IADC Committee Newsletter

DRUG, DEVICE AND BIOTECHNOLOGY

October 2013

IN THIS ISSUE

Ginger Appleberry and Catherine Corless outline the recent FDA guidance on mobile medical apps, including a discussion of what types of apps require FDA approval.

Does My Mobile App Need FDA Approval? The FDA Weighs In

ABOUT THE AUTHORS

Ginger Appleberry is a trial attorney who is a member of the Business Litigation and Dispute Resolution and Health Care practice groups of Locke Lord LLP. Ms. Appleberry has experience representing pharmaceutical companies in governmental investigations, False Claims Act and Qui Tam suits. She also has experience defending products liability and personal injury actions and other state and federal court matters throughout the United States. She can be reached at gappleberry@lockelord.com.

Catherine Corless is a member of the Products Liability and Professional Liability Defense Practice Groups in the Little Rock, Arkansas office of Mitchell, Williams, Selig, Gates & Woodyard, P.L.L.C. Ms. Corless focuses her practice on medical malpractice defense and drug and device litigation. Most recently, she has participated in representing a major pharmaceutical company in mass-tort multidistrict litigation trials and other state and federal court trials throughout the United States. She can be reached at ccorless@mwlaw.com.

ABOUT THE COMMITTEE

The Drug, Device and Biotechnology Committee serves as an educational and networking resource for in-house counsel employed by pharmaceutical, medical device and biotech manufacturers and the outside counsel who serve those companies. The Committee is active in sponsoring major CLE programs at the Annual and Midyear Meetings as well as internal committee programs. The Committee also publishes a monthly newsletter that addresses recent developments and normally contributes two or more articles to the *Defense Counsel Journal* annually. In the future, the Drug, Device and Biotechnology Committee will be focusing on increasing its use of technology to make it an even more valuable resource for its members.
Learn more about the Committee at www.iadclaw.org. To contribute a newsletter article, contact:

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Drug, Device and Biotechnology Committee "Leadership Spotlight"

Michelle Fujimoto
Vice Chair of Programming for the Midyear Meeting

Michelle is former managing partner of the Orange County office and specializes in products liability litigation, with a focus on pharmaceutical and medical device defense. She has more than 25 years of experience in complex products liability, mass tort, toxic tort, and other science-driven litigations. Michelle also provides risk management assessment and best practices counseling to clients ranging from start-up companies to Fortune 500 companies. Michelle is a member of the International Association of Defense Counsel (IADC), where she serves on the Diversity Committee and as the Drug, Device & Biotech Committee's Vice Chair of Mid-Year Programming. She previously served as the Vice Chair of Publications, as well as Vice Chair of Programs for selected meetings. In addition, Michelle is active in the Defense Research Institute (DRI), sitting on the Steering Committee for the Drug and Medical Device Section and on the Programming Committee for DRI's 2010 Women In Law Seminar. Honors and awards include selection as one of "The Best Lawyers In America" (2011, 2013, 2014) and "The Best CaliforniaLawyers" (2012); a feature in Who's Who Legal's The International Who's Who of Product Liability Defence Lawyers (2010,, 2012, 2013); inclusion in Expert Guide's Guide to the World's Leading Product Liability Lawyers (2010); and a nomination for the Orange County Business Journal's 2009 "Women In Business Award."

In her current position as Vice-Chair of Programming for the upcoming Mid-Year Meeting at the Aviara resort, Michelle hopes that you can attend programs sponsored by this committee at that meeting. Specifically, there will be programs entitled: "Overcoming Tensions Between Drug/Device Defendants and Treating Physicians;" "Diary of an Expert – An Insider's View of the Proper Care and Feeding of Experts," and "What Can Lawyers Learn From Actors? Turning Your Problem Witness Into a Star." We hope to see you at the Mid-Year Meeting!!

Now, on to our monthly article.

I. Introduction

Widespread expansion of patient and physician use of mobile health (mHealth) technologies including health text messaging, mobile apps, and remote monitoring has dramatically changed the way healthcare is being delivered. On September 23, 2013, the Food & Drug Administration provided guidance that suggests that it recognizes a need for the regulation of certain medical apps, but it does not intend for this regulation to deter further innovation that could ultimately benefit patients.[1]

The FDA guidance reveals that the agency intends to focus its enforcement power on the subset of medical apps that it perceives as presenting the greatest risk to patients. The "FDA believes it is important to adopt a balanced, approach to mobile medical apps that supports continued innovation, assuring appropriate patient protections," stated Christy Foreman, Director of the Office of Device Evaluation. "We believe that focusing FDA oversight on a narrow subset of mobile apps will encourage the development of new products while providing appropriate patient protections."

The FDA certainly does not regulate the sale or general consumer use of smartphones or tablets. The FDA's oversight only applies to mobile apps that perform medical device functions, and at this time, the FDA plans to limit its regulation to those that pose a sufficient risk to patient safety.[2] A mobile medical app like other medical devices may be classified and regulated by the FDA as class I (general controls), class II (general and special controls with premarket approval) or class III (general controls and premarket approval).

II. What is a Mobile Medical App?

The FDA defines "Mobile Medical App" to be a mobile app[3] that qualifies as a medical device under the FD&C Act and (1) is intended to be used as an accessory to a medical device, or (2) transforms a mobile platform into a medical device.

