HOUSE JUDICIARY SUBCOMMITTEE ON REGULATORY REFORM, COMMERCIAL AND ANTITRUST LAW HEARING:
Antitrust Concerns and the FDA Approval Process

STATEMENT FOR THE RECORD SUBMITTED BY: Express Scripts, July 27, 2017

Express Scripts appreciates the opportunity to offer a statement to the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law hearing entitled "Antitrust Concerns and the FDA Approval Process."

Headquartered in St. Louis, Express Scripts is the nation's largest stand-alone pharmacy benefit manager (PBM). We manage drug benefits for more than 80 million Americans, including those in health plans, union-sponsored plans, state employee health plans, and public purchasers, including TRICARE, Medicare Part D, and Medicaid. Our services include providing network-pharmacy claims processing, home delivery pharmacy care, specialty pharmacy care, benefit-design consultation, drug utilization review, formulary management, and medical and drug data analysis services.

Express Scripts drives unique solutions to address rising prescription drug prices. As was published in our 2016 Drug Trend Report, due to the tools we have implemented in plans covering employees and their families, per-person spending last year on prescription drugs increased just 3.8 percent – 26.9 percent less than the 5.2 percent increase in 2015. Aligned with the best interests of our clients and patients, we are committed to doing whatever it takes to provide the best care and value.

We are pleased that the Subcommittee is holding today's hearing to examine anticompetitive behaviors that undermine the Food and Drug Administration (FDA) approval process and delay the introduction of generic drugs and biosimilar therapies. Express Scripts supports policies that lower the price of prescription drugs by promoting competition in the marketplace and accelerating approval of generic drugs and biosimilars. Competition is the key to containing drug prices, and we are proud that our generic fill rate is more than 80 percent.

The FDA's Risk Evaluation and Mitigation Strategies (REMS) program provides an important protection for patient safety by ensuring that the benefits of a drug or biological product outweigh its safety risks. Certain brand manufacturers, however, have exploited a loophole in the law to prevent generic and biosimilar competition for products with and without REMS requirements. These manufacturers employ restricted distribution networks to deny generic and biosimilar manufacturers access to the product samples needed to obtain FDA approval. In fact, some manufacturers have implemented these restricted distribution programs solely to delay competition, independently from any FDA mandates. The Federal Trade Commission (FTC) has cautioned that "this conduct may prevent the Hatch-Waxman framework from functioning as Congress intended."

We applaud Subcommittee Chairman Tom Marino and Ranking Member David Cicilline for introducing H.R. 2212, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Express Scripts supports this measure to address anticompetitive practices by

creating a clear pathway for generic and biosimilar manufacturers to access the sample products needed to bring lower-cost drugs onto the market. Competition is key to addressing prescription drug costs, and the CREATES Act is an important step in preventing bad actors from undermining the FDA approval process and delaying generic market entry.

Thank you for the opportunity to share our views. We thank the Committee for addressing this complex but crucial topic for American patients and families, and we hope to continue to be a resource to the Committee in its work to ensure competition in the pharmaceutical market.