

The Legal Landscape of **DIGITAL THERAPEUTICS**

AS THE TECHNOLOGY RAPIDLY EVOLVES SO MUST THE REGULATORY FRAMEWORK.

WRITTEN BY TAYLOR STILWELL

DIGITAL THERAPEUTICS (DTX) ARE HEALTH SOFTWARE INTERVENTIONS that help treat and manage a variety of medical conditions. Examples of DTx currently on the market include a video game that improves attention and function in children with ADHD, an insulin management smart phone app that connects to a blood glucose device and is monitored by trained health care providers, and a seizure-monitoring wearable device that uses an algorithm to determine if certain signals classify as a seizure.

Unlike general wellness apps or wearable fitness devices, digital therapeutics are evidence-based and undergo clinical validation. DTx may or may not require a prescription and are generally considered medical devices subject to regulatory oversight by the Food and Drug Administration (FDA). The market for these technologies is expected to grow to \$104 billion by 2032, raising a variety of legal considerations.

Regulatory

DTx are regulated by the FDA as Software as a Medical Device (SaMD). SaMD products are evaluated for their

perceived potential risk and are assigned to one of three classes: Class 1 (low risk, minimal requirements), Class 2 (moderate risk, controls like labeling requirements or clinical data thresholds), and Class 3 (high risk, special controls and pre-market approval required). Requests for authorization of DTx are submitted to the FDA via one of two paths. The de novo pathway requires clinical data that demonstrates the safety and efficacy of the device. The device then becomes a predicate for other devices.

Under the 510(k)-clearance pathway, new DTx may submit clinical data showing equivalence to the predicate devices. There have been several attempts to streamline the approval process for DTx to account for the rapidly changing technology, including a pilot program for pre-certification. Although the FDA implemented some changes, the pilot program was not continued, and the FDA has called for legislative changes to implement a more streamlined process.

Privacy

DTx involve the collection and

processing of a large amount of personal data and, as such, are subject to an assortment of privacy laws at the state, national, and international levels. The safe keeping of this data is important due to its extremely sensitive nature. For example, DTx offering cognitive behavioral therapy for users with substance use disorders might not only have a user's name, address, and health information, but also entries that quantify substance use or personal notes. For DTx that are prescribed by a covered entity, that data will be subject to the relatively stringent protections under the Health Insurance Portability and Accountability Act (HIPAA). DTx not subject to HIPAA may still be subject to state or international laws—e.g., DTx operating in California might be subject to the California Privacy Rights Act, while DTx operating in Texas will be subject to the Texas Data Privacy and Security Act. It is unclear whether these state laws—most of which were passed before the meteoric rise of DTx—are equipped to handle the privacy challenges.

Federal Payors and Reimbursement

DTx have the potential to increase access to health care by providing clinical-level care from a cellphone. That potential is hampered if the federal government, which accounts for 32% of total national health spending, does not provide reimbursements. As recently as 2022, DTx were not reimbursed by federal payors, even if FDA-approved. Medicare and Medicaid are increasingly willing to explore coverage for DTx, with new billing codes being introduced in 2025. While the rise in federal reimbursement is promising, it also creates the potential for heightened fraud and abuse, not unlike the fraud and abuse seen from the mass adoption of telehealth technologies.

Artificial Intelligence

DTx leverage AI to process and

compute vast amounts of data to personalize treatment plans and predict outcomes. AI algorithms recently have been scrutinized for biases resulting from machine learning that can result in unfair or inaccurate outcomes, especially for marginalized populations. Besides bias, AI raises concerns about accuracy, transparency of medical decision-making, and liability. If a decision made by AI results in patient harm, who is at fault—the software developer, the prescriber, or the monitoring provider? While these issues are not unique to DTx, the concern is heightened by the delicate nature of the conditions DTx have been approved to treat.

As telehealth continues to expand, and as individualized medicine becomes more popular, DTx are poised for substantial growth, providing an accessible solution for a variety of health conditions.

With this innovation comes legal uncertainties. The legislative and regulatory framework will have to evolve to address such a rapidly changing technology, especially as clinical validation continues to show the efficacy and promise of DTx. For attorneys, staying ahead of these legal developments will be crucial in the coming years. **TBJ**

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TAYLOR STILWELL

is an associate of Katten Muchin Rosenman. She can be reached at taylor.stilwell@katten.com.

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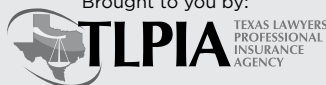
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