



POST-APPROVAL SUMMIT

Politician, Serono Speak at Meeting

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- The Post-Approval Summit at Harvard, now in its third year, is the most cerebral conference on our calendar. It is also the meeting most larded with VIP speakers, including a preponderance of physicians who run a) large swaths of international companies or b) big slices of a regulatory bureaucracy in the U.S. or Europe.

The meeting is organized by **Outcome**, a technology firm based in Cambridge. Outcome specializes in registries and post-approval projects; it is based across town from the Boston campus of Harvard Medical School, where the conference unfolds. Surgeon **Richard Gliklich** runs the company and the meeting when not teaching at Harvard Medical School.

Gliklich recently lead a federal effort to compile a forthcoming handbook of best practices in clinical trial registries. We hope to be able to say more about that soon.

In some ways, there were two parallel conversations at the Outcome conference. They reflect the conversation that the industry is having with itself, and the conversation that society is having about the industry. The first conversation is about what *will* happen to shape clinical development in the future. The second is about what *has* happened in the recent past.

To illustrate the second conversation, the Post-Approval Summit invited Rep. Edward Markey, a Massachusetts Congressman. Depending on your perspective, Mr. Markey is part of a political mob trying to rewrite the rules governing the industry—or a passionate advocate of long-overdue reform.

Pointing Fingers

Markey was charming. But his remarks were a reminder that for some in Washington, drugs like Fen-Phen, Vioxx and Ketek are not historical footnotes. Rather they are live controversies, open grievances. Recalling Congressional efforts to understand recent decisions at the FDA, Markey said: “We were repeatedly stonewalled by the FDA. After many years of little or no Congressional scrutiny, the FDA has become accustomed to avoiding accountability.”

From Markey’s perspective, the FDA is an agency that has gone astray. He’s familiar with the **Institute of Medicine study** of drug safety. But his own criticism is far hotter than that mildly-worded report. “Our country’s drug safety system is broken and desperately needs to be reformed,” said Markey, “It doesn’t take an expert to know that when we see headline after headline about different drugs harming or even killing people. Something needs to be changed.”

Reputation At Risk

Markey said that the reputation of the FDA would continue to decline without a major effort to reorganize and invigorate the agency. “With each scandal, that reputation is tarnished and people lose trust in the agency.”

Markey did not entirely ignore the fact that (as other speakers and the IOM report contend) insufficient Congressional funding for FDA is one reason for its current predicament. To be fair, Markey did concede the agency might need more resources. But he said money alone would not fix the FDA.

Fixing FDA

The ingredients missing from the FDA, Markey said, are oversight, authority, transparency and safety. He believes that the FDA’s power should extend well after a drug has been approved. “Our drug safety and risk management systems should evolve as the knowledge about the use of the drug evolves,” Markey said. “The FDA needs to put greater emphasis on safety. The FDA should be engaged in a formal process of active surveillance.”

Markey explicitly suggested altering the balance between budget funds dedicated to approving drugs and those dedicated to monitoring them after approval.

Serono Speaker

A short time after Markey concluded his talk, it was striking to hear a speaker with a very different perspective. The audience could be forgiven for thinking that Paul Lammers arrived from a different galaxy than the one Markey inhabits. In fact, Lammers is chief medical officer at EMD Serono. His take on society’s drug safety dilemma was more measured and familiar.

Lammers reviewed some of the recent numerical trends around clinical trials and industry productivity, as well as drugs yanked from the market. But he was basically looking ahead, not back.

Lammers was candid about the inevitability of changes to the regulatory landscape. What seems to worry him is a haphazard, duplicative mandate by different national jurisdictions or regulatory agencies within the same country. While the nature of new requirements remains unknown, more post-approval studies seem likely, he suggested. “The question is the feasibility of doing those commitments in a reasonable time frame,” says Lammers.

Raving About Russia

Russia, he said, was a region that was proving especially useful for his company. Serono has done nine trials there. Flashing slides from a Russian clinical site, with many graphical icons indicating locked and completed data, Lammers said the research from the former Soviet Union was of high quality. Lammers didn’t elaborate on the matter, but the higher percentage of physicians entering data in Russia vs. nurses or clerical employees in the U.S. may be one explanation. “We have been very pleased with the results,” Lammers says. “All the data has been entered correctly. Quality has been great. Compare that to some of the sites in the U.S. and Europe. It’s quite different.”

Editor's note: We'll have more reports from the Post-Approval Summit in the weeks ahead, including FDA remarks at the meeting.

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