

August 13, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education,
Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education,
Labor and Pensions
U.S. Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

As health care stakeholders representing diverse organizations, we share the goals of your Innovation Initiative of supporting medical innovation and improving the process for the discovery and development of new drugs and treatments. We commend you for your bipartisan work toward achieving these important objectives.

Generic medicines are the backbone of America's pharmaceutical market, bringing nearly \$1.5 trillion in savings to the U.S. healthcare system over the past decade and assuring patient access to life-saving cures. The competition provided by generic drugs is also vital in spurring innovation and research into new cures. It is critical that this initiative maintains the balance of Hatch-Waxman and avoids delaying patient access to lower cost generics.

The new biosimilar market in the United States will give patients access to safe, effective and more affordable alternatives to brand-name biologics. The Food and Drug Administration's (FDA) approval of the first biosimilar this year ushers in a new era for the U.S. healthcare system, and it is vital that the initiative also avoids delaying patient access to more affordable biosimilars.

As the HELP Committee continues its examination of the drug discovery and development process in the coming months, we urge you to maintain the important balance between access and innovation of Hatch-Waxman. We urge you not to include increases in exclusivity for brand manufacturers that would have the effect of burdening consumers, large and small businesses, and state and federal governments with unnecessary increased prescription drug costs through delayed generic and biosimilar entry.

We are concerned by proposals that would grant additional exclusivity and threaten generic competition. For example, the Dormant Therapies Act would create a substantial barrier to patient access to life-saving generic medicines and biosimilars for a large number of drugs. The OPEN Act would allow manufacturers to receive increased exclusivity for new indications without any significant improvements over existing therapies on the market. We urge you not to include these or other exclusivity proposals that would increase federal prescription drug spending and delay patient access to more affordable generics and biosimilars.

We look forward to continuing to work with you on the Innovation Initiative. Thank you for the consideration of our views.

Sincerely,

AARP

Academy of Managed Care Pharmacy (AMCP)

American Association of Colleges of Pharmacy (AACCP)

America's Health Insurance Plans (AHIP)

BlueCross BlueShield Association

Express Scripts, Inc.

Families USA

Healthcare Supply Chain Association (HSCA)

Kaiser Permanente

National Association of Chain Drug Stores (NACDS)

National Coalition on Health Care (NCHC)

National Committee to Preserve Social Security & Medicare

Ohio Public Employees Retirement System (OPERS)

Pharmaceutical Care Management Association (PCMA)

Prime Therapeutics

Public Sector HealthCare Roundtable

UAW Retiree Medical Benefits Trust

CC:

Members of the Senate Committee on Health, Education, Labor and Pensions