# The FDA publishes guidance on general wellness products

The US Food and Drug Administration ('FDA') released on 20 January its General Wellness: Policy for Low Risk Devices: Draft Guidance for Industry and Food and Drug Administration Staff ('GW Guidance'). This document represents a new approach for the FDA in regard to general wellness products, as the FDA will refrain from enforcement of regulatory requirements on such products. The guidance is of particular note for the mobile health ('mHealth') industry, as Yarmela Pavlovic and Blake Wilson of Hogan Lovells explain.

On 20 January 2015, the US Food and Drug Administration ('FDA' or the 'Agency') announced an updated approach to products used to promote healthy lifestyles. The policy, announced in the GW Guidance[1], would result in the FDA refraining from enforcement of all regulatory requirements for so called general wellness products regardless of whether they meet the definition of a 'medical device' as that term is defined in the Food Drug and Cosmetic Act ('FDC Act'). Currently, some such products would not be considered medical devices, while others might be subject to enforcement discretion and still others potentially actively regulated.

The GW Guidance was included in the FDA device centre's 'A-list' of priority guidances to be released in 2015, and is tied to a string of guidances that pertain to proposals in the FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework (3 April 2014) ('Health IT Report'). The draft Health IT Report proposes that the FDA would only maintain active oversight for certain types of higher-risk software-based medical devices and also clarifies the distinction between wellness and disease-related claims. Parallel efforts to restructure the regulation of software and mobile medical apps have also been working their way through Congress. Specifically, a draft version of the 21st Century Cures Act[2] ('Draft Cures Act'), released on 27 January 2015, proposes to amend the FDC Act by exempting 'health software'[3] from the FDC Act's definition of medical device. The Draft Cures Act is the most recent development in a series of legislative and lobbying efforts, which have hereto failed to take hold. It remains to be seen whether this most recent legislative effort will affect the FDA's regulation of mobile medical apps. In the meantime, the FDA appears to be moving ahead with its own internal initiatives to better clarify the types of technologies subject to its active oversight.

## General Wellness Guidance

The GW Guidance explains that in order to qualify as a low risk general wellness product, and therefore not subject to the FDA's active oversight, a product must (1) be intended only for general wellness use, as that term is defined in the GW Guidance, and (2) present a very low risk to users' safety. The GW Guidance further clarifies the intended use criterion by outlining two types of relevant claims:

- General Health Claims - an intended use claim that relates to maintaining or encouraging a general state of health or a healthy activity. Note that this type of claim may not reference a disease or condition.
- Disease-Related Claims - an intended use claim that associates the role of a healthy lifestyle with helping to reduce the risk of developing, or the impact of, a chronic disease or condition.

Although the FDA has previously alluded that products in the first category may not be subject to their oversight, and may not even meet the definition of a medical device, the draft guidance proposes to go another step and also exempt from regulation products that are aimed at using healthy lifestyles to reduce the risk or impact of chronic diseases. Previously, merely mentioning a specific disease or condition was thought to potentially put such a product into the FDA's zone of interest.

General Health Claims should discuss improvement or maintenance of a general healthy state, or a function associated with a general state of health. For instance, a mobile app may claim to help users improve mental acuity so long as it does not mention a specific disease or condition (e.g. Alzheimer's, attention deficit disorder, etc.).

Disease-Related Claims should promote, track, or encourage a healthy life choice, and associate that choice with reducing the risk of developing, or helping a sufferer to live better with, a certain chronic disease or condition. The FDA further clarifies the parameters around its proposed policy by explaining that for a product to be exempt from regulation, it must be well understood and accepted that the healthy lifestyle choices in question may play an important role in health outcomes for the chronic disease or condition. According to the FDA, a well understood and generally accepted association will typically be described in peer-reviewed scientific publications. For example, according to the guidance, an acceptable Disease-Related Claim might be: App X helps promote healthy sleeping habits, which as part of a healthy

lifestyle, may help reduce the risk of developing type 2 diabetes.

