December 18, 2013

The Honorable Max Baucus
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable David Camp
Chairman
House Ways and Means Committee
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Orrin Hatch
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Sander Levin
Ranking Member
House Ways and Means Committee
1106 Longworth House Office Building
Washington, DC 20515

Dear Chairman Baucus, Chairman Camp, Ranking Member Hatch and Ranking Member Levin:

As the Senate Finance Committee and House Ways and Means Committee consider options for paying for a permanent repeal to the Sustainable Growth Rate (SGR) formula and proposals to reduce the federal deficit, we the undersigned consumer, labor and pharmaceutical and biosimilar supply chain industry stakeholders urge you to include an important policy known to provide savings to the Medicare program. We propose inclusion of an offset that assures that Risk Evaluation and Mitigation Strategies (REMS) are used to protect patient safety and that REMS and other restricted access programs are not used to impede affordable access to generic drugs and biosimilars at the expense of consumers and federal payors.

In the 112th Congress, Sec. 1131 of S. 3187 (the Food and Drug Administration Safety and Innovation Act, or "FDASIA") sought to address this issue for solely pharmaceutical products under a Food and Drug Administration (FDA) required REMS program. The Congressional Budget Office (CBO) scored the savings to Medicare at $753 million over 10 years. Although the Senate-passed provision was not ultimately signed into law, it serves as a viable basis for developing a policy that could provide tremendous savings by allowing generic drug manufacturers and biosimilar manufacturers to have access to samples of reference products covered by a REMS program or a self-imposed restricted access program.

By way of background, the Food and Drug Administration Amendments Act of 2007 (FDAAA) authorized the FDA to implement REMS to ensure that the benefits of a pharmaceutical drug and biologic outweigh its risk by establishing pre-market and post-market safety programs for certain products. REMS programs were initially put in place to control the public distribution of particularly dangerous drugs, attaching extra levels of distribution procedures and warnings for patients receiving the products. Unfortunately, REMS programs and other restricted access programs are being used to block access to comparator products to halt generic drug and biosimilar product development and are thereby blocking fair and timely generic drug and biosimilar competition.

Generic and biosimilar applicants' access to product samples for testing purposes is critical to ensuring continued access to affordable medicines. While FDA-required REMS programs and voluntary restricted access programs can be legitimately designed for drugs and biologics with a safety risk in a way that ensures appropriate distribution for the patient benefit to outweigh the risks, certain branded drug and biopharmaceutical companies are increasingly manipulating these

programs to exclude generic drug and biosimilar manufacturers from the distribution network. The result is generic and biosimilar companies' inability to acquire samples for development and testing, and therefore halting the development of lower cost alternatives to necessary medicines. Evidence to date has shown that generic and biosimilar manufacturers have the ability and a consistent track record over the years of safely handling and testing reference products, including products that may cause serious side effects and are accordingly covered under REMS programs.

We recognize the many challenges your Committees face as you look for ways to reduce the deficit and pay for repealing the SGR. Ensuring that REMS and self imposed restricted access programs are no longer used to deny affordable generic and biosimilar products to consumers is a proven way to provide savings to the federal government as well as the health care industry as a whole. We urge you to include language that would eliminate these abuses.

At a time of great budgetary challenges for consumers and for the federal government, it is especially important that savings to Medicare and advances in health care delivery ensure that barriers to fair and timely generic drug and biosimilar competition are addressed, and that safe, effective and affordable medicines are made available to consumers.

Thank you for your leadership, and for your consideration of our request.

Sincerely,

Actavis plc
Amneal Pharmaceuticals
Apotex Corp.
BlueCross BlueShield Association
Express Scripts Inc.
Generic Pharmaceutical Association (GPhA)
Hospira, Inc.
Humana
International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW)
Momenta Pharmaceuticals, Inc.
Mylan Inc.
National Association of Chain Drug Stores (NACDS)
National Coalition on Health Care (NCHC)
Pharmaceutical Care Management Association (PCMA)
Portico Benefit Services
Prime Therapeutics
Roxane Laboratories, Inc.
Teva Pharmaceuticals
UAW Retiree Medical Benefits Trust
U.S. Public Interest Research Group (U.S. PIRG)

cc: The Honorable Patty Murray
The Honorable Jeff Sessions
The Honorable Paul Ryan
The Honorable Chris Van Hollen