Client Alert

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Regulating a Healthy Lifestyle? FDA Distributes New Draft Guidance on "General Wellness Products"

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On January 16, 2015, the Food and Drug Administration (FDA) promulgated a much-anticipated draft guidance[1] concerning the classification and regulation of general wellness products. The draft guidance is the FDA's latest attempt to provide some regulatory clarity in the wake of the explosion in popularity of wearable wellness devices and general fitness products. The draft guidance—which slightly loosens the FDA's hold on general wellness products—comports with the FDA's current policy of refocusing its resources on high-risk products and away from products that present low risk to the end-user.

BACKGROUND

Historically, the FDA has not regulated devices intended to benefit a user's overall health and wellness, unless those products made claims about disease prevention, treatment, mitigation, or cure. In the FDA's prior guidance of 1995, it stated that it would regulate fitness equipment only if the equipment was "intended to be used for medical purposes[.]" On the other hand, if the equipment was to be used for "general physical conditioning," the equipment was outside the FDA's regulatory scheme.

However, even if the equipment was only used for physical conditioning, it could still be subject to rigorous FDA regulation if the promotional materials made any medical claims or associated the device with improved medical outcomes. Such regulation includes premarket notification requirements, labeling requirements, good manufacturing practices requirements, and Medical Device Reporting (MDR) requirements. This left many wellness products with the choice of foregoing marketing activities that made reference to improved medical outcomes or facing onerous FDA regulation.

THE GENERAL WELLNESS DRAFT GUIDANCE

The January 2015 draft guidance concerning general wellness products finally clarifies what constitutes a "general wellness product" and allows for certain well-known promotional claims about health to be made by the manufacturers of these products.

Under the draft guidance, a general wellness product is defined as one intended for general wellness use that presents a very low risk to users' safety. In order to qualify as low risk, the product must not be (i) invasive; (ii) involve an intervention or technology that may pose a risk to users' safety (such as lasers, radiation exposure, or

[1] FDA guidance documents do not establish legally enforceable responsibilities, but rather describe the FDA's current thinking on a topic.

implants); (iii) raise novel questions of usability; or (iv) raise questions of biocompatibility. The FDA specifically lists exercise equipment, video games, software programs, and other products commonly available in retail stores as examples of devices likely to be included within the above definition of a general wellness product.

If a product falls within definition of a general wellness product, it must also have one of two identified uses in order to be covered by the new draft guidance. The product must have (1) "an intended use that relates to maintaining or encouraging a general state of health or healthy activity," or (2) "an intended use claim 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."

The first identified "use" category of general wellness devices are those that make no reference to diseases or conditions, including products relating to weight management, physical fitness, sleep management, and self-esteem. These types of devices have traditionally been, and continue to be, outside the FDA's regulatory purview.

More interesting is the second category of general wellness intended uses, which the draft guidance explains can be broken down into two subcategories: (i) those intended to be used to promote, track, and/or encourage choices that "as part of a healthy lifestyle, *may help reduce the risk of* certain chronic diseases or conditions," and (ii) those intended to be used to track and/or encourage choices that, "as part of a healthy lifestyle, *may help living well with* certain chronic diseases or conditions."

According to the FDA, manufacturers of devices that fall into these subcategories may now, as part of their promotional materials, make claims that using the product may help reduce the risk of disease, or help someone live better should they suffer from a certain disease or condition. The following types of claims are permissible under the draft guidance: "Product X promotes physical activity, which, as part of a healthy lifestyle, may help you reduce the risk of high blood pressure"; or "Product Z tracks activity sleep patterns and promotes healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes." Another example of a permissible claim is the statement that a calorie tracker may promote a healthy weight and/or may help living well with type 2 diabetes, or may assist in healthy living with high blood pressure. Notably, health-related claims in marketing materials (like the examples provided by the FDA) are only permissible under the draft guidance when it is well known that a healthy lifestyle is associated with the improved health outcome.

The FDA has also provided a decision algorithm so manufacturers can determine if their product qualifies as a general wellness product under the draft guidance.

LIKELY IMPACT OF NEW DRAFT GUIDANCE

The shift presented by the draft guidance is significant; if implemented, general wellness device manufacturers would be able to say more about the well-known health benefits of their products without risking FDA regulation. Indeed, under the draft guidance, manufacturers are permitted to link products to potential health outcomes, implying that the product itself may help mitigate or reduce the risk of certain diseases. Such statements—though only permitted when it is "well understood and accepted" that a healthy lifestyle is associated with the improved outcome—were impermissible (or at best, questionable) under the FDA's prior guidance.

This change may prove particularly important for the wearable activity tracker market, which has experienced significant growth in the last year. Under the guidance, promotional materials can now make specific health-related claims; manufacturers are no longer limited to marketing claims such as "helps you stay active" or "gives you feedback about your daily activity." Permitting a manufacturer to make specific health-related claims—such as "encourages activity that, as part of a healthy lifestyle, may help reduce high blood pressure"—likely opens up the market for consumer segments that may not have been interested in merely "tracking their daily activity" but are, for example, keenly interested in reducing their blood pressure.

Given these likely benefits, manufacturers should consider commenting on the draft guidance to help further shape the final outcome and to ensure that the draft guidance is implemented. Comments are due by April 20, 2015.

The draft guidance is a step in the right direction for the FDA. The shift away from needlessly regulating low-risk products, and toward allowing manufacturers to use well-known and accepted health benefits in their promotional marketing, is a welcome one.

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