



Congress of the United States

House of Representatives

Washington, DC 20515

February 29, 2008

The Honorable Andrew C. von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane, Room 15-47
Rockville, MD 20857

**Re: Supplemental Applications Proposing Labeling Changes for Approved
Drugs, Biologics, and Medical Devices (Docket No. 2008N-0021)**

Dear Dr. von Eschenbach:

We are writing to express our concerns regarding the above-entitled proposed rule issued January 16, 2008.¹ The proposed rule seeks to substantively amend current regulations that require pharmaceutical and medical device companies to promptly update their drug and device labels with new safety information. It strongly encourages these companies to consult the FDA prior to changing their labels to warn of health risks, despite the urgency of the potential hazard and the FDA's prior interpretations of labeling requirements. We have profound concerns with these changes. It is unclear why an agency that is clearly in crisis would seek to limit consumers' access to information about crucial health and safety risks. Therefore, we request that the FDA withdraw its proposed rule.

The House Committee on Energy and Commerce (Subcommittee on Oversight and Investigations) held a hearing on January 29, 2008 to hear expert testimony from members of the FDA's scientific advisory board and the Government Accountability Office regarding the state of the agency. The consensus was clear that the agency suffers from a high turnover rate of scientists, an inadequate information technology system, a weak organizational structure, and a rapidly declining inspection force. This is compounded by the increase in drug ingredients from foreign countries, further stretching the FDA's financial and personnel resources. As a result, even with the industry's payment of user fees, it has become increasingly difficult for the agency to efficiently review pharmaceutical and medical device applications and supplemental filings regarding warning label changes in a timely manner. The agency, therefore, must continue to require pharmaceutical and device companies, who are in the best position to know of potential drug and device hazards, to amend their product labels to warn consumers of such risks at the earliest possible moment.

¹ This letter is intended to be included among the public comments that the agency receives regarding the proposed rule.

The FDA's dire lack of resources may explain the dramatic decrease in FDA enforcement actions in recent years. According to a House Committee on Government Reform report,² FDA enforcement actions have declined dramatically in recent years. The number of warning letters issued by the FDA for violations of federal requirements, the true measure of enforcement activity, has fallen by over 50%, from 1,154 in 2000 to 535 in 2005, a 15-year low.³ Internal FDA documents also show at least 138 cases in which FDA field inspectors found violations of FDA safety requirements, but the FDA failed to take any enforcement action against the pharmaceutical manufacturer.⁴ Whatever the reason for this overwhelming lack of enforcement, it further illustrates the critical importance of requiring drug and medical device companies to update their warning labels, without prior FDA approval, at the earliest sign of potential hazards. The public cannot afford to wait for the FDA to act to enforce safety labeling requirements given the FDA's recent failure to take appropriate enforcement actions.

During our debate on the Food and Drug Administration Amendments Act of 2007 (FDAAA), we expressed our concerns about the problems with resources and enforcement within the FDA. Therefore, we sought to strike an appropriate balance between providing the FDA with the necessary authority to protect consumers from adverse drug events and preserving the ability of Americans to pursue common law remedies to hold drug manufacturers accountable for failing to warn consumers of dangerous drug side effects. As a result, we included language in the FDAAA to preserve the status quo, allowing the FDA and state remedies to remain complementary and necessary safeguards to protect American families. However, we believe the FDA's proposed rule directly contradicts this language by reversing a drug manufacturer's obligation to warn of new risks and hazards and, instead, allowing these companies to claim immunity from liability because they had no duty to warn. This is contrary to congressional intent and to the FDA's mission to protect the public health.

Accordingly, we urge the FDA to carefully reconsider its actions and withdraw this proposed rule. We appreciate your time and attention to this matter.

