ConsumersUnion

POLICY & ACTION FROM CONSUMER REPORTS

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

March 7th, 2016

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 deep concern regarding two of the bills scheduled for legislative mark-up on March 9th --The Combination Products Innovation Act of 2015(S.1767) and The Advancing Breakthrough Medical Devices for Patients Act of 2015(S.1077). As patient safety consumer advocates who have worked extensively on medical device safety issues, we believe these bills would weaken approval standards and potentially put patients at risk for harm.

The Combination Products Innovation Act of 2015 (S. 1767) would allow more combination products such as implantable contraceptive devices and epipens that have both a device and a drug component, to be classified as devices instead of as drugs or biologics. These changes are not in the best interest of consumers as the review and approval process for many medical devices requires no testing for safety and effectiveness, and is much less rigorous than that of drugs and biologic products. The Safe Patient Project strongly opposes any action or provision that would effectively lower approval standards for combination products by making it easier for a greater number to be classified and reviewed as devices.

The Advancing Breakthrough Medical Devices for Patients Act of 2015 (S. 1077) would, in order to create expedited review for devices deemed "breakthroughs," lower the already insufficient clinical standards for medical device approval. The bill would expand the types of devices that qualify as a breakthrough to include ones that may simply be in the "best interest of patients." The Safe Patient Project is deeply concerned about the broad nature of this definition and the lack of concrete, data-based evidences it requires. We believe that this would lead to an increased number of devices applying for and receiving this designation without first showing any significant and clinically-proven benefit for consumers. This bill would also allow the FDA to use shorter and smaller clinical trials, surrogate endpoints instead of measures of patient function and outcome, and adaptive trials or Bayesian statistics in place of more rigorous clinical testing. The Safe Patient Project strongly opposes each of these changes as they would allow more devices with less scientific evidence onto the market. We do not believe this is in the best interest of consumers.

Consumers Union commends the Committee's attention to biomedical innovation and dedication to improving patients' lives through scientific discovery. We believe, however, that these bills would not encourage innovation. The essential goal of not harming patients can be achieved without distracting from true innovation; innovation and technological advancement only benefit consumers when there is a strong scientific basis for approval and a robust surveillance system.

We urge the Committee to reject these bills and to ensure that any Senate biomedical innovation legislation does not include similar provisions that would lower the bar for medical device approval, or allow more combination products to proceed through the device approval process. We hope to serve as a resource as the Committee continues the process of crafting and refining this legislation so that consumer protections are the foundation of the Senate's innovation legislation package.

Respectfully submitted,

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Cc: Senate Health, Education, Labor & Pensions Committee