FDA Clarifies Enforcement Position Regarding Evolving Health Technology

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Recently, the U.S. Food and Drug Administration ("FDA") has issued a flurry of guidance and draft guidance in an effort to better define the types of products that the FDA will choose to actively regulate.[1] In one of these documents, the FDA sought to identify low-risk "general wellness" products for which FDA does not intend to enforce compliance with FDA regulatory requirements, even if such products are medical devices. In another of these documents, the FDA clarifies for which devices it will not enforce compliance with regulatory controls by virtue of their status as medical device data systems, medical image storage devices, or medical image communications devices. These recent statements from the FDA, coupled with further clarification on a recent FDA-hosted webinar (discussed further at Section IV), underscore the following key themes:

- The FDA is trying to be nimble in its regulatory response to new, evidently low-risk products in the marketplace and, in doing so, has demonstrated willingness to decline to enforce regulation over products that clearly or potentially fall within the statutory definition of the term "medical device."

- These statements help to establish "guard rails" for businesses engaged in the manufacture or distribution of wellness products, or products that store, transmit or display medical device data. In particular, these statements are helpful in assessing whether the product itself, the company's marketing of the product, the product's labeling, or other factors give rise to a concern that the "intended use" of the product is one that would subject the product to active regulation as a medical device.

- That being said, it is important not to overstate the significance of statements such as these. The exceptions set forth in the draft guidance and guidance discussed in this article are narrow and, in some instances, only underscore the FDA's long-established, substantial discretion in determining which products it chooses to actively regulate. Furthermore, while the trend seems to be an easing of FDA regulatory activity in this space, the fact that these statements are being proposed and issued as guidance—and not notice and comment rulemaking—also means that the FDA could easily shift course, modify or expand its guidance in the event it underestimated the risks presented by these products.

- Even in circumstances in which the FDA has indicated that it does not intend to enforce regulatory requirements that might otherwise apply to a product, the product is not necessarily exempt from all potential enforcement. That is, the product may be subject to regulation by agencies such as the Federal Trade Commission or Consumer Product Safety Commission.

I. OVERVIEW OF STATUTORY AND REGULATORY LANDSCAPE

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA has the authority to regulate medical devices. Accordingly, a threshold issue that manufacturers and distributors of health-related products often face is whether their products are regulated as medical devices. Subject to certain exceptions, section 201(h) of the FDCA defines a "medical device" to include any "article . . . which is . . . (a) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (b) intended to affect the structure or any function of the body of man or other animals" (emphasis added).

Whether a product is considered a medical device under this definition is dependent upon the product's intended use, which is generally established not with reference to its mechanical design, but rather with reference to claims made about the product. For example, in considering whether personal sound amplification products ("PSAPs") should be regulated as medical devices (as hearing aids are), the FDA stated:

> While some of the technology and function of hearing aids and PSAPs may be similar, the intended use of each article determines whether it is a device or an electronic product. The intended use may be

established by labeling materials. Promotional materials that make claims or suggest the use of a PSAP for hearing impaired consumers, such as in the description of the types and severity of hearing loss, establish an intended use that causes the product to be a device and therefore subject to the regulatory requirements for a hearing aid device, as described in this guidance.[2]

Recently, the FDA has begun to state publicly that, even for some products that fall within the broad statutory definition of the term "medical device," the FDA does not intend to actively exercise its regulatory authority. For example, in the FDA's guidance on mobile medical applications ("Mobile Medical Apps Guidance"), which was issued in 2013 and more recently updated in response to the MDDS Guidance (discussed at Section III of this article), the FDA defined a number of categories of mobile medical applications which may fall within the definition of the term "medical device," but for which the FDA does not intend to enforce requirements under the FDCA.[3] The draft guidance and guidance discussed in this article represent a mix of FDA statements that it does not consider certain products to be medical devices, and FDA statements that it does not intend to enforce compliance with certain regulatory controls on certain products, notwithstanding the fact that they are, or may be, medical devices.

II. DRAFT GUIDANCE ON LOW-RISK GENERAL WELLNESS PRODUCTS

This past January, the FDA issued a draft guidance[4] entitled "General Wellness: Policy for Low Risk Devices" ("General Wellness Draft Guidance"). Under the General Wellness Draft Guidance, the FDA has indicated that it does not intend to examine low-risk general wellness products to determine whether they are medical devices, or, if they are devices, whether they comply with the premarket review and post-market regulatory requirements for devices under the FDCA and FDA regulations. In order to be eligible for this exemption, the product must both (1) be intended for only "general wellness use" and (2) present a very low risk to users' safety. Comments regarding the draft guidance may be submitted to the FDA until April 20, 2015.