Sincerely,



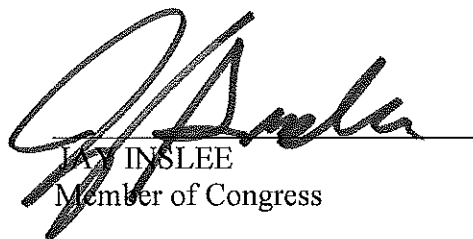
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Member of Congress



GENE GREEN
Member of Congress



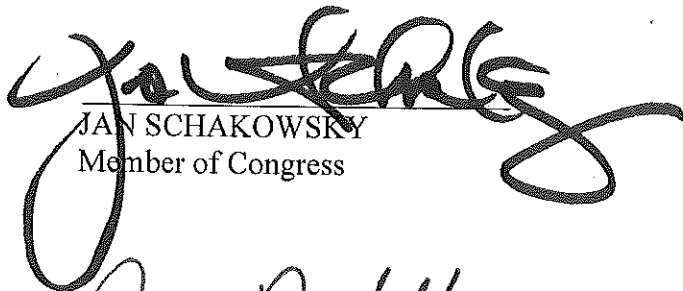
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Member of Congress

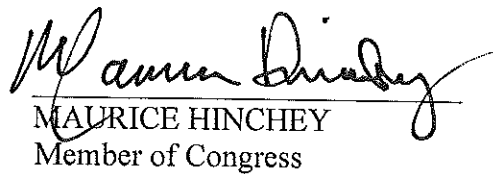


JAY INSLEE
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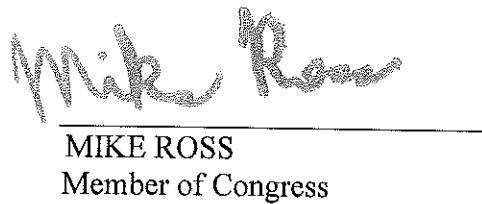
³ *Id.*

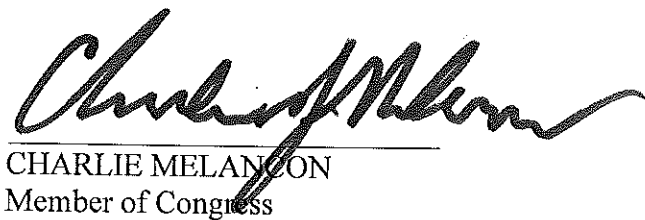
⁴ *Id.*


JAN SCHAKOWSKY
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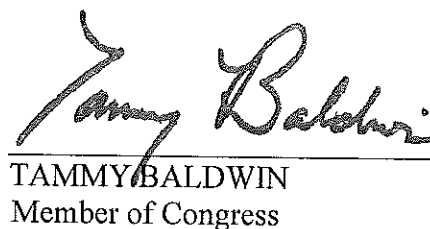

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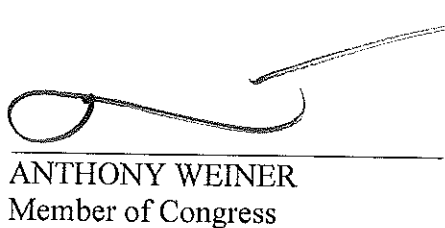

MIKE ROSS
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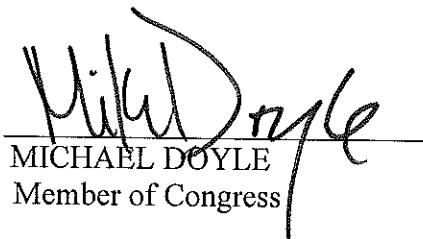

CHARLIE MELANCON
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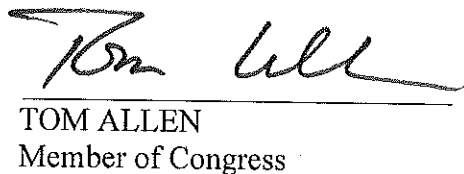

JOHN BARROW
Member of Congress

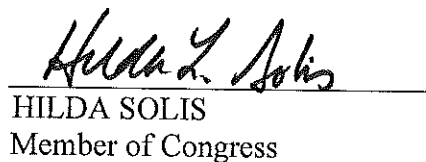

ELIOT ENGEL
Member of Congress

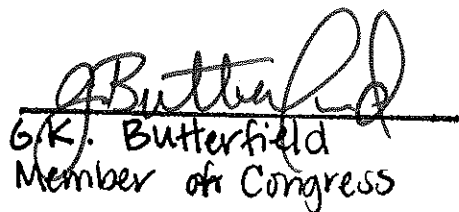

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