S. 930 -- The Food and Drug Administration Safety Act of 2005

Summary of Major Provisions

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OVERVIEW

The FDA Safety Act significantly reforms FDA's inadequate postmarket drug safety program, correcting structural and regulatory shortcomings that have contributed to the agency's high-profile drug safety failures in recent years.

The bill establishes a strong Center for Post-market Drug Evaluation and Research, which reports directly to the FDA Commissioner. The Center is given primary responsibility and significant new authorities to evaluate postmarket safety and efficacy. The bill removes postmarket drug surveillance functions from the FDA division that approves new drugs (CDER), eliminating the conflicts-of-interest created when those who approve drugs are also responsible for admitting safety problems after approval. Existing functions of the Office of Drug Safety, currently under CDER, are transferred to the new postmarket Center.

The new Center can require additional safety studies for drugs at any point after approval and can determine, on the basis of a wide variety of data sources, that a drug poses an unreasonable safety risk. When it does so, it is also *required* to order corrective action to mitigate risk. If corrective action is insufficient, the Center may withdraw or suspend the drug.

SPECIFIC PROVISIONS:

- **General Responsibilities of the Center --**
  - Ensure the safety and effectiveness of approved drugs;
  - Conduct and improve postmarket surveillance of approved drugs;
  - Determine whether approved drugs pose an unreasonable safety risk and take corrective action to mitigate risk;
  - Determine whether additional safety or efficacy studies should be required of sponsors and ensuring their timely submission; and
  - Inform the public about the safety of approved drugs.

- **Authorities of the Center --**
  - Review new drug applications prior to approval and require, where appropriate, sponsors to conduct postmarket studies;

- Require, at any time *after* approval, additional clinical studies to evaluate safety and effectiveness;
- Conduct, or require sponsors to conduct, epidemiological studies of drugs;
- Make determinations, at any time after approval, that a drug presents and unreasonable safety risk;
- Order corrective action to reduce unreasonable risks, including requirements that sponsors:
  - Modify drug labels to improve risk communication
  - Modify approved uses to reduce risk and ensure safe use
  - Restrict distribution to safe use
  - Establish a patient registry
  - Secure informed consent of patients prescribed the drug
  - Monitor sales and usage
  - Provide patient or physician education
  - Establish a risk management plan
  - Submit promotional materials to the Center 30 days prior to dissemination and include safety and other risk communication disclosures
- Withdraw or suspend approval if corrective actions cannot mitigate unreasonable safety risks or if sponsors fail to take corrective action or complete studies ordered by the Center;
- Review advertising and promotional materials for new drugs for the first two years after approval and require improved risk communication to consumers in such materials; and
- Review advertising materials for drugs for which postmarket study requirements have not been fulfilled and require enhanced disclosures in such materials.

- **Consultation and Coordination**: To enhance communications and ensure coordination between the drug approval and postmarket centers, the new postmarket Center shall consult with the Center for Drug Evaluation and Research (CDER) before requiring additional postmarket studies, taking corrective action or withdrawing a drug. Similarly, before approving a drug, CDER must consult with the new postmarket Center.
- **Public Information:** Secretary shall, at least every 90 days, publish information about postmarket studies required, progress reports for outstanding studies and results of completed studies, along with any unreasonable risk determinations made by the Center.
- **Penalties:** If a sponsor fails to complete a postmarket study or take corrective action ordered by the Center, the Secretary may impose substantial civil penalties. Currently, FDA does not have authority to impose civil penalties for regulatory infractions related to drugs.
- **Funding:** Authorizes funding for the Center of $50 million in 2006, increasing to $150 million by 2010--five times the FY2006 budget for the current Office of Drug Safety.