PUBLIC NOTICE

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FCC AND FDA ANNOUNCE AGENDA FOR JOINT WORKSHOP ON MEDICAL TECHNOLOGY INNOVATION AND WIRELESS TEST BEDS

Chairman Tom Wheeler and Commissioner Mignon Clyburn of the FCC, and Dr. William Maisel, Deputy Director, Center for Devices and Radiological Health, FDA, will address workshop participants

Washington, D.C. – On Tuesday, March 31, 2015, the Federal Communications Commission (FCC) and the Food and Drug Administration (FDA) will host "Promoting Medical Technology Innovation – The Role of Wireless Test Beds." This public workshop will be held from 9:00 a.m. to 4:30 p.m. EST in the Commission Meeting Room at FCC Headquarters, located at 445 12th St. S.W., Room TW-C305, Washington, D.C. 20554.

The workshop will convene experts from industry, medicine, academia, and government to focus on the role of wireless medical test beds and their influence on the development of converged medical technology for clinical and non-clinical settings. A wireless test bed is an environment where devices can be evaluated across a range of interference scenarios.

As the rapid pace of innovation blurs traditional boundaries between consumer health technology, medical devices, and communications, the agencies seek to better understand how wireless test beds can be used and configured to meet the challenges and to take advantage of the opportunities this convergence presents. Consumers are increasingly using wireless health and care management tools at home; indeed, the emergence of the "hospital in the home" concept opens new areas of medical technology innovation that must take into account the need for wireless coexistence.

The workshop is another step in the ongoing FDA/FCC collaboration and leadership in promoting innovative medical technologies, and is being organized by the Connect2Health^{FCC} Task Force, the FCC Office of Engineering and Technology, and the FDA Center for Devices and Radiological Health.

The FCC and the FDA encourage the participation of a broad range of stakeholders, including device manufacturers, health care facilities and clinicians, test labs, standard-setting bodies, innovators, other government agencies, patient safety groups, researchers, and entrepreneurs, among others.

Register by e-mailing testbeds@fcc.gov. Detailed registration and event information, as well as a tentative workshop agenda, are provided below. Questions from the public are welcomed during the workshop and should be directed to livequestions@fcc.gov or through Twitter using #testbeds.

-TENTATIVE AGENDA-

9:00-9:15 a.m. **Welcome, Greetings from FCC and FDA**

9:15-9:30 a.m. **Overview of FCC and FDA Ongoing Collaborative Efforts and Interest in Wireless Test Beds for Converged Medical Devices**

Julius Knapp, Chief, Office of Engineering and Technology, FCC
Bakul Patel, Associate Director for Digital Health, Center for Devices and Radiological Health, FDA

9:30-10:45 a.m. **Session One: Defining the Need for and Scope of Wireless Medical Device Test Beds**

What issues and potential problems arise as medical devices go wireless? What are the potential implications of medical devices using unlicensed spectrum? Are there current programs examining wireless medical device coexistence in hospitals and other health care facilities? Are there different needs for pre-deployment testing and post-installation monitoring? Are medical device test beds needed, and if so, why? What is the desired output or outcome of using wireless test beds? How do they help protect patient safety? Are there any challenges and/or limitations from using a test bed? Are new issues emerging that make the need for these test beds more or less important (e.g., hospital to home; broader consumer use outside medical facilities; mBANS, more connected devices/Medical IoT)?

Moderators:

- *H. Stephen Berger,* President, TEM Consulting; Chair, ANSI ASC C63 Subcommittee 7 on Spectrum Etiquette; Chair, ANSI C63.27 Working Group on Wireless Coexistence Testing; Co-Chair, AAMI Medical Device Wireless Committee
- *Dr. Julian Goldman,* Medical Director, Biomedical Engineering, Partners HealthCare System; Attending Anesthesiologist, Massachusetts General Hospital/Harvard Medical School; Director, Medical Device Interoperability Program; Co-Chair, AAMI Interoperability Working Group

Discussants:

- *Shawn M. Jackman,* Director, Strategic Planning, Network Services, Kaiser Permanente
- *Kerry McDermott,* Vice President, Public Policy and Communications, Center for Medical Interoperability; former Director of Healthcare, FCC
- *Phil Raymond,* Wireless Architect, Philips Healthcare; Chair, Wi-Fi Alliance, Healthcare Marketing Task Group
- *Rick Tevis,* Senior Director, Clinical Engineering, Geisinger Health System
- *Donald Witters,* Biomedical Engineer, Center for Devices and Radiological Health, FDA

10:45-11:00 a.m. **Break**

11:00-12:00 p.m. **Session Two: Overview of Current Public and Private Wireless Medical Device Test Bed Programs and Initiatives**

What are some of the current, most innovative public and private wireless medical device test bed programs today, and where are they housed (e.g., hospitals, non-hospital settings, homes, universities, etc.)? What components and characteristics comprise these test beds? Are there different types of medical device test beds (e.g., hardware, software, etc.)? Where do these devices operate in the radio frequency? Is there a central repository of test results/data that the medical community and other stakeholders can access? What types of medical devices and innovations are being tested? How are tests and simulations being conducted in these settings? What testing standards, if any, are being applied for current wireless medical device test beds? Who are the primary users of wireless medical device test beds

(researchers, manufacturers, doctors, innovators, entrepreneurs) and what knowledge can be gleaned from them?

