



Contact:
Bradley Merrill Thompson
317.514.5008

Proposed Legislation to Remove FDA Oversight of Medical Software Would Put Patients at Serious Risk

Alliance of Healthcare Providers, Device and Software Makers Says Congress Shouldn't Short-Circuit FDA Progress in Parsing High Risk, Low Risk Apps

WASHINGTON -- Legislation that would remove a wide range of mobile healthcare applications and other medical software from federal oversight would pose serious, potentially life-threatening risks to patients and consumers. Rather than pre-empting the ongoing Food and Drug Administration (FDA) effort to identify low risk apps that shouldn't require FDA review, Congressional staff should participate in the FDA process, holding the agency accountable for moving quickly and achieving the right balance.

"The PROTECT Act seems a misnomer. Instead of protecting consumers the act actually eliminates vital consumer health protections," said Bradley Merrill Thompson, general counsel for the mHealth Regulatory Coalition (MRC). "The rush to avoid expert reviews of complex technologies with far-reaching health ramifications ignores the fact that we cannot separate the high risk from the low risk apps using broad terms in legislation."

The MRC is an alliance of medical device manufacturers, healthcare providers, software developers and others dedicated to creating an environment that encourages innovation in mobile health technology while protecting patient well-being.

Thompson explained, "Software used in the diagnosis and treatment of patients runs the gamut from very low risk software such as an app that reminds patients when to take their medications, to very high risk software such as programs that allow doctors to view ultrasound and other radiological images on a tablet so they can accurately diagnose and treat a patient." He further explained, "The problem is there presently are hundreds of different categories of software, growing all the time, and they're simply not susceptible to being grouped into a few simple buckets."

"And that's the problem the backers of this legislation are confronting. With so many factors that determine the risk of a piece of clinical software, two Washington, D.C. based advocacy groups are pushing legislative language that works about as well as a meat cleaver in surgery."

Whether intended or not, the PROTECT Act would deregulate the following high risk applications and scores of others:

- Software intended to diagnose possible melanomas when the consumer takes pictures of a potentially-cancerous mole with a smartphone camera. "What if someone using this software doesn't see a doctor because flawed software misses the melanoma?" said Thompson.

- Applications intended to notify nurses immediately when a patient's health is rapidly deteriorating. "Imagine the ramifications if the app doesn't work as intended and healthcare professionals reach the patient's bedside too late," he said.
- Software used to calculate the correct dosage of radiation to treat a cancerous tumor, which has to factor in patient comorbidities, whether the patient is receiving chemotherapy and whether the patient is getting radiation before or after surgery. "It is inconceivable that applications of this complexity would go into the marketplace without FDA approval, yet the PROTECT Act would eliminate those safeguards," Thompson said.

Congressional legislation works best when an issue can be addressed through broad principles. But where, as here, the devil is all in the details and technologies are constantly changing, Congress is ill-equipped for the task. With the marketplace producing software in literally hundreds of different flavors that are all over the map in terms of risk with little commonality, the better forum for conducting the nuanced assessments to discern high from low risk is FDA.

To be clear, Congress does have a very important role to play. Thompson explained, "We believe congressional scrutiny is essential for ensuring that FDA produces guidance that clearly distinguishes the regulated from the not in the most appropriate way. Continued innovation in the mHealth space depends upon the industry getting that guidance in a timely way. For almost three years, the MRC has been pressing FDA to clearly delineate the difference, for example, between disease-related technologies that should be regulated and general wellness-related technologies that should not. Likewise we have been asking the agency to specify when accessories to regulated products are themselves regulated. We have yet to see those guidance documents, and congressional participation in this process would be most welcomed."

To be fair to FDA, the agency is developing a comprehensive regulatory pathway for health IT software and mobile medical applications. In 2012, in a very productive step, Congress mandated through Section 618 of the FDASIA Act that FDA, together with the Federal Communications Commission and the Office of the National Coordinator, provide recommendations, scheduled to be released very soon, on how to create an appropriate regulatory framework for this technology. At Congress' urging, this process included convening 30 experts from a wide range of outside stakeholders to advise the agency on the most appropriate risk factors to consider. Thompson was one of those experts, as were a few other MRC members.

Thompson observed, "Regrettably, though, the currently proposed legislation is not helping matters but in fact is serving as a distraction to the important work the agency needs to complete. Indeed, FDA officials are saying that they feel they need to wait for the FDASIA process to be completed before they can move forward with the guidance that the MRC has been pressing them for years to produce."

"Simply put, the PROTECT Act doesn't protect anyone. Patients and consumers should not be asked to rely on software that might give them a false sense of security. We need to pursue a better, safer course to encourage health innovation, which will involve working with FDA to draw a more detailed and nuanced line" he said.