DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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2021 Retrospection Highlight

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Digital Health and Multiple Device Function

The digital health space continued to grow in 2021, and is becoming an integral part of healthcare during the COVID- 19 pandemic. Over the past two years people have become more accustomed to telehealth and taking an active role in their health, including using wearable technology to monitor health and wellbeing.

Although polls show that most individuals prefer in-person healthcare visits[1], there is no doubt that individuals also prefer to take a more active role in their own healthcare. This includes making use of their own wearable sensor data for diagnostic purposes, the use of mobile medical applications to allow individuals to make their own healthcare decisions, and participation in clinical trials using an individual's real-world data collected from digital health technologies.

The pace of digital health technological innovation continues to outpace the regulatory capabilities of FDA and its authority granted by Congress. The 21st Century Cures Act, passed into law over five years ago does not adequately address the current technology space and the regulatory issues presented. As a result, FDA has been left to regulate on the fly through guidance documents and enforcement discretion during the recent past. For example, because the 21st Century Cures Act was too prescriptive with respect to the ever-evolving and ever-growing medical device landscape, for which FDA could not reasonably keep up, FDA was required to take a risk-based approach to reasonably regulate the digital health landscape. Following the enactment of the 21st Century Cures Act, FDA released a number of guidance documents to help interpret its stance on the law and

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[1] 53% of individuals polled prefer in-person visits to video visits. Predmore ZS, Roth E, Breslau J, Fischer SH, Uscher-Pines L., *Assessment of Patient Preferences for Telehealth in Post–COVID-19 Pandemic Health Care*, JAMA Netw Open. 2021;4(12):e2136405. doi:10.1001/jamanetworkopen.2021.36405

enforcement priorities, including the following: General Wellness: Policy for Low-Risk Devices, Policy for Device Software Functions and Mobile Medical Applications; Clinical Decision Support Software; and Multiple Function Device Products: Policy and Considerations.

These guidance documents have broadened industry's ability to bring low-risk devices to the market and remain outside FDA's enforcement. In contrast, the guidance on Multiple Function Device Products: Policy and Considerations have allowed for broader applications within FDA review of medical devices. Under this policy, during a pre- market or postmarket review (e.g. PMA, 510(k) review, establishment inspection) FDA will only review the aspects of the device that are subject to FDA's enforcement. Those aspects that are deemed "other functions," whether those functions are outside the definition of a device, exempt from review, or subject to FDA's enforcement discretion, will only be reviewed to the extent they impact the device functions that are subject to FDA enforcement. This policy has a large effect on digital health products that incorporate both device functions, such as hearing aids and EKG monitors, with functions that are outside the scope of a medical device, such as sensors used to detect exertion during exercise.

Of course, FDA retains broad latitude to review these functions as part of an FDA review when the "other function" may be an impact on the device function. Therefore, companies need to think about how they design hardware and software to isolate the different functions and have a robust risk-management process that will allow the company to demonstrate why the "other function" would not impact the device function. Without such evidence FDA may dig into this "other function" and slow down the review of the device, delaying clearance or approval.

Beyond these guidance documents, FDA also implemented a Software Precertification Pilot Program in 2017 that would introduce a new regulatory pathway that focuses on assessing the safety and effectiveness of software and subsequent integrations based on a company's "culture of quality"

rather than an evaluation of the software product. In general industry, specifically larger established firms, has applauded this pathway because it removes regulatory barriers to market. ***However, less established firms that have not proven the same "culture of quality" with FDA may remain stuck in an overly burdensome pathway that will place these companies, and ultimately the consumer, at a disadvantage.*** Yet, pathways to market for medical devices are statutorily defined within the Food, Drug, and Cosmetic Act (FD&C Act), and without amendment this pre-certification pathway is not likely to come to fruition. As of the end of 2021, the competitive and legal concerns regarding this pathway remain.

In 2022, FDA will continue to grapple with how to best regulate the digital health space. The Cures 2.0 Act was introduced into Congress in 2021, and will continue to move through Congress in 2022. However, the bill, in its current form, is not likely to trigger any short-term changes to the FD&C Act as it relates to digital health, including any implementation of FDA's pre-certification program. The current draft of the bill only requires that FDA provide a report that outlines how FDA ensures collaboration and alignment. In addition, the bill requires FDA to outline approaches and establish a task force to recommend ways for patients to engage in real-word data generation. ***Therefore, in 2022 we can expect the same level of uncertainty as we have seen in the past few years, as FDA continues to update its enforcement policy through a risk-based approach.*** This approach this cuts both ways. On the one hand companies can take advantage of FDA's enforcement discretion and find creative ways to remain outside FDA's regulatory scheme. On the other hand, these same companies will be subject to FDA's evolving positions and always be waiting for the other shoe to drop, which may create uncertainty for companies, especially smaller ones, looking to enter the digital health space.

FDA's evolving thinking will be once again in the forefront in 2022 as it once again expected to release updated and new guidance documents, including final guidance on Clinical Decision Support Software, and draft guidance on Marketing Submission Recommendations for A Change Control Plan for

Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions and Risk Categorization for Software as a Medical Device: FDA Interpretation, Policy, and Considerations. Like the related suite of already released digital health guidance documents, these publications will provide digital health companies with leeway to navigate the FD&C Act, particularly for low-risk devices. ***However, companies will need to have the end in mind and plan for the regulatory position within FDA to shift at any time.*** In summary, we can expect more of the same in 2022.

DuVal & Associates
Drug, Device and Food Law

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