# Lilly CEO Says Appropriate Assessment of Both Benefits and Risks Critical in Regulatory Process

## With PDUFA V reauthorization rapidly approaching, Lechleiter calls for balanced decision-making

WASHINGTON, Nov. 2, 2011 /PRNewswire/ -- To sustain medical innovation, the FDA must accelerate the adoption of a Benefit-Risk framework to inform decision-making in the regulatory process, said John Lechleiter, Ph.D., chairman, president and CEO of Eli Lilly and Company (NYSE: LLY).

In an address at the *FDA News* Fourth Annual Risk Management and Drug Safety Summit, Lechleiter called for a regulatory process that focuses both on recognizing and appreciating benefits while identifying and minimizing risks. Such a balanced approach would help increase the flow of needed medicines to patients and reverse a trend of fewer new drugs getting approved, he said.

"The stakes are high," Lechleiter said. "The only way to make inroads against [chronic and other] diseases is to sustain the pace of medical progress."

The upcoming reauthorization of the Prescription Drug User Fee Act (PDUFA) V provides an important platform to address these issues. PDUFA, first enacted in 1992, sets the foundation for how FDA will manage the drug review process for five years, beginning in October 2012.

Lechleiter stressed the importance of a non-partisan course for reauthorization. "As a basis for the drug review process, PDUFA is too important to get bogged down in partisan politics," Lechleiter said. "As Congress considers reauthorization next year, we hope to see a 'clean' bill — one free of extraneous and controversial provisions that would politicize the bill and further complicate matters for all parties."

Even after PDUFA V, Lechleiter said the regulatory system must continue to evolve to meet 21st century needs. He outlined five characteristics of a "state of the art" regulatory approval system:

- **Timely** — "There are far too many conditions for which therapy is inadequate or nonexistent. We need a system that is not only effective, but efficient as well."
- **Predictable** — "The system must be predictable in its judgments, its decisions, and the criteria on which those decisions were based — whether scientific, ethical, legal, etc."
- **Consistent** — "The system must be consistent across review divisions using standardization and repeatable processes — so that an innovator clearly understands the regulatory requirements and so that institutional learning can be harnessed to replace time-consuming one-off learning by review groups and division."
- **Transparent** — "The system needs to be transparent in its judgments and criteria so [stakeholders] understand the rationale for its decisions."
- **Scientifically rigorous** — "This requires scientific expertise within the agency — or access to the expertise — that understands, engages in, and influences the constantly evolving external scientific environment and ensures that standards are up-to-date."

Lechleiter also discussed ways to strengthen a medicine's benefit and lower its risk, including calling for greater emphasis on improved outcomes for individual patients, through the development of tailored therapeutics.

"From the point of view of patients and their doctors, a tailored therapy will provide a better benefit/risk trade-off, because they can have a higher degree of confidence that it will work effectively and with minimal harmful side-effects relative to the benefit obtained," said Lechleiter. "From a value-for-money standpoint, tailored medicines should also reduce the heavy costs associated with non-responders. In other words, payers will get what they are paying for."

Lechleiter concluded his speech by calling for a change in the mindset and culture: from one focused disproportionately on risk to one that seeks to balance risk and benefit.

"We look forward to a partnership (between industry and FDA) that is uniquely effective in finding the appropriate balance and

advancing the interest of public health."

**About Eli Lilly and Company**

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information -- for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

**C-LLY**

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO )

SOURCE Eli Lilly and Company