

March 14, 2007

An Open Letter to:

**Chairman Edward Kennedy and Senator Mike Enzi,
Chairman John Dingell and Representative Joe Barton
Members of the Senate Health, Education, Labor and Pensions Committee
Members of House Energy and Commerce Committee**

The Food and Drug Administration (FDA) is facing a serious crisis that has significant implications for the nation's health.

The panel of experts recently convened by the Institute of Medicine (IOM) identified serious problems in the nation's capacity to determine drug safety and made a series of recommendations, calling on the FDA to "embrace a culture of safety in which the risk and benefits of medications are examined during their entire market life."^{1,2}

The Prescription Drug User-Fee Act (PDUFA), in which brand name drug manufacturers pay a fee for each new drug the agency reviews, is an important cause of the difficulties faced by the FDA. Last year, this amounted to over \$300 million, or over one-third of the entire budget for FDA's Center for Drug Evaluation and Research. PDUFA has helped to foster the public's perception that industry has become the primary client of FDA rather than the American people; this perception has contributed to the erosion of trust in FDA.

Unlike other user fee programs in the federal government, PDUFA requires the FDA to negotiate with representatives of the users, in this case the Pharmaceutical Research and Manufacturers of America (PhRMA), about how the agency may allocate its resources. The negotiated arrangement finances the drug approval process but neglects the equally important task of risk management once these drugs are on the market. This negotiated arrangement, which has explicitly limited its ability to conduct post-marketing drug safety surveillance and other critical activities, clearly diminishes the capacity of FDA to do its work on behalf of the nation.

User fees may appear to save the taxpayers money, but at an unacceptable cost to public health. In one study, PDUFA-imposed deadlines on FDA staff to complete reviews quickly are associated with subsequent withdrawals, warnings and other post-approval regulatory actions.³ In fact, premature approval of a drug with safety problems, or an inadequate means of detecting problems that emerge after marketing (as occurred with Vioxx) actually cost the taxpayers far more than the Treasury appears to save through user fees. The human costs of delayed detection of safety problems are considerable.

With the expiration of PDUFA this year, the FDA and PhRMA have negotiated terms for a five year reauthorization.⁴ This negotiation, completed behind closed doors, had only limited input from the public. Unfortunately, the proposal crafted by the FDA and PhRMA does not come close to addressing the problems identified by the IOM.

In February, four former FDA Commissioners agreed that the nation would be better served if Congress directly appropriated the money the FDA needs to do its job right, without the constraints imposed by PDUFA.⁵

We oppose reauthorizing PDUFA and other user fee programs modeled after it in the form negotiated by the FDA and PhRMA; instead, we support increased direct appropriations for the FDA, as is done with most federal agencies. The supposed “savings” realized through user fees make no sense in light of the added medical and economic costs that are generated by an inadequate drug safety surveillance system. Direct appropriation is the most effective way to ensure FDA’s independence and commitment to drug safety.

As called for by the IOM and a recent Government Accountability Office report⁶ on this topic, Congress and the nation must carefully re-assess the system in which drugs are developed, tested, approved and followed post-approval. Ideally, the plans for new funding sources and for new activities to improve drug safety would be completed before Sept 30, 2007. But this re-assessment cannot be done in the very short timeframe scheduled for PDUFA reauthorization.

However, if PDUFA must be reauthorized this year, in order for the nation to be able to have the substantive debate required for such an important and complex issue, we call on you to re-authorize it for no more than one year, and immediately schedule a series of hearings and investigations to examine ways to ensure that our drugs are effective and safe, and that the FDA itself is sound.

This limited re-authorized PDUFA should be structured to enable the FDA to do the best job it can in advancing the health of Americans. Any reauthorized PDUFA must have the following characteristics:

- Allow FDA leadership to determine how the agency allocates the fees collected to fulfill *all* aspects of its mission.
- Deadlines or targets for speed of review must be eliminated or modified to allow flexibility and adequate time for evaluation and analysis by reviewers.
- New performance goals must be linked with safety or other public health outcomes, not just speedy approval decisions.
- Adequate resources must be made available for scientific research and training for FDA scientific and medical staff, including in drug safety epidemiology and risk management.

The FDA’s mission is to protect and advance the public’s health. As it currently exists, and would exist in its proposed form, PDUFA stands in the way of this objective.

Sincerely,

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Open Letter to Sen. Kennedy, Sen. Enzi, Rep. Dingell, Rep. Barton

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¹ Committee on the Assessment of the US Drug Safety System, Alina Baciuc, Kathleen Stratton, Sheila P. Burke, *Editors*. *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. Institute Of Medicine, National Academies Press, Washington DC 2006

² Psaty BM, Burke SP. Protecting the health of the public--Institute of Medicine recommendations on drug safety. *N Engl J Med*. 2006;355(17):1753-1755.

³ Carpenter D. et al. Deadline Effects in Regulatory Drug Review: A Methodological and Empirical Analysis. Available at: http://defending-science.org/newsroom/upload/Carpenter_FDA_Deadlines.pdf

⁴ Federal Register January 16, 2007 (Volume 72, Number 9) pps1743-1753

⁵ Transcript of SKAPP Policy Workshop on Strengthening the FDA, February 21, 2007. Available at http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=2043

⁶ Government Accountability Office. *Drug Safety: Improvements Needed in FDA's Postmarket Decision-making and Oversight Process*. March 2006. Report no. GAO-06-402. Available at: <http://www.gao.gov/new.items/d06402.pdf>.