MEMORANDUM OF UNDERSTANDING
BETWEEN THE
FEDERAL COMMUNICATIONS COMMISSION
AND THE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

I. Preamble:

The Food and Drug Administration (FDA) as part of the Department of Health and Human Services and the Federal Communications Commission (FCC), all United States Federal Government entities and hereinafter also referred to as "agencies," agree to work together to promote initiatives related to the review and use of FDA-regulated medical devices, as defined by the Federal Food, Drug and Cosmetic Act (*see* 21 U.S.C. § 321(h)) that utilize radiofrequency emissions or otherwise fall under the jurisdiction of the FCC, as provided by the Communications Act of 1934, as amended (*see* 47 C.F.R. § 151 *et seq.*).

II. Parties:

The FCC is an independent federal establishment created by the Communications Act of 1934, 47 U.S.C. § 151 *et seq.* The FCC is responsible for, among other things, governing radio devices so as to provide for effective operation and communication, including allocations of frequencies and specification of technical requirements to avoid harmful interference between users.

The FDA is a regulatory agency responsible for protecting the public health through the regulation of food, cosmetics, and medical products, including drugs, biological products, animal drugs, and medical devices. The FDA administers the Federal Food, Drug and Cosmetic Act (*see* 21 U.S.C. § 321-399b) and applicable sections of the Public Health Service Act (*see* 42 U.S.C. § 262), among other statutes. Among its duties, the FDA approves pre-market applications, conducts inspections of manufacturing facilities, and monitors post-marketing adverse events.

III. Authority:

The FCC enters into this MOU in furtherance of its responsibility to provide for effective operation and communication between radio devices, including allocation of frequencies and specification of technical requirements to avoid harmful interference between users. *See* 47 U.S.C. § 151, 152, 301, 302.

The FDA enters into this MOU in furtherance of its responsibilities related to the

safety and effectiveness of medical devices, which include broadband and wireless enabled medical devices. *See* 21 U.S.C. § 321.

IV. Purpose:

The MOU between the FCC and the FDA is intended to promote collaboration and ultimately to improve the efficiency of the regulatory processes applicable to broadband and wireless enabled medical devices. This MOU applies only to areas where stakeholders are affected by the FCC and the FDA regulatory authority. This MOU is designed to enhance knowledge and understanding between the agencies and to increase the efficiency of their respective regulatory processes by providing for the sharing of information and expertise between the agencies for broadband and wireless enabled medical devices, and to increase regulatory predictability and understanding of regulatory requirements for medical device providers. The goals of the collaboration are to explore ways to:

a. Further enhance information sharing efforts in order to further ensure the safety and efficacy of medical devices.

b. Improve the efficiency of the agencies' regulatory processes in areas where their jurisdiction overlaps, such as with respect to various medical devices that utilize broadband and wireless technology.

c. Promote efficient utilization of tools and expertise for product analysis, validation, and risk identification.

d. Build infrastructure and processes that meet the common needs for evaluating broadband and wireless enabled medical devices.

V. Background:

In recent years, an increasing number and variety of medical devices that provide patient or individual monitoring, therapy, treatment, and responsive intervention have been and are being developed that rely on radio communications for their operation. Some of these devices provide significant advances in both preventive health care and in recovery and restoration of function from illness and injury. Given their respective responsibilities and jurisdiction as described above, as well as their respective resident expertise, the FDA and the FCC have a shared interest and role in identifying the challenges and risks posed by the proliferation of medical implants and other devices that utilize broadband and wireless technology. This MOU is intended to enhance the coordination between the FCC and the FDA with respect to such devices, and to improve efficiency in the areas where the agencies' expertise and jurisdiction overlap. It is anticipated that this

will be an ongoing effort, and it may be followed by additional MOUs or amendments to this MOU.

VI. Substance of Agreement:

a. The agencies will collaborate in holding a public meeting to gather information and perspective from all affected parties.

b. The agencies will use the input from the public meeting, as well as that gathered in bilateral conferences, to cooperatively identify and eliminate or reduce unnecessary hindrances for both agencies as they relate to broadband and wireless enabled medical devices.

c. Each agency will establish a liaison officer to facilitate the actions carried out under this MOU.

d. The FDA and the FCC agree to share information pursuant to the protocols established herein in Appendix A.

e. The FDA and the FCC agree to notify each other when either obtains information that it recognizes will be useful to the other agency in the performance of its duties or in its general knowledge and understanding of developments and regulatory concerns in the field of broadband and wireless enabled medical devices.

f. The FDA and the FCC agree that each initial request for information will be made by and transmitted to the agency liaison officer designated according to Section VI.c. of this MOU. Subsequent communications pertaining to that issue may occur between other staff as outlined in the initial request for information.

g. The FDA and the FCC agree that any agency may decide not to share information or expertise in response to a particular request for information made according to the procedures established under Section VI.d., or to limit the scope of information and expertise sharing in response to a particular request. A decision not to share information in response to a specific request may be based on several factors, including, for example, the amount of resources necessary to fulfill the request, the reasonableness of the request, the responding agency's priorities, or legal restrictions. In the event that the agencies can not reach consensus on a decision to share or not share information, the issue will be referred to the respective agency signatory for resolution.

h. The FDA and the FCC agree to establish reasonable timelines for

responding to information requests and to refer instances of delays to the agency liaison officer for resolution.

