



July 16, 2013

The Honorable Marsha Blackburn
217 Cannon House Office Building
Washington, D.C. 20515

The Honorable Greg Walden
2182 Rayburn House Office Building
Washington, D. C. 20515

The Honorable Phil Gingrey
442 Cannon House Office Building
Washington, D.C. 20515

The Honorable Gene Green
2470 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
2368 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressmen Blackburn, Gingrey, Walden, Green and Congresswoman DeGette,

On behalf of the Advanced Medical Technology Association (AdvaMed), thank you for the opportunity to provide comments on the draft legislation related to regulation of health information technology (IT), software, and medical health technology. We understand that the draft was put forward with a goal to solicit feedback from stakeholders, and we appreciate the opportunity to comment.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than \$30 million in sales annually.

We appreciate your interest in the topic of regulation of health information technology. As you know, this area of technology is undergoing tremendous growth, and it is important to ensure that patient safety remains our highest priority, while still encouraging innovation.

To that end, AdvaMed believes that the following four broad principles are critical for an effective effort to regulate health IT:

1. **Regulation of either software or health IT (including software) should be platform agnostic.** By "platform agnostic" we mean that neither the platform used to run health IT, nor any IT hardware that is part of the health IT, should determine whether or how it is regulated. Additionally, if health IT is regulated, the platform used to run health IT should not determine which agency regulates it.
2. **If a product fits the current definition of a medical device, it should be regulated as a medical device.** The current test for whether a product falls under the FDA medical devices regulatory system is whether it meets the Federal Food, Drug & Cosmetic Act's definition of a

medical device. ¹ We believe that health IT should be handled similarly to other FDA-regulated medical devices. If it meets that definition, it should be regulated using the same risk classification and safety and efficacy evaluation as any other medical device. We also recommend avoiding any overlap of regulation by the Office of the National Coordinator for Health Information Technology (ONC) or others.

3. **Where appropriate, regulating agencies should collaborate.** When aspects of the product could create overlapping jurisdiction (such as health IT that includes, controls, or otherwise interacts with wireless information transmission), FCC should play an appropriate coordinating role with FDA. Where multiple agencies focus on different products or different aspects of the same product, they should reference the same or similar regulatory processes so that a company's products subject to multiple agencies can use the same process to meet requirements.
4. **Regulation should harmonize with well-established international standards.** Historically, a leading inhibitor of medical device innovation has been the lack of global harmonization of regulatory requirements. This lack of global regulatory harmonization may force country-specific verification and validation activities and lifecycle management decisions, which is both costly and complex. This cost and complexity can easily stifle innovation. Building a domestic health IT regulatory environment upon well-accepted, international consensus standards and technical reports, (e.g., ISO 14971, IEC 62304, and IEC/TR 80002-1), should lead to a regulatory environment that protects the public from unnecessary risks and encourages innovation.

We believe that these principles, if implemented, will ensure a well-understood and effective means for regulating products that meet the legal definition of a medical device, while maintaining patient safety as the primary priority.

Again, thank you for the opportunity to provide comments, and we would welcome the opportunity to discuss these issues further.

Sincerely,



JC Scott
Senior Executive Vice President, Government Affairs
AdvaMed

¹ A device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - recognized in the official National Formulary, or the United States Pharmacopocia, or any supplement to them,
 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."