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

March 12, 2014

Dear Dr. Hamburg,

Generic medicines are the backbone of America's pharmaceutical market, bringing trillions of dollars in savings for patients and the health care system, and fueling competition and innovation. 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 uncertainty throughout the drug supply chain.

We fully support a streamlined, efficient process for updating safety information regarding the use of pharmaceutical products for health care practitioners and the general public. However, the Proposed Rule includes revisions to regulations governing generic drugs with respect to both when and how a labeling change would be required that could have unintended negative consequences. For example, the proposed rule creates the regulatory framework whereby multiple, different labeling, including different warnings, can simultaneously exist in the marketplace for multiple generic versions of a drug. This would be inconsistent with FDA's longstanding, unwavering emphasis on consistency in drug labeling and potentially confusing for health care professionals.

As drafted, this Rule also would burden consumers, taxpayers, large and small businesses, and state and federal governments with billions of dollars in increased costs for generic medicines.

A new report by Matrix Global Advisors highlights the significant economic repercussions of this Proposed Rule:

- The Proposed Rule could be expected to increase spending on generic drugs by $4 billion per year (or 5.4 percent of generic retail prescription drug spending in 2012).
- Of this, government health programs could pay an additional $1.5 billion, and private health insurance, $2.5 billion for generic drugs.

The Proposed Rule also may expose pharmacists, physicians, generic drug manufacturers and others in the health care system to substantial new tort liability costs; these, in turn, would 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 that was intended with the advent of generic medications.

As principals in the health care system, manufacturers must make certain that life-saving medicines include accurate, up-to-date labels for providers, prescribers, caregivers and patients. As a matter of public policy, any proposal to significantly change prescription drug labeling impacts an array of healthcare stakeholders beyond manufacturers – including patients, pharmacists, providers, distributors, group purchasing organizations, and employers.

The FDA and others need to fully explore the potential unintended consequences that the Rule may have on patient access and national health care costs. Permitting labeling changes for generic drugs without FDA approval counters 30 years of law requiring generic and brand medicines to have the same labels.

We believe that simple changes to the proposed rule can achieve all of FDA's objectives related to efficient communication of important safety information. At this critical juncture, we look forward to working with you, and all stakeholders to identify a course of action that does not put patient safety or patient savings at risk.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)
American Association of Colleges of Pharmacy (AACP)
American Pharmacists Association (APhA)
American Society of Health-System Pharmacists (ASHP)
Amerinet
Amerisource Bergen
Cardinal Health
Cardiovascular Research Foundation (CRF)
CVS Caremark
Express Scripts
H. D. Smith
Healthcare Distribution Management Association (HDMA)
Healthcare Supply Chain Association (HSCA)
Innovatix
McKesson Corp.
MedAssets
National Association of Chain Drug Stores (NACDS)
National Coalition on Health Care (NCHC)
Novation
Pharmaceutical Care Management Association (PCMA)
Premier Healthcare Alliance
Rite Aid
Walgreens
Walmart