. 