The Honorable Paul Ryan
Speaker of the House
United States House of Representatives
Washington, D.C. 20515

The Honorable Nancy Pelosi
Minority Leader
United States House of Representatives
Washington, D.C. 20515

November 29, 2016

Dear Speaker Ryan and Leader Pelosi,

On behalf of Consumers Union, the policy and mobilization arm of Consumer Reports, we write to urge you to oppose the renegotiated 21st Century Cures Act. As patient safety consumer advocates who have worked extensively on drug and medical device safety issues, we are deeply concerned that this legislation would weaken approval standards and potentially put patients at risk for harm.

Medical innovation legislation should not move forward without mandatory funding for NIH and FDA. Consumers Union objects to the funding in the current bill being subject to yearly appropriations as this does not guarantee the funding levels that both agencies need to undertake the work required of them in this legislation.

Consumers Union supports rigorous clinical testing for drugs and strongly opposes the use of shorter and smaller clinical trials, surrogate endpoints instead of measures of patient function and outcome, and reliance upon qualified data summaries in drug approval. We believe a shift towards less rigorous approval standards, such as these, could lead to an increase in approvals without drug manufacturers demonstrating any significant and clinically-proven benefit to consumers. This has the potential to harm patients and to increase spending on costly new treatments and procedures that, at best, simply lack evidence to back up their claims or, worse, actually provide no tangible improvement in treatment for consumers.

Similarly, the bill's "breakthrough pathway" for devices would create an expedited review that would lower the already insufficient clinical standards for medical device approval. The definition of "breakthrough" devices is overly broad and would rush their approval without first demonstrating safety or effectiveness for consumers. Consumers Union strongly opposes any measure to weaken the enforcement authority of the FDA on such matters. While there has been recent increased attention to post-market surveillance of medical devices, a comprehensive publicly accountable system does not yet exist. A well-functioning post-market oversight system should prioritize patient safety, detect problems quickly, and not loosen reporting requirements for any class of device.

We also oppose the inclusion of an accelerated approval pathway for regenerative medicine that allows for approval based on the use of surrogate endpoints and post-approval studies. As this pathway – a lower standard of evidence -- was not debated in the original legislation, we believe more time is needed to review and evaluate its impact on consumers.

Consumers Union believes that any effective effort to address the crisis of antibiotic resistance must: define the limited population to which the pathway applies; specify that an approved antibiotic is tested against the specific organism which it purports to treat; and require that the antibiotic be better than the current standard of care for the specific, limited purpose. The current version of this bill fails to address these issues. Moving forward without these safeguards could lead to more inappropriate antibiotic overuse and therefore more antibiotic resistance, which would undermine the promise of new antibiotic development.

Given our concerns and the expedited timeline, Consumers Union respectfully urges you to oppose the 21st Century Cures Act. We should be able to trust that the FDA has fairly vetted drugs and devices to determine if they work and to ensure they will not harm patients. Innovation and technological advancement only benefit consumers when there is a strong scientific basis for approval and a robust post-market surveillance system.

Respectfully submitted,

Lisa McGiffert

Victoria Burack

Cc: House Energy and Commerce Committee