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LEGAL ALERT

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Senate Approves Bill to Increase Regulatory Powers of FDA

by Angela Lutich

Background

The user fee arrangement currently in effect between industry and the government, which provides the Food & Drug Administration ("FDA") approximately half of the funding for drug review and approval, is scheduled to expire on September 30, 2007. Commentators refer to the renewal of this arrangement as a "must pass" because if Congress fails to act by summer, FDA could be forced to notify hundreds of senior scientists, doctors and statisticians, whose skills are in demand in the private industry, that their jobs might be at risk.

In connection with its evaluation of the user fee arrangement, the Senate is evaluating other pressing concerns regarding the FDA, specifically issues associated with post-market surveillance. Most of the pharmaceutical resources of the FDA have traditionally have been devoted to approving new drugs, with less attention paid to post-market safety. There is a consensus that the system in place for keeping track of drug side effects has been ineffective and that the FDA lacks the ability to act quickly when safety problems are uncovered.

On May 9, 2007, by a vote of 93 to 1, the Senate passed a bill, co-sponsored by Senators Edward M. Kennedy (D-Mass) and Michael B. Enzi (R-Wyo), that renews the user fee arrangement with industry and that gives the FDA new powers for policing drug safety and protecting consumers.

Brief Summary of Proposed legislation

The Senate bill, titled the FDA Revitalization Act, proposes a renewal of the user fee arrangement between industry and government. Far beyond this proposal, however, the Senate bill calls for a fundamental change in the philosophy and operations of the drug agency, requiring it to focus on the entire life cycle of a drug, not just the years before its approval, as well as the experience of patients who later take it. The primary purposes of the proposed legislation are to give the FDA more power to do the following, which is explained in more detail below:

- require pharmaceutical companies to take steps to address problems with drugs already on the market;
- restrict the use and distribution of medicines found to pose serious risks to consumers; and
- create a computerized system to scan medical and pharmacy records for indicators of trouble with new medications.

Renewal of User Fee Arrangement

The Senate bill provides for the renewal of the user fee arrangement through 2012, raising the total received from industry of more than $300 million this year to $539 million in 2008 and $916 million in 2012.

Post Market Surveillance of Drugs

The FDA's current system relies on anecdotal reports from doctors and captures only a small fraction of adverse reactions. The legislation would incorporate that system into a broader surveillance network for all new drugs. The proposed system would scan millions of records in billing files from government healthcare programs and private insurers, with patients' identities protected, and raise red flags where appropriate. In addition, a key provision of the Senate bill would require the FDA to review the safety of some potentially risky medications at 18 months and at three years after approval.

Publication of Clinical Trial Results

The Senate bill also contains provisions that would reduce secrecy in the drug development process by requiring public disclosure of most clinical trials and their results, as well as the release of memos that reflect internal FDA dissent about medications awaiting approval. The goals of this provision are twofold: to make it difficult for drug companies to hide evidence of safety problems and to make it

easier for patients to learn of clinical trials testing drugs that could save their lives.

Post-Market Studies

Currently, the FDA can only ask manufacturers to conduct follow-up studies, and such requests are frequently ignored. Often, the agency must go through protracted negotiations with a manufacturer to get a stronger warning. The proposed legislation authorizes the agency to craft an individual risk management plan for any drug thought to pose a significant danger. Pharmaceutical companies that violate the risk plans would face fines of up to $2 million. In addition, the Senate bill gives FDA the authority to order additional safety studies and/or clinical trials of approved drugs and to require additional precautions like special training for doctors and close monitoring of patients.

Drug Labeling

Under current law, the government and drug companies sometimes negotiate for months over changes in drug labeling. For example, it took 14 months to change the Vioxx label to warn doctors and patients of the danger. Under the Senate bill, the government could order changes in a label to be accomplished within a specified time frame.

Other Provisions

The bill would more than double the size of the staff that monitors drug safety.

The bill would give financial incentives to drug companies to study the effects of their products in children. The reward would be scaled back for drugs that already had sales of more than $1 billion a year in the United States.

The bill would require stricter production and labeling standards for cat and dog food and would create a system to detect tainted pet food and notify the public of recalls.

Provisions that were Removed from the Senate Bill

Despite initial proposals that would have granted the FDA the power to prevent drug companies from advertising a new drug for up to two years, the Senate implemented a weaker standard that allows the government to fine drug companies for false or misleading advertising, which can amount to $150,000 per violation.

The Senate nullified a plan for wide-scale importation of lower-priced prescription drugs from Canada, Europe and other industrialized countries.

The Senate also left out an amendment to create a system for FDA approval of cheaper generic versions of complex and expensive biologic drugs.

Next Steps

Just a few days after passage of the Senate bill, the House proposed its version of the bill. The House bill calls for an independent

center, comprised of professional scientific analysts independent of the initial drug review process, to conduct post-market surveillance, so that the same persons who approve a drug are not responsible for monitoring it once it reaches the market. In addition, the House bill prohibits the FDA from collecting fees paid by the drug and medical device manufacturers that it regulates, mandating instead that those funds be deposited into a general fund of the Treasury, with certain mandatory spending levels. A vote by the House is expected later this summer.

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