

DIGITAL HEALTH

CROSS-PRACTICE CAPABILITIES

THE FAST-CHANGING DIGITAL HEALTH MARKET

presents tremendous opportunities and equally significant risks. Ropes & Gray's deep experience with key issues posed by the rapid convergence of technology, health care, medical devices and pharmaceuticals makes us a valuable partner for any participant in this arena.

TODAY'S HEALTH CARE INDUSTRY is in a constant state of invention. Wellness apps, electronic health records, wearable technology that can enhance everything from personal fitness to self-monitoring of diabetes and other conditions—all illustrate the ways in which companies are seizing the opportunities emerging daily in this market.

But as opportunities proliferate, so do the challenges and risks associated with storing and handling sensitive health data and other personal information, particularly when agencies such as the FDA, FTC, ITC and U.S. Department of Health and Human Services have yet to define the appropriate regulatory requirements.

ropesgray.com/practices/digital-health

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LEGAL ADVICE ACROSS THE BUSINESS CYCLE

Ropes & Gray offers the resources of a multidisciplinary team that can advise you on the most critical areas related to operating in the digital health market. Our practice strengths in such a broad range of key areas enable us to help digital health companies at each stage of their experience:

- Collecting and using data
- Conducting platform security assessments
- Managing anti-kickback issues, Medicare reimbursement and other sales-related considerations
- Assessing and mitigating risk, and ensuring compliance
- Financing growth and expansion
- Licensing and collaboration
- Meeting corporate governance requirements and expectations
- Addressing litigation and enforcement issues

WIDE-RANGING PRACTICE STRENGTHS

Ropes & Gray provides unsurpassed perspective on the regulatory, privacy, business and financial considerations facing any company with digital health operations or aspirations.

BY THE NUMBERS

80+

Attorneys in our digital health group

**\$1.3
Billion**

Raised in private financings for digital health clients

30 Chambers-recognized digital health attorneys

15 practice areas comprising our digital health group

**\$22
Billion**

Recent aggregate digital health market transactions

PRIVACY & DATA SECURITY

Our leading privacy & data security practice regularly advises clients on HIPAA and other privacy laws governing the use and handling of sensitive personal and health information. Additionally, our data breach response team advises clients on internal investigations and helps them establish and test audit and incident responses before a breach occurs.

REGULATORY/HEALTH CARE

We are well positioned to help you comply with the rapidly evolving laws, regulations and oversight governing the U.S. and global digital health market. Our FDA regulatory team has extensive experience in all relevant areas, including FDA classification of software as a medical device, device clearance and approval, FDA Quality System Regulation, adverse event reporting, and device labeling. In addition, our FTC regulatory team has extensive experience counseling companies on FTC data privacy issues and handling FTC investigations.

We have also worked closely with both vendors and users to design, develop, license, implement and operate health IT systems that securely and effectively integrate patient health information into a centralized network.

INTELLECTUAL PROPERTY

Establishing an intellectual property strategy can be challenging for digital health companies. As a result, digital health companies typically rely on a combination of patent, copyright, trade secret and contract rights to protect their businesses. Our attorneys have vast experience helping clients develop and implement a practical strategy for the various intellectual property rights on which their businesses depend. Additionally, our IP litigators have a record of courtroom success in a variety of patent infringement, trademark and false advertising cases.

LICENSING AND COLLABORATION

Remaining competitive in the digital health market often requires collaboration, which presents challenges relating to the rapidly changing technological landscape. We are deeply experienced in all aspects of licensing and collaborations relevant to digital health vendors and users, including co-promotion, marketing and distribution agreements, strategic alliances, outsourcing, supply and manufacturing agreements, and joint ventures.

M&A/FINANCE

The mix of health care, life sciences and technology companies involved makes investing in the digital health market particularly complex. Our longstanding leadership in M&A and private equity, wide-ranging transactional experience, and long track record in capital markets and private financings give us a thorough understanding of the issues facing digital health investors and companies alike.

CORPORATE GOVERNANCE

Regulators and third parties increasingly focus on ensuring that digital health enterprises have the proper corporate governance safeguards to protect the integrity of the business and its data. We routinely advise companies on critical compliance and governance issues, including the development of structures that promote regular, accountable oversight and proper employee training.

FOR MORE INFORMATION



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