Moderators:

- *Dr. Wendy Nilsen,* Health Science Administrator, National Institutes of Health; Program Director, National Science Foundation
- *Seth Seidman,* Senior Electrical Engineer, Center for Devices and Radiological Health, FDA

Discussants:

- *Greg Bowden,* Senior Reliability Engineer, Medtronic, Inc.
- *Mick Conley,* Development Manager Industry Programs, Underwriters Laboratories Inc.
- *Dr. Hazem Refai,* Associate Professor, University of Oklahoma; Founder and Director of the Wireless Electromagnetic Compliance and Design Center
- *Daria Stehling,* Consultant; Member of CTIA M2M sub-working group, the ANSI C63 SC7, and contributor to ANSI C63.27 working group on coexistence standards
- *Dr. William Young,* Senior Engineer, National Institute of Standards and Technology

12:00-1:00 p.m. **Lunch Break**

1:00-1:30 p.m. **Spotlight Session — Future of Healthcare and Medical Device Innovations**

Featuring: Dr. Harry Greenspun, Director, Center for Health Solutions, Deloitte Services LP

1:30-2:45 p.m. **Session Three: Identifying and Prioritizing Key Features, Functions and Gaps in Wireless Medical Device Test Beds**

What would a wireless medical device test bed ideally look like? What can be done to enable more efficient testing? Are there gaps in the availability of test beds, test equipment, and/or test subjects? Are there gaps in standards for wireless medical devices that inhibit testing? What are the impacts of wireless test beds on patient care? Are the necessary features and functions, and any gaps in wireless medical test beds different for small versus large players? What should the role of the federal government, and more specifically the FCC and FDA, be in promoting these test beds? What, if any, changes should be made in the regulatory process to enable more efficient testing? How can the development of wireless medical device test beds be accelerated? What are the roles of medical device manufacturers, hospital IT departments, technology developers, and networking infrastructure providers?

Moderators:

- *Ed Cantwell,* Chief Operating Officer, Center for Medical Interoperability
- *Ira Keltz*, Deputy Chief, Office of Engineering and Technology, FCC

Discussants:

- *Dr. Steven Baker,* Senior Principal Engineer, Welch Allyn
- *Rick Hampton,* Wireless Communications Manager, Partners Healthcare System
- *Fanny Mlinarsky,* President, octoScope, Inc.
- *Chris Riha,* Senior Director, Technology Services Group, Carilion Clinic Health System
- *Ed Wyatt,* Senior Systems Engineer, Ruckus Wireless, Inc.

2:45-3:00 p.m. **Break**

3:00-4:15 p.m. **Session Four: Driving Innovation and Safe Coexistence of Wireless Medical Technologies**

What is the future of wireless health and connected health? As care moves from the clinical setting to the retail or home setting, how is coexistence affected? How are the coexistence issues similar or dissimilar between those settings? In light of the ongoing health care transformation, how can medical devices be future-proofed? What is next on the horizon for wireless test beds in clinical and non-clinical settings? How can relevant stakeholders develop a learning environment for wireless medical technologies so that information can be shared while balancing proprietary interests? What are some strategies to evaluate, catalog, and disseminate knowledge related to intelligent integration of medical devices into wireless systems in various settings. Are there other models (beyond or in conjunction with) wireless test beds to consider?

Moderators:

- *Dale Hatfield,* Senior Fellow, Silicon Flatirons Center for Law, Technology and Entrepreneurship, University of Colorado at Boulder; former Chief, Office of Engineering and Technology, FCC
- *Robert Havasy*, Vice President, Personal Connected Health Alliance; Executive Dir., Continua

Discussants:

- *Surjit Ahluwalia,* Director, Advanced Services, Cisco Systems
- *Dipankar (Dipu) Ganguly,* Chief Executive Officer, AkibaH, Inc.
- *Scott Gresbach,* Program Leader, GE Healthcare Global Services
- *Robert Jarrin,* Senior Director, Government Affairs, Qualcomm Inc.
- *Jeffrey Tri,* Section Head, Information Technology, Mayo Foundation for Education and Research

4:15-4:30 p.m. **Closing**

-REGISTRATION AND EVENT INFORMATION-

The event is free and open to the public. Registration is strongly encouraged. The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability.

Registration: To register and get on our e-mail list for the event, please e-mail testbeds@fcc.gov with "Registration" in the subject line and provide your name, organization affiliation and contact information.

Live Webcast: A free webcast of the live event, with open captioning over the Internet, will be available at FCC.gov/live. Event details are available on http://www.fcc.gov/health.

Public Input: The agencies also seek public input regarding questions for workshop participants. Suggested questions can be e-mailed to testbeds@fcc.gov with the subject line: "Workshop Questions." During the workshop, audience members will have an opportunity to submit questions in writing, online at livequestions@fcc.gov, and through Twitter using #testbeds. Questions will be reviewed and, time permitting, may be asked by the moderators. There will also be an opportunity to submit written comments (via e-mail to testbeds@fcc.gov) about any portion of the workshop.

Reasonable Accommodations: Reasonable accommodations for people with disabilities are available upon request. Include a description of the accommodation and contact information in case we need more information. Make your request as early as possible by sending an e-mail to fcc504@fcc.gov or calling the Consumer and Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (TTY).

Contacts: For additional registration or logistical information, please contact Shannon Hyatt by e-mail at testbeds@fcc.gov or by phone at (202) 418-1887. Please direct press inquiries to Katie Gorscak, Connect2Health[FCC] Task Force, FCC, at (202) 418-2156 or katie.gorscak@fcc.gov; and to Andrea Fischer, Office of Media Affairs, FDA, at (301) 796-0393 or andrea.fischer@fda.hhs.gov.

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