

**John J. Castellani**  
PRESIDENT AND CHIEF EXECUTIVE OFFICER



May 9, 2012

The Honorable Fred Upton  
2123 Rayburn House Office Building  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Henry Waxman  
2322A Rayburn House Office Building  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the nation's leading biopharmaceutical research companies, I am writing to express support for H.R. 5651, the Food and Drug Administration Reform Act of 2012 (FDARA), which your committee is scheduled to mark up today. We applaud you both for your ongoing leadership in introducing legislation that represents a step forward for America's biopharmaceutical workers and, most importantly, for the patients who depend on innovative medicines for their lives – now and in the future.

First and foremost, FDARA reauthorizes the Prescription Drug User Fee Act (PDUFA), which has been a remarkable success since first becoming law in 1992. Prior to PDUFA, new medicines clocked average review times of 29 months, which meant patients waited up to three years for needed therapies; this figure has dropped to 13 months in recent years. Importantly, FDARA also includes new, productive reforms reflecting the Food and Drug Administration's PDUFA-V performance goals letter that will help to make the review process more efficient and more predictable. It also includes proposals that would help to advance the FDA's ability to support the growing challenges – and opportunities – provided by our evolving understanding of science and the mechanisms of disease.

Failure to reauthorize PDUFA would lead to a debilitating decrease in FDA resources, crippling FDA's ability to operate the essential human drug review program and leading to large layoffs among agency employees. Thanks to your leadership, Congress is on track to reauthorize this legislation on time, which means a strong, continued regulatory program that helps to support biopharmaceutical innovation and bring the resulting medical advances to the patients who need them.

Also, I commend you for your support for permanent reauthorization of the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). BPCA and PREA have been exceedingly successful in improving medical care for children by driving

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research to create innovative medicines for use in pediatric patients. Prior to their passage, roughly 70 percent of medicines taken by children lacked pediatric dosing information. As of 2008, thanks to BPCA and PREA, between 50 percent and 60 percent of medicines had been studied in some part of the pediatric population. Permanent reauthorization of these programs will help us continue this important progress.

PhRMA supports your efforts to move the process forward toward our shared goal of timely passage in the House, and we appreciate the opportunity to continue to work with you collaboratively to advance policies that support innovation and enhance patient access to safe and effective medicines.

Sincerely,

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.