VII. General Provisions:

The FDA and the FCC shall establish procedures that include proper safeguards against unauthorized use and disclosure of the information exchanged under this MOU. Proper safeguards shall include the observation of policies and procedures that ensure that the information shared under this MOU shall be used solely in accordance with each agency's respective statutory duties and responsibilities for the purposes outlined in Section IV, and in compliance with the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act of 1974, as amended (5 U.S.C. 552a), the Freedom of Information Act (5 U.S.C. 552), and their implementing regulations, as well as the HIPAA Privacy Rule (45 CFR Parts 160 and 164). The FCC and the FDA shall establish appropriate administrative, technical, procedural, and physical safeguards to protect the confidentiality of information governed by the above statutes, as well as internal agency information, and to prevent unauthorized access to the information provided by the other agency.

Access to confidential information shared under this MOU shall be restricted to authorized FDA and FCC employees, agents, and officials who require access to perform their official duties in furtherance of the provisions and the objectives of this MOU. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information, and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws. Contractors, their subcontractors, and agents requiring access to the information shared under this agreement in order to perform their duties will be required to sign the appropriate confidentiality or nondisclosure agreement used by the respective agency by which they will commit to keep the information confidential. Authorized use of derivative works that include such confidential information shall observe the same practices with respect the confidential information contained therein.

The FDA and the FCC agree to promptly notify the other agency of any actual or suspected unauthorized disclosure of information shared under this MOU.

If an agency that has received information under this MOU receives a Freedom of Information Act (FOIA) request for the shared information, it will immediately refer the request to the information-originating agency, via the designated liaison officer identified below, for it to respond directly to the requestor regarding the releasability of the information. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will issue directly from the other agency.

If an agency that has received information under this MOU receives a subpoena that may cover the shared information, it will immediately notify the information-originating agency, via the designated liaison officer identified below, and the two agencies will confer on how to respond.

VIII. Resource Obligations:

This MOU represents the broad outline of the agencies' intent to enter into specific agreements for collaborative efforts in areas of mutual interest to the FDA and the FCC. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing agreements or arrangements between the agencies and does not affect the ability of the agencies to enter into other agreements or arrangements related to this MOU. The FDA and the FCC agree to take actions under this collaboration that are consistent with existing laws and regulations, and that nothing in the MOU shall be construed as changing the current requirements under the statutes and regulations administered and enforced by the FDA and the FCC including but not limited to: Title 42 of the United States Code, the Federal Food, Drug, Cosmetic Act, Title 47 of the United States Code, and the Communications Act of 1934. Further, nothing contained in this MOU constitutes a mandate or a requirement imposed on the FDA or the FCC that is additional to the mandates or requirements imposed on the FDA or the FCC by Federal statutes and regulations.

IX. Liaison Officers:

A. For the Federal Communications Commission:

Bruce Romano
Chief Counsel
Office of Engineering and Technology
Federal Communications Commission
445 12th St., SW
Washington, DC 20554
202-418-2470

B. For the Food and Drug Administration:

Bakul Patel
Policy Advisor
Office of the Center Director
Center for Devices and Radiological Health
10903 New Hampshire Avenue
White Oak 66, Room 3543
Silver Spring, MD 20993

301-796-5528

X. Term, Termination, and Modification:

This agreement, when executed by both agencies designated herein, will have an effective period of performance of five years from the date of the latest signature, and may be modified or terminated by mutual written consent by both agencies at any time, or may be unilaterally terminated by either agency upon a ninety-day advance written notice to the other.

APPROVED AND ACCEPTED FOR
FOR THE FEDERAL COMMUNICATIONS COMMISSION

By:_____
Steven VanRoekel
Managing Director
Federal Communications Commission

Date:_____

APPROVED AND ACCEPTED
THE FOOD AND DRUG ADMINISTRATION

By:_____
Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health

Date:_____

APPENDIX A

PROCESS FOR INFORMATION SHARING

Pursuant to Section VI.g. of the Memorandum Of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the Federal Communications Commission (FCC), any agency "may decide not to share information or expertise in response to a particular request for information made according to the procedures established under Section VII, or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section VII.

When, under the current MOU, staff at the FDA or FCC request from the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, and need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

"Information that is shared under this request will be under the 2010 FDA-FCC Memorandum of Understanding to Share Information. We agree not to disclose any shared information in any manner without your written permission with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

"Pursuant to the 2010 FDA-FCC Memorandum of Understanding to Share Information, this communication may contain privileged and/or confidential information exempt from public disclosure**.** It may not be disclosed or shared in any manner without our express written consent with advance notice to the originating agency**."** With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.