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May 8, 2012

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, D.C. 20515

The Honorable Joseph R. Pitts
Chairman
Committee on Energy & Commerce
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone, Jr
Ranking Member
Committee on Energy & Commerce
Subcommittee on Health
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Upton, Chairman Pitts, Ranking Member Waxman, and Ranking Member Pallone:

Thank you for your leadership in advancing forward the reauthorization of the Prescription Drug User Fee Act (PDUFA). One of the greatest weapons in the fight against serious illness is a regulatory system which allows innovative companies to bring forward new medicines in a timely manner. The PDUFA program is the backbone of that regulatory system and Amgen believes that its timely reauthorization is critical to ensuring patient access to innovative new treatments.

Amgen discovers, develops, manufactures, and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives.

The Prescription Drug User Fee Act (PDUFA) has advanced public health with respect to patient safety and access to new medicines. The program has allowed the Food and Drug Administration (FDA) to remain a strong regulator, while at the same time, has created efficiencies in the regulatory review process to ensure patients have timely access to new medicines. Yet, to continue to promote innovation, more must be done to facilitate greater transparency and predictability at FDA. The PDUFA V agreement will enhance communications between the FDA and sponsors to resolve scientific issues, improve the outcome and predictability of drug reviews, and strengthen FDA regulatory science.

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Additionally, your legislation establishes dedicated user fees for the review of biosimilar products, as well as includes a number of complementary regulatory enhancements to facilitate development of medicines for rare diseases, reforms to predict and combat drug shortages, and improvements to enhance the safety of the global supply chain. We commend you for your leadership and believe the legislation will make a meaningful difference in ensuring that patients continue to have access to safe and effective medicines. At Amgen one of our core missions is to serve “every patient, every time” and these reforms will enable that mission to continue to be realized.

Amgen looks forward to continuing to work with you to enact a timely PDUFA reauthorization. The work you are undertaking now will have a significant impact on the review process for new medicines, and ultimately, the patients we aspire to serve. Thank you for your leadership.

Sincerely,

A handwritten signature in black ink, appearing to read "David Beier". The signature is fluid and cursive, with a large initial "D" and "B".

David Beier
Senior Vice-President
Global Government Affairs, Communications and Philanthropy