

Margaret A. Hamburg, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

March 13, 2014

Dear Dr. Hamburg,

Generic medicines provide affordable, life-saving medicines to millions of patients, and save trillions of dollars for consumers and the health care system. Patient, physician, pharmacist and payor access to generic medicines rests on the foundation of the Food and Drug Administration's (FDA's) approval of generic medicines as scientifically equal to the brand medicine in drug safety, efficacy and quality. However, the FDA's Proposed Rule on generic labeling could result in multiple versions of labels for the same medicines, which in turn may create dangerous uncertainty.

As patient advocacy organizations, patient safety is our foremost concern. When it comes to labels for prescription medicines, we have one bedrock principle: **drug labels must be FDA-approved and grounded on scientific evidence.**

The FDA's Proposed Rule on Labeling differs from current law, because for the first time since the passage of the Hatch-Waxman Act, generic drugs could have different labeling from each other and the reference product. Uniform safety information provides certainty for patients, doctors, pharmacists and nurses and assures all healthcare practitioners that they can rely on consistent information to inform their decisions and patient conversations. Identical, FDA-approved labels underscore a critical point — once generic medicines pass through extensive FDA review, they are proven scientifically equal to the brand medicine in terms of safety, efficacy and quality.

By creating a framework under which one drug could have multiple different warning labels, the proposed rule would compromise patient safety. Multiple versions of critical safety information would lead to unnecessary confusion and uncertainty for prescribers and other healthcare professionals, with harmful consequences for patients. Requiring generic manufacturers to make unilateral changes prior to FDA approval will lead to a flood of unnecessary labeling changes. The exaggeration of risk and inclusion of unsubstantiated warnings will cause provider confusion and discourage the use of beneficial treatments.

The Proposed Rule also may create additional financial burdens for pharmacists, physicians, generic drug manufacturers and others in the health care system. These could require generic manufacturers to adjust prices to stay in business, withdraw products, or decline to launch new affordable versions of brand medicines. This would have a chilling effect on the ability of generic manufacturers and others in the pharmaceutical supply

chain to provide affordable medicines to millions of Americans and people across the globe. This is the opposite effect of what was intended with the advent of generic medications.

Patients and healthcare practitioners must continue to have access to consistent, transparent information in order to best inform treatment decisions and promote safety. The FDA's rule as presently drafted could severely undermine those goals and lead to unintended consequences.

We would welcome the opportunity to work with others in the health care system, in a multi-stakeholder collaboration, to assist the FDA in strengthening the current labeling regulations. Inclusiveness has to be the operating principle. The FDA should hear from who could offer expertise, experience, and perspective.

Sincerely,

Attention Deficit Disorder Association (ADDA)

Easter Seals

Institute for Safe Medical Practices

National Alliance of Mental Illnesses (NAMI)

National Association of County Behavioral Health & Developmental Disability Directors (NACBHDD)

Scleroderma Foundation

Veterans Health Council

Vietnam Veterans of America