

Digital Health

Technology is changing the way the health care industry operates. With changes come new challenges and opportunities — as well as a dramatic shift in the competitive and regulatory landscape. We bring a real-world sensibility to your challenges, helping you to remain competitive and compliant everywhere you operate. Our cross-jurisdictional team of more than 40 life sciences and health care lawyers with a focus on digital health take a technology-based approach to counseling on digital health products and services. We provide you with strategic guidance on how to leverage opportunities for growth, minimize legal barriers, comply with rules, protect your data, and realize its value.

Our team advises on the design, approval process, and regulation of digital health products. We also regularly work with companies and health care providers on pricing and reimbursement frameworks. We advise on all aspects of health privacy and cybersecurity, including breach response, risk assessment, privacy policies, and transactions. We help navigate collaborative arrangements such as commercial joint ventures and research studies and provide full commercial and corporate support for transactions. We advise across the full spectrum of deal aspects including intellectual property rights, licensing, data exploitation, and risk. We also regularly counsel on risk mitigation strategies for liability, providing preventative strategies for product liability, professional liability and negligence, as well as helping you step by step should new liabilities arise.

Contacts

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Practices

Health Law

Industries

Life Sciences and Health
Care

Representative experience

Advising a leading pharmaceutical company in its digital health strategy in 21 jurisdictions.

Representing a high-technology company in connection with its life science business ventures, including exclusive licenses and joint ventures, to develop digital health products.

Advising several pharmaceutical and medical device companies on the regulatory status and the dissemination and marketing of mobile applications.

Advising a leading consumer product company on the development and classification of a consumer-oriented wearable sensor and associated mobile application.

Assisting a major diabetes manufacturer in seeking PMA approval for a sensor augmented insulin pump.

Advising on various regulatory aspects of international telemedicine, including cross-border healthcare, data privacy, and medical device aspects.

Advising a number of clients on the classification and regulation of software for communication between medical devices and physicians'/patients' smartphones and agendas.

Advising a pharmaceutical company on compliance aspects, terms of use, and data privacy of a mobile health app for patients' use.

Assisting a major pharmaceutical company with an enterprise-wide review of Telephone Consumer Protection Act compliance issues.

Advising a biopharmaceutical company on its agreement with a supplier of digital technologies (e.g., data capture solutions) for use in clinical trials.

Representing biotechnology company in administrative law proceedings related to financial penalty imposed by Ministry of Health concerning a mobile health app.

Assisting the German Federal Government in the IP clearance for the German e-health card.

Advising developers of wearable technology and digital health platforms on liability risk mitigation strategies.

Representing global technology company before EU national authorities in dispute with competitors concerning appropriate classification of software that supports a medical device.

Assisting medical device manufacturers with structuring their connected medical device services to facilitate cross-border data transfers and streamline EU data protection constraints.

Advising multiple global medical device manufacturers on the development of variations to existing medical devices for use in sports activities and/or a healthy lifestyle.

Co-authoring a study for the French CNIL on the regulation of connected health (“quantified self”) devices.

Latest thinking and events

News

COVID-19 Report for Life Sciences and Health Care Companies

News

FDA finalizes policy on multi-function medical devices’ premarket submissions

News

COVID-19 Report for Life Sciences and Health Care Companies (27 - 31 July 2020)

News

COVID-19 Report for Life Sciences and Health Care Companies (20 - 24 July 2020)

News

COVID-19 Report for Life Sciences and Health Care Companies (13 - 17 July 2020)

News

COVID-19: Daily Report for Life Sciences and Health Care Companies (6 - 10 July 2020)