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Digital Health

Our capabilities across the continuum of care

Our team of attorneys and professionals assists participants in the digital health sphere in all stages of product and company development, from formation to financing to exit strategy. We advise clients on online services for clinical consultations and prescriptions, including issues related to the status of the patient, physical examination, medical record retention, informed consent requirements and the establishment of a provider-patient relationship. We also help health care providers and other industry stakeholders evaluate new payment and reimbursement models.

Our eHealth and telemedicine clients include:

- Hospitals and health systems
- Universities and academic medical centers
- National trade associations
- Disease management associations
- Physician groups
- Technology startups
- Telehealth networks and associations
- Technology vendors
- Pharmaceutical companies
- Medical device suppliers

How Can We Help?

Our team helps clients to advance business opportunities in all stages of development.

Forming new entities and drafting organizational and relational agreements between them

Developing compliance programs, assisting with accreditation and certification programs, and implementing anti-counterfeiting measures

Obtaining financing and other sources of capital on terms that support and protect the company

Establishing and executing an intellectual property strategy to help protect technologies and business

Establishing payment and reimbursement models

Helping set up internet-based help services and platforms

Structuring technology and service agreements to help achieve results, create accountability and address risks

Maximizing, monetizing and commercializing new and enhanced technologies

Advocating for laws and policies to advance digital health and improve market outcomes

Reviewing platform content and advertising for compliance with FDA and FTC requirements

Determining corporate form and governance structures for digital health technology companies and related provider organizations, as applicable

Advising on state and federal laws impacting digital health services and platforms (e.g., privacy, security, licensure, FDA approval, etc.)

Responding to warning letters and enforcement actions

Evaluating and mitigating intellectual property (e.g., patent, trademark, copyright, etc.) risks for products/services/content

Protecting trade secrets by advising on strategy, litigating issues of misappropriation and enforcing the confidentiality obligations of employees

Litigating intellectual property, privacy, counterfeiting and contractual issues

Providing counsel on data governance, including data use, exchange, and handling as well as policies, manuals, and training

Consulting on digital health policy, funding, and stakeholder engagement

Developing partnerships to enhance patient experience and outcomes

Leveraging technology as a means of affiliation and engagement

Implementing exit strategies to facilitate proper economics and risk allocation

Technology and Innovation

- Advise on the acquisition, licensing, implementation and support of the full breadth of technologies and services required to offer digital health services
- Negotiate agreements with technology vendors to deliver solutions and services that improve care, reduce costs, improve efficiencies and financial performance, and manage resources and capacity
- Provide strategic advice regarding the use of technology to advance affiliation and growth and develop new lines of clinical and non-clinical services
- Structure partnerships to develop and commercialize innovative solutions
- Guide our clients from vendor section through the licensing and acquisition process
- Work closely with stakeholders to negotiate and draft agreements that reflect our clients' business objectives

Privacy, Cybersecurity and Data Governance

- Advise on state privacy laws, HIPAA Privacy and Security Rules and substance use disorder confidentiality rules under 42 CFR Part 2
- Provide emergency response to security incidents or breaches, perform security incident risk analysis assessments, notify victims and applicable governmental agencies, represent clients in breach investigations by the OCR and state and federal governmental agencies, and litigate class-action lawsuits when necessary
- Establish programs to protect the privacy and security of medical records, assist with registry formation, set up appropriate electronic health records systems, assist with the maintenance, conversion, and use and disclosure of health information, and manage e-discovery issues
- Coordinate overall strategy for dealing with simultaneous government and regulatory inquiries, private party lawsuits, and potential disputes with vendors and third parties related to indemnification rights and obligations

Food and Drug Administration (FDA) Issues / Clinical Research and Trials

Guide through every stage of research and product development to determine the applicability of FDA and related laws and regulations — and provide experienced advice to navigate regulatory and commercial interactions.

FDA OVERSIGHT

- Determine whether products and activities are regulated by the FDA
- Discover how FDA guidance impacts regulatory status and requirements (especially important with products with rapidly evolving regulatory environments, such as software/medical apps, human tissue/cells and certain lab tests)
- Assist with regulatory audits, inspections and recalls
- Advise clients regarding compliance requirements, policies and training

CLINICAL RESEARCH

- Share guidance on requirements for FDA-regulated research, human subject protection and data integrity
- Handle all research-related agreements
- Advise on informed consent issues
- Counsel on study governance, including the use of data monitoring committees and data safety monitoring boards
- Provide insight on privacy and data security in research
- Assist with regulatory audits and inspections
- Ensure research programs adhere to all accepted clinical trial guidelines, including clinical trial design and agreements, FDA approvals and commercialization
- Draft and negotiate clinical trial agreements
- Develop research compliance programs, policies and procedures, and provide training to manage the ongoing program
- Guide through trial development, regulatory strategy, contracting, publication, privacy and security issues and reimbursement

FDA MARKETING AND CLAIMS

- Counsel regarding product packaging and label claims
- Review promotional materials for regulated products under FDA and related requirements
- Assist with enforcement such as warning letters
- Advise on state marketing code concerns and Sunshine Act reporting requirements

Other Marketing and Antitrust Issues

TELEPHONE CONSUMER PRIVACY ACT (TCPA)

- Analyze existing business operations marketing and customer communications to create or modify procedures to mitigate future litigation risk and cost
- Implement practical compliance strategies that minimize the risk of a lawsuit, closely monitoring exceptions to portions of the TCPA that are unique to certain HIPAA-regulated entities and their activities
- Regularly track developments and trends in the dynamic area of TCPA law

