18 October 2016

Docket No. FDA-2016-D-1264 for *Dissemination of Patient-Specific Information From Devices by Device Manufacturers*
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: MDPC Comments on Draft Guidance concerning Dissemination of Patient-Specific Information From Devices by Device Manufacturers (Docket No. FDA-2016-D-1264)

To Whom It May Concern,

These comments are submitted on behalf of the Medical Device Privacy Consortium ("**MDPC**"). The MDPC is a group of leading companies addressing health privacy and security issues affecting the medical device industry. Members of the MDPC manufacture a diverse range of products, from molecular diagnostics to medical imaging equipment to implantable devices, for example.

The MDPC appreciates the opportunity to comment on the FDA's proposed Guidance regarding Dissemination of Patient-Specific Information From Devices by Device Manufacturers ("**Guidance**").

General Comment

The MDPC agrees with the FDA's statement that the FD&C Act does not "generally require[ ]" a manufacturer of a marketed device to provide data from the devices to patients. However, the MDPC cautions that the FDA should also avoid taking a position on whether the manufacturer should include context, interpretation or explanation of the data. Our concern is that requiring the manufacturer to make patient data interpretable is essentially requiring manufacturers to assume a role for which they are neither suited nor licensed. Providing interpretation of results and the context in which to understand them is the function of a physician or other health care professional, not manufacturers.

Instead, the MDPC recommends that the FDA clarify that medical device labeling for prescription or restricted products does not prevent the manufacturer from providing patients their data, and limit this guidance to providing specific guidance for manufacturer on what factors to consider in determining whether providing additional context around any data provided to the patient constitutes labeling.

Section II (Background)

Lines 34-37 and 53-54

The MDPC supports the FDA's efforts to ensure that patients receive better access to healthcare information, including patient information collected through medical technology at the legal direction of their physicians. As the definition of "patient-specific information" is currently drafted, however, the guidance could be interpreted as requiring manufacturers to act as gatekeepers to determine whether a medical device was used "consistent with the intended use" before information could be provided to patients. Physicians may prescribe a device for whatever use they deem medically appropriate, and, therefore, placing the manufacturer in a position of determining whether it can pull information and respond to a patient request based on whether the use is "consistent with the intended use of the device" is not feasible in most circumstances since there likely will be no way for the manufacturer to know if the use is on label.

Moreover, even if the manufacturer does know, the required response will be unsatisfying to the patient – that the manufacturer has data but cannot provide it because the use is off-label. The MDPC proposes the following change in Lines 53-54: "Although not generally required under the Federal Food, Drug, and Cosmetic Act (FD&C Act), manufacturers may share patient-specific information (recorded, stored, processed, retrieved, and/or derived from a legally marketed medical device) with patients at the patient's request, without obtaining additional premarket review before doing so." The MDPC also recommends revising the definition of "patient-specific information" on Lines 34-37 to remove the reference to "consistent with the intended use" to accommodate this change.

Section III (Patient-Specific Information Dissemination Policy)

Lines 55-58

Section 201(m) of the FD&C Act defines labeling to include "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." Here, the information consists of test results or outcomes, which are not labeling under the FDA's definition. It is not accompanying the article, but is rather the output. The FDA does not treat lab results as labeling, and should not treat this information as labeling either.

Lines 61-64

It appears that the language in this section could be read either as a directive or as merely an observation and also appears to assume that medical device manufacturers have access to the kind of information that may be sought by patients. In many cases, a medical device manufacturer does not have direct access to patient-specific information on medical devices, nor would it have the necessary rights to obtain and disclose such information even if access is available. If the FDA proposes to issue a directive requiring manufacturers to respond to patient requests for information, it should initiate a formal rulemaking proceeding to weigh that proposal to include such considerations. The MDPC proposes instead that the FDA revise this language to clarify that manufacturers have an option as to

whether or not to provide the information directly to the patients. The MDPC proposes the following change on Lines 63-64: "Alternatively, patients may contact the manufacturer directly and request access to their patient-specific information, though manufacturers are not required to respond to such requests."

