

Dr. Steven Ostroff
Acting Commissioner of Food and Drugs
Food and Drug Administration (FDA)
10903 New Hampshire Avenue
Silver Spring, MD 20993

April 27, 2015

Dear Dr. Ostroff,

As participants in the drug supply chain, we know firsthand that generic medicines are the backbone of America's pharmaceutical market, providing trillions of dollars in savings for patients and the health care system, and fueling competition and innovation.

While we fully support a streamlined, efficient process for updating labeling safety information regarding the use of pharmaceutical products for health care practitioners and the general public, the agency's proposed rule on generic labeling as drafted could result in multiple versions of labels for the same medicines, which in turn may create uncertainty throughout the drug supply chain. Therefore, we commend the Food and Drug Administration (FDA) for acknowledging our concerns with the proposed rule and for reopening the comment period and holding a public hearing.

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 report by Matrix Global Advisors finds that 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.

Further, a survey co-released by the Generic Pharmaceutical Association and the National Coalition on Healthcare revealed that the healthcare providers that patients rely on most to explain safety information about their prescription drugs – physicians, physician assistants, and pharmacists – have serious concerns about the rule. And fully eighty-one percent said that FDA approval should be required before any safety label information is changed.

We believe that simple changes to the proposed rule can achieve all of FDA's objectives related to efficient communication of important safety information. Due to the concerns outlined above, we fully support the science-based alternative called the Expedited Agency Review (EAR), which has the support of both generic and brand name drug manufacturers because it relies on the FDA to review new safety information for multi-source products and requires FDA to take action on a label change made on all multi-source products within a defined time period.

We continue to support the FDA in its mission, which is to protect the public health and ensure patient safety, not evaluate drug manufacturers' liability insurance. This alternative meets all of our shared public health goals regarding multiple-source drugs without comprising patient safety or access.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)

American Association of Colleges of Pharmacy (AACP)

American Society of Health-System Pharmacists (ASHP)

CVS Health

Express Scripts

Healthcare Distribution Management Association (HDMA)

Healthcare Supply Chain Association (HSCA)

McKesson Corporation

National Association of Chain Drug Stores (NACDS)

Ohio Public Employees Retirement System (OPERS)

Pharmaceutical Care Management Association (PCMA)

Rite Aid

Walgreens