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FDA Issues Final Guidance on General Wellness Products

On July 28, 2016, the United States Food and Drug Administration (FDA) finalized guidance stating that the agency does not plan to regulate "general wellness products," including software applications, provided they present a low risk to the safety of users and other persons. Under this policy, FDA will not regulate many products that the agency believes meet the statutory definition of a "device" and thus could be subject to FDA regulation. Manufacturers or developers of products that may meet the definition of general wellness products should carefully consider the limitations of this policy, with particular focus on whether their advertising claims fall within the "intended use" definitions set forth in the guidance.

Importance of "Intended Use"

Like the draft guidance, the final guidance explains that FDA will not apply either pre- or post-market regulatory requirements to "general wellness products" that pose a low risk to a user's or another person's safety. Examples of such products include software programs, exercise equipment, audio recordings, video games, personal fitness trackers, sleep monitors, and other products, including mobile applications, 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 of a product is determined primarily by the advertising and promotional claims the manufacturer or distributor makes for the product, although it may also be determined by other circumstances surrounding the product's marketing, sale, or distribution. Under the guidance, the intended use of a general wellness product 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. relate to the role of a healthy lifestyle by helping to reduce the risk or impact of certain chronic diseases or conditions, where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.

The first category is the simpler of the two to understand because it draws a bright line: it entirely excludes products not intended to address specific 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. Arguably, even without this guidance document, many such products would fall outside the statutory definition of a medical device.

The second category presents more interpretive challenges. It addresses products intended 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. The guidance states that, to fall within the intended use of a general wellness product, such lifestyle choices must be "well accepted" as playing an important role in helping patients with the particular disease or condition. FDA states that 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. Other examples FDA provides of chronic diseases for which a healthy lifestyle is associated with risk reduction or help in living well with that disease include heart disease and type 2 diabetes. FDA also provides specific examples of software apps intended to help users live well as part of a healthy lifestyle with migraine headaches and anxiety.

We anticipate that many companies seeking to promote products for specific diseases or conditions will need to consider carefully whether their products meet the definition of a general wellness product under this category.

FDA also states in the guidance that a general wellness product may "only" be intended for a general wellness use. A product that has a general wellness use but also has other intended uses, therefore, would not be a general wellness product under the guidance and may be subject to FDA regulation.

Focus on Risk

In addition to having a general wellness intended use, FDA states that a product must meet additional "low risk" criteria to fall within the policy of non-regulation. In the final guidance, FDA eliminated the draft guidance's proposal that such products must have "very low" risk. The final guidance also clarifies that a product is not considered low risk, and thus not within the scope of the policy laid out in the guidance, if it (a) is "invasive" (i.e., it penetrates or pierces the skin or mucous membranes), (b) is implanted, or (c) involves technology that may pose a risk to user safety if specific regulatory controls are not applied, such as risks from lasers or radiation exposure. The final guidance eliminates some of the amorphous language that had been included in the draft, which stated that a product would not be considered low risk if it raised "novel questions of usability" or "questions of biocompatibility."

In evaluating risk, FDA recommends that manufacturers and developers consider whether FDA actively regulates products of the same type as the product in question. The guidance also gives a number of examples of products that would not be considered low risk. Examples include:

- A sunlamp product promoted for tanning purposes, due to risks to a user's safety, including skin cancer.
- A neurostimulation product that claims to improve memory, due to the risks to a user's safety from electrical stimulation.
- A product that claims to enhance a user's athletic performance by providing suggestions based on the results of relative lactic acid testing, due to invasive sampling (venipuncture) and risks to other persons if specific regulatory controls are not applied (e.g., venipuncture may pose a risk of infection transmission).

Examples of products that would be considered low risk general wellness devices, by contrast, include:

- A mobile application that plays music to "soothe and relax" an individual and to "manage stress."
- A mobile application that solely monitors and records daily energy expenditure and cardiovascular workout activities to allow awareness of one's exercise activities to improve or maintain good cardiovascular health.
- A mobile app that reminds users to keep exposed skin out of direct sunlight when the UV index is high.
- A portable product intended to monitor pulse rate during exercising or hiking.
- A product intended to mechanically exfoliate the face, hands, and feet to make the skin smoother and softer, but that cannot be used in a manner that penetrates the skin.

What's Next?

The latest FDA guidance contributes to FDA's efforts to clarify its policies regarding the regulation of products that potentially meet the definition of a medical device, with particular focus on the rapidly expanding market for digital health applications and products. This guidance is part of a broader effort by the agency to clarify its digital health policies, which have also been addressed in FDA's guidance documents on Mobile Medical Applications, Medical

Device Data Systems, and medical device accessories. Another draft guidance document expected to be forthcoming would address clinical decision support (CDS) tools, and is expected to continue the general "de-regulatory" trend in the digital health area.

Developers of health-related software and other general wellness products also should bear in mind that they remain subject to other key federal and state laws and regulations. These include advertising and privacy requirements enforced by the Federal Trade Commission (FTC), product safety rules enforced by the Consumer Product Safety Commission (CPSC), HIPAA protections against unauthorized disclosure of protected health information enforced by the Department of Health and Human Services' Office of Civil Rights (HHS OCR), and state false advertising and consumer protection statutes enforced by state Attorneys General. For example, a 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.

Click here to read the FDA's notice in the Federal Register regarding the publication of its final guidance. 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.