Whether a mobile app meets the medical device definition depends on the manufacturer's intended use as demonstrated by labeling claims, advertising materials or statements by the manufacturer. A mobile app will be classified as a medical device when its intended use is to diagnose disease or it is intended to affect the structure or any function of the body.[4] The FDA provides an example of how the intended use of a mobile app can transform a previously unregulated mobile app into a regulated device – ex: a mobile app that makes an LED operate is not a medical device if the manufacturer intended for it to be used to illuminate objects generally. However, that mobile app would be considered a device similar to an opthalmoscope if the manufacturer marketed the mobile app as a light source for doctors to examine patients.[5]

Despite giving what seems to be a clearly "safe" example of using an app for medical purposes, the FDA states that it intends to focus its regulatory oversight on Mobile Medical Apps whose functionality could pose

[1] The complete guidance may be found at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.

[2] Guidance at 8.

[3] "App" is defined as a software application that can be executed (run) on a mobile platform (e.g., smartphone) or web-based software application that is tailored to a mobile platform but is executed on a server.

[4] Guidance at 8.

[5] Guidance at 8.

a risk to a patient's safety if the Mobile Medical App did not function properly.[6]

III. What type of apps has the FDA chosen not to regulate?

The guidance indicates that the majority of mobile apps on the market will not be regulated by the FDA because either (1) the mobile app does not meet the definition of a medical device under §201(h) of the FD&C Act, or (2) the mobile app meets the definition of a medical device, but poses a low risk to the public so the FDA has decided to exercise enforcement discretion by not regulating the apps that it deems to be lower risk.[7]

Examples of mobile apps that the FDA does not intend, at this time, to enforce requirements under the FD&C Act:

- Help patients self-manage their condition without providing specific treatment or treatment suggestions – ex: adhering to pre-determined medication dosing schedules, managing salt intake, promoting strategies for optimal nutrition, and achieving a healthy weight;
- Provide patients with simple tools to organize and track their health information; – ex: simple tools for patients with chronic diseases to log, track or trend their events or measurements and share this information with their health care provider as part of a disease management plan (perhaps charting, but not taking, a patient's blood pressure);
- Provide easy access to information related to patients' health conditions or treatments – ex: apps that use a patient's diagnosis to provide best practice treatment guidelines for common illnesses or conditions, or apps that are drug-drug interaction or drug-allergy look-up tools;
- Help patients document, show, or communicate potential medical conditions to health care providers – ex: videoconferencing portals specifically intended for medical use and enhancing communications, or apps specifically intended for medical uses that utilize the mobile device's built in camera or a connected camera for purposes of documenting or transmitting pictures;
- Automate tasks for health care providers – ex: simple medical calculations taught in medical school for routine use in clinical practice; and
- Enable patients or providers to interact with their Personal Health Record (PHR) or Electronic Health Record (EHR).

IV. Who is a Mobile Medical App Manufacturer?

A Mobile Medical App Manufacturer includes anyone who initiates specifications, designs, labels, or creates a software system or application for a regulated medical device in whole or from multiple software components. However, Mobile Medical App manufacturers do not include the following: (1) persons who exclusively distribute mobile medical apps without engaging in their manufacturing function – ex: "iTunes App store," "Blackberry App World," or "Google play;" (2) providers of tools, services, or infrastructure used in the development, distribution, or use of a mobile medical app. – ex: internet service provider; (3) licensed practitioners who manufacture or alter a

[6] Guidance at 4.
[7] Guidance at 4.

mobile medical app solely for use in their professional practice and do not label or promote their mobile medical app to be used by other individuals; and (4) persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce the devices into commercial distribution.[8]

V. Impact of FDA Regulation

The FDA does not anticipate that regulation will delay mobile medical apps entry into the market. Over the past three years, Foreman stated that on average it has taken 67 days for the FDA to review mobile medical apps, which is within the statutory 90-day timeframe under the 510(k) process. Foreman reminded the subcommittee that the FDA has been "regulating medical device software for decades and medical device software on mobile platforms for more than ten years." To date, she said the agency has reviewed approximately 100 mobile medical apps, including remote blood pressure, heart rhythm, and patient monitors, as well as smartphone-based ultrasounds, EKG machines and glucose monitors.

In addition, during a briefing on the new guidance, Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health, reassured that if an app maker is currently selling an unapproved product that the FDA intends to regulate, regulators may try to bring the companies into compliance without interrupting sales.

Obviously, this guidance does not answer all the issues raised by mobile apps. In fact, the guidance expressly states that it does not address the regulatory approach that will apply to mobile apps and other software that perform patient-specific analysis to aid in or support clinical decision-making – commonly referred to as Clinical Decision Support (CDS) software. The FDA has indicated that future guidance is forthcoming that will address the specifics of a regulatory framework for CDS software.

The significance and impact of the FDA's guidance has yet to be seen; however, defense counsel should be aware of the FDA's direction so that counsel can provide guidance if advice is sought on the promotion and marketing of a mobile app. Further, defense counsel should be on alert if the company receives reports of "off-label" usage of its app by health care providers or patients. If the company has a concern that an app that it did not intend to be a mobile medical app may be used as a mobile medical app, it may be beneficial to your client in the long term to have the client submit the app to the FDA for review and approval.

[8] Guidance at 9.

PAST COMMITTEE NEWSLETTERS

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