A. "General Wellness" Intended Uses

As to the first element, the General Wellness Draft Guidance provides that products will be considered to have a general wellness use, where the product has intended uses that are limited to one or both of the following:

1. ***An intended use claim that relates to maintaining or encouraging a general state of health or a healthy activity without any reference to diseases or conditions.***

- Examples of these intended uses include weight management, physical fitness, relaxation or stress management (where there is no reference to anxiety disorders or other diseases or conditions), mental acuity, self-esteem, sleep management, or sexual function.

- Examples of claims that can be made to support these intended uses include claims to promote a healthy weight; promote physical fitness; "increase, improve, or enhance the flow of qi"; increase or improve muscle size or body tone; tone or firm the body or muscle; or enhance cardiac function.

- Examples of claims that do not fall into the category of general wellness claims include claims that the product will treat or diagnose obesity, treat an eating disorder, help treat anxiety, or restore a structure or function impaired due to a disease (e.g., a claim that a prosthetic device enables amputees to play basketball).

2. ***An intended use claim that associates the role of a healthy lifestyle with helping to reduce the risk or impact of "certain chronic diseases or conditions" (which diseases and conditions are not specified), and where it is "well understood and accepted" that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.***

- Such claims can fall into two subcategories: (a) intended uses to promote, track, or encourage choices which, as a part of a healthy lifestyle, may help to reduce the risk of certain chronic conditions (i.e., preventing the disease); and (b) intended uses to promote, track, and/or encourage choices which, as a part of a healthy lifestyle, may help living well with certain chronic diseases or conditions (i.e., mitigating the impact of the disease). Notably, no treatment claims are permitted.

- Such claims "should only contain references where it is well understood that healthy lifestyle choices may reduce the risk or impact of a chronic disease or medical condition." The FDA provides that "the claim that the healthy lifestyle choice(s) may play an important role in health outcomes should be generally accepted; such associations are typically described in peer-reviewed scientific publications."

- Examples of permitted claims include claims that a product "promotes physical activity, which, as a part of a healthy lifestyle, may help reduce the risk of high blood

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pressure" or "tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet, . . . [which] may help living well with high blood pressure and type 2 diabetes."

A few aspects of the "tolerated" intended uses set forth in the General Wellness Draft Guidance are interesting. First, some of the "wellness" claims falling into the first category are quite broad. For example, the General Wellness Draft Guidance categorizes a claim of enhanced cardiac function as a "general wellness" claim. Manufacturers should be careful in how they make such claims, in order to avoid making direct claims that the product will treat a particular disease. Also, with regard to the second category of claims, it is not clear which disease states the FDA regards as those "certain chronic diseases or conditions" about which claims may be tolerated. The General Wellness Draft Guidance gives high blood pressure, heart disease, and type 2 diabetes as examples, but does not state whether there are others. Further, it is worth noting that the General Wellness Draft Guidance does not expressly require scientific proof of the association between a healthy lifestyle choice and the reduced risk or impact of a chronic disease or medical condition. Rather, the General Wellness Draft Guidance states that "general acceptance" of such a link is all that is required to fall within the scope of the draft guidance, and that such associations are "typically described" in peer-reviewed literature. Finally, the statement regarding the flow of qi implies that alternative medicine claims might be considered to be wellness claims, even though they could be interpreted as claims relating to the cure, mitigation, treatment or prevention of disease.

B. "Low Risk" Products

The FDA has not provided an exhaustive definition of which products present a "very low risk to users' safety," within the meaning of the General Wellness Draft Guidance. However, the FDA has provided that if any of the following factors are present, the device is not considered low risk and is not covered by the General Wellness Draft Guidance:

- The product is invasive (i.e., penetrates or pierces the skin or mucous membranes of the body).
- The product involves an intervention or technology that may pose a risk to a user's safety if device controls are not applied, such as risks from lasers, radiation exposure, or implants.
- The product raises novel questions of usability.
- The product raises questions of biocompatibility.

