



February 8, 2013

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Advancing the Food and Drug Administration Safety and Innovation Act of 2012

Dear Secretary Sebelius:

We, the Telecommunications Industry Association (TIA), congratulate you on your successful efforts to enhance the United States' health care system to date. On behalf of the information and communications technology (ICT) manufacturer, vendor, and supplier community, we write to urge you to spearhead an effort to promote innovation, protect patient safety, and avoid regulatory duplication by convening a formal working group pursuant to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).¹

About TIA

TIA is and has been a standards development organization since its inception in 1988, and is one of the largest SDOs accredited by ANSI. TIA's standards committees create consensus-based voluntary standards for numerous facets of the ICT industry, for use by both private sector interests and government, which are directly affected by the policies of the U.S. Government in the sweeping area of health information technology. Among other areas, TIA's standards committees develop protocols and interface standards relating to current U.S. Government technology priorities in such areas as fiber optics, public and private interworking, telecommunications cable infrastructure, wireless and mobile communications, multimedia and voice over internet protocol (VoIP) access. TIA's standards reach into areas such as Smart Grid, emergency communications infrastructure, and – of particular relevance to the FDASIA – health care ICT and machine-to-machine (M2M). TIA's hundreds of member companies provide, develop, manufacture, and supply ICT products and services, including components of EHR systems that qualify for Medicare and Medicaid EHR incentive payments under the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009.² TIA members occupy critical roles in the mHealth community, producing many of the mobile devices, medical products and applications which have become increasingly powerful tools for innovative health care solutions.

¹ Pub. L. 112-144 (FDASIA).

² Pub. L. No. 111-5 (2009), at § 13000 *et seq.*

Forming a Federal Advisory Committee to Aid Compliance with Section 618 of the FDASIA

The FDASIA requires you, in consultation with the Commissioner of Food and Drugs (FDA), the National Coordinator for Health Information Technology (ONC), and the Chairman of the Federal Communications Commission (FCC), to post on each of these agencies web sites “a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”³ This is required to happen within 18 months of enactment of the FDASIA, which was July 9 of 2012, resulting in a deadline at end of 2013.

The FDASIA also allows you to, in consultation with the FDA, ONC, and FCC, convene a working group of external stakeholders and experts to provide appropriate input on the strategy and recommendations required for the report, which, if formed, would see representation of numerous key stakeholder constituencies including representatives of patients, consumers, health care providers, startup companies, health plans or other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, employers, and other stakeholders with relevant expertise.⁴

TIA members are part of the overwhelming consensus of stakeholders who believe that medical devices, enabled by high-speed wireless communications, hold great potential to help medical professionals more quickly and efficiently support patients, while also providing consumers with better access to health information and tools in a secure manner. While new technologies hold great potential to advance the medical field, ICT companies who invest and innovate in this sector sometimes face regulatory uncertainty. For example, due to the overlapping jurisdiction between the agencies, it is not always clear to new developers which agencies they must work with. Further impacting this environment are numerous government activities, such as policy pronouncements or ongoing regulatory developments pursuant to the HITECH Act. The working group contemplated by the FDASIA could, by incorporating input from stakeholders including those constituencies named in Section 618 as noted above, provide clarity on issues such as:

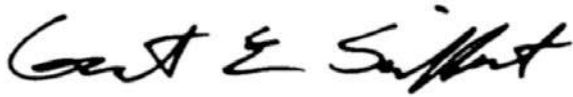
- Which agencies oversee the legal marketing of mobile medical applications?
- Regulatory clarity on converged medical devices and guidance from each respective agency that oversees the marketing and availability of such devices.
- How the corresponding agencies are collaborating, information sharing and coordinating activities relative to health IT, including mobile medical applications.

³ FDASIA *at* § 618(a).

⁴ FDASIA *at* § 618(b).

We therefore urge you to, pursuant to Section 618 of the FDASIA, convene a formal working group consistent with the Act. We also recommend that this group be created under the Federal Advisory Committee Act.⁵ The ICT manufacturer community is important to, and would very engaged in, this effort, and I urge you to contact TIA if we can be of service.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Grant E. Seiffert". The signature is fluid and cursive, with the first name "Grant" being the most prominent.

Grant Seiffert
President
Telecommunications Industry Association

⁵ Federal Advisory Committee Act (FACA; 5 U.S.C. Appendix — Federal Advisory Committee Act; 86 Stat. 770, as amended).