Summary
The Food and Drug Administration Amendments Act of 2007

Title I. Prescription Drug User Fee Amendments of 2007

Title I reauthorizes the prescription drug user fee program through fiscal year (FY) 2012. Changes to the prescription drug user fee program fall into three major categories: increased revenue for the human drug review program, enhancements for premarket review of human drug applications, and enhancements to modernize and transform the postmarket safety system.

Title I includes the Administration's request for an increase in the total annual user fees collected to $392.8 million for FY 2008, an $87.4 million increase over the current base. The increases in fees take into account inflation and increased resources needed to conduct certain activities, known as a workload adjustment. Title I also increases the amount of fees devoted to postmarket safety. H.R. 2900 contains an additional $225 million in user fees that will be collected over five years. These additional funds are intended to be used for drug safety activities, supplementing all other drug safety resources. The bill contains a "reverse trigger" that states there should be a dollar for dollar reduction in the new user fee for every new dollar appropriated for post market safety.

Title I establishes a new program to assess, collect, and use fees for the voluntary review of prescription drug direct-to-consumer (DTC) television advertisements. The current authorization for this program expires at the end of Fiscal Year 2007.

Title II. Medical Device User Fee Amendments of 2007

Title II reauthorizes medical device user fees through FY 2012. Changes to the medical device program fall into two major categories: increased revenue for the device review program, and enhancements to the process for premarket review of device applications. Fee increases over the next five years will be used to cover the anticipated costs related to rent, security, and statutorily mandated payroll and benefit increases.

Title II includes two new types of fees an annual establishment registration fee and an annual fee for filing periodic reports, for devices approved under a PMA, to FDA at least annually that provide information on manufacturing and design changes, and new studies involving their products. These fees are intended to generate about 50 percent of the total fee revenue. This title authorizes $7,100,000 in appropriations for additional postmarket safety activities. The bill also includes a provision that will streamline and improve the third-party inspection program. The current authorization for this program expires at the end of Fiscal Year 2007.

Note: Failure to reauthorize the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act by the end of July could force the Food and

Drug Administration to issue Reduction in Force (RIFs) to many of the employees involved in the review of new drug and biologic applications and the review of medical devices.

Title III. Pediatric Medical Device Safety and Improvement Act

Title III provides incentives to device manufactures to create medical devices specifically designed to meet the needs of pediatric patients. It also gives FDA the authority to review these devices in a manner distinct from devices in general, and to require postmarket safety and efficacy studies of these devices. The provisions of Title III only apply to devices that are used in 4,000 or fewer individuals.

Title III modifies the existing humanitarian device exemption (HDE) for medical devices to allow manufacturers of HDE-approved devices specifically designed to meet a pediatric need to make a profit from the sale of such devices. This HDE modification will sunset in 2013.

Title IV. Pediatric Research Equity Act of 2007

Title IV reauthorizes, for five years, the FDA's authority to require a manufacturer of a drug or biologic who submits an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to also submit a pediatric assessment. Title IV grants the Secretary of the Department of Health and Human Services (HHS) authority to require pediatric tests in appropriate circumstances. The current authorization for this program expires at the end of Fiscal Year 2007.

Title V. Best Pharmaceuticals for Children Act of 2007

Title V reauthorizes, for five years, FDA's authority to grant {an additional six months} of marketing exclusivity to a manufacturer of a drug in return for FDA-requested pediatric use studies and reports. Title V also includes provisions to encourage pediatric research for products that are off-patent or for products whose manufacturer declines to conduct FDA-related studies.

Title V increases to 180 days the time limit that the Secretary has for all exclusivity decisions. This title also strengthens labeling requirements to reflect study results in a timely and consistent fashion. The current authorization for this program expires at the end of Fiscal Year 2007.

Title VI. Reagan-Udall Foundation

Title VI creates the Reagan-Udall Foundation for the Food and Drug Administration. The purpose of the Foundation is to establish a private-public partnership to advance FDA's Critical Path Initiative to modernize medical product development, accelerate innovation, and enhance product safety. Title VI sets forth the duties of the Foundation to include identifying unmet needs in the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, biologics, and drugs. Other duties include establishing goals and priorities to meet the identified unmet needs, and awarding grants to advance the goals and priorities identified.

