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Navigating the Legal Complexities of a Digital Health Transaction

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Digital health is now at the forefront of deal activity in the life sciences and health care sector. The acquisition earlier this week by Johnson & Johnson subsidiary Apsis of France-based Orthotaxy, a software developer at the cutting edge of robotic-assisted orthopedic surgery, and the \$118 million equity funding announced earlier today of privately held prostate surgery robotics company Procept BioRobotics, are just the latest in a series of digital health transactions that are transforming the life sciences and health care industries.

Last week, Swiss pharmaceutical giant Roche agreed to shell out a stunning \$1.9 billion to acquire Flatiron Health, which has transformed a traditional electronic medical records business into an advanced digital platform providing data to



optimize oncology-focused clinical trials through partnerships with the National Institutes of Health, the National Cancer Institute and hundreds of community oncology practices.

Grail, an early cancer detection start-up that raised \$1.3

billion in its Series B funding round in 2017, focuses on the overlap of life sciences, cloud computing, big data and artificial intelligence.

Johnson & Johnson was itself involved in one of the earliest landmark transactions in digital

health when its Ethicon Endo-Surgery subsidiary agreed to collaborate with Alphabet's Verily Life Sciences. The Verb Surgical joint venture, established in 2015, employs robotics, visualization, advanced surgical instrumentation, data analytics and connectivity to build a next-generation open-surgical platform.

In house counsel, business development professionals and investors say the increasing convergence of the life sciences and technology industries is creating opportunities and challenges in equal measure. In both industries, practitioners are now required to solve issues related to the ownership of shared data, the protection of patient privacy and complex regulations.

Life sciences companies seeking to improve health care quality and patient outcomes as they innovate around the generation and sharing of data are driving much of this activity, along with payers such as private health care insurance companies and the federal government's own Medicare and Medicaid programs. All share a

goal of finding a way to monetize health care data and create personalized or individualized care plans.

So what do these trends suggest? First, that the promotion of value-based health care, underpinned by the individual patient experience, is now paramount. How this ultimately is achieved remains unknown. Big data and artificial intelligence will surely each play a role. But how the Food and Drug Administration should regulate in a world where, for example, artificial intelligence or machine learning may change the standard of care given to a patient remains unknown. Will companies have to seek FDA approval each time their robot-assisted surgical device adapts itself to a new surgical setting, or will the regulators take a more practical outcome- or risk-focused view?

Some believe that drugs, small molecules and biologics, will one day be commoditized and that it will be the software—algorithms uniquely tailored to a patient—that determine just how the drugs or a sequence of therapies are administered. By extension, the continuous

upgrading and refinement of such software would be what ultimately drives value in the health care sector.

Whatever the long-term future for life sciences, in house lawyers and their business counterparts as well as outside advisors who are able to navigate the convergence of business and legal issues surrounding the life sciences and technology industries will have a competitive advantage over those who ignore the parallel convergences that are taking place, continuing to focus instead on life sciences and technology as distinct and separate fields.

***Kristopher Brown** is a partner in the corporate & securities practice group in the New York City office of Dechert LLP, where he focuses on M&A, private equity and venture capital transactions. Dechert was involved in legal aspects of each of the Orthotaxy, Verb Surgical and Grail transactions referenced above.*