Issue Brief

The Accessory Rule—Traditional Regulatory Approach Overburdens mHealth Technologies

A Technology Trend. The future belongs to sharing medical device data among various technology platforms and mobile devices. Everything that produces or receives medical device data, whether therapeutic or diagnostic, will likely be connected to a network. So, for example, a blood glucose meter will be connected to a cell phone, which will connect to a cell tower, which will connect to a local area network, which will connect to a server, which will dump data in an electronic medical record (EMR), which a physician will view on a tablet or smartphone. The traditional approach to regulating products connected to medical devices is outdated in today's environment where a web of medical and non-medical products interconnect. The old approach results in over-regulation of many mHealth products - products that simply do not involve sufficient risk to warrant regulatory oversight.

Historical FDA Policy. FDA has generally regulated products that connect to medical devices by placing them in the same regulatory classification as the "parent" medical device. FDA considers these connected products to be accessories to the "parent" device.

The Challenge: This approach would seem to regulate accessories once removed, twice removed—indeed, the whole family tree – at the same level as the "parent" device. The Agency's theory was simply: if an accessory breaks, the risk to the patient would be the same as if the parent medical device broke.

However, that does not always make sense. Consider the example of a simple USB cable that can be purchased off the shelf at any electronics store to connect a smart phone to a computer. If that USB cable is intended and marketed to be used with a glucose meter to enable the download of data from the glucose meter to a smart phone, that USB plug would be considered an accessory to the glucose meter and would be regulated the same way as the blood glucose meter - as a Class II device. This results in regulatory overkill, as harmless widgets get heightened regulatory scrutiny just because they help transfer data from a Class II or Class III medical device.

MRC Recommendation: We recommend the Agency take three (3) critical steps to provide clarity with respect to the treatment of accessories, avoid unnecessary up-regulation and overly burdensome requirements and protect patient safety by assuring appropriately substantiated claims of compatibility.

1. FDA should establish classification regulations that define and characterize the risk associated with the most common mHealth accessories that it intends to regulate. Much like with FDA's recent MDDS rule, the purpose here would be to establish more appropriate, risk-based classifications specific to the accessories that make up the various categories within the family tree.

2. FDA must allow a degree of self–regulation of claims that certain products are compatible or interoperable with a medical device. The MRC recommends that FDA regulate claims of compatibility by requiring the company making such claims to adequately substantiate the claim and assure it remains accurate as the product or medical device changes over time.
3. The Agency should publish a guidance document that includes, among other things, how to determine whether an mHealth product is an accessory, and what regulatory oversight applies. Specifically, we propose that FDA regulate accessories based on the intended use as follows:
    - Class I: Accessories to medical devices that are not reasonably expected to directly affect the safety and effectiveness of the medical device.
        - An example of an accessory fitting this description is a mobile medical app that collects data from a blood glucose meter as a secondary display. Another example could be a phone jack splitter that connects to a remote monitoring system while allowing the user also to connect a standard telephone.
    - Class II accessories should include all regulated accessories that do not fall within Class I, unless the accessory changes the intended use of the connected device.
        - To make this determination, the FDA could employ its approach for determining whether a new 510(k) would be required for an existing device.

The MRC proposal avoids over-regulation and tailors the regulatory burdens to the actual risk of the device while fully protecting the public health with regard to the compatibility of these connected devices.