EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

May 1, 2007
(Senate)

STATEMENT OF ADMINISTRATION POLICY

S. 1082 – Food and Drug Administration Revitalization Act

(Sen. Kennedy (D) MA)

The Administration strongly supports reauthorization of the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). These two programs account for nearly one quarter of the Food and Drug Administration's (FDA) annual budget and support more than two thousand Agency employees who work diligently to ensure the safety and efficacy of the medical products on which the American people rely. Reauthorizing PDUFA and MDUFMA will enhance FDA's ability to more efficiently and effectively regulate drugs, biological products, and medical devices, a critical component of the Agency's public health mission. Additionally, the Administration is committed to reauthorizing the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), which have provided invaluable information to the Agency about medical products' interaction with pediatric populations.

The Administration shares the goal of S. 1082 to provide FDA with the appropriate tools and resources to enhance the safety and efficacy of the products the agency regulates. However, the Administration has serious concerns with S. 1082 in its current form and will work with Congress to address them as the legislative process moves forward.

The Administration appreciates that portions of S. 1082 are consistent with the Administration's recommendations for reauthorization, which strengthen FDA's ability to ensure the safety and availability of new drugs and medical devices, create a new program for review of television advertisements, and strengthen post-market review. These user fee programs expire at the end of the current fiscal year, and their timely reauthorization is critical to the ability of FDA to continue to carefully and expeditiously review and approve new drugs and devices to benefit the health of the American people.

The Administration is committed to further improving drug safety through better tools for surveillance of drug events, improved scientific tools for evaluating drug safety problems, and better means of communicating drug safety problems to providers and patients. However, the Administration is concerned that the bill, as written, would require significant resources to implement burdensome process changes that will not contribute meaningfully to improving drug safety. For example, the prescriptive timeframes to develop and process Risk Evaluation and Mitigation Strategies are particularly burdensome and are not likely to contribute to improving drug safety. Additionally, the Administration is concerned about the provision in S. 1082 that would use increased user fees to fund certain additional drug safety activities that were not agreed to during the statutorily required Agency-industry negotiations. This provision reopens and is inconsistent with the Administration PDUFA proposal that was developed through

extensive consultation.

There are other provisions in S. 1082 that also raise serious concerns. Specifically, the bill would make changes to the BPCA and PREA to reduce the incentives to conduct clinical trials for children, thus reducing the effectiveness of the program. It also would impose administrative burdens that would make the programs inefficient and in many ways unworkable. These provisions would reduce the flexibility the agency needs to conduct these programs, require an inefficient duplication of scientific expertise, and cause delays in the review of pediatric assessments. Both BPCA and PREA have been very successful in providing the necessary incentives for drug companies to conduct pediatric clinical trials to improve our understanding of how drugs work in children, thus enhancing the quality of their medical care. BPCA and PREA should be extended without modification.

Potential Amendments: Follow-on Protein Products and Importation of Prescription Drugs

The Administration supports the goal of making safe and effective drugs available and affordable for American consumers. While some in Congress may be interested in attaching legislation related to follow-on protein products to this bill, the Administration believes that these complex issues should be considered thoroughly through a robust scientific, regulatory, and legal discussion. Sufficient discussion has not yet occurred and should not be abbreviated for the convenience of a particular legislative vehicle. Any legislative proposal considered to authorize a regulatory pathway for follow-on protein products must, as a first priority, ensure the safety and efficacy of the resulting products, thus protecting patient safety. Furthermore, it should also include adequate intellectual property protections for innovators, in order to maintain the research enterprise that has generated life-saving medications. The Administration believes further discussion must take place before addressing these issues in legislation. The Administration strongly opposes the inclusion in this bill of any provision related to follow-on protein products.

The Administration would also strongly oppose any provision that might be added on the Senate Floor regarding the importation of prescription drugs that does not address the serious safety concerns identified in the December 2004 Department of Health and Human Services Task Force Report on Prescription Drug Importation. The Administration believes that allowing importation of drugs outside the current safety system established by the FDA without addressing these serious safety concerns would threaten public health and result in unsafe, unapproved, and counterfeit drugs being imported into the United States. As a result, if any such importation provision were included in the final version of the bill presented to the President, the President's senior advisors would recommend that he veto the bill.

The Administration strongly opposes the inclusion of any unrelated provisions that would disrupt the timely reauthorization of the user fee program. The Administration looks forward to working with Congress to reauthorize PDUFA and MDUFMA expeditiously to avoid any disruptions to these successful programs.

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