March 7, 2016

The Honorable Sylvia Mathews Burwell
United States Secretary of Health and Human Services
200 Independence Avenue
Washington, DC 20201

Dear Secretary Burwell,

We are writing to urge the Obama Administration to move forward with finalizing the FDA's Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products (Docket No. FDA-2013-N-0500) rule.

As you know, the Food and Drug Administration (FDA) proposed regulations in 2013 to clarify the ability, and the responsibility, of generic drug manufacturers to initiate safety, efficacy, and dosing updates to their products' labeling. We strongly supported the proposed rule when it was first released. Nearly three years later, we see an even greater need for its completion.

Requiring all prescription drugs to carry up-to-date safety warnings is essential for improving the safety and efficacy of all FDA approved drugs as well as for shoring up needed consumer safeguards and protections. This essential rule will enable generic drug manufacturers to revise drug labeling through the changes-being-effected (CBE-0) process that brand-name manufacturers have used since the 1980s. Extending this process to generic drug manufacturers will give physicians, patients, and their family members access to better and more accurate information about the risks and benefits of the medications they are taking, regardless of whether a drug is brand-name or generic.

Generic manufacturers currently are barred from updating product labeling with new warning information, except in response to a brand-name update or FDA order. But shortly after a generic enters the market, typically the brandname manufacturer precipitously loses market share and in many cases, the brand-name ceases production of the drug altogether. In fact, most prescription drugs sold in the United States are generics.

As a result, the current system's heavy reliance on brand-name manufacturers to initiate all labeling changes, even after generics enter the market, no longer makes sense. Both brand-name and generic drug manufacturers must have the ability to update drug labels expeditiously. Allowing generic manufacturers to initiate safety updates, as brand-name companies have done for 30 years, is essential for patients. As the Government Accountability Office reported in January: "FDA lacks reliable, readily accessible data on tracked safety issues

and postmarket studies needed to meet certain postmarket safety reporting responsibilities and to conduct systematic oversight." The GAO findings only highlight the need for manufacturers—whether brand-name or generic—to have responsibility for the adequacy of product labeling. Promptly updated labeling allows physicians and patients to make better informed health decisions and can help prevent serious harm to patients.

Since the rule was first proposed, there have been attempts to delay or water down the rule. One alternative offered would go so far as to prevent brand-name manufacturers, in certain circumstances, from promptly updating safety information, again, as most prescription drugs sold in the United States have done since the 1980s. That alternative proposal would be a significant step backward for consumer safety.

Over 24,000 people have signed a petition asking FDA to move forward in finalizing the proposed rule, to ensure that all prescription medicines, including generic drugs, carry current and accurate safety warnings. We urge the Administration to ensure that the proposed rule regarding generic manufacturers' ability and responsibility to initiate labeling updates is finalized as soon as possible. Until then, millions of patients and families face unnecessary health risks.

Thank you for your consideration.

Sincerely,

Alpha-1 Foundation
American Medical Student Association
American Medical Women's Association
Annie Appleseed Project
Brain Injury Association of America
Breast Cancer Action
Connecticut Center for Patient Safety
Consumer Federation of America
Consumers Union
COPD Foundation
Lupus Foundation of America
MRSA Survivors Network
National Center for Health Research
National Consumers League
National Multiple Sclerosis Society
National Physicians Alliance
National Psoriasis Foundation
National Women's Health Network
Our Bodies Ourselves
Prevent Blindness

Public Citizen
Sjögren's Syndrome Foundation
The TMJ Association, Ltd.
U.S. PIRG
Union of Concerned Scientists, Center for Science and Democracy
WoodyMatters

Cc:
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