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FDA's Draft 'Wellness' Guidance Potentially Expands the Universe of Unregulated Products

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On January 16, the FDA released a draft guidance on ''General Wellness: Policy for Low Risk Devices.'' Public comments may be submitted for 90 days after publication in the Federal Register.

The draft guidance reflects the FDA's continued effort to provide clarity particularly to the mobile app development community, which otherwise often seems wary of introducing software for an openly medical purpose. Indeed, the FDA describes as a ''decision algorithm'' its step-by-step methodology for determining what is a ''low risk general wellness'' product, hinting that the draft guidance is written specifically with software developers in mind.

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The FDA's guidance on general wellness products has particular relevance for software developers.

The draft guidance takes a new path, in part, from the FDA's usual approach of focusing on the formal definition of medical device and then explaining why certain products do not fall within the definition. Instead, the FDA states that it does not even intend to ''examine''

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whether ''low risk general wellness'' products are devices, or whether they comply with the Food, Drug, and Cosmetic Act.

'Low Risk' Claims

The FDA states that a device that presents an ''inherent'' risk to a user's safety—evidently regardless of the level of risk—is not ''low risk'' and therefore not covered by the wellness policy. A device presents an ''inherent'' risk if it:

- is invasive;
- involves an intervention or technology that may pose a risk to a user's safety if unregulated by the FDA, such as risks from lasers, radiation exposure, or implants;
- raises novel questions of ''usability'' (an unusual regulatory concept for devices that the FDA does not elaborate on); or
- raises questions of biocompatibility.

If the FDA currently actively regulates a product of the same type, it is unlikely to be considered ''low risk.''

Two Categories of 'General Wellness' Claims

The FDA draft guidance sets forth two categories of products that qualify as ''general wellness'' products, based on the intended use of the product. Each category is described below.

1. Products intended to help maintain or encourage a general state of health or healthy activity.

The key to fitting within this category is to *avoid a reference to a specific disease or condition*. This is a rather traditional approach to avoiding FDA regulation, since the definition of medical device is focused on the diagnosis of disease or condition or the cure, mitigation, treatment, or prevention of disease.

The FDA lists seven specific types of claims—not identified as examples and thus ostensibly a closed set—that fit within this category:

- weight management;
- relaxation or stress management;
- sleep management;
- mental acuity;
- self-esteem (e.g. devices with a cosmetic function);
- physical fitness, including products intended for recreational use; and
- sexual function.

Specific examples the FDA gives of claims that fit within each of these seven types of claims are those that:

- promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals;
- promote relaxation or manage stress, or increase, improve, or enhance the ''flow of qi'';
- track sleep trends;
- improve mental acuity, instruction following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition or eye-hand coordination;
- mechanical exfoliation of the face, hands and feet to make the skin smoother and softer and improve self-esteem;
- promote physical fitness, such as to help log, track, or trend exercise activity, measure aerobic fitness, improve physical fitness, develop or improve endurance, strength or coordination, or improve energy; and
- enhance or improve sexual performance.

On the other hand, the FDA notes that claims that include reference to specific diseases such as obesity, anorexia, autism, and erectile dysfunction do not fall within this category.

2. Products intended to promote, track, and/or encourage choices that may help to (i) reduce the risk of or (ii) help live well with certain chronic diseases or conditions.

The focus on empowering individuals with information to make ''healthy lifestyle choices'' as a basis for regulatory forbearance is rather unconventional. Claims may refer to specific diseases or conditions only when it is well-understood (e.g. described in peer-reviewed scientific publications) that healthy choices may reduce the risk or impact of a chronic disease or condition.

Specific examples the FDA gives of claims that fit within this category are those that:

- promote physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure;
- track caloric intake and help manage a healthy eating plan to maintain a healthy weight and balanced diet to help live well with high blood pressure and type 2 diabetes; and
- track sleep patterns and promote healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes.

It is not immediately clear why only products that assist with ''chronic'' diseases or conditions should qualify under this category. For example, a mobile app that gives a reminder to wash one's hands to help prevent a temporary cold or flu seems to promote the type of ''healthy lifestyle choice'' that reduces the risk of disease that the FDA intends to encourage.

Examples of Low Risk General Wellness Products

As further evidence the FDA's draft guidance was written for the benefit of mobile app developers, several of the examples the FDA gives of ''low risk general wellness'' products are mobile apps, as follows:

- mobile apps that play music to ''soothe and relax'' and to ''manage stress'' (gee, thanks FDA for con-

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firming Kenny G and Enya are not mobile medical app developers subject to FDA regulation);

- mobile apps that monitor and record daily energy expenditure and cardiovascular workout activities to ''allow awareness of one's exercise activities to improve or maintain good cardiovascular health;'' and
- mobile apps that monitor and record food consumption to ''manage dietary activity for weight management and alert the user, healthcare provider, or family member of unhealthy dietary activity.''

The FDA's draft guidance is a welcome advance in the FDA's thinking and should encourage the further development of mobile apps and other products that help to promote healthy lifestyles, even activities that are designed to help reduce the risk of (what most of us would call prevent) or reduce the impact of (what most of us would call treat) specific diseases when generally accepted scientific evidence supports such claims.