



Lilly's CEO Calls for Reform of Nation's Drug Safety System

FDA, health care industry, and the medical community collaboration would share data via a national health IT system

CLEVELAND, Oct 02, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Sidney Taurel, chairman and chief executive officer, Eli Lilly and Company (NYSE: LLY), in a speech today at the Cleveland Clinic, called on the health care industry, medical community and U.S. government to actively collaborate on a health information technology system that would provide more rapid and useful insights on the effectiveness of medicines while improving drug safety.

His proposal, along with other benefits that would flow from a true healthcare "Information Revolution," was outlined for an audience of some of the nation's medical thought-leaders attending Cleveland Clinic's 2007 Medical Innovations Summit. Taurel was the keynote speaker.

"The use of prescription medicines always will be a matter of balancing benefits and risks," Taurel said. "Fortunately, systems are now within our grasp to more quickly identify both the true benefits and the full extent of risks associated with medicines in widespread use."

Although traditional drug trials will continue to test new hypotheses about medicines after they have reached the market, Taurel outlined how a well-functioning health IT system could serve not only to frame hypothesis for so-called "Phase IV" clinical research, but also become the practical equivalent of massive, real-world trials. Such a system would collect detailed data from day-to-day medical practices and feed insights quickly, seamlessly and at a lower cost to doctors, regulators, and drug manufacturers. The result would be a more accurate picture of a drug's safety and efficacy than exists today.

Taurel also explained that intent of the newly enacted FDA Amendments Act of 2007 is to promote much wider involvement of health plans, academic medical centers and other sponsors in Phase IV research.

"The time is ripe for FDA, the health care industry, and the medical community to collaborate on a reform of our nation's pharmacovigilance system," said Taurel. "Such reform will allow us to speed up the recognition of safety signals and understand the true efficacy of new medicines more quickly."

Taurel noted that to fully realize a better drug safety system would require the large-scale implementation of Electronic Medical Records (EMRs) - patient-specific repositories of clinical information on diagnoses, treatments, and outcomes. Properly "blinded" to protect patient privacy, EMRs ultimately could include genetic information as well, in order to tailor therapies to patient groups in which they work best. He traced some of the obstacles to implementing robust, secure EMRs, and offered solutions.

Taurel explained that as EMR systems build out, they provide what amounts to a 'commons' in which organizations can collaborate to share health information.

For example, Lilly, Pfizer, and Johnson & Johnson are collaborating with 'e-Health Initiative' - a not-for-profit health information technology group - as well as with the Indiana Health Information Exchange and the Partners Healthcare System in Boston. The goal is to test how safety signals can be located and understood using existing data, potentially leading to a better understanding of the risk and benefits of medicines.

"This sort of public-private experiment, along with national standards and regional expansion, will soon create a mass of basic infrastructure that could produce the sort of knowledge that will truly revolutionize patient care," concluded Taurel. "We need to open our minds to the notion that electronic health care data represents a legitimate resource - to which access should in most cases be widespread and easy."

Those attending the talk included clinical, medical affairs and regulatory and business development executives, senior executives at medical device makers and pharmaceutical companies, investment bankers, investors and venture capitalists, researchers and the press.

About the Cleveland Clinic's Medical Innovations Summit Please go to <http://www.clevelandclinic.org/innovations/summit/default.htm>.

About Lilly

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