Diane Romza-Kutz Partner
dromzakutz@thompsoncoburn.com
Thompson Coburn LLP, Chicago

The FDA's new Digital Health Plan

The US Federal Food and Drug Administration ('FDA' or 'Agency') Commissioner Dr Scott Gottlieb has used an FDA blog post to announce plans for a new digital health devices initiative, specifically the initiative's Digital Health Innovation Plan, which is intended to provide tools to the Agency that encourage device makers to be innovative and put resources into the development of new digital health devices. Diane Romza-Kutz of Thompson Coburn LLP describes what's known about the Plan so far.

This latest blog posting focused on only what appears to be a piece of the initiative, the Digital Health Innovation Plan. According to statements by Commissioner Gottlieb, this Plan focuses in large part on post market entry regulation of medical devices which will now fall within the Agency's view of digital health. It appears that this initiative will be highly focused on devices such as mobile medical applications as well as other digital health devices that are used in 'clinical decision making.' The Commissioner sees this Plan as providing tools to the Agency which encourage device makers to be innovative and put resources into the development of new digital health devices that promote and protect public health.

The predicate for this new Digital Health Plan, according to the Commissioner, is the 21st Century Cures Act (the 'Act'). This Act was passed in December 2016 with a great deal of support from industry and a great deal of criticism from certain consumer organisations. Medical device manufacturers were seen as winners under this Act. Under the Act, the FDA was directed to establish a new programme to deal with new and innovative devices ('breakthrough devices'). This programme was intended to bring technologies to market not only more quickly but safely. The Act also attempts to build the framework for a strategy related to electronic health records which is intended to encourage interoperability between electronic health records systems. Although the Plan's impetus is the Act, it is worth noting that the Act itself redefines devices to exclude certain software functions/capabilities.

Breakthrough devices are of key importance to the medical device industry. The Act establishes an expedited review program for devices which qualify for this designation. At the heart of this expedited review program is a streamlined process for review of devices. This streamlined process is accomplished through implementation of a list of new requirements, the most interesting requirement being a training program for reviewers to ensure that the reviewer has sufficient expertise to review the breakthrough device. It is anticipated by the industry that many of these breakthrough devices will have digital components.

This new Plan initiative announced by the Commissioner can be seen as a continuation of the efforts that the Agency has been making in dealing with information technology as it is used in medical devices. These efforts began in earnest in 2012 and have continued with new sets of guidance on topics such as cyber security concerns related to digital health information. It is expected that the Plan will focus on a number of areas including wireless devices, mobile applications, telemedicine, interoperability, and when software is a medical device. Although the FDA has published at least eight separate guidance documents since 2014 related to digital health, it is expected that the Plan will go further than these current sets of guidance, particularly since there is a large gap in the number of years when the Agency was silent despite the growing digital health market. Maybe as importantly, it is expected that the Plan will identify low risk digital health technologies that fall outside the scope of the FDA's regulatory authority or ones that can get to market without FDA review or pre-market approval. It is expected that, in addition to certain mobile applications discussed below, such low risk technology would include software that supports administrative functions.

Many believe that much of the initial focus of the Plan will be a discussion on mobile medical apps. Although the Agency published its first sets of guidance on mobile medical applications approximately three years ago, much of the Agency's approach over the last few years has been one of a more hands off approach. Now with the focus on public health, the Plan will look to encourage the security of the data collected as well as interoperability of these applications/devices where appropriate. This would include using actual experiential data as a way to support new and evolving technology. However, in looking at the low risk technologies that would fall outside the scope of the FDA's regulatory authority, it is expected that technologies such as mobile applications that are intended to only maintain or encourage healthy lifestyles will not be included for further regulation under the Plan, consistent with the changes as a result of the Act.

It is expected that the Plan will be managed and executed by the newly created Digital Health Unit housed within the Center for Devices and Radiological Health ('CDRH'). Although there remains a lack of clear definition around the Plan at this point, that is expected to change in the near future. The industry can expect more guidance from the Agency once the Unit is fully in place within CDRH and the details of the Plan are published. The industry remains hopeful that the Plan and subsequent direction of the FDA will be in the spirit of the Commissioner's announcement, that being the encouragement of innovative technologies to improve healthcare and patient safety.