Lines 65-72

The MDPC has reservations about the reliance on the Health Insurance Portability and Accountability Act (HIPAA) as a basis for FDA policy or guidance documents because the law is administered by another office – HHS' Office for Civil Rights (OCR). Instead, MDPC submits that an exclusive focus on FDA's interpretation of the Federal Food, Drug and Cosmetic Act would strengthen this guidance document by ensuring consistency with the agency's jurisdictional authority.

In addition, the MDPC notes that the second paragraph on page five appears to misconstrue HIPAA rules. HIPAA does not apply to most medical device manufacturers; instead, its scope is limited to health care providers who bill insurers directly through covered transactions, health plans, and health care clearinghouses. Since few device makers bill payors directly, they are not covered entities under HIPAA. Accordingly, the statement that HIPAA is "intended to prevent manufacturers from sharing this information with covered entities (e.g., health plans, healthcare providers that electronically transmit health information) without the patient's consent" misconstrues both the intent and scope of the HIPAA Privacy Rule. In fact, HIPAA expressly permits sharing patient data for purposes of treatment or payment for that treatment, without the need for a patient's authorization. Indeed, the vital role of a medical device manufacturer in patient treatment has been recognized by the Office of Civil Rights, which has noted that a medical device company representative may directly assist a health care provider in operating rooms during surgery.[1] The FDA's statement on the intent and scope of HIPAA should be removed from the final guidance.

Lines 73-78

The MDPC is concerned that FDA's direction that manufacturers should make information "usable" by patients, including "the content of information provided, the context in which patient information from medical devices should be understood, and the need for access to additional, follow-up information from the manufacturer or a healthcare provider," would require manufacturers to assume a role for which they are neither suited nor licensed.

Providing interpretation of results, context in which to understand them and the need for additional information from the manufacturer is the function of a physician or other health care professional. The majority of the devices that would be affected by this standard are not over-the-counter or consumer directed products. They are sophisticated devices that measure complex results and require expert

[1] http://www.hhs.gov/hipaa/for-professionals/faq/490/when-may-a-covered-health-care-provider-disclose-protected-health-information-without-authorization/index.html

interpretation. The FDA's proposal is to essentially turn all of these devices into Over-The-Counter products, with manufacturers providing patients information and an explanation of what they mean, potentially eliminating the role of the health care provider. Device manufacturers should not take on such a role. Moreover, such a wholesale change across all medical devices is not one that can be accomplished by a brief Guidance document.

The MDPC proposes removing the entire discussion surrounding the provision of "usable" information from the Guidance. Instead, the FDA should consider whether such provision of data is necessary for a particular device or class of devices, either through the premarket review process or through regulation.

Subsection A (Content)

Lines 83-90

This section similarly appears to require manufacturers to assume a role that is appropriate for a physician. It would require significant training and experience for manufacturers to implement "appropriate measures to ensure that the information provided is interpretable and useful to the patient" and "to prevent the disclosure of confusing or unclear information that could be misinterpreted." Most devices do not produce simple binary reports that come out with a yes or no answer, but instead develop multiple data readings over time that are complex to understand and explain. The MDPC recommends that the FDA remove this section from the Guidance, and consider how it might address this potential need for specific devices or classes of devices, either through the premarket review process or through regulation.

Lines 90-92

The guidance in this section appears to address labeling as if it were coterminous with new manufacturer reporting requirement described in this document. Labeling is defined as "written, printed or graphic matter (1) upon any article or any of its containers or wrapper, or (2) accompanying such article." The data that the guidance would require manufacturers to report is the output of the medical device or what results from the device performing its function to advise physicians. Thus, the MDPC proposes that this section be removed.

Lines 93-96

The MDPC also notes that this section's requirement that manufacturers provide the whole history of the patient record may be inconsistent with the earlier requirement that manufacturers provide information that is interpretable and not confusing or unclear or misleading. The requirement for the whole history of the patient record would likely result in just the kind of uninterpretable and confusing information that the guidance seeks to avoid. Thus, the MDPC proposes eliminating the "whole history" requirement.

The MDPC welcomes the opportunity to provide the FDA with comments on its Guidance concerning Dissemination of Patient-Specific Information From Devices by Device Manufacturers and appreciates the FDA's consideration. Please do not hesitate to contact us with any questions.

Sincerely,

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Secretariat and Legal Counsel

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