March 12, 2014

The Honorable Deb Fischer
United States Senate
383 Russell Senate Office Building
Washington, DC 20510-2706

The Honorable Angus King
United States Senate
359 Dirksen Senate Office Building
Washington, DC 20510-1903

The Honorable Marco Rubio
United States Senate
284 Russell Senate Office Building
Washington, DC 20510-0908

Dear Senator Fischer, Senator King, and Senator Rubio,

The undersigned patient organizations are writing in support of S. 2007, the PROTECT ACT, which would clarify the regulation of medical device and health information technology software. Your legislation is an important first step in updating how new health information systems and software are regulated to help ensure that products are safe and that patients and their caregivers continue to have access to these innovative technologies.

Patients and their caregivers are using health information software on their smartphones and tablets to manage their health and wellness, particularly among the chronically ill and those with service-connected conditions. Wide availability, ease of use, and familiarity with these technologies have allowed patients and their caregivers to integrate disease management and wellness activities into their daily routines, thereby increasing adherence to care plans, and reducing preventable hospitalization.

We are concerned the recent actions to regulate mobile health apps and other health IT software have created confusion in the market about what technologies may be regulated next. Patients and their caregivers are already benefitting from integrating these technologies into their health and wellness routines but uncertainty about future availability may give them pause out of fear that a product could become suddenly unavailable if the FDA decides to regulate.

Further, this uncertainty may be inhibiting development of promising applications that can help patient populations with specific needs and generate better patient-caregiver-provider engagement. We understand from some software developers that the costs of approval may inhibit some from developing these products at all or may dramatically increase their price to consumers. This is particularly true for products that are developed for less-common conditions: the cost of FDA medical device regulation may disincentivize system and software developers to create products that will be a great benefit to a relative few and instead target more common conditions with a larger customer base.

We believe your bill strikes and appropriate balance by clarifying which products are subject to FDA regulation and where an alternative process would be appropriate. We believe all of these

issues stem from the fact that the FDA is using a decades old law to regulate new technologies. This makes little sense as the current structure was created to address discrete devices, not interconnected, networked, Internet based applications, and data. Because mobile medical apps are fundamentally different than traditional medical devices, we urge Congress to update the law to provide both clarity and lower cost to entry for these products.

Finally, the patient and caregiver communities have long pressed FDA to approve drugs and devices at a pace faster than the progression of disease. We believe this legislation will better define the universe of health information technology so that FDA can focus its limited resources, staff, and expertise on expediently ensuring the safety of new medical technologies that pose the highest potential for risk to patients and getting them to those who need them faster.

We support your offices for pursuing this legislation and look forward to working with you to help ensure it is enacted into law.

Sincerely,