However, the policy proposed in the GW Guidance does not extend to products that pose inherent risks to user safety, including (1) invasive products, (2) products that would pose a risk to a user's safety if device controls were not applied (e.g. lasers, implants, etc.), (3) products that raise novel questions of usability, and (4) products that raise questions of biocompatibility.

It should be noted that the GW Guidance is a draft, and the policy proposed will not take effect until the Guidance is finalised.

## Discussion

While the GW Guidance is applicable to all types of low risk general wellness products, the FDA's proposed policy was certainly crafted with mobile apps in mind. This is evident from the examples chosen to illustrate low risk general wellness products, which included mobile apps that:

- play music to sooth and relax an individual and manage stress;
- solely monitor and record daily energy expenditures and cardiovascular workout activities to help improve or maintain cardiovascular health; and
- monitor and record food consumption to help manage dietary activity for the purpose of weight management.

The approach proposed in the GW Guidance, as it pertains to mobile apps, builds upon the Agency's 25 September 2013, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff[4] ('App Guidance'). In the App Guidance, the Agency announced that it would exercise enforcement discretion for mobile apps intended for logging, tracking, decision making, etc., related to the development or maintenance of general fitness, health or wellness.

**While the GW Guidance reduces the regulatory burden for low risk general wellness medical devices, the wording also raises questions regarding the parameters of the FDA's policy**

In the GW Guidance, the Agency explicitly expands its scope to cover products that make disease-related claims. This change is not only new in the mHealth space, but also breaks with the FDA's historical position on the issue. For example, the FDA previously noted that exercise equipment used for 'medical purposes' (e.g., based on disease-specific claims) is actively regulated by the Agency[5].

While the GW Guidance reduces the regulatory burden for low risk general wellness medical devices, the wording also raises questions regarding the parameters of the FDA's policy. For example, the GW Guidance states that certain chronic diseases and conditions may be referenced, and provides examples that are ubiquitous within the mHealth space (heart disease, high blood pressure, and type 2 diabetes). However, the FDA does not clarify whether any chronic disease or condition - with the requisite association to healthy lifestyle choices - may be referenced. Perhaps more importantly, the draft policy provides little detail regarding the level of association that must be established between a healthy lifestyle choice and its ability to reduce the risk or impact of a chronic disease or condition.

Regarding the 'low risk' requirement in the GW Guidance, more thorough explanation in a future version of the guidance would significantly improve clarity. For instance, while the examples given (e.g., lasers, implants) are more clearly associated with potential risk to health, explanation of when risk is posed by standalone apps and other non-invasive products would be helpful. In addition, the GW Guidance lists novel questions regarding usability as a bar to being a low risk product. However, it is unclear what the Agency would view as novel usability issues. This point is particularly important in the context of mobile apps, which are constantly modifying and re-inventing how users interact with their mobile devices.

Finally, note that this draft policy continues the trend of the FDA exempting certain product types from regulation by guidance document. However, some in industry have criticised this general approach as guidance documents are not necessarily binding on the Agency and only reflect current thinking. Thus, the Agency is theoretically free to change that policy without prior notice at any time. If the Agency were to engage in rulemaking to achieve such policies, the result would be more concrete change that could be clearly relied upon by industry. Nonetheless, the current efforts by the FDA are likely less burdensome for industry than active regulation.

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1. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf (lvisited 26 Jan 2015). Those wishing to make comments on the draft may via www.regulations.gov (FDA-2014-N-1039) until 20 April 20 2015.
2. 21st Century Cures Act [Discussion Document], H.R. [_], 114th Cong. §§ 2061–2063 (2015).
3. Under the Draft Cures Act, health software would include - among other things - non-medical software that: is intended to organise and present medical information for use in maintaining health or wellness; is intended for use by patients for self-management or self-monitoring of a disease or condition, including management of medications. Ibid. at §§ 2061, 2063 (2015).
4. http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf (last visited 28 January 2015).
5. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082166.pdf (last visited 27 January 2015).