Written by **Bob Adelmann** on February 9, 2012

How Leviathan Works: FDA to Regulate Medical Apps

The press release issued by the U.S. Food and Drug Administration (FDA), which operates under the Department of Health and Human Services (HHS), on July 19, 2011, signaled the beginning of its regulatory process, this time concerning "mobile medical apps." The announcement made it plain that such regulation certainly fell under its jurisdiction, as if declaring it made it so: "The use of mobile medical apps on smart phones and tablets is revolutionizing health care delivery," according to Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "Our draft approach calls for oversight of only those mobile medical apps that present the greatest risk to patients when they don't work as intended."

Beginning its existence in 1927 as the Food, Drug, and Insecticide organization (becoming the Food and Drug Administration in 1930), a significant expansion of the FDA's reach sprang from the elixir sulfanilamide disaster which resulted in the deaths of more than 100 people in 1937. Under the Roosevelt administration this was an opportunity to be seized, and the Federal Food, Drug and Cosmetic Act (FFDCA) was passed in 1938 under which Congress "gave authority" to the Food and Drug Administration to oversee the safety of food, drugs, and cosmetics.

The July 19 announcement allayed concerns that the FDA was going to regulate every app somehow related to food, or drugs, or cosmetics. The press release said the agency would attempt to regulate only "a small subset of mobile medical apps that impact or may impact the performance or functionality of currently regulated medical devices." These would include, initially at least:

> Apps that are used as an accessory to a medical device already regulated by the FDA such as an app that allows a physician to make a diagnosis based on an image retrieved from a cloud by a smartphone or tablet
>
> Apps that transform a smartphone or tablet into a regulated medical device by using attachments, sensors or other devices, such as an app that turns a smartphone, for example, into an ECG machine via sensors

The FDA then "clarified" what they were after with another announcement that it didn't want to inhibit or frighten off developers of apps: "The FDA encourages further development of mobile medical apps that improve health care and provide consumers and health care professionals with valuable health information very quickly [but] in order to balance patient safety with innovation, it is important for the FDA to provide manufacturers and developers of mobile medical applications with a clear and predictable outline of our expectations."

Translation: The FDA will "guide" the development of these apps so that patients are protected and doctors are enabled.

On September 12 and 13, 2011 the FDA held a public workshop in Silver Spring, Maryland, to "seek input on its oversight approach" for those mobile medical apps it had already deemed to be under its purview. The purpose of the workshop was benign, of course: "The FDA encourages feedback from manufacturers, health care providers and others on how its proposal [to regulate such devices] may support the balance between promoting innovation and assuring safety and effectiveness."

The next step in the process was to secure acceptance and encouragement from the healthcare media that looks favorably upon such regulation in order to give those regulations credibility: This is how things are done, this is how they should be done, and it's all for the public good. An article in Mobihealthcarenew.com went into detail about the various apps that would be regulated, in order to give developers "guidance" in their efforts to comply with the yet-to-be-written rules and regulations soon to emanate from the FDA. Not one word of protest was raised about any possible overreach by the FDA in such regulation. The tone of the article was one of acceptance and appreciation for the good work the FDA was doing.

An apologist for the FDA, Paul Cerrato, writing in *Informationweek.com* cited concerns some people were having about the FDA's potential overreach, and attempted to allay them with explanations that the FDA intended to set up a "tier" of apps, with maximum regulation and oversight being applied to the top tier, and much less regulation being applied to such apps as those that count calories or send reminders when to take a pill. Cerrato said: "I don't envy the FDA's mandate. Finding the balance between over- and under-regulation is no easy task." What's neatly left out, of course, is how the FDA was ever given such a "mandate" or whether another option (how about NO federal regulation — see Underwriters Laboratories below) even exists.

Another reliable apologist for Leviathan, the *New York Times*, was obviously pleased with how regulations were going, citing a radiation oncologist who is already using an FDA-approved app to assist his patients:

> Dr. Patrick Gagnon … uses the app when he sees patients in his Fairhaven, Massachusetts office. He pulls his iPhone out of his pocket, and then he and a patient, side by side, can view images on it and discuss treatment.

"It's a nice way to go through a scan with a patient," he said.

The *Times* did mention that approval for this app, called Mobile MIM, by the FDA *took two and a half years* to obtain, and the cost to MIM Software, the developer, to obtain the coveted FDA approval, was estimated to be $75 million.

The *Times* also quoted another physician who goes along with Leviathan looking over his shoulder, Dr. Iltifat Husain, a medical resident at Wake Forest University. Husain expressed some concern that the FDA *would slow down some applications' debuts* but then affirmed: "It's exciting to see the FDA getting involved."

Others have more serious questions about the FDA's mission in regulating apps, and how such regulation can work in the current regulatory environment populated by other agencies such as Medicare, Medicaid, and the Federal Communications Commission, to name only the most obvious.

The one question left out of the conversation as the FDA marches steadily onward in its regulatory

quest is this: What options might the free market provide in the absence of the FDA? Underwriters Laboratories is a private independent safety certification company founded in 1894 that develops test procedures for products and tools for evaluating their safety and efficacy. Why couldn't they do the job as requested by insurance companies providing liability coverage on these apps? UL isn't alone nor perhaps even the best free-market choice: Baseefa in the United Kingdom provides the same services as UL, along with the Canadian Standards Association (CSA) and American companies MET Laboratories and NTA.

It's a measure of how much Leviathan has grown that free-market alternatives to protect the safety of consumers aren't even part of the conversation.

Correction: The article incorrectly estimated the cost by MIM Software to obtain FDA approval for its medical app. We indicated their cost was $75 million. The company says their cost to obtain approval was "around $170,000." We regret the error and appreciate receiving the correct information from MIM Software.