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Could FDA Be the Next NFL Commissioner? What Happens When a Medical Device Becomes Part of the Required Uniform

Recently, the *New York Times* reported on a decision by the National Football League (NFL) to expand league-wide a 2012 pilot program involving the use of a post-injury sideline assessment tool. The expanded program will permit all team physicians and trainers to use the assessment tool, which is composed of an iPad and a downloadable application ("NFL Concussion App") to compare a player's personal pre-season baseline and post-injury test results on a side-by-side basis in real time. This can then be used to diagnose concussions and determine whether a player should be removed from a game to limit the potential risk for long-term injury.

In July 2011, the US Food and Drug Administration (FDA) published its draft guidance describing how it intends to regulate mobile medical applications ("2011 Draft Guidance").[1] Focused specifically on those devices used to support the US's growing reliance on mobile health technologies or "mHealth" in clinical practice, the 2011 Draft Guidance provides a proposed regulatory blueprint for industry and agency employees themselves to consider when commercializing such products.

The 2011 Draft Guidance applies to mobile platforms that are handheld in nature, including products such as mobile smartphones, iPhones and iPads, patient monitoring devices and other wireless devices, and on which a mobile medical application operates if the product meets the following statutory definition of a medical device:

> '... an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent' that is 'intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man...' or '... intended to affect the structure or any function of the body of a man or other animals...' and is either 'used as an accessory to a regulated medical device or transforms a mobile platform into a regulated medical device…'[2]

Of all the mobile medical applications available on the market for clinician and patient use today, FDA only intends to regulate a very small subset of that total number. These include those intended for uses similar to existing medical devices. Examples of such products include applications that provide a questionnaire for collecting patient specific results and either: (1) compute the prognosis of a particular condition or disease; (2) perform calculations that result in an index or score; (3) calculate dosage for a specific medication or radiation treatment; or (4) provide recommendations that aid a clinician in making a diagnosis or selecting a specific treatment for a patient.[3]

But did FDA really intend to regulate iPads and things like the NFL Concussion App?

Even if that was not the agency's intent, in practice that is very much what might feasibly happen. According to the *New York Times* article,

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[1] *See* Draft Guidance for Industry and Food and Drug Administration Staff – Mobile Medical Applications, *CDRH* (July 2011).
[2] 21 USC §321(h).
[3] Draft Guidance, *supra* note 2.

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> The mandatory post-injury sideline concussion assessment tool, instituted for the 2012 season along with a baseline test done during physicals at the start of preseason, will now be used in app form by all 32 teams, a method that was tried by a handful of teams in a pilot program last season. *The hope is that being able to compare the results of a baseline test and a post-injury test side by side in real time will speed diagnosis and help doctors and trainers recognize when a player should be removed from a game.* The league also plans to have independent neurological consultants on the sideline during each game to assist the team physician in diagnosing and treating players.

Intended for the purposes of diagnosing player post-impact concussions, the NFL Concussion App appears to fall within the scope of FDA's 2011 Draft Guidance rendering it an FDA regulated medical device just like an infrared brain hematoma detector (21 CFR 882.1935), which requires the submission and clearance of a 510(k) notice; or a self-expanding peripheral stent system (FDA product code: NIP), which requires Agency Pre-Market Approval. Under FDA's proposed regulatory model, it is possible that even some modifications or updates to the NFL Concussion App might trigger the need for supplemental submission and agency review.

And when the NFL Concussion App is expanded beyond the NFL itself to other sports like hockey, wrestling, soccer and skiing, and the application is modified for use in those particular sports, will subsequent agency review be needed? If yes, it is possible that FDA officials might seize uncleared devices during the middle of Wrestle Mania 2014 or high school soccer games.

Although laughable, a variation of this hypothetical scenario could in fact be reality if the FDA finalizes and then strictly enforces the current language of the 2011 Draft Guidance. Accordingly, the FDA should amend its proposed regulatory approach before finalizing and implementing the system contained in the 2011 Draft Guidance. FDA's final requirements should provide greater clarity on what constitutes a regulated mobile medical device and medical application; and provide greater flexibility when making changes to an existing cleared medical application.

In the meantime, companies developing and manufacturing mobile devices should be familiar with the 2011 Draft Guidance and its criteria for determining whether a proposed application falls within the scope of FDA regulation. Companies should be designing their devices and corresponding applications with the 2011 Guidance Document in mind. It would be prudent for companies to develop FDA regulatory approval strategies at the same time they are thinking about items such as performance testing, data privacy and security, and power sources.

Contact

Scott A. Edelstein
T +1 202 626 6602
scott.edelstein@squiresanders.com

Karl M. Nobert
T +1 202 626 6630
karl.nobert@squiresanders.com