NATIONAL COALITION ON HEALTH CARE

Working Together for an Affordable Future

November 6, 2014

The Honorable Steve Stivers
United States House of Representatives
Washington, DC 20515

The Honorable Peter Welch
United States House of Representatives
Washington, DC 20515

Dear Representative Stivers and Representative Welch:

The National Coalition on Health Care (NCHC) applauds your introduction of the *Fair Access for Safe and Timely (FAST) Generics Act of 2014* (H.R. 5657), which ensures that generic drug companies have fair and competitive access to drug product samples for development and testing.

NCHC is a coalition of more than 80 member organizations— representing health care providers, purchasers, payers, and consumers— committed to promoting an affordable, high-quality health system in the United States. As the nation's oldest and most diverse group working to achieve comprehensive health system reform, we recognize the importance of market competition from generic drugs to lower prescription drug prices and curb rising health care costs. The FAST Generics Act creates a process for brand-name drug manufacturers to provide product samples to generic competitors, thereby supporting generic market entry that leads to health care savings for consumers and taxpayers. We strongly support this legislation.

Generic medications have generated nearly $1.5 trillion in savings for the health system in the past ten years alone.[1] However, the full cost-saving potential of generics has been stymied by brand-name drug manufacturers' misuse of Risk Evaluation and Mitigation Strategies (REMS) and other restricted access programs. Nearly 40 percent of new FDA drug approvals are included in REMS programs.[2] Although these programs are intended to improve patient safety, brand-name drug manufacturers are exploiting

[1] Generic Pharmaceutical Association. (2014, August 10). Generic Drug Savings in the U.S. Retrieved from http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf
[2] Generic Pharmaceutical Association. (2014, July). Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry. Retrieved from http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf

these restrictions to withhold potential generic competitors' access to drug product samples, which impedes their development of generic drugs. The consequence is higher prescription drug prices and lost savings to consumers, taxpayers, and the federal government. Specifically, REMS misuse for small-molecule drugs represents at least $5.4 billion in lost savings annually.[2] If misuse were to extend to biologics once a biosimilar pathway is established, delayed biosimilar entry from restricted access would contribute to an even greater loss of potential savings.

The FAST Generics Act would close the REMS loophole by prohibiting the use of REMS regulations to restrict generic competitors' access to brand-name drug samples. Further, your legislation would establish a pathway for potential generic competitors to request and obtain product samples for development and testing. These improvements to REMS provide critical support for the development and market entry of generic drugs, curbing the rising prices of pharmaceutical drugs and upholding the cost containment success of the historic Hatch-Waxman Act.

The FAST Generics Act of 2014 has the potential to lower drug prices for consumers and cut federal spending, which would yield significant health care savings. We look forward to working with you to advance this important legislation.

Sincerely,

John Rother
President and CEO,
National Coalition on Health Care