Title VII. Conflicts of Interest

Title VII continues the requirement that all individuals under consideration for appointment to serve on an advisory committee to disclose to the Secretary all financial interests that would be affected by the advisory committee's actions. Under the bill, the FDA must determine the total number of waivers given over all advisory committees for 2007. The number of waivers permissible in 2008 would be five percent less than the aggregate number for 2007. The succeeding four years would also see a five percent reduction a year in the number of waivers that could be granted for a total 25% reduction in the aggregate number of waivers over the next five years. The global cap on waivers provides a more flexible approach to filling advisory committee positions than the original House bill when there is difficulty finding the necessary expertise in a given field.

Disclosure of the waiver must be made public 15 or more days prior to the meeting of the advisory committee and must be posted on the Internet. Title VII allows experts with a financial conflict of interest to present information to the committee.

Title VIII. Clinical Trial Databases

Title VIII establishes two separate databases: one for a clinical trials registry and the other for clinical trials results. All clinical trials conducted to test the safety and efficacy of either drugs or devices are subject to the database reporting requirements. The databases would apply to both privately and publicly-funded clinical trials. Title VIII requires that both databases be disclosed to the public through the Internet. Title VIII provides civil monetary penalties (CMPs) for noncompliance.

Title IX. Risk Evaluation and Mitigation Strategies

Title IX provides FDA with the authority to require labeling changes under appropriate circumstances and provides for an increased level of civil monetary penalties for violations of the Federal Food, Drug, and Cosmetic Act. Title IX provides FDA with a process to prereview television pharmaceutical advertisements. Specifically, this title strengthens FDA's ability to monitor and remedy false and misleading television advertising and provides an administrative procedure and CMPs for violations.

Title IX creates a "Risk Evaluation and Mitigation Strategy" (REMS) process, which grants the Secretary the authority to require a REMS, if the Secretary determines for new drug and biologic license applications, for drugs and biologics that have already been approved, and for supplemental applications seeking approval of a new indication for use of the drug if the REMS is necessary to ensure that the drug's benefits outweigh its risks. The only mandatory requirement of a REMS would be to so an annual assessment every year for the first three years of the REMS and review data on the use of drug products after the seventh year. A REMS could also include requirements for distribution of medication guides or certain restrictions on distribution and use. It also directs the Secretary to establish an active postmarket drug surveillance infrastructure.

Title IX also includes the "pay for" needed for the legislation. The reauthorization of pediatric exclusivity costs $200 million over 10 years. The legislation includes modifications to the citizens' petition process. Some have claimed that innovator companies file citizens' petitions right before the FDA can approve a generic application claiming a specified legal or scientific reason that the FDA should not approve the generic application. The legislation would state the FDA can not deny approval of an application on the basis of a citizens' petition, with an exception for the protection of the public health. The legislation also states that upon filing a citizens' petition that the filer must certify that the information contained in the petition is full and accurate. Finally, the legislation requires the FDA to act on a citizens' petition within a 180 days of filing and requires a filer to wait 180 days after filing before it can go to court to challenge the generic approval.

Title X -- Food Safety

Title X helps improve food safety primarily by creating a reportable food registry. Certain parties are required to report incidents where food might be adulterated and pose a significant risk to health. Important information concerning such reportable foods will help track problems and allow for a rapid response by the Food and Drug Administration and other responsible parties.

Title X also helps ensure the safety of pet food by requiring rulemaking to establish ingredient and processing standards and a safety surveillance system.

Title XI -- Miscellaneous

Title XI establishes an incentive system for certain drugs or devices for certain diseases that effect global populations that otherwise might not have sufficient market incentives. Such drugs or devices can be rewarded with a voucher that can be sold to provide for priority review of a given drug or device.

Title XI also contains certain incentives for the development and enhanced access to antibiotics.