Consortium to Study Genetics of Adverse Events

BY TIMOTHY F. KIRN
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Seven drug makers have formed the Serious Adverse Events Consortium to study the genetics of serious adverse drug reactions.

The group is one of several consortiums 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 two first projects, the Serious Adverse Events Consortium will investigate patients' genetic susceptibility to Stevens-Johnson Syndrome and to drug-induced liver toxicity.

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

The conditions to be studied in the first two projects are so rare, tens of thousands of patients will likely need to be studied.

"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. All data will be available for public use.

For the drug companies, 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 at the University of North Carolina, Chapel Hill.

The data also could improve future drug design, noted Dr. Watkins, who is not involved in the consortium.

"It is great the pharmaceutical companies are starting to study this area," said Howard Coleman, CEO of Genelex Corp., Seattle, a company that does 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."

The consortium includes 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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