COLLABORATIVE TRANSFORMATION

FOCUS ON INNOVATION CENTERS

KEY CONSIDERATIONS FOR INVESTMENTS IN ENTITIES DEVELOPING INNOVATIVE FDA-REGULATED PRODUCTS

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Digital health and other life sciences/tech developers, particularly those producing innovative new solutions, offer dynamic opportunities for investors, in part due to the continued evolution of the US Food and Drug Administration's (FDA's) approach to regulatory oversight. Read on for key takeaways that hospital and health system (HHS) innovation executives should consider when investing in companies that are developing FDA-regulated products:

- Despite leadership changes at the FDA, the agency's mission will stay the same: to ensure that the medical devices, drugs and biologic products that get to market are safe and effective. However, that mission is increasingly informed by a **heightened focus on regulatory flexibility**, particularly in the development of FDA-regulated software and mobile applications. For example, the FDA historically required FDA-regulated software developers to obtain prior clearance or approval for significant updates to previously approved or cleared products. This requirement delayed patient and healthcare personnel access to modified versions of these products, even though the changes could often be made fairly quickly. FDA is now considering several programs that have the potential to meaningfully improve patient and healthcare personnel access to innovative new products, including pre-certification and an evolving approach to oversight of artificial intelligence and machine learning-enabled products.

- In response to the rapid pace of innovation and the proliferation of unconventional partnerships, FDA—and particularly the Center for Devices and Radiological Health—is pursuing a **proactive, risk-based approach to regulating novel products** such as personalized medicine. The agency is increasingly open to engaging and collaborating with industry in an effort to get innovative products to market faster and increase patient access. For example, developers of first-of-a-kind digital health and diagnostic products historically have been required to go through the onerous premarket approval pathway, but increasingly, such developers have been able to avail themselves of the agency's streamlined de novo 510(k) pathway.

- FDA's increased transparency and collaborative stance offers particular benefit to **smaller companies and start-ups in the medical device and biologic spaces**, for which timely FDA approval or clearance can make the difference between survival and failure. The expense of clinical trials and preparation of a premarket submission, and the time required for FDA to review the same, can be a gating issue for small companies. FDA's willingness to engage with stakeholders pre-submission not only gives companies an opportunity to address key FDA considerations at a time when it is still relatively easily to do so—it dramatically increases the chance that their potentially groundbreaking technologies and therapies will see the light of day on a timeline consistent with the company's resources. As HHSs consider investment in such start-ups or companies, evaluating how they approach FDA strategy (e.g., whether they are already in communication with the FDA) is critical to understanding their timeline to market and/or their ability to obtain premarket approval or clearance for their desired indication(s).

- Even as FDA seeks to reduce regulatory barriers and increase speed to market for innovative products, it must still ensure safety and efficacy. The agency is achieving that balance in part through increased **post-market surveillance data collection**, the extent of which is typically negotiated by the FDA and the product's sponsor prior to regulatory clearance or approval. HHS investors should be aware that these study requirements may allow a developer to get a product on the market more quickly, but only in exchange for the time and expense required to engage in a thorough assessment of a product's safety and efficacy when used in a real-world setting.