February 14, 2014

The Honorable Tom Harkin, Chairman
HELP Committee
United States Senate
Washington, DC 20510

Dear Chairman Harkin,

As members of the Patient, Consumer, and Public Health Coalition, we strongly oppose the Preventing Regulatory Overrreach To Enhance Care Technology (PROTECT) Act of 2014. The Act, as drafted, would have the harmful consequence of exempting so-called "health software" and "clinical software" devices from FDA oversight. Also, the Act is premature. Congress is awaiting a study commissioned in 2012 to guide policymakers on this very issue.

Health care providers and patients rely on the FDA to establish that a device is reasonably safe and effective. Without FDA to carefully scrutinize the risks and benefits of a device, patients' health may be seriously harmed. Even if the device itself is not harmful, if it is not proven effective, then patients could be harmed by inaccurate results that are either anxiety-producing or erroneously reassuring; these outcomes could result either in unnecessary testing or serious illness or death.

Medical devices are clearly defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act. The PROTECT Act muddles the definition of a device, by creating new categories of products that can potentially overlap with the current definition of medical device, but are exempt from regulation as devices.

We are extremely concerned that this bill will deregulate a broad swath of medical devices that rely on software and will create opportunities for rampant "gaming" to avoid regulation. For example, MRIs and CT scanners, or heart monitoring devices, might no longer be regulated by the FDA. This would put the health of millions of Americans at risk.

We adamantly disagree with the Act's finding that the National Institute of Standards and Technology should be the Federal agency that has oversight on standards used by clinical software. NIST's mission is

to promote U.S. innovation and industrial competitiveness, whereas the FDA's mission is to protect the public's health by assuring the safety and efficacy of drugs, biological products, and medical devices.

The Act also is premature. The Food and Drug Administration Safety and Innovation Act (FDASIA) mandated a Health Information Technology (HIT) report, which is due to be released this year. The report will make recommendations on "an appropriate, risk-based regulatory framework to health information technology including mobile medical applications." The report sought input from a broad range of stakeholders including patients, consumers, health care providers, start-up companies, health plans, venture capital investors, small businesses and others. Rather than move rashly on legislation that could harm patients, Congress should wait for the recommendations from the HIT report and discuss them thoughtfully.

We strongly urge you to oppose this bill because it could deregulate medical technology crucial to patient health, causing patients unnecessary risk, and because it proposes congressional action before Congress can review the report to address this issue mandated in FDASIA.

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For more information, contact Paul Brown at (202) 223-4000 or pb@center4research.org