

May 2016

Dear Chairman Lamar Alexander and Ranking Member Patty Murray of the U.S. Senate Health, Education, Labor and Pensions (HELP) Committee:

We, the undersigned organizations represent healthcare providers, clinical researchers, public health experts, and consumer advocates across the country. Over the last three months your committee has marked-up and passed bills with a goal of creating a package of Senate health reforms that could ultimately become an unofficial counterpart to the 21st Century Cures Act passed by the U.S. House of Representatives.

We write to urge that members invested in patient safety, access to affordable medicines, and biomedical innovation observe “regular order” as these Senate bills are combined into one package, introduced, and voted on before the full Senate, and potentially conferenced with the much more far-reaching House 21st Century Cures Act.

Any maneuver resulting in a final legislative package that includes some or all of the dangerous provisions in the House 21st Century Cures Act that were not discussed during the Senate mark-up would constitute an unacceptable end-run around a normal legislative process, exactly the kind of cynical maneuvering feeding public distrust with the workings of the U.S. Congress.

We are concerned that as the Senate counterpart moves through the legislative process, floor amendments and conference committee negotiations could include proposals that endanger the lives of patients and curb access to affordable treatments. This includes proposals that would dangerously require the FDA to recklessly speed the review of certain “breakthrough” medical devices by restricting the FDA’s ability to request new evidence during clinical development, and lower drug approval standards by pressuring the FDA to rely more heavily on “evidence from clinical experience,” meaning sources other than randomized, controlled clinical trials, the gold standard for medical research.

An additional example of the many proposals we fear is section 2151 of the 21st Century Cures Act. This section would bar generic entry of certain medicines into the market for a longer period, denying patients access to affordable life-saving medicines.

These and other dangerous proposals should be omitted from any final legislation. The threat of their inclusion is real, as worrying provisions from the 21st Century Cures Act are already making their way through Congress as proposed attachments to “must-pass” appropriations legislation. Proposals that were inserted as policy riders in the House appropriations process were lifted from Title II of the 21st Century Cures Act. Title II dealt with drug and medical device approval standards and development. Your committee and the Senate as a whole must ensure that these proposals are kept far away from any FDA reform package.

The sweeping 21st Century Cures Act that passed the U.S. House of Representatives contains many provisions that put lives at risk. They have no place in your bill as your package is voted on before the full Senate and enters conference.

Sincerely,

The Annie Appleseed Project
Article 25

Breast Cancer Action
Center for Medical Consumers
Knowledge Ecology International
Health GAP
Public Citizen
National Physicians Alliance
Treatment Action Group
Universities Allied for Essential Medicines
The Veterans Health Council
Vietnam Veterans of America
Young Professionals Chronic Disease Network