

Top 10 FDA Advisory Committee Tips

Drug development consultant shares best practices for delivering a successful argument before regulators

by Lloyd Dunlap

PRINCETON, N.J.—U.S. Food and Drug Administration (FDA) Advisory Committee success was a hot-button topic for discussion at the recent Center for Business Intelligence (CBI) conference, where pharmaceutical industry leaders gathered to debate the changing rules, regulations and best practices for preparing to deliver sound arguments for a drug, device or biologic's approval at committee hearings.

Pete Taft, founder and CEO of Princeton-based drug development communications firm PharmApprove, presented his "Top 10 Advisory Committee Tips," (see sidebar) focusing on the best way to deliver a successful argument during an FDA Advisory Committee hearing.

Taft and his company have acted as consultants on more than 50 drug development communications programs, including more than 30 Advisory Committee preparation projects, in the United States and overseas over

the past 10 years, and the activity now accounts for 50 percent of the company's business. The company works in partnership with development teams to create the strongest argument for approval at every stage of the development process—"when they have one chance to get it right," as Taft puts it.

"All the easy drugs have been developed," Taft notes, and adds that the Vioxx experience "drew the line" on regulatory review. Today, he says, about half of Advisory Committee hearings are covered by the press.

When he observes (#2) that the best scientists don't always make the best presenters, he cautions against rewarding a scientist's drug-development contribution with an assignment for which he or she may simply not be well suited.

"It may be better under such circumstances to keep your scientific experts in the bullpen where they can be called upon if

and when their expertise would be useful," he observes.

Taft's advice to work from scripts (#3) is based on his experience that the venue is more like a Congressional hearing or grand jury testimony than a strictly rational appeal, but he emphasizes that he isn't inviting rote memorization. Rather, he

work hard to teach the techniques, tricks and insights that comprise good public speaking.

"We redline the script to enhance economy of expression," he says, adding that his team sometimes sounded a bicycle horn when a presenter takes 90 seconds to answer a "yes-or-no" question.



ALL THE EASY DRUGS HAVE BEEN DEVELOPED, says Pete Taft, founder and CEO of Princeton-based drug development communications firm PharmApprove. The Vioxx experience "drew the line" on regulatory review, Taft says, adding that the best scientists don't always make the best presenters.

says, the script is the midwife that helps in the editing and familiarization process.

"It's a tool to be ultimately thrown away because you know the material so well," he states. Having it down in writing can also come in handy if the A-Team presenter is hit by a bus or moves to Jamaica, he adds.

While he agrees that the FDA and its Advisory Committees are both concerned with safety and efficacy (#5), "the agency's job is to protect the regulatory box while the panel can go any way it wants in a much more free-wheeling context." In the Q&A sessions (#6), he observes, market utility is one issue that such panels frequently explore.

"Our job is to figure out what the Advisory Committee will see as the issues concerning the drug in question," Taft says.

Agreeing that scientists don't much care for the KISS approach (#8), Taft says he and his team

Finally, he says, he gets little pushback about his emphasis on rehearsing (#10), although he frankly admits that the pedagogy that lies at the heart and soul of many academicians makes them PharmApprove's toughest customers.

Currently, PharmApprove teams are helping to prepare four drug teams and one device team for upcoming Advisory Committee hearings, providing services including strategy development, messaging and editorial, medical writing, presentation coaching, slide creation and project management.

Let PharmApprove help you and your team present your strongest argument for approval when you have one chance to get it right.

Contact us at 609 683 0700 or visit www.pharmapprove.com

Pete Taft's Top 10 Advisory Committee Tips

1. Make preparation for the panel the number one priority.
2. Choose a team that can deliver your message with authority and power.
3. Work from scripts.
4. Don't get caught up in the "slide Olympics."
5. Don't confuse the FDA as an agency with the panel.
6. Work hard on Q&A; that's where you win or lose.
7. Welcome tough outside feedback, and get it early.
8. "Would you please keep things simple?"
9. "Be clear, be clear, be clear."—Napoleon
10. "Rehearse, rehearse, rehearse. And when you're sick of rehearsing, rehearse again."