FTC AND CONSUMER PROTECTION

- Help understand the array of international laws and guidelines relating to advertising, marketing and privacy issues
- Provide counsel on full range of FTC consumer protection issues, ranging from door-to-door solicitations to geolocational privacy

ANTITRUST

- Comprehensive antitrust counseling enabling you to aggressively compete with the bounds of antitrust laws
- Defending clients in antitrust investigations and subpoena inquiries from the FTC, DOJ and state attorneys general
- Securing antitrust clearance of clients' strategic transactions, joint ventures and collaborations with competitors

HIPAA PRIVACY AND SECURITY

- Review and prepare marketing authorizations, review marketing language in data sharing agreements, and analyze uses and disclosures of health information to determine whether activities are considered marketing or fall within exceptions

IP: Patent, Trademark, and Trade Secret Issues

- Manage and protect brands and innovations by building and enforcing business-focused trademark, patent, and trade secret portfolios
- Protect strategic and innovative information by drafting and enforcing confidentiality obligations for employees
- Anticipate, protect and defend against intellectual property claims brought by others
- Structure, draft and negotiate agreements, including patent and trademark licenses, information technology agreements, clinical trial agreements, material transfer agreements, joint development agreements and data analytics agreements
- Guide marketing practices with advice on advertising substantiation and compliance
- Partner to take ideas and products from concept to market
- Analyze IP landscapes to facilitate technology developments and conduct freedom-to-operate analysis to mitigate IP risks

Venture Capital, Private Equity and M&A

- Assist startups, mature businesses, investors and buyers with transformative transactions:
  - Capital raising, including angel, seed and venture financings
  - Private equity transactions
  - M&A, including founder exits and acquisitions
  - Spinout and carveout transactions
  - Licensing, both inbound and outbound

Telehealth/Telemedicine/Pharmacy

- Ensure technology complies with applicable state and federal privacy and security regulations
- Assist with EHR selection, contract negotiation, implementation and deployment
- Advise on health care analytics including Big Data issues
- Negotiate and implement telemedicine arrangements with providers, technology platforms and third parties
- Advise on state board of medicine and board of pharmacy compliance issues
- Assist with program compliance and accreditation
- Advise on operational issues, including payer credentialing, patient verification and medical record management
- Advise on regulatory requirements that impact design options for telemedicine programs incorporated into comprehensive employee benefit programs

Stark/Fraud and Abuse

- Provide guidance to comply with fraud and abuse laws, which can be both financially and reputationally damaging
- Counsel on Stark Law, Anti-Kickback Statute and False Claims Act compliance, facilitate repayments when necessary
- Design compliance programs, policies and procedures to address Stark and fraud and abuse laws
- Advise on how to respond and defend against federal and state health care fraud, qui tam, whistleblower and False Claims Act lawsuits

Policy Development and Advocacy

- Advise on comprehensive legislative and regulatory advocacy strategies to ensure client priorities are realized by government.
- Provide industry-leading expertise and advice on the most pressing policy issues facing digital health and telehealth stakeholders
- Develop client priorities into attainable policy proposals and work daily with client and policymakers to advance client goals
- Directly advocate client priorities before policymakers in Congress and within federal agencies
- Monitor and anticipate government actions and opportunities that could impact client business and engage proactively to ensure client priorities are considered
- Engage like-minded stakeholders to build momentum for client policy priorities
- Develop and manage collations to convene digital health thought leaders, identify public policy ideas and direct policy development and advocacy
- Draft legislation, comment letters, correspondence to lawmakers and agencies, policy documents and communications materials to support client advocacy strategy

Track record of success: Transformative guidance

Regulatory

- Assisted a direct-to-consumer telemedicine provider in its formation and initial operations, including structuring management services/PC relationships, telemedicine platform contracting and evaluating its website and advertising content for compliance with FDA and FTC requirements.
- Assisted several pharmaceutical manufacturers with compliant direct-to-consumer advertising programs leveraging telehealth options to increase patient access to their products.

FDA

- Assisted Pear Therapeutics, a company focused on advancing prescription digital therapeutics, on coverage and reimbursement issues related to new product launch with related stakeholder awareness and advocacy initiatives.

Litigation

- Represented Eli Lilly in litigation against SensorRx involving fraud and trade secret claims related to a digital health application for migraine tracking and management.
- Represented a national pharmacy chain with respect to opioid litigation. Many claims are based upon alleged breach of state and federal regulations pertaining to the licensure of pharmacies and pharmacists, the operation of pharmacies (including reporting requirement and record maintenance), and the distribution of various scheduled drugs.
- Represent Surescripts, an electronic prescribing network, in an FTC investigation of its business practices.

Advocacy

- Serve as primary strategic policy advisors to the American Telemedicine Association, the premier national organization solely committed to the advancement of telehealth.
- Staff the Telehealth Encounters Count Coalition, a new multi-stakeholder coalition, to ensure Medicare risk-adjusted programs do not disincentivize the use of telehealth.
- Advocate to expand policy under the Ryan Haight Online Pharmacy Consumer Protection Act. This policy protects behavioral health clinics and addiction treatment facilities' use of telemedicine to prescribe necessary controlled substances remotely, providing access without jeopardizing safety.

Intellectual Property

- Advised a software developer company on a meaningful use measurement tool for a medical software patient data portal.
- Advised a manufacturing company in development, component contract manufacturing and investment in brain stimulation devices.

Key Contacts

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- FDA
- Telehealth/Telemedicine/Pharmacy

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