Product Liability Implications in the Digital Health Industry

An in-depth look at the changing landscape by DLA Piper

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Pharmaceutical and medical devices are becoming “smarter” these days, and the former bright line between digital health and life sciences sectors continues to blur. In this highly competitive industry, life science companies are rethinking product development and incorporating smartphone apps and other wireless and/or wearable components to produce novel therapeutics.

While the definition of digital therapeutics remains fluid, this concept has attracted considerable attention from investors, with StartUp Health Insights' estimating that more than $8.1 billion was invested in the digital health industry in 2016 alone.

However, as digital health products become commercialized and their use in the practice of medicine becomes more mainstream, there will be a greater likelihood of patient injuries, which may expose companies to product liability litigation and heightened regulatory scrutiny. Below are some product liability considerations for companies and investors in the health care and life sciences sectors who are contemplating entry into the digital health frontier.

At a high level, the policy rationale for product liability is to hold product manufacturers responsible for injuries caused by their finished products and to fairly compensate injured persons. But applying this traditional paradigm to digital health products is complicated for many reasons. For one, it may be difficult to identify the “product” at issue. For example, where a smartphone app connects to a medical device and wirelessly controls the device’s function, it may be unclear who is
liable: is it the app software developer, the smartphone manufacturer, the device manufacturer, some of the above, or all of the above? Injured persons will most likely take the most expansive approach, alleging that all parties involved in the manufacture of the digital health product should be held liable and arguing that liability should be apportioned at the end stages of the litigation. As a result, life science companies and startups could be forced to defend against potentially meritless claims for years. Because the law surrounding digital products is lagging behind technology, courts in some jurisdictions may need to address these threshold questions as a matter of first impression.

We anticipate that both sides will find unique challenges in establishing cases for, and defending against, common legal theories of strict liability, negligence and breach of an express or implied warranty related to the manufacture, warnings and instructions, and, design of digital health products. Consider the above-mentioned example of a device controlled by a smartphone app. One question that could arise is whether the duty to warn encompasses regular software updates, and, if so, who should bear the risks that come with that duty: the software developer? The device manufacturer? Both? For companies defending against these claims, some affirmative defenses may be weakened or deemed inapplicable. The defense of preemption, for instance, may be difficult to establish for certain digital health products that are not subject to direct FDA oversight, such as general wellness products and low-risk mobile health apps.

In addition to product liability risks, other substantive legal issues warrant consideration. Among these are FDA regulation, patient privacy, cybersecurity and intellectual property. Since the laws and
regulations governing digital health products are ever-evolving, companies and investors in the cross-section of health care and life sciences sectors should consult their legal counsel to mitigate these risks throughout the product life cycle.

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