FDA Draft Guidances on General Wellness Products and Device Accessories Continue Risk-Based Approach to Health IT

On January 20, 2015, the United States Food and Drug Administration (FDA) issued two new draft guidance documents, announcing the agency's plans not to regulate "general wellness products" (including certain software programs) and to apply a new, risk-based framework to medical device accessories. Although not limited to the health IT sphere, both draft guidance documents address issues identified as requiring clarification in the April 2014 FDASIA Health IT Report. These draft guidance documents are consistent with the risk-based approach to regulation described in the FDASIA Health IT report, and which is reflected in FDA's final guidance on Mobile Medical Apps and draft guidance on Medical Device Data Systems. Just days later, FDA applied the accessory policy by allowing the marketing of the first set of mobile medical apps for automatically sharing data from a continuous glucose monitor (CGM) in real-time using an Apple mobile device such as an iPhone.

General Wellness Product Draft Guidance

According to the draft guidance, FDA will not apply either pre- or post-market regulatory requirements to "general wellness products" that pose a low risk to a user's safety. Examples of such products include software programs, exercise equipment, audio recordings, video games, and other products commonly available from retail establishments or downloaded from online sources. General wellness products, for the purposes of the guidance, must fall into one of two categories, based on intended use. The intended use must either:

1. relate to maintaining or encouraging a general state of health or a healthy activity, without any reference to particular diseases or conditions, or
2. associate the role of a healthy lifestyle with helping to reduce the risk of impact of certain chronic diseases or conditions, where it is well accepted that the healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

The first category applies to products that encourage a general state of health or a healthy activity, but do not make any reference to particular diseases or conditions. Such products might promote, for example, weight management, stress management, or sexual function, but without referring to particular diseases such as obesity, anxiety disorders, or erectile dysfunction.

The second category addresses products to promote, track, or encourage choices that, as part of a healthy lifestyle, "may help reduce the risk of" or "may help living well with" certain chronic diseases or conditions. This category would apply, for example, to a software app that claims to promote physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.

For both categories, the product must meet additional "low risk" criteria. It may not be "invasive" (i.e., may not penetrate or pierce the skin or mucous membranes), involve an intervention that may pose a risk to user safety (e.g., lasers, radiation exposure), raise novel questions of usability, or raise questions of biocompatibility.

Medical Device Accessory Draft Guidance

The definition of a "device" under the Federal Food, Drug, and Cosmetic Act includes any "accessory" to a device. Medical devices are assigned to one of three regulatory classes based on the level of control needed to

provide reasonable assurance of their safety and effectiveness. FDA's longstanding policy has been that an accessory to a classified device takes on the same classification as the "parent" device, which can lead to relatively low-risk accessories taking on the higher classification of the parent.

Under this policy, for example, software that accepts inputs from a medical device usually takes on the classification of the connected device, or a simple surgical instrument labeled for use with a Class II medical device implant system usually takes on the classification of the implant system, even though these accessories might be relatively simple and lower-risk than the parent devices. In the Mobile Medical Apps guidance, FDA stated that a mobile app used as an accessory to a regulated device would be considered a "mobile medical app" potentially subject to FDA regulation, but did not address FDA's approach to regulating them.

Under the draft guidance, FDA acknowledges that accessories are not always as risky as the parent devices with which they are intended to work. It therefore proposes to determine the risk of accessories, and the regulatory controls applicable to them, in the same manner it determines the classification of devices that are not accessories. FDA states that it will not impute all the risks of the parent device to the accessory, but instead will evaluate the accessory's impact on the parent device and any unique risks of the accessory independent of the parent device. This marks a potentially significant shift in FDA regulatory policy.

The draft guidance urges companies to rely on the *de novo* classification process under Section 513(f)(2) of the FDCA to request classification of new types of accessories, and provides additional details for how to file a *de novo* request for a new type of accessory. The key advantage of the *de novo* process is that an accessory may be marketed immediately if FDA classifies the accessory into Class I or II. The *de novo* process, however, may not be appropriate for certain accessories, specifically those accessories within a type of device that has already been classified by regulation or order or has received premarket approval. In such cases, a company may instead seek reclassification or an exemption from the requirement to submit a 510(k) premarket notification.

The draft guidance also sets out a proposed definition of "accessory." This is FDA's first detailed explanation of its understanding of that term, which has been in the statute since the enactment of the Medical Device Amendments of 1976. Although the practice of defining such a key regulatory term through a guidance document rather than a regulation may be questionable, industry will likely welcome the additional transparency on FDA's interpretation of this term.

As explained in the draft guidance, an article is an accessory to a device if it is intended to "support, supplement, and/or augment the performance of one or more parent devices," and a "parent" device is a "finished device whose performance is supported, supplemented, and/or augmented by one or more accessories." FDA explains that whether an article is intended for use with a parent device will generally be determined by the labeling and promotional materials for the potential accessory, rather than by the labeling and promotional materials for the parent device. FDA also points out that articles that do not meet the definition of an accessory will not be treated as accessories simply because they may be used in conjunction with a medical device. Thus, for example, an off-the-shelf computer monitor used to display medical data from connected medical devices would not be considered an accessory to those devices unless it was intended for that use.

On January 23, FDA demonstrated how the accessory policy will work by allowing the marketing of a set of mobile medical apps that permit the sharing of data from a continuous glucose monitor (CGM) with others in real-time using an Apple mobile device such as an iPhone. These apps would meet the definition of an accessory to the CGM devices and thus, under FDA's traditional policy, require the same form of 510(k)

premarket clearance that FDA requires for CGMs. Instead, FDA has applied its *de novo* authority to allow such devices to be marketed as 510(k)-exempt, meaning no FDA premarket notification is required.

What's Next?

These latest FDA draft guidances, although they have implications beyond health IT, contribute to FDA's efforts to clarify its policies across the range of health IT applications and products. In addition to accepting comments on these draft guidance and eventually finalizing them, one of the key outstanding items that FDA has announced it is developing is a draft guidance on clinical decision support (CDS) tools. In the FDASIA Health IT Report, FDA proposed to exercise enforcement discretion not to regulate "most" CDS tools, but stated that it would regulate a "subset" of CDS tools as medical devices. How FDA defines that subset of CDS products will have important implications for the future regulation of software that can be used to help determine treatment options for patients. The first three draft guidance topics that FDA's Center for Devices and Radiological Health listed on its FY2015 "A-list" were General Wellness Products, Medical Device Accessories, and Medical Device Decision Support Software. With the first two of these guidances now published in draft, the CDS draft guidance may not be far behind.

Developers of health-related software also should understand that FDA is not the only potential regulator of their products. A recent Federal Trade Commission (FTC) action against Focus Education, a company that claimed its video games lessen the symptoms of Attention Deficit Hyperactivity Disorder, shows the importance of ensuring that all claims of health-related benefits are well substantiated. The FDA, FTC, or state agencies all may have authority to take action against companies that promote software for unproven health-related benefits.

If you would like to discuss the foregoing or any other related matter, please contact any member of Ropes & Gray's FDA regulatory team or your usual Ropes & Gray advisor.