

June 17, 2015

The Honorable Steve Stivers
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Peter Welch
2303 Rayburn House Office Building
Washington, DC 20515

Dear Congressmen Stivers and Welch –

We are writing in support of the Fair Access for Safe and Timely (FAST) Generics Act of 2015. The increasing prevalence of companies abusing restricted access programs to delay generic entry makes your legislation vital to maintaining competition in the pharmaceutical marketplace and ensuring patient access to affordable, life-saving medications.

As you know, the intent of Risk Evaluation and Mitigation Strategies (REMS) program is to ensure that the benefits of a drug or biological product outweigh its risk. These FDA-mandated programs provide additional information to patients and providers, and in certain cases restrict the distribution of the product so that only certain approved entities can dispense the drug. When Congress passed legislation in 2007 authorizing REMS, it recognized that companies could use these programs to delay generic competition and therefore explicitly prohibited such conduct in the statute. However, due to a loophole, certain companies have been using tactics that initially grew out of REMS Elements to Assure Safe Use (ETASU) requirements to delay generic competition for REMS and non-REMS products alike. Specifically, companies are employing restricted distribution networks to deny manufacturers of generics and biosimilars access to product samples they need to obtain FDA approval and market entry. These abuses are growing and the resulting delay in generic and biosimilars competition is costing patients, the federal government, and the health care system billions of dollars annually. A July 2014 analysis by Matrix Global Advisors found that using restricted access programs to prevent generic competition costs the health care system \$5.4 billion annually, including \$1.8 billion to the federal government. As companies expand this practice to biosimilars, it would result in approximately \$140 million in lost savings for every \$1 billion in biologics sales.

The FAST Generics Act is a commonsense measure that prioritizes patient safety and public health. Your legislation establishes clear processes that will facilitate the provision of samples to generic manufacturers and prevent companies from denying the implementation of shared REMS programs. The bill also defines certain anticompetitive practices with respect to restricted access programs, thus closing the existing loophole around current REMS prohibitions.

Thirty years ago, Congress enacted the Hatch-Waxman Act — one of the most successful pieces of health care legislation to become law. It opened up the pharmaceutical marketplace

to competition, by creating a balance between patient access to safe and affordable, life-saving medicines and the development of new, innovative drug products. Competition from generic drugs has saved the health care system \$1.5 trillion over the past decade and \$239 billion in 2013 alone. Companies that exploit restricted access programs delay generic competition and undermine the intent of Hatch-Waxman at the expense of patients. The FAST Generics Act restores the balance between access and innovation. We applaud you for your efforts to eliminate these abuses, and we look forward to working with you to enact it into law.

Sincerely,

Generic Pharmaceutical Association (GPhA)

Express Scripts

Healthcare Supply Chain Association (HSCA)

International Union, United Automobile, Aerospace & Agricultural Implement Workers of America (UAW)

National Association of Chain Drug Stores (NACDS)

National Coalition on Health Care (NCHC)

Ohio Public Employees Retirement System (OPERS)

Pharmaceutical Care Management Association (PCMA)

Premier Healthcare Alliance

Prime Therapeutics

Public Sector Healthcare Roundtable

UAW Retiree Medical Benefits Trust

CC:

The Honorable Fred Upton, Chairman, House Committee on Energy and Commerce

The Honorable Frank Pallone, Ranking Member, House Committee on Energy and Commerce

The Honorable Joe Pitts, Chairman, Subcommittee on Health

The Honorable Gene Green, Ranking Member, Subcommittee on Health