

September 9, 2014

The Honorable Barbara Mikulski
Chairwoman
Committee on Appropriations
United States Senate
S128, US Capitol
Washington, DC 20510

The Honorable Richard Shelby
Ranking Member
Committee on Appropriations
United States Senate
S-146A US Capitol
Washington DC 20510

Dear Chairwoman Mikulski and Ranking Member Shelby:

In November 2013, the Food and Drug Administration (FDA) proposed to revise its regulations to allow generic drug manufacturers to initiate safety updates to their products' labeling.¹ We strongly support the FDA's proposal.

Generic manufacturers currently are barred from providing new warning information, except in response to a brand-name update or FDA order. Yet most prescription drugs sold in the United States are generic versions, and the brand-name manufacturer often stops selling the drug after generic versions come on the market.

Allowing the generic manufacturers to initiate safety updates, as brand-name companies have done for 30 years, is essential to patients and consumers, as promptly updated warnings can provide informed consent to patients and physicians and prevent serious harm to patients.

Recently, **the House Committee on Appropriations** included a few sentences in its report of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill for fiscal year 2015 that would **unnecessarily delay** the FDA's ability to finalize the proposed rule and leave patients and consumers exposed to the current inadequate safeguards.

Patients and consumers deserve up-to-date information about the prescription drugs they use, including the most up-to-date safety warnings. Allowing generic drug manufacturers the flexibility to update safety labeling as soon as they become aware of new information is important to protect the health of all Americans and maintain the public's trust in generic drugs. The FDA's proposal deserves the strong support of Congress and all those who care about public health in the United States.

We strongly oppose the inclusion of the House Language and ask for your support in making sure that it is not included in any final appropriations report for the Food and Drug Administration, or any other legislation.

Thank you for your consideration.

Alliance for Justice
Alpha-1 Foundation
American Autoimmune Related Diseases Association
American Medical Student Association
American Medical Women's Association
Annie Appleseed Project
Brain Injury Association of America
Breast Cancer Action
Center for Justice & Democracy at New York Law School
Center for Medical Consumers
Center for Science and Democracy at the Union of Concerned Scientists
Connecticut Center for Patient Safety
Consumers Union
COPD Foundation
Jacobs Institute of Women's Health
Lupus Foundation of America
Mothers Against Medical Error
National Center for Health Research
National Consumers League
National Eczema Association
National Latina Institute for Reproductive Health
National Physicians Alliance
National Women's Health Network
New Yorkers for Patient & Family Empowerment
Our Bodies Ourselves
Prevent Blindness America
Public Citizen
Public Justice
Reproductive Health Technologies Project
Sjogren's Syndrome Foundation
The TMJ Association
U.S. PIRG
WARS
WoodyMatters

The organizations listed above can be reached through Paul Brown at (202) 223-4000 or at pb@center4research.org

¹ *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products (78 Fed. Reg. 67985).*