

Bio-IT World

FDA Official Forecasts Effect of Genetics on Medicine

By Nancy Weil, IDG News Service

May 18, 2005 | Within the next five years, pharmacogenomics will take stronger hold in medicine, with genetics becoming more key to drug development and providers moving toward a more personalized approach to healthcare, a U.S. Food and Drug Administration (FDA) official predicted Wednesday.

"I think we're going to see some rapid changes" in how genetics is used in healthcare and drug development, said Lawrence Lesko, director of the FDA Office of Clinical Pharmacology and Biopharmaceuticals in the Center for Drug Evaluation and Research. He delivered the keynote address to open the second day of the fourth annual Bio-IT World Conference + Expo in Boston.

The FDA is focused on the role of genetics and the emerging importance of pharmacogenomics, which are drugs developed using genetics, and is putting into place related guidelines and regulations, said Lesko, offering an overview of what the FDA has done recently in that regard.

As for genetic testing, which is a linchpin of using genetics in drug development and healthcare, Lesko forecast that standard test platforms will be adopted in the next few years and there also will be more complete testing available to patients. As an offshoot of that progress, problems with interpreting test results will be lessened as vendors "are going to see a business here." There already are point-of-care testing systems hitting the market, and those will become more widespread and reliable, as will predictive algorithms for test interpretation.

Pharmacogenomics also will be incorporated into guidelines for standards of care, Lesko said. Although in somewhat limited use today, genetics testing enables doctors to alter drug dosages based on a patient's genome, which can reveal, among other things, how well an individual will tolerate particular drugs.

Support for genetics-based medicine must come from insurance providers before "personalized medicine" becomes the norm, he said. Insurers are beginning to provide reimbursement for genetics testing and other

elements of personalized medicine, Lesko said. Such medical care involves taking into account not only an individual's genome, but also other aspects of the patient, including age, weight and family history.

Ultimately, personalized medicine involves giving patients more control over their medical records and who has access to those, which more and more will be kept in digital form, he said. It also means that a team of providers, including doctors, specialists, laboratory staff and pharmacists will be involved in the process of determining care and medicine dosages.

Recent highly publicized cases of drugs that have proven to have serious safety issues, including the painkiller Vioxx, which was removed from the market, have taught drugmakers and the FDA important lessons, Lesko said. It is now more widely accepted that determining toxicity across a wide population range is difficult to do. However, genetics-based medicine will help patients be better able to weigh the likely effects of a drug on them as individuals against possible risks, he said.

That means that some older drugs that have been found to be toxic in a higher percentage of people than is acceptable can be "retooled" because genetics testing will help determine which patients can take such medicines without high risk. In some studies, certain drugs have been shown to have a "virtually nil" risk in patients with particular genetic compositions, he said.