

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

March 14, 2014

Dear Dr. Hamburg,

The American health care system has a long history of underserving patients of color. While great strides have been made around improving the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities, much remains to be done. Generic medicines are a critical part of addressing the access and economic factors which often act as barriers to health care for these populations.

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. Disappointingly, the FDA's Proposed Rule on Generic Labeling, as drafted, would create substantial confusion for pharmacists, doctors, nurses, patients and others in the health care system by allowing for multiple, different drug labels in the market for the very same product, upending 30 years of law and regulation.

This would not only jeopardize patient safety, but as a recent economic study has shown, would also create billions of dollars in annual increased costs for consumers, taxpayers, large and small businesses, and state and federal governments. The rule would decrease patient access, impede healthcare decisions and delivery, and make fewer generic drugs available for patients who need them most.

Recent studies have continued to raise serious concerns about the level of generic utilization among lower-income patients about generic drugs.ⁱ The research suggests that there are cultural barriers to understanding of generic efficacy that can lead patients to miss out on the cost-savings generic medications offer. Even more worrying, this research shows it can lead to dangerous non-compliance. The FDA's Proposed Rule will only add to these challenges.

A new report by Matrix Global Advisors shows that the Proposed Rule would cause spending on generic drugs to increase by \$4 billion per year. Of this, government health programs would pay \$1.5 billion, and private health insurance, \$2.5 billion. These increases would ultimately result in higher patient costs for generic medicines, putting life-saving therapies out of reach for the most vulnerable patients.

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.

The FDA and others need to fully explore the potential unintended and harmful consequences that the Rule may have on patient access -- particularly those patient populations currently underserved by our nation's health care system -- and national health care costs. Inclusiveness has to be the operating principle. The FDA should hear from providers who serve racial and ethnic minority populations who could offer expertise, experience, and perspective.

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,

International Association of Black Professional Fire Fighters

National Alaska Native American Indian Nurses Association (NANAINA)

National Association of Hispanic Nurses

National Black Chamber of Commerce

National Black Nurses Foundation

National Coalition on Black Civic Participation

National Coalition of Ethnic Minority Nurse Associations

National Dental Association

National Minority Quality Forum

Philippine Nurses Association of America

Student National Dental Association

ⁱ *Perceptions of and Barriers to Use of Generic Medications in a Rural African American Population, Alabama*, 2011 Keri Sewell, MPH, Susan Andreae, MPH, Elizabeth Luke, BS, Monika M. Safford, MD *Preventing Chronic Disease*, 2012;9