Hogan Lovells

Medical Device Law

Bringing a medical device to market involves addressing a host of issues: regulatory approval, patents, financing, manufacturing, distribution, and more. After your product debuts, the challenges continue throughout its life cycle, from running compliance programs to responding to enforcement actions. And if you're operating globally, the last thing you want to do is to oversee a patchwork of different firms in different locations.

That's where Hogan Lovells comes in. We operate on a global scale, coordinating among lawyers in offices in all of the world's major medical markets to sequence and streamline regulatory approvals. In the U.S., we've been helping companies get new products approved by the Food and Drug Administration (FDA) since the Medical Device Amendments of 1976 was signed into law.

We understand how to do things in a better way to expedite the FDA approval process, streamline how much data is needed for approval to be granted, and design programs to successfully launch products and ensure continuing compliance. We can also help you develop reimbursement strategies and build the necessary infrastructure for a transaction or initial public offering.

We are unique in achieving all this because of our interdisciplinary team. Many of our lawyers have worked for regulatory agencies and in private industry, and have backgrounds in biostatistics, medicine, biomedical engineering, material science, and genetics, among other

Key contacts

Janice M. Hogan,
Philadelphia

Jonathan S. Kahan,
Washington, D.C.

Trending Topics

Individualized therapies and the future of drug regulation

As science continues to uncover new applications of cell, tissue, and gene therapies, regulators are adopting a more flexible, forward-looking perspective on safety and effectiveness.

The emergence of intelligent systems in health care

With AI being implemented across the health care continuum, FDA and other agencies find themselves contending with the prospect of regulating a

disciplines. This means we understand the technology and can make better arguments on your behalf. From inception and approval to debut and product maturity, we provide guidance that takes into account the complex considerations where business and compliance meet.

Awards and rankings

- Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2018
- Highly Recommended for FDA Medical Devices, *LMG Life Sciences*, 2018
- Regulatory Firm of the Year, *LMG Life Sciences Awards*, 2018
- Ranked second tier for health care and life sciences in the U.S., *The Legal 500*, 2018
- Band 1 for Life Sciences, *Chambers Global*, 2018
- Band 1 for Life Sciences, *Chambers Europe*, 2018

Latest thinking and events

Hogan Lovells Publications

FDA proposes a process for receiving nonbinding feedback on an establishment's response to an FDA Form 483
Medical Device Alert

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Podcast series: False Claims Act 2018 and the road ahead
Podcast

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Would you like an extra application with that? FDA mulls requiring dual applications for combination products