December 5, 2016

The Honorable Mitch McConnell
Senate Majority Leader
S-230, The Capitol
United States House of Representatives
Washington, D.C. 20510

The Honorable Harry Reid
Senate Minority Leader
S-221, The Capitol
United States House of Representatives
Washington, D.C. 20510

Dear Leader McConnell and Leader Reid,

On behalf of the Biotechnology Innovation Organization (BIO), I am writing to offer our strong support H.R. 34, the 21st Century Cures Act, and urge the Senate to pass this important legislation.

Senate Health, Education, Labor and Pensions (HELP) Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA), and the members of the Committee have worked tenaciously to create legislation that will help expedite the development of the next generation of breakthrough medicines to save lives and decrease and eliminate suffering of millions of patients, while helping to reduce other healthcare costs. Along with House Energy and Commerce Committee Chairman Fred Upton (R-MI), Ranking Member Frank Pallone (D-NJ), and Congresswoman Diana DeGette (D-CO), they crafted a bill that passed the House of Representatives with overwhelming, bipartisan support last week.

21St Century Cures takes important steps towards placing patients at the center of the drug development process by establishing a framework for incorporating patient views into the development and regulatory review process in a more structured and transparent way, both with respect to patient input for benefit-risk assessments and use of patient experience in data in regulatory decision-making.

BIO believes this legislation will help spur the development of treatments focused on rare conditions and other unmet medical needs by extending the Rare Pediatric Disease (RPD) Priority Review Program (PRV). The RPD PRV program is a vital tool in helping foster the development of new treatments for children with rare diseases, providing hope to many patients, families and caregivers.

Our member companies also play a central role in ensuring the development and manufacture of medical countermeasures (MCMs) to protect our nation's citizens against chemical, biological, radiological, and nuclear (CBRN) attacks as well as naturally-occurring infectious disease threats, such as pandemic influenza. This legislation includes provisions that improve the public-private partnership in such areas by streamlining the contracting process and increasing transparency around future MCM funding needs across all types of threats. This is particularly important since most of these products do not have a commercial market to help spur investment. Significant barriers to countermeasure development still exist and your legislation takes critical steps towards addressing these so

that we as a nation will be more fully prepared to effectively respond to health security threats.

Additionally, BIO is pleased about the focus on precision medicine through genomics and regulatory science, and increasing FDA's scientific capacity by improving access to adequate funding, enhancing the ability to recruit and retain world-class scientific experts, and permitting greater scientific exchange. We also appreciate the important first steps taken to allow for a broader range of healthcare economic information sharing with payers, which will facilitate the move towards a value-based marketplace for biopharmaceuticals.

We again commend the tremendous efforts of Chairman Alexander, Ranking Member Murray, and all members of the Senate HELP Committee, and we look forward to the passage of H.R. 34.

Sincerely,

James C. Greenwood
President & CEO