

Insurer, FDA Start Program to Track Drug Side Effects

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In an unexpected move, WellPoint, Inc.—the nation's largest insurer—and the Food and Drug Administration (FDA) will be working together to launch the first real-time drug surveillance system. Beginning in early 2009, WellPoint will scan the medical information of over half of its 35 million members to find hidden patterns or medical problems that might be linked to medications or drug combinations. Because WellPoint has been charting medical claims and prescription drug use among their vast member base, they are uniquely positioned to embark on this drug safety program with the FDA.

The drug-safety monitoring system used by the FDA is considered by many to be spotty, slow, and passive and is one major reason why the FDA has been under constant fire for failing to protect consumers against the unintended harmful effects of drugs. The agency receives much of its data from stressed physicians and large pharmaceuticals and captures less than 10% of bad reactions, according to the U.S. Government Accountability Office.

After problems with Merck & Co.'s Vioxx painkiller being linked to heart attacks and problems with GlaxoSmithKline's popular diabetes drug Avandia and Eli Lilly's schizophrenia pill Zyprexa, Congress passed a law mandating that the FDA set up a new, more comprehensive computerized system with records of tens of millions of patients to scan for problems with medications. Rather than re-create its own database, the FDA will contract with insurers and other health systems to receive information from their databases and will look to WellPoint, UnitedHealth Group Inc., and other major insurers for information. Those insurers, in turn, are increasingly using their capabilities to intervene in their plan members' care. "We're bringing together all these different groups in a network so that we can ask them to look at the same question at the same time," says Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research. In addition to WellPoint, "we need to partner with a lot of groups because they'll represent different populations."

The FDA plans to use this database network in a number of ways, for instance, to follow-up on signals of potential problems that are revealed, but not significant enough to point to a risk, during a new drug's pre-approval testing. Meanwhile, other alerts will continue to be received from doctor reports or academic studies. Concurrently, WellPoint and others will work to create sufficient artificial intelligence so that spikes or signals of potential problems can be realized.

In addition to its huge database of medical and pharmacy claims data, WellPoint will work with data from the lab test results and medical-chart information of at least 20 million members. This information—according to its executives—should enable early intervention in possible drug-linked medical problems. WellPoint confirmed that during the medical data mining process, patient identities would remain anonymous.

More and more, insurers use drug safety-surveillance capabilities instead of waiting for warnings from the government. "Instead of waiting for the FDA to make a decision, we'll be able to react" by alerting WellPoint patients and their physicians," says Marcus Wilson, head of the WellPoint unit HealthCore.