Other than setting forth these factors that preclude products from being categorized as "low risk," the FDA recommends that manufacturers or distributors wishing to benefit from the General Wellness Draft Guidance consider whether FDA regulates products of the same type as the product in question. The FDA gives, as an example of a product that should not be considered "low risk," a Class II medical device subject to special controls addressing risks to health associated with the use of the device, including tissue injury, trauma and infection. Nevertheless, given the FDA's risk-based approach to regulation – which inherently relies on interpretations and judgments about claims, risks and, ultimately, device classification – it may be difficult to glean much certainty by reference to other products.

III. GUIDANCE ON DEVICES THAT STORE AND TRANSFER DATA

On the heels of its General Wellness Draft Guidance, the FDA issued final guidance on February 9th, 2015 outlining its regulatory approach to certain medical devices that merely store, transmit or display data. Recognizing "that the progression to digital health offers the potential for better, more efficient patient care and improved health outcomes" in turn necessitates enhanced interoperability between medical devices and health information technology, the FDA stated that it does not intend to regulate medical device data systems ("MDDS"), medical image storage devices, or medical image communications devices (the "MDDS Guidance").

MDDS, medical image storage devices, and medical image communications devices are Class I, 510(k)-exempt devices that are otherwise subject to FDA "general controls."[5] An MDDS is a device (including hardware and software) that is intended to transfer, store, convert from one format to another according to preset specifications, or display medical device data.[6] The FDA has explained that an MDDS only performs these limited functions with regard to medical device data. By contrast, an MDDS does not: (1) modify the data; (2) control the functions or parameters of any connected medical device; or (3) include devices intended for active patient monitoring.[7] Here, the FDA offers the following as MDDS examples:

- Software that collects output from a ventilator about a patient's CO2 level and transmits the information to a central patient data repository.
- Software that stores historical blood pressure information for later review by a healthcare provider.
- Software that converts digital data generated by a pulse oximeter into a digital format that can be printed.
- Software that displays a previously stored electrocardiogram for a particular patient.

The MDDS Guidance also states that, in addition to MDDS, the FDA does not intend to enforce compliance with regulatory controls for the following categories of medical devices: (1) medical image storage devices (defined as a

device that provides electronic storage and retrieval functions for medical images)[8] and (2) medical image communications devices (defined as a device that provides electronic transfer of medical image data between medical devices).[9]

As the agency has "gained additional experience with these types of technologies" it has determined that they "pose a low risk to the public." Accordingly, consistent with its risk-based approach to the regulation of low-risk medical products, the FDA intends to opt out of enforcing the regulatory controls applicable to MDDS, medical image storage devices, and medical image communication devices.

Under the FDA's risk-based regulatory framework, it is important to carefully consider which products fall within the product categories that fall within the MDDS Guidance, and those products with similar, but not identical, functionality, to which the MDDS Guidance does not apply. For instance, in issuing the MDDS Guidance, the FDA indicated that devices that simply "display" medical device information are MDDS and, therefore, fall within the FDA's enforcement discretion. However, contemporaneously with the issuance of the MDDS Guidance, the FDA updated its previously-issued Mobile Medical Apps Guidance, which affirmatively states that products that "display . . . medical images directly from a Picture Archiving and Communications System (PACS) server"[10] would be subject to FDA regulatory oversight. In issuing the rule down-classifying an MDDS from Class III (high-risk) to Class I (low-risk) in 2011, the FDA expanded on the potential overlap between an MDDS and other device categories:

> FDA intends for the MDDS definition to be broad, to capture systems that feature the functions identified in this rule but that do not fall under another device type regulation. Numerous device classifications exist for products that perform data and information transfer, storage, display, conversion, and/or similar management functions. The MDDS classification only applies to devices that meet the MDDS definition and do not have additional functions that are outside the scope of an MDDS and that fall within an existing classification. An LIS and a PACS (§§ 862.2100 and 892.2050, respectively) are two device classifications that encompass functionality similar to an MDDS, but they have other specific intended uses or features that are outside the scope of the MDDS rule. A PACS may have similar functionality as an MDDS, but a PACS may perform digital processing, unlike an MDDS. Moreover, a PACS deals only with medical images, while an MDDS may deal with images and other medical data. A LIS, classified under the calculator/data processing module for clinical use regulation, may store clinical data; but a LIS is also able to process data, unlike an MDDS. Another device that is potentially similar to an MDDS is a medical image management system (MIMS), classified under the medical image communications device regulation (21 CFR 892.2020). But a MIMS transfers medical images, unlike an MDDS.[11]

