

NEW GUIDANCE DOCUMENTS FROM FDA SEEK TO CLARIFY REGULATION FOR WELLNESS DEVICES AND MEDICAL DEVICE ACCESSORIES

On January 20, 2015, the Food and Drug Administration (the "FDA" or "Agency") published two draft guidance documents designed to fulfill promises it made in the multi-agency Food and Drug Administration Safety and Innovation Act ("FDASIA") Health IT report. The first draft guidance is intended to promote the innovation of general wellness devices and software applications by identifying certain types of low risk products for which the FDA will not enforce any regulatory requirements. The second draft guidance proposes to regulate medical device accessories based on the risks they present when used as intended, rather than the risks presented by the parent medical device with which the accessory is used.

BACKGROUND

The Federal Food, Drug and Cosmetic Act authorizes the FDA to regulate as a medical device any instrument, machine, software or other type of product, including component parts and accessories, intended or promoted for use in the diagnosis of disease or other conditions; in the cure, mitigation, treatment or prevention of disease; or intended to affect the structure or any function of the body of man or other animals. Because the definition of a medical device is broad, it captures many types of health IT, arguably including many consumer-facing general wellness products like Apple iWatch, calorie-tracking software and FitBit. Responding to pressure from industry over the past decade, the FDA has begun clarifying the regulatory environment applicable to many new types of medical software and related products. For example, in 2013, the FDA finalized a guidance on Mobile Medical Applications, in which the Agency wrote it would not enforce regulatory requirements on mobile software applications that pose a low risk to users, provided the products do not make disease-specific claims. In April 2014, the FDASIA Health IT report was issued, in which the FDA again agreed to refrain from actively regulating low risk health IT products and further promised to provide clarity on questions regarding when software may qualify as a regulated medical device accessory and on the regulation of clinical decision support software generally. For Hall Render's article discussing the Mobile Medical Apps Guidance and the FDASIA Health IT report, click [here](#). The following June, the FDA proposed in another draft guidance document that medical device data systems ("MDDS"), which are devices used to transfer, store, convert, format and display data from other medical devices, should also be exempt from all regulatory requirements. On February 6, 2015, the FDA finalized that MDDS Guidance. To read Hall Render's article discussing the new MDDS Guidance, click [here](#).

WELLNESS DEVICES

In the new draft guidance document entitled **General Wellness: Policy for Low Risk Devices** (the "draft Wellness Devices Guidance"), the FDA explains that it "does not intend to examine low risk general wellness products to determine whether they are [medical] devices . . . or whether they comply with the premarket review and post-market regulatory requirements for [medical] devices." The Agency describes general wellness products as having either: (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity (i.e., no correlations to or marketing for specific disease states); or (2) an intended use that associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions 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. According to the Agency, products in the first category include exercise equipment, audio recordings, video games and generally many software programs and devices commonly obtained from retail establishments. Examples of physical conditions for which they may be promoted to assist include weight management, physical fitness, stress management, mental acuity, self-esteem, sleep management and sexual function. Products will fit the second category of general wellness devices only if claims that healthy lifestyle choices may reduce the risk or impact of a chronic disease or medical condition are well understood. According to the FDA, examples of chronic diseases for which a healthy lifestyle is associated with risk reduction or help in living well with that disease include high blood pressure, heart disease and type 2 diabetes. Although "well understood" is not defined, the FDA writes that an acceptable association between disease state and lifestyle would typically be found in peer-reviewed scientific publications. Based on the Federal Trade Commission's interpretation of the Federal Trade Commission Act, it is likely that at least one well-controlled clinical investigation is required in order to make such claims. Regardless of the category, the product must also present "a very low risk to users' safety," meaning that it may not be invasive (e.g., penetrate or pierce the skin), pose a risk to a user's health (e.g., exposure to lasers or radiation) or raise biocompatibility questions. The FDA also wrote that a product will not be deemed

“low risk” if it “raises novel questions about usability,” although the Agency did not provide examples of “novel questions.”

ACCESSORIES TO MEDICAL DEVICES

In the other draft guidance document, entitled [Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types](#) (the “draft Accessories Guidance”), the FDA attempts for the first time to clarify what the Agency deems to be “accessories” to medical devices. FDA proposes that an “accessory” is an item intended to support, supplement, and/or augment the performance of one or more medical devices. An example of an accessory could be a smartphone app that is a companion to a medical device. The Agency further proposes to regulate medical device accessories based on the risks they present when used as intended with their parent devices and not based on the risks of the parent devices. Often the risk of the parent device may be higher than that of the accessory. As an example, the Agency states that “if a parent device warrants regulation as a Class II device but an accessory to the parent device presents lower risks, we would regulate the accessory as a Class I rather than a Class II device.” This proposal would be a substantial departure from the Agency’s current thinking, which has historically been that the risks of the parent device are automatically assigned to its accessories. Unlike in both the Mobile Medical App Guidance and the draft Wellness Devices Guidance, the FDA did not provide examples of accessories that would or would not be regulated as medical devices. Rather, the Agency encourages manufacturers of accessories to use FDA’s “de novo” classification process to request that the Agency perform a risk-based review of accessory types that are not currently classified. As such, the draft Accessories Guidance provides little actual guidance to developers or users of medical device accessories. Other issues that the FDA did not address as requested by industry stakeholders include:

- Provide assurance that interoperability claims will not automatically characterize a product as a medical device accessory;
- Describe how FDA will differentiate between accessories and non-regulated components of a system; and
- Provide guidance on how the agency intends to regulate claims associated with accessories.

PRACTICAL TAKEAWAYS

Although both draft guidance documents indicate that the FDA remains generally committed to allowing many low risk health care-related products to be developed without active oversight by the Agency, substantial questions remain. For example, clarity is needed on what may trigger “novel questions about usability” such that a wellness device may become subject to higher scrutiny. Additionally, as clinical decision support tools become more prevalent in both the home and hospital environments, the limited exemption from FDA oversight for wellness devices may soon be outdated. Uncertainty as to regulatory status may also cause confusion as to what rules must be followed (e.g., payment of medical device tax, unique device identification) for not only product developers but also health care providers, which have separate obligations (e.g., adverse event reporting, meeting standards of The Joint Commission) of their own. The Agency is seeking comments from the public on both proposed guidance documents until April 20, 2015. If you have any questions about the FDA’s regulation of medical devices or the regulation of health IT generally or are interested in submitting comments to the FDA, please contact Mark R. Dahlby at (414) 721-0902 or mdahlby@hallrender.com or your regular Hall Render attorney. Please visit the Hall Render Blog at <https://hallrender.com/resources/blog/> for more information on topics related to health care law.