



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

SEP 14 2007

The Honorable Michael B. Enzi
Ranking Minority Member
Committee on Health, Education, Labor,
and Pensions
United States Senate
Washington, D.C. 20510

Dear Senator Enzi:

We are writing once more to express our grave concern that to date Congress has failed to complete reauthorization of the Prescription Drug User Fee Act (PDUFA), the Medical Device User Fee Modernization Act (MDUFMA), and the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA).

As we informed you on August 2, if Congress fails to complete the reauthorization of the drug and device user fee programs by September 21, this will unfortunately lead to FDA beginning to issue reduction-in-force (RIF) notifications to employees that funding for their positions will expire. As part of this process, it will be necessary to inform and bargain with the National Treasury Employee Union (NTEU) on impact and implementation.

It is incumbent that we be clear: FDA's lack of authority to continue to collect user fees and the resulting financial impact on the Agency would force the issuance of RIF notices if Congress fails to act. Issuing RIF notices would have a devastating impact on the Agency. Not only would it affect nearly 2000 Federal employees' jobs, but it could cripple the Agency's critical public health roles of approving and ensuring the safety of drugs, devices and food.

We understand that some are proposing temporary extensions of the programs to allow continued negotiation, but this does not present a solution. In fact, continuing uncertainty about the future arising from the fact that Congress has failed to complete these bills will cause FDA employees to seek employment opportunities outside of the Agency. In 1997 when Congress failed to timely reauthorize

Page 2 - The Honorable Michael B. Enzi

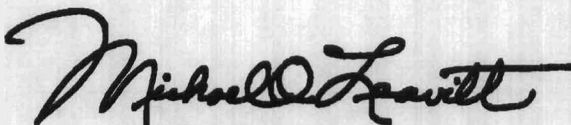
PDUFA and instead passed an extension, the delay caused departures to the extent that it took 18 months for FDA to return to full staffing levels. If a similar situation were repeated, it would be devastating to the Agency.

As you know, PDUFA and MDUFMA provide vital resources for the FDA to conduct safety and effectiveness reviews for life saving drugs and medical devices. In addition, BPCA and PREA have been very successful in providing the necessary incentives and tools for drug companies to conduct pediatric clinical trials to improve drug labeling for children, thus enhancing the quality of their medical care.

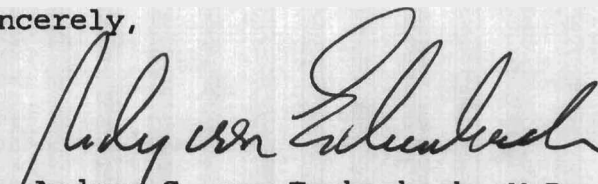
At a time when the nation faces critical issues of the safety of our nation's drug and food supply, it is imperative that we have a strong FDA. Congress has the ability to prevent the issuance of RIF notices by taking swift and appropriate action; failure to complete these reauthorizations threatens FDA's ability to fulfill its public health mission, creating unnecessary uncertainty among the very FDA employees who are central to protecting and promoting our nation's public health.

We strongly urge you to take all possible steps to ensure the reauthorization of these critical public health programs by September 21, and we stand ready to assist in this effort.

Sincerely,



Michael O. Leavitt
Secretary



Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs