



FEDERAL COMMUNICATIONS COMMISSION

June 28, 2012

JULIUS GENACHOWSKI
CHAIRMAN

The Honorable Brian Bilbray
U.S. House of Representatives
2410 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Bilbray:

Thank you for your letter regarding coordination between the Commission and the Food and Drug Administration (FDA) to make wireless medical devices available for public use. As you are obviously aware, mobile applications (software programs that run on smart phones and other mobile communications devices) are opening new and innovative ways for technology to improve health and health care. We welcome the opportunity to provide you with information regarding our agencies' respective and collaborative efforts to provide a regulatory environment that protects and promotes patients' safety and privacy and provides for innovation in this significant and rapidly changing field.

The FCC is responsible for ensuring an environment in which radio communications of all kinds can operate effectively, including the wide variety of uses in medical, quasi-medical applications and those only tangentially related to medical concerns. As the FDA points out in its response to your inquiry, it has a public health responsibility to oversee the safety and effectiveness of medical devices including those that use radio communications as a technology component.

I have asked Bruce Romano, Associate Bureau Chief of our Office of Engineering and Technology, to prepare responses to your various questions. You will note that the FCC and the FDA have worked together closely on this issue. The two agencies have a history of excellent collaboration in other areas of mutual regulatory oversight and we both are committed to continuing our efforts in mobile medical applications. Each agency is providing separate responses to the questions raised in your April 3 letter; however we have shared and coordinated our answers to ensure the most effective response.

Page 2—The Honorable Brian Bilbray

Please find attached the FCC responses to your questions, and let me know if I can be of any further assistance.

Sincerely,

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Julius Genachowski

Enclosure



FEDERAL COMMUNICATIONS COMMISSION

June 28, 2012

JULIUS GENACHOWSKI
CHAIRMAN

The Honorable Marsha Blackburn
U.S. House of Representatives
217 Cannon House Office Building
Washington, D.C. 20515

Dear Congresswoman Blackburn:

Thank you for your letter regarding coordination between the Commission and the Food and Drug Administration (FDA) to make wireless medical devices available for public use. As you are obviously aware, mobile applications (software programs that run on smart phones and other mobile communications devices) are opening new and innovative ways for technology to improve health and health care. We welcome the opportunity to provide you with information regarding our agencies' respective and collaborative efforts to provide a regulatory environment that protects and promotes patients' safety and privacy and provides for innovation in this significant and rapidly changing field.

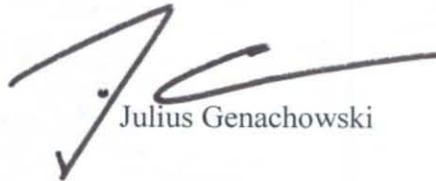
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Page 2—The Honorable Marsha Blackburn

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Julius Genachowski

Enclosure



FEDERAL COMMUNICATIONS COMMISSION

June 28, 2012

JULIUS GENACHOWSKI
CHAIRMAN

The Honorable Michael Burgess
U.S. House of Representatives
2241 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Burgess:

Thank you for your letter regarding coordination between the Commission and the Food and Drug Administration (FDA) to make wireless medical devices available for public use. As you are obviously aware, mobile applications (software programs that run on smart phones and other mobile communications devices) are opening new and innovative ways for technology to improve health and health care. We welcome the opportunity to provide you with information regarding our agencies' respective and collaborative efforts to provide a regulatory environment that protects and promotes patients' safety and privacy and provides for innovation in this significant and rapidly changing field.

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Page 2—The Honorable Michael Burgess

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Julius Genachowski

Enclosure



FEDERAL COMMUNICATIONS COMMISSION

June 28, 2012

JULIUS GENACHOWSKI
CHAIRMAN

The Honorable Phil Gingrey
U.S. House of Representatives
442 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Gingrey:

Thank you for your letter regarding coordination between the Commission and the Food and Drug Administration (FDA) to make wireless medical devices available for public use. As you are obviously aware, mobile applications (software programs that run on smart phones and other mobile communications devices) are opening new and innovative ways for technology to improve health and health care. We welcome the opportunity to provide you with information regarding our agencies' respective and collaborative efforts to provide a regulatory environment that protects and promotes patients' safety and privacy and provides for innovation in this significant and rapidly changing field.

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Page 2—The Honorable Phil Gingrey

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Julius Genachowski

Enclosure



FEDERAL COMMUNICATIONS COMMISSION

June 28, 2012

JULIUS GENACHOWSKI
CHAIRMAN

The Honorable Joseph R. Pitts
U.S. House of Representatives
420 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Pitts:

Thank you for your letter regarding coordination between the Commission and the Food and Drug Administration (FDA) to make wireless medical devices available for public use. As you are obviously aware, mobile applications (software programs that run on smart phones and other mobile communications devices) are opening new and innovative ways for technology to improve health and health care. We welcome the opportunity to provide you with information regarding our agencies' respective and collaborative efforts to provide a regulatory environment that protects and promotes patients' safety and privacy and provides for innovation in this significant and rapidly changing field.

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Page 2—The Honorable Joseph R. Pitts

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Julius Genachowski

Enclosure



FEDERAL COMMUNICATIONS COMMISSION

June 28, 2012

JULIUS GENACHOWSKI
CHAIRMAN

The Honorable Greg Walden
Chairman
Subcommittee on Communications and Technology
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Walden:

Thank you for your letter regarding coordination between the Commission and the Food and Drug Administration (FDA) to make wireless medical devices available for public use. As you are obviously aware, mobile applications (software programs that run on smart phones and other mobile communications devices) are opening new and innovative ways for technology to improve health and health care. We welcome the opportunity to provide you with information regarding our agencies' respective and collaborative efforts to provide a regulatory environment that protects and promotes patients' safety and privacy and provides for innovation in this significant and rapidly changing field.

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Page 2—The Honorable Greg Walden

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Julius Genachowski

Enclosure

1. What specific joint actions have your agencies undertaken to date to implement the Memorandum of Understanding? Please include public meetings, inter-agency meetings, data sharing, publication of and/or consultation on guidance documents and reports, and other activities relevant to implementation of the MOU.

Following the public workshop in late July 2010, FCC and FDA have worked together in a variety of ways to implement the MoU and advance mobile health.

The senior leadership and appropriate technical staff from the FDA and FCC have met formally in August 2010, November 2010, March 2011, and most recently on May 1, 2012. These meetings occur infrequently because individual issues are coordinated on an as needed or ongoing basis as reflected below.

- A major point of discussion during the July 2010 FCC-FDA workshop was the need for a guidance document on how mobile medical apps would be treated under the FDA regulations. The FDA subsequently prepared the draft, coordinated it with FCC and published the draft for public comment in July 2011. The FDA has received extensive comments and is determining what steps may be appropriate next.
- Wireless technologies offer a revolutionary way to advance health care, such as through remote monitoring of patients by physicians. The FCC has been laser focused on ensuring that wireless technologies have access to adequate spectrum so that wireless health care and other applications may flourish. The FCC and the NTIA have taken numerous actions in this regard and are continuing to do so.
- FCC in November 2010 coordinated a draft Notice of Proposed Rule Making with the FDA proposing to revamp the experimental licensing program, including establishing program licenses for health care institutions to study new wireless medical technologies. The Mayo Clinic, in particular, expressed interest in this proposal. The FCC plans to take action on this proposal later this year.
- FCC coordinated with FDA an order adopted in November 2011 providing new spectrum for medical nerve stimulators to restore motion to people who have been disabled.
- FCC coordinated with FDA an order issued in November 2011 granting a waiver to Second Sight for a device to provide a vision capability to persons who are blind.
- In May of this year, the FCC adopted rules providing spectrum and technical rules for "medical body area networks" that will improve the quality of health care and patient results and will help reduce health care costs. This rulemaking was coordinated at all stages with the FDA.
- The FCC has coordinated with the FDA on an ongoing basis various RF safety issues for wireless medical devices.
- The FDA and FCC staff met in November 2011 on developing IEEE 802.15.6 standard for human body communications (HBC) to discuss concerns about potential interference to active implants such as cardiac pacemakers.
- FDA and FCC staff have had numerous interactions with West Wireless to promote wireless technologies for health care. Both FDA and the FCC participated in a

workshop sponsored by West Wireless Health Institute in April 2011. FDA and FCC met with West Wireless at CDRH in August 2011 to discuss their ideas for a reference wireless architecture for health care facilities. West Wireless spoke at the FCC's workshop on small cells in December 2011. Discussions about this idea are ongoing.

- FDA Commissioner Hamburg and FCC Chairman Genachowski met at a small business event in April 2011 and discussed progress on the MoU and wireless health agenda.
- FCC Chairman Genachowski gave a keynote address at the mHealth Summit in November 2011 along with Health and Human Services Secretary Kathleen Sebelius. FCC and FDA staff participated together on several panels at this event.
- A member of the FCC staff made a presentation on FCC-FDA cooperation at the AdvaMed Chief Scientific and Technical Officers meeting in October 2011.
- The FDA and the FCC participate in an interagency working group on mHealth organized by the National Institutes of Health and have each made presentations on their respective activities. The working group meets about once a quarter.
- FCC and FDA both participated in a workshop in March 2012 sponsored by NIH to explore public-private partnerships to promote mHealth.
- Also in March 2012 FCC staff participated in and sat on a panel for a web conference with FDA and other agencies sponsored by HHS regarding the current regulation of and safety and security concerns for mobile devices used in health care.
- On June 6, 2012, the FCC convened an mHealth summit with FDA's participation bringing together leaders from hospitals, device manufacturers, financing groups, wireless carriers, and several other government agencies to provide a forum for interactions and to discuss medical communications and devices and the regulatory process.
- FCC staff has initiated discussions with the FDA about the possibility of relocating critical care telemetry equipment currently operating on TV channel 37 to another frequency band to address potential issues relative to the planned TV band incentive auctions.
- FCC and FDA staff have discussed a number of other matters of mutual interest as appropriate such as hearing aid compatibility of wireless phones and potential interference to medical devices from RF identification systems,
- The FCC's Technological Advisory Council is examining issues related to machine-to-machine communications, including health care applications, to identify and recommend ways to better facilitate introduction of this technology.

Both the FDA and FCC are cooperating with the General Accounting Office for its study related to the cybersecurity of medical devices.

In sum, the FDA and FDA have vigorously carried out the coordination contemplated in the MoU and will continue to do so.

2. Who oversees each agency's policy development (including regulations, guidance, etc.) for wireless health devices and their supporting infrastructure, and how do the agencies

coordinate their respective policy measures with each other, as well as the Office of the National Coordinator for Health IT (ONC) given ONC's responsibility for ensuring the certification process for electronic health records and EHR modules used in the Meaningful Use program?

The FCC's Chairman and Commissioners are ultimately responsible for the rules and regulations adopted by the FCC on all matters. The Office of Engineering and Technology (OET) and the Wireless Telecommunications Bureau are primarily responsible for developing and recommending regulations, policies, and guidance having to do with wireless devices, including those devices and systems intended specifically for various medical applications and those that are used for multiple communications purposes including incidentally medical-related uses.

As described in response to Question 1, above, the FCC and FDA work together in the field to educate each other about the nature and functions of various devices, systems and services, according to their respective expertise, and to ensure that there is understanding of their respective jurisdiction in order to ensure relevant issues are addressed and avoid any unnecessary duplication of effort.

The FCC does not coordinate with ONC as it is not involved in the maintenance or security of medical health records or in EHR modules. We are aware of FDA's close collaboration with ONC.

3. What primary activities related to wireless health devices are underway at each agency? Please include efforts that are conducted independently and jointly, as well as those in conjunction with ONC.

The FCC's principle activities are described in the response to question 1.

4. We envision device to EHR or EHR module interoperability in the near future. What communication or coordination activities have taken place between FDA, FCC and ONC and what plans do your agencies have to coordinate regulatory requirements across the Agencies?

Electronic Health Records are primarily a matter of concern and jurisdiction for FDA and ONC; the FCC's spectrum and device regulations would not cover the kinds of security concerns that appear to be implicated by this question, and a response is more appropriately provided by FDA. We do note that HHS shared with us for review its pending study and report on the availability of open source health information technology systems.

5. What efforts have been undertaken or are being planned to better leverage staff expertise relative to wireless medical devices and supporting infrastructure across the agencies?

As illustrated in response to Question 1, the FCC coordinates closely with the FDA and is called on by and participates in the activities of other relevant federal agencies to provide its expertise regarding network security and interference and spectrum management. As indicated in response to Question 4, one recent example of this is that HHS has reached out to FCC for review of its pending Study and Report on the Availability of Open Source Health Information Technology Systems.

6. Both FDA and FCC have publicly discussed efforts to make possible wireless "testbeds" for the important purpose of better understanding how wireless health devices coexist in health care settings and advancing medical device interoperability. Please provide an update on these efforts, including each agency's role in the development of wireless "testbeds" and the promotion of interoperability.

Action is moving forward on several fronts. First, as addressed in Question 1, the FCC has proposed rules and is working on final rules to expand its experimental licensing program to, *inter alia*, promote advancement in the development of medical radio devices by creating a medical experimental authorization that would be available to qualified hospitals, Veterans Administration (VA) facilities, and other medical institutions. These proposals would enable the creation of cutting-edge test-bed facilities, where manufacturers and developers could try out new wireless medical technologies and assess operational readiness, including in typical environments. In addition, these changes could spur the development of new ideas and innovations. A medical experimental authorization would allow for the testing and operation of new medical devices that use wireless telecommunications technology for therapeutic, monitoring, or diagnostic purposes that have not yet been submitted for equipment certification, or for devices that use RF for ablation, so long as the equipment is designed to meet the FCC's technical rules.

In addition, the FCC and FDA are both working to establish common understanding of considerations for using wireless technology in medical devices. We expect this will gain significant momentum with the publishing of FDA's final wireless guidance.

In addition, as illustrated in response to Question 1, the FCC is participating in FDA's efforts to establish a greater public-private partnership platform and to create a forum to share information between various interested and affected parties who would not normally connect with one another. The FCC is part of the FDA-championed group along with other stakeholders including researchers, device manufacturers, wireless service providers, healthcare providers, healthcare advocates, involved regulatory agencies and other federal institutions, insurers, and academics. The agencies hope that these efforts will contribute to improvements in regulatory science in the areas of medical device interoperability.

The FCC supports FDA's interoperability efforts in: understanding the landscape of efforts in medical device interoperability; articulating value proposition of interoperable medical devices; identifying metrics that can show progress in the medical device interoperability adoption and determining best methods to communicate with the users, device makers and others on the ongoing efforts in developing standards, implementations and needs. The FCC is also helping

other parties understand and participate in the regulatory environment that affects these concerns and in aiding in their understanding of the limitations of medical device interoperability.

As an accurate understanding of the landscape is developed, the FDA and FCC can identify gaps and opportunities to ultimately equip both agencies with accurate input to inform our respective regulatory programs and policies.

7. How are FDA and FCC coordinating review processes for devices that may be subject to regulation by each agency? Please include mechanisms that are in place or are being planned to prepare for the increasing application of wireless technologies in medical device innovation.

The FCC and FDA have different responsibilities and therefore their respective product approval processes are different. At the same time, it is important for each to understand the other's expertise, jurisdiction, and processes, and our diligence in that regard is reflected in our other response herein, particularly our response to Question 1.

The FDA's CDRH is responsible for assuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational and consumer products. Medical devices are subject to a premarket clearance or approval process that is operated by CDRH. FDA conducts premarket reviews of most medical devices prior to the device entering the market. The approval process varies by the type of device and its application.

The FCC is responsible for spectrum management and RF safety of wireless devices. The FCC's Office of Engineering and Technology (OET) administers an equipment authorization program that ensures compliance with the required radio frequency emission characteristics of a device required by FCC rules and regulations. Wireless medical devices will almost invariably address and incorporate FCC requirements prior to submission to the FDA as part of the design and development of their medical devices. Given this, there is little apparent benefit in coordinating the FDA and the FCC approval process for any given device. If a device raises a novel issue or concern, the FCC and FDA can and do discuss this routinely.

8. How are FDA and FCC approaching regulation of wireless network infrastructure, both internal and external to health care facilities, relative to its role in enabling transmission of health care data? Please include current or planned efforts to help various stakeholders understand jurisdictional delineation and agency approaches to related concerns such as transmission security and integrity.

Similar to our response to Question 7, the FCC and FDA have different responsibilities and particular concerns, but it is important for each to understand the other's expertise, jurisdiction, and processes. The FDA has indicated in its mobile medical apps draft guidance (in consultation with the FCC) that it is taking a narrowly-tailored approach towards this promising area.

The FDA has recognized that wireless network infrastructure internal and external to healthcare facilities does not meet the definition of device and therefore, it does not have jurisdiction over those networks and their approval or operation. On the other hand, the FCC regulates the licensing and operational radio aspects of those infrastructures. Both agencies understand that providing clarity on this is necessary and we have been and working will continue to work with FDA to make this clear in its final guidance and communications.

9. Please provide a single point of contact with whom we might engage to support FDA and FCC in their coordinated efforts.

Currently Bakul Patel, Policy Advisor, in the Office of the Center Director, CDRH, FDA and Bruce Romano, Associate Chief, Office of Engineering and Technology, Federal Communications Commission are the official contacts for the Memorandum of Understanding.