Group to Look at Genetics of Drug Adverse Events

BY TIMOTHY F. KIRN
Sacramento Bureau

A group of seven of the largest drug manufacturers has formed a consortium to study the genetics of serious adverse drug reactions.

The Serious Adverse Events Consortium will work closely with the Food and Drug Administration on the projects that it will undertake.

This group is one of several consortiums that were recently organized, with encouragement from the FDA, to support costly research initiatives. Others include the Predictive Safety Testing Consortium, the Biomarkers Consortium, and the Microarrary Quality Control project.

In its first two projects, the Serious Adverse Events Consortium will investigate genetic susceptibility to Stevens-Johnson Syndrome and also to drug-induced liver toxicity.

The scope of such projects would be beyond the capability of any one company or institution, said Arthur L. Holden, the chairman of the new consortium.

The two conditions targeted in the first two projects are so rare that it will probably be necessary to study tens of thousands of individuals.

"We really look forward to the results of these two projects," said Dr. Janet Woodcock, deputy commissioner of FDA, in a teleconference announcing the partnership. "They will greatly increase our knowledge."

All data from the consortium will be available for public use.

The Stevens-Johnson Syndrome project will be based at Columbia University, New York. The consortium expects that some results could be forthcoming by next year, Mr. Holden said.

The drug-induced liver toxicity project will include many patients enrolled in two European research networks. Drug-induced liver injury is now the leading cause of acute liver failure in the United States.

For the drug companies involved in the consortium, the effort could help avoid scenarios in which a few adverse events prevent the approval of drugs that cost large sums to develop.

Adverse-event susceptibility information also might prevent some drugs from being taken off the market unnecessarily, Mr. Holden said.

"It is a tragedy when a drug gets to late development, and then two or three patients develop a problem and its approval gets dropped," said Dr. Paul Watkins, an investigator with the Drug-Induced Liver Injury Network and a professor of medicine at the University of North Carolina, Chapel Hill.

Although the initial goal of the new consortium is to develop ways to identify susceptible people, the information also could improve future drug design, noted Dr. Watkins, who is not involved in the new consortium.

Some observers may question whether genetics contributes to drug-induced liver failure.

However, "it is great the pharmaceutical companies are starting to study this area," said Howard Coleman, who is the the chief executive officer of Genelex Corp., a Seattle-based company that completes enzyme-mediated testing of drug metabolism.

"It's good to see, because even with the most common drug reactions, this kind of work needs extraordinary numbers of patients," he said.

The consortium members include Abbott, GlaxoSmithKline, Johnson & Johnson Pharmaceutical Research and Development, Pfizer, Roche, Sanofi-Aventis, Wyeth, Illumina Inc., and research groups at Newcastle (England) University and Columbia University. ■

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