June 6, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Tom Harkin
Chairman
Committee on HELP
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, D.C. 20515

The Honorable Michael B. Enzi
Ranking Member
Committee on HELP
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Harkin, Ranking Member Enzi, Chairman Upton and Ranking Member Waxman:

On behalf of the undersigned consumer, labor and pharmaceutical and biosimilar supply chain industry stakeholders, we respectfully urge you to accept Sec. 1131 of S. 3187 (the Food and Drug Administration Safety and Innovation Act, or "FDASIA") as you reconcile differences between the House and Senate user fee packages. This provision properly assures that REMS are used to protect patient safety and are not used to impede affordable access to generic drug and biosimilars at the expense of consumers and federal payors.

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. These 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, these REMS 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. However, branded drug companies are increasingly using REMS programs established by the FDA to restrict distribution exclusively to certain entities within the supply chain and to patients, precluding distribution to generic drug and biosimilar manufacturers. In addition, many companies are using self-imposed restricted distribution programs, without a formal mandate from FDA, as a tool to restrict distribution, which also results in generic and biosimilar companies' inability to acquire samples for development and testing.

We are deeply appreciative of the Senate HELP Committee's efforts to include Section 1131 in the FDASIA to prohibit branded companies from misusing a REMS program to avoid generic and biosimilar competition. Again, we respectfully urge you to retain this provision in the final user fee package agreed upon by the Senate and House. Such an effort would ensure that REMS programs are no longer used to deny affordable generic and biosimilar products to consumers.

At a time of great budgetary challenges for consumers and for the federal government, it is especially important 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.

Sincerely,

AARP
Actavis, Inc.
AFL-CIO
Apotex Corp.
Blue Cross Blue Shield Association
California Public Employees' Retirement System (CalPERS)
Express Scripts, Inc.
Generic Pharmaceutical Association (GPhA)
Hospira, Inc.
Humana
Momenta Pharmaceuticals, Inc.
Mylan Inc.
National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)
Pharmaceutical Care Management Association (PCMA)
Prime Therapeutics
Ranbaxy Pharmaceuticals, Inc.
Roxane Laboratories, Inc.
Service Employees International Union (SEIU)
Teva Pharmaceuticals
Watson Pharmaceuticals
WellPoint, Inc.