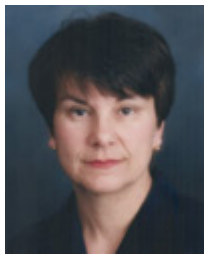


CDER Stresses 'Active' Post-Approval Surveillance

By Catherine Varmazis

June 16, 2008 | BOSTON | Speakers at the recent Post-Approval Summit* left no doubt that we are entering a new era of *active* surveillance of post-approval drugs. Richard Gliklich, chairman of the conference, said a number of forces have recently changed the role of post-approval research from “what had been an afterthought to something far more intrinsic” to the delivery and evaluation of health products.

Congress’ reauthorization last fall of the FDA Amendments Act (AA) is the most recent legislative impetus for these changes. But changed public expectations and escalating healthcare costs are also exerting pressure for a serious overhaul.



Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research (CDER), said that under the AA, CDER’s role in the safety of marketed drugs will expand both on the analytic side as well as in the post-market phase, when it will act “in an influence mode” with the industry. Despite the “good cop” allusion, Woodcock said the new provisions “have teeth,” and there are penalties for noncompliance.

She described the CDER’s Safety First/Safe Use initiative under which this will be accomplished and also hinted at the Sentinel Initiative, which was formally [announced](#) a week later.

Janet Woodcock

Woodcock said Title 9 of the AA, which focuses on post-market safety, was Congress’ response to many of weaknesses they saw in FDA’s authority in the last 10 years as safety problems emerged. “It was a surprise to the public and many member of Congress that the FDA didn’t have this authority,” she said. The new provisions give FDA the ability to require post-market epidemiologic studies of clinical trials at any time during the post-market period.

Under its new authority, FDA will be able to require sponsors to make safety label changes and to develop risk evaluation and mitigation strategies (REMS), which “intersect” with RiskMAPs but do not replace them.

The AA also mandates that the FDA build new ways to do active post-market surveillance, said Woodcock. “This is a historic shift from the idea that you do the clinical trial, throw the drug over the wall (from the FDA’s perspective) and then send us your Medwatch reports and let us know what happens.”

Woodcock said the oversight required by the AA was not possible sooner because “we had a very small armamentarium—we didn’t have the technological tools for post-approval studies” 20 years ago.

New systems will have to be built to implement these changes, but they will not be in the form of a “gigantic database in Washington, D.C.” partly because of privacy concerns. Instead, the FDA will rely on public/private partnerships between CDER and industry to build a distributed network for population-based studies and a multidisciplinary approach to the review of drug safety data.

Plans are also under way to establish a center for advanced computational analysis of drug safety data, said Woodcock, stressing the need for more scientists and informaticians with the right combination of skills to staff the center.

*May 14-15, 2008, at the Harvard Medical School.