Issue Brief

Intended Use Claims— Regulatory Ambiguity Limits Meaningful Education and Disease Management

A Trend of Managing Health through Lifestyle Choices. Today, we are more aware of how lifestyle choices can impact our health generally and affect certain diseases and conditions more specifically. We also have access to mobile technologies that provide information about an individual's health or condition in their daily environment. Much of this information was not previously available outside of the traditional healthcare setting, but can today be used by patients and consumers to inform lifestyle decisions. As a result, individuals are able to more actively manage their overall health. This engagement has the potential to not only benefit the individual but also public health at large.

Historical FDA Policy. FDA regulates products that are *intended for use* in the diagnosis, treatment, or prevention of disease or a medical condition. Intended use is determined, in part, by the claims a manufacturer makes about its product.

The Challenge. The FDCA was written in a different era—where disease was the doctor's domain and the impact of lifestyle choices was not well-understood. The traditional approach to regulate products is outdated in today's environment where patients and consumers use technology to engage and invest in their wellness as a way to improve their overall health. The line between treating a disease and maintaining a healthy lifestyle is blurred and so is the line between regulated and unregulated claims. Without further clarity, many mHealth products could become over-regulated based on their claims even though they present virtually no or low risk to patients. This will have the further adverse effect of stifling innovation in an area that has the potential to radically improve public health and wellness.

Take, for example, the developer of a mobile app that monitors and tracks a user's daily exercise. This developer might claim that using the app can reduce the risk of heart disease or diabetes or help treat obesity. That same developer may claim that its app can be used to monitor daily activity, manage your heart health, or improve the user's physical condition.

Which of these claims would make this app a regulated medical device? The ambiguity in the definition of a medical device and/or the words in the claims themselves results in a lack of regulatory clarity and predictability for many of these mHealth products.

MRC Recommendation. FDA must provide a predictable, risk-based regulatory framework which excludes low risk products that benefit consumer engagement and public health from active regulation. MRC specifically recommends FDA take the following three (3) actions:

- FDA should clearly distinguish between health and wellness claims and disease claims, and identify what claims would trigger regulation.

- FDA should also issue guidance on determining which mHealth products are subject to enforcement discretion. This category should specifically include those products that may meet the definition of a medical device but are low risk and benefit public health through educating users and enabling more active management of one's disease or condition.
- FDA should clarify that the use by a health care professional of data gathered by mHealth products should not automatically exclude a product from enforcement discretion. Rather, the determination should be based on the manufacturer's claims as to the intended use of the data by a health care professional.

The MRC proposal avoids over-regulation and provides a predictable regulatory framework for technology vendors new to the medical device industry. It also advances public health by enabling users to be actively involved in their wellness and health through these innovative technologies.