



POLICY & ACTION FROM CONSUMER REPORTS

April 6th, 2016

The Honorable Senator Lamar Alexander
Chairman,
U.S. Senate Committee on
Health, Education, Labor & Pensions

The Honorable Senator Patty Murray
Ranking Minority Member,
U.S. Senate Committee on
Health, Education, Labor & Pensions

Dear Senator Alexander and Senator Murray,

On behalf of the Safe Patient Project at Consumers Union, the public policy and advocacy arm of Consumer Reports, we are writing to express our support for several of the bills scheduled for legislative mark-up on April 6th. As patient safety and consumer advocates who have worked extensively on these issues, we appreciate the Committee's attention to protecting consumers.

Consumers Union supports the Promise for Antibiotics and Therapeutics for Health Act (S. 185) as amended. We applaud the Committee's diligent work to ensure that current clinical approval standards are maintained and that the pathway remains limited to antibacterials. Standards for clinical trials must remain robust to ensure the safety of new antibiotics brought to market; lower clinical trial standards could expose patients to potentially harmful products that are ineffective. We also support the inclusion in the bill of antibiotic resistance monitoring at Federal facilities, reporting on antibiotic resistance and use by healthcare entities, and additional support for antibiotic stewardship. Requiring reporting of antibiotic use and antibiotic resistant trend is essential to combat antibiotic resistance, and this information should be publicly available.

We also commend the Committee's attention to the issues addressed in the FDA and NIH Workforce Authorities Modernization Act (S.2700). It is of the utmost importance that these agencies be sufficiently staffed with top-notch professionals who are paid competitive salaries. The ability of both to do their work to protect the safety and well-being of the American public and to invest in potentially life-saving scientific discoveries depends upon this.

Consumers Union supports the Committee's focus on disease burden, social determinants of health, and diverse subpopulation research included in the NIH Strategic Plan and Inclusion in Clinical Research Act. In order to develop safe, appropriate, and effective medicines and treatments for all consumers, clinical research must include sufficient numbers of women, minorities, and relevant age categories. We support the specific inclusion of sexual and gender minorities as important populations worthy of increased research focus.

We would strongly oppose any amendment that would undermine medical device safety and effectiveness standards or weaken the enforcement authority of the FDA on such matters. Additionally, we oppose any form of post-market surveillance that does not prioritize patient safety and any loosening of reporting requirements for any class of device. We urge the Committee to reject any such amendments.

Consumers Union thanks the Committee for your attention to medical innovation and dedication to improving patients' lives through scientific discovery. We are pleased with the bipartisan efforts that prioritized patient safety, evidence-based standards, and inclusive clinical research through the bills slated for the last round of legislative mark-up. We hope to continue to serve as a resource on issues involving patient safety and consumer protections as these biomedical innovation bills proceed to the Senate floor.

Respectfully submitted,

A handwritten signature in black ink that reads "Lisa McGiffert". The signature is written in a cursive, flowing style.

Lisa McGiffert
Director, Safe Patient Project
lmcgiffert@consumer.org

Cc: Senate Health, Education, Labor & Pensions Committee