

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

September 30, 2014

Dear Dr. Hamburg:

While much has been done in recent years to expand access to health care in America, racial and ethnic minority populations continue to face significant barriers to improved health. As policymakers seek to develop health policies and programs that will help eliminate health disparities, generic medicines play a critical role in addressing the access and economic factors impacting care for patients of color.

However, most often when these health policies and programs are being discussed and developed, racial and ethnic minority populations have had a limited presence during the discussions. These populations too often do not have a timely opportunity to comment on complex statistical data necessary to gain a full understanding of the matters under deliberation. Therefore, it is imperative that during the Food and Drug Administration's deliberations around its Proposed Rule on Generic Drug Labeling, racial and ethnic minority populations have a seat at the table to be able to discuss and understand the issue.

Recent studies have continued to raise serious concerns about the level of generic utilization among lower-income patients.<sup>1</sup> 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 Food and Drug Administration's (FDA's) Proposed Rule on Generic Labeling, as drafted, likely will only add to these challenges.

A 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.

Patient, physician, pharmacist and payor access to generic medicines rests on the foundation of the 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 calls this bedrock principle into question. As reported by the National Newspapers Publishers Association earlier this year, "Patient's advocate groups and some health care providers worry that drugs that are scientifically identical will carry very different warning labels, adding to patient confusion and may cause some consumers to shun life-saving generic drugs completely."

Recently, Farleigh Dickinson University's Public Mind interviewed 450 randomly selected physicians, physician assistants and pharmacists on the proposed rule via telephone survey on behalf of the Generic Pharmaceutical Association (GPhA) to further explore the potential impacts of this proposed rule on health care providers.

The results reveal serious concerns among respondents that the proposed rule would have a negative impact on their patients and their ability to do their job. And, these health professionals also were overwhelmingly in favor of making sure that generic drug safety labels are not changed without FDA approval. The survey results show that the Proposed Rule would cause confusion for both health care providers and patients:

- More than three-quarters (76%) of those surveyed say their patients would be at least somewhat confused by multiple labels for the same medicine.
- Eight in 10 (88%) say multiple labels would be very confusing (53%) or somewhat confusing (35%) for themselves.
- Among prescribers, 60% said the change would have an impact on their willingness to recommend generic drug in the future.

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 could 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.

For the foregoing reasons, the FDA should fully explore the potential unintended and harmful consequences that the Proposed Rule may have on patient access – particularly those patient populations currently underserved by our nation's health care system – and national health care costs before proceeding further with its finalization. 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.

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,

Meharry Medical School  
Minority Organ Tissue Transplant Education Program  
NAACP  
National Association of Neighborhoods  
National Association of Black Social Workers  
National Caucus and Center on Black Aged, Inc.

National Congress of Black Women, Inc.  
National Hispanic Medical Association  
National League for Nursing  
National Medical Association  
National Newspaper Publishers Association  
National Optometric Association  
National Organization of Black County Officials  
National Organization of Black Legislative- Women  
New St. Paul Tabernacle Church of God and Christ  
Southern Christian Leadership Conference  
Student National Medical Association  
Chi Delta Mu Fraternity  
Delta Sigma Theta Sorority  
Institute for the Black World/21st Century

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<sup>i</sup> *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