Accordingly, while a device allowing for the "electronic display of medical device data" falls within the definition of an MDDS, and, similarly, a PACS is defined as a device that "provides . . . [the] display . . . of medical images," the FDA opts to regulate a PACS on the basis that it could be used in active patient monitoring or analyzing medical device data (e.g., to render a diagnosis).[12]

As noted above, the "MDDS" category does not include devices intended to be used in connection with active patient monitoring. In this regard, the FDA explained that devices are intended for active patient monitoring when the "clinical context requires a timely response (e.g. in-hospital patient monitoring)" or the "clinical condition (disease or diagnosis) requires a timely response (e.g. a monitor that is intended to detect life-threatening arrhythmias such as ventricular fibrillation or a device to actively monitor diabetes for time-sensitive intervention)." By way of example, the following devices are considered to be intended for use in connection with active patient monitoring:

- a nurse telemetry station that receives and displays information from a bedside hospital monitor in an ICU.
- a device that receives and/or displays information, alarms, or alerts from a monitoring device in a home setting and is intended to alert a caregiver to take an immediate clinical action.
- By contrast, examples of devices that perform monitoring, but the FDA does not consider to be intended for use in connection with active patient monitoring, include applications that:
- transmit a child's temperature to a parent/guardian while the child is in the nurse/health room of a school.
- facilitate the remote display of information from a blood glucose meter, where the user of the meter can independently review their glucose levels, and which is not intended to be used for taking immediate clinical action.
- With respect to the last example, the FDA clarified that "[i]n these cases, remotely displaying information such as the most recent blood glucose value or time-lapse between blood glucose measurements is not considered active patient monitoring." Thus, in addition to considering competing product characterizations and classifications, manufacturers assessing the application of the MDDS Guidance will need to determine whether their products are intended for use in connection with active patient monitoring.

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IV. THE LATEST FROM FDA.

On Tuesday, February 24th, the FDA hosted a webinar to provide an overview of and clarify and answer questions regarding the MDDS Guidance, General Wellness Draft Guidance, and Mobile Medical Apps Guidance. The FDA also discussed a January 20, 2015 draft guidance: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429672.pdf under which FDA proposed to conduct an independent, risk-based evaluation of "medical device accessories" (i.e., products intended to support, supplement, and/or augment the performance or one or more "parent devices"), rather than classifying such products in the same way as the accessory's "parent device."

During the webinar, FDA representatives also fielded a number of questions from participants and, in so doing, offered further insight into the agency's perspective on a number of aspects related to the guidance statements.

- IRB Determinations. Addressing a question regarding the potential utility of the Mobile Medical Apps Guidance or General Wellness Draft Guidance in the context of Institutional Review Board ("IRB") compliance (and particularly whether a product is a nonsignificant risk device), the FDA clarified that the IRB would continue to be obligated to evaluate the safe use of the products independently, regardless of the FDA's other enforcement positions on low-risk products. While acknowledging that the FDA's position that products meeting certain criteria are lower risk may be part of the IRB's decision-making process, the FDA representatives emphasized that these guidance statements only clarify the FDA's enforcement priorities, but do not re-define what meets the legal definition of a medical device. Accordingly, the FDA's view as to which products may benefit from the agency's current enforcement discretion, does not affect whether such products are medical devices.

- Active Patient Monitoring. With respect to MDDS, FDA clarified that the regulatory definition excludes any use that involves active patient monitoring which, in turn, comes down to whether the product is intended to be relied upon in deciding to take an immediate clinical action. Moreover, the concept of immediate clinical action can extend to many settings, and is not necessarily dependent on either where the product is used (e.g., in a home versus a clinical setting) or when it is used (e.g., secondary or tertiary alarm notification).

- Software Accessories. In addressing the agency's approach to medical device accessories, the FDA representatives clarified that (with respect to, for example, 510(k) submissions), it will not differentiate software accessories from accessories more generally. That is, accessories have their definition as stated in the draft guidance ("intended to support, supplement, and/or augment the performance or one or more parent devices"), which would also apply to software accessories.

