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Regulatory Insights for Life Sciences and Health Care Investments: Digital Health

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Investing in the life sciences industry without an understanding of the key regulatory factors that could determine a product's success or failure could cost you millions of dollars.

As the industry readies itself for the 2019 edition of the annual pilgrimage to the J.P. Morgan Healthcare Conference in San Francisco, our market-leading Global Regulatory Team has prepared a series of updates covering the following topic areas that we hope will help guide your 2019 investment decisions.

- Drug pricing and reimbursement
- Regulatory changes in Europe
- Medical device and technology
- Digital health
- Data privacy and cybersecurity
- Value-based purchasing
- Cell and gene therapies
- CFIUS reporting obligations

Commercial Value of Digital Health Technologies Hinges on Key Regulatory Questions

Imagine you've identified an innovative, patented digital technology that promises to have a revolutionary impact on health and wellness in the United States. While there are a number of legal considerations in understanding whether the digital health company may be a success, examining its potential FDA regulatory review pathways is a key aspect in assessing if the technology may instead prove to be an unmitigated disaster. The following are critical regulatory issues that should be at the front of every investor's mind.

Is it regulated as a medical device?A single digital health product may or may not be considered a regulated medical device in a variety of jurisdictions depending on its intended use. In the U.S., the exact same product could be an FDA regulated device or an unregulated product,

depending on how it is intended to be used. At present, digital health technologies generally fall into one of three FDA regulatory categories:

- *Not a medical device (i.e., no FDA regulation).* Products in this category include digital health products that do not meet the statutory definition of a medical device, which was amended in December 2016 by the 21st Century Cures Act to exclude some digital health and software-based technologies (e.g., administrative support software, electronic health records, among others). Other types of unregulated technologies include those that are purely for fitness and sports purposes.
- *Low-risk medical device subject to enforcement discretion.* FDA has established a number of different policies whereby they agency exercises its discretion and refrains from enforcing its requirements (i.e., enforcement discretion). These policies, when taken together, reflect a determination that the relevant products don't present enough risk to warrant FDA attention. Enforcement discretion is just that, "discretionary." Any grant of enforcement discretion is not binding on FDA and may be changed at any time. Examples of products currently subject to enforcement discretion include:
    - Certain products intended to help maintain a healthy lifestyle to reduce the risk or impact of certain chronic diseases or conditions;
    - Certain mobile apps that help patients self-manage information about their disease or condition; and
    - Certain low-risk "patient decision support" software that provide recommendations to patients based on well-established public information.
- *Actively regulated as a medical device (class I, II, or III).* FDA generally regulates digital health products, including standalone software, that meet the statutory definition of a medical device pursuant to the same risk-based framework as other medical devices, unless those products are subject to enforcement discretion, as discussed below. For key considerations impacting medical device investments and transactions, see article: *Regulatory hurdles vex medtech startups: Factors to consider when investing in R&D projects.*

Impact of regulatory status on product valuation. Whether or not a digital health technology is regulated as a medical device often impacts the valuation of the product, as well as the timeline for commercialization in the United States. For example, unregulated products may have a shorter time to market and potentially a larger user population, but may fetch a lower price-point and be limited to less-impactful promotional claims. In addition, digital health technologies with medical claims that fit into the existing and evolving reimbursement paradigms may have a different market opportunity than products that are exclusively self-pay consumer products. At the same time, regulated products may have a longer time to market and higher development costs, but may be promoted for more weighty applications and eligible for third-party reimbursement. Appropriate weighing of these considerations is critical to understanding the commercial potential of novel digital health technologies.

Impact of regulatory status on promotional claims. Digital health products that are not medical devices, or that are subject to enforcement discretion, can only be marketed in a way that does not trigger FDA regulation or enforcement. Promotional claims for these products cannot result in an "intended use" that meets the definition of a medical device. For example, to qualify for enforcement discretion as a low-risk medical device, digital health technologies must fall into one of the categories that FDA has articulated. More medically important claims may trigger greater FDA regulation. A thorough evaluation of proposed marketing claims for digital health technologies is critical to understanding whether the product may be legally commercialized in the United States without prior FDA authorization, as well as which legal requirements apply to the product and its manufacturer. A clear understanding of the claims associated with each regulatory category plays a key role in assessing the commercial potential of new digital health technologies.

Cybersecurity concerns. Whether regulated or not, cybersecurity concerns should be at the front of any digital health investor's mind. Cybersecurity breaches can lead to negative publicity, loss of good will, and loss of customer confidence, not to mention costly remedial activities. For regulated products, FDA recently announced enhanced cybersecurity requirements that will need to be met prior to placing new medical devices on the U.S. market. Developers of new digital health technologies should have a clear plan for addressing these critical regulatory requirements.

Rapidly evolving regulatory paradigms. FDA has been hard at work creating new potential regulatory paradigms for addressing the unique challenges associated with digital health products. Just weeks ago, FDA published a request for comments on a proposed framework for regulating the output of digital health applications disseminated by or on behalf of drug manufacturers with one or more of their prescription drugs. This proposed framework builds on FDA's trend toward providing clarification and guidance related to digital technologies, as evidenced by:

- FDA's digital health software precertification program ("Pre-Cert," analyzed here, here, here, and here)
- FDA's April 2018 Medical Device Safety Action Plan
- FDA's April 2018 draft guidance on Multiple Function Device Products (analyzed here)
- FDA's July 2017 Digital Health Innovation Action Plan (analyzed here)
- Other guidance documents (analyzed here) that aim to clarify the framework for the regulation of software and digital health products to bring FDA regulatory policy into line with the 21st Century Cures Act.

Thorough regulatory due diligence is key to successful digital health investments and transactions: knowing what is regulated, what isn't regulated, and how to tell the difference, as we

analyzed in our 2018 Digital Health Issues Guide. Hiring experienced FDA regulatory counsel could mean the difference between making a strategic investment and taking on unreasonable risk.

Our Global Regulatory Team

We help organizations navigate the world's multiplying regulatory regimes as they cross industries and borders alike. At Hogan Lovells, we believe that regulation is neither a force to be feared nor an obstacle to be overcome. Regulation is simply a reality of doing business today, and the organizations that understand it holistically and navigate it well are the ones that will succeed. Our team helps industry understand, anticipate, and influence the shifting - and often volatile - regulatory landscape. We partner with your business to create smart, operational solutions that mitigate risk, create new opportunities, and power your enterprise to advance.

Our Global Life Sciences and Health Care Team

Navigating complexities in the life sciences and health care industries is no easy task. Successfully competing in the space requires a partner with a holistic, collaborative approach and a global perspective. For life sciences innovators of all sizes, anywhere in the world, Hogan Lovells is that partner — from cutting-edge start-ups and boutique venture funds to world-renowned research institutions and health systems to global biopharmaceutical conglomerates. With more than 500 life sciences and health care lawyers around the world, we provide a seamless experience everywhere you do business. And no matter the challenge — from creation to commercialization of a life-saving therapy, regulatory compliance to an international patent dispute, the formation of a strategic alliance to a complex, global merger — we've been there before and we understand how to prepare you for what happens next, helping you to anticipate risks and address future issues before they arise.

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