



## **Wyeth on FDAAA**

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- Because of the random sighting of Ira Spector at one conference or another, we've always had a soft spot for **Wyeth**. We don't know Spector—no need to fret he has been consorting with the news media. But from remarks by Spector and his lieutenants over the years, we've gathered Wyeth seems to have anticipated most of the challenges of the eclinical era, and to have aimed for aggressive competitive and operational goals. It's hard not to admire their efforts.

So we had high hopes for Wyeth's Joseph Camardo at last week's Post Approval Summit at Harvard. The meeting is sponsored by **Outcome**, a technology firm specializing in registries, but has the ambiance of the Ivy League terrain in which it is staged every spring. This year's effort was well-attended, and we've only begun to extract the nuggets from our notes. High-level FDA officials presented, as did speakers from abroad. (Those articles will be completely divergent from this one.)

### **Sorry, No Signal**

What with all the noise around FDAAA, hundreds of articles, entire wind farms being powered off politicians' comments on FDAAA, this correspondent assumed (being hopeful by nature) that something might have changed or shifted.

Um, no.

For the record, Camardo is an M.D. and senior VP of global medical affairs at Wyeth. He's safely in the top five percent of charm and elan among industry types, starting his talk with a jibe. "I guess I should be happy there will *be* approvals," he said in a reference to the previous talk. "That's been a problem for a lot of us."

He didn't discuss technology. We wish he had. "We want to analyze data rapidly," Camardo said.

### **Charm Offensive**

Camardo won over the crowd, confessing to product approvals he shepherded through the FDA during a 20-year career. He also noted that he had personally prescribed a Wyeth

product to a favorite patient weeks before it was withdrawn from the market. (There's no word on whether his mother is suing him.)

There is a sense that less may be changing than is perceived: "The post approval world of the future is not, in my opinion, a huge radical change from the post approval world of the past," Camardo said. You really don't have to read any farther.

He didn't state it so baldly. But it sounded like Camardo believes the industry should prepare for re-runs of what it's had during the past few years of watching Vioxx, Vytroin, Ketek, Trasylol and other controversial drugs being given black box warnings or yanked by the FDA after years of haggling and medical journal editors warning of safety issues. Even Wyeth has had issues in this regard, of course.

### **Expect Surprises**

"We should plan to prepare for surprises. The expectations for new drugs can be managed," he says. "The removal of drugs will be rare."

Camardo was logical. He ruminated on the disparity of scientific tools and general expertise into assessing efficacy, on the one hand, where the industry has deep familiarity, as opposed to assessing safety, which he views as a field deserving more attention.

"If we put our minds to it," Camardo said, "we can improve the quality, accuracy and complete of spontaneous reports."

### **Speed Matters**

So far, so good. Camardo also supports a better system to communicate risk to the public. Said Camardo: "The public will be happy if we address and solve problems quickly. That's what they want. We have to get more modern communications methods."

He went on to say that the public receives real-time reports of natural disasters from around the world, and that citizens may expect equally rapid dissemination of information about their pharmaceutical products and medical devices.

Camardo mocked the notion that physicians may be finding out about adverse events in a major national newspaper. "That's like the pilot of US Airways finding that the airport is closed by finding it on the radio, rather than from air traffic control," said Camardo. "That doesn't make sense to me."

### **Reality Check**

As delightful as Camardo's presentation was, as reasonable as it was, it worried us. He seems to be comfortable with the status quo. He seems to be at ease with the industry's usual waiting for the next safety controversy. True or not, that is an unfortunate impression to

leave. To our regret, he didn't specify which systems or processes will be needed (at Wyeth, FDA and elsewhere) to be more responsive to fast-moving events.

So it's time to say (and there's no time like the present) that the pharmaceutical industry's efforts to analyze data in real time have failed. So have its efforts to communicate with the public about drug safety. Slow responses to the public and the excessive use of paper are intimately related topics.

### **Forgive Us Our Soapbox, As ...**

Another tragedy, in our view, is that this industry does possess a few dozen smart speakers like Camardo. Such people could persuasively, slowly, help dissolve the most negative perceptions of the industry that have arisen. But the industry doesn't use them. They're held in reserve. This is like keeping Special Forces commandos safely on a military base in North Carolina in the middle of a war.

When crises erupt, the personable and charming high-level industry people are (as far as we can tell) locked up in a bunker under a golf course in the nicer areas of New Jersey. Too bad. CNN and the Wall Street Journal can readily find others who are happy to talk about the industry. Those folks have a very different story to tell.