- Development of Pre-Approved Claims. Presumably with reference to the General Wellness Draft Guidance—in particular the notion that disease-related general wellness claims should be generally accepted (e.g., supported by scientific evidence)—one webinar participant asked whether the agency would consider developing a set of pre-approved claims, based on scientific evidence, that companies (both small and large) could use in promoting general wellness products (i.e., akin to qualified health claims in the food space). The FDA representative noted the agency did give consideration to developing a framework for approving claims. However, while remaining open to suggestions as to how FDA could undertake such a process going forward, the FDA representative explained the agency has no present intention of instituting such an approach, largely given the expected resources it would require.

V. OUTSTANDING ISSUES

The FDA's most recent statements regarding low-risk products provide some valuable insight into FDA's enforcement priorities, but they also serve as an important reminder that a number of questions remain unanswered regarding such products. Most fundamentally, these statements do not indicate that the FDA has materially changed the way it construes the term "medical device." Even where the FDA guidances have answered the question of which products are medical devices, they have generally done so in a way that is consistent with prior interpretive authority. Additionally, the FDA's statements do not provide a comprehensive view into the enforcement landscape, since a number of other agencies have authority to regulate the products that are the subject of the guidances. Finally, it remains to be seen how the FDA will harmonize the statements discussed in this article with the agency's existing rules and interpretive authority. In the meantime, manufacturers should narrowly construe the guidances. Failure to do so could result in a conclusion that a product (such as a PACS) that would, on its face, seem to benefit from the enforcement position set forth in the guidance, would be mischaracterized as "low-risk," since existing FDA regulations preclude it from benefiting from the enforcement position set forth in the relevant guidance. Reliance on such a conclusion could result in unexpected, costly, and disruptive enforcement.

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[1] On February 9, 2015, the FDA issued final guidance documents on medical device data systems (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf) and mobile medical apps (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf). The FDA also recently posted draft guidance on its general wellness policy for low risk devices (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf) and medical device accessories (available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429672.pdf). The FDA has explained that "[t]hrough these actions, we continue to clarify which medical devices are of such low risk that we will no longer focus our regulatory oversight on them or we will regulate them under a lower risk classification, narrowly tailoring our approach to the level of risk to which patients or consumers are exposed." http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm433146.htm.

[2] U.S. Dep't of Health & Human Servs., Food & Drug. Admin., "Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" (Feb. 25, 2009), available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm127086.htm; *see also* U.S. Dep't of Health & Human Servs., Food & Drug. Admin., "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff" (Nov. 7, 2013), available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm373461.htm (making largely the same point, and adding, "Examples of such labeling claims and language that would establish an intended use as a medical device include: (1) a description of the types and severity of hearing loss; (2) a description of listening situations that are typically associated with and indicative of hearing loss; and (3) wording to suggest that the product is an alternative to a hearing aid.").

[3] U.S. Dep't of Health & Human Servs., Food & Drug. Admin., Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015), available at http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf.

[4] The draft guidance does not have the force of law. Even when finalized, it will constitute only the FDA's current thinking on the topic, and will not create or confer any rights for or on any person, nor will it bind the FDA or the public.

[5] 21 C.F.R. § 880.6310 (classifying MDDS); 21 C.F.R. § 892.2010 (classifying medical image storage devices); 21 C.F.R. § 892.2020 (classifying medical image communications devices). *See also* Medical Devices; Medical Device Data Systems Final Rule (76 Fed. Reg. 8637) (Feb. 15, 2011) (down-classifying MDDS from Class III (high-risk) to Class I (low-risk)). The FDA's "general controls" obligations include, among other things, establishment registration, device listing, and adherence to the Quality System Regulation/Good Manufacturing Practices.

[6] 21 C.F.R. § 880.6310.

[7] In the preamble to the MDDS regulation, the FDA explained that the word "active" represents "any device that is intended to be relied upon in deciding to take immediate clinical action." Medical Devices; Medical Device Data Systems Final Rule, 76 Fed. Reg. 8637, 8644 (Feb. 15, 2011).

[8] 21 C.F.R. § 892.2010.

[9] 21 C.F.R. § 892.2020.

[10] 21 C.F.R. § 892.2050 (defining and classifying PACS) (emphasis added). Notably, a PACS is listed as a Class II radiology device (diagnostic device) that includes "software components [that] may provide functions for performing operations related to image manipulation, enhancement, compression or quantification."

[11] Medical Devices; Medical Device Data Systems Final Rule, 76 Fed. Reg. 8637, 8642 (Feb. 15, 2011)

[12] U.S. Dep't. of Health & Human Services, Food & Drug Admin., Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff (Feb. 9, 2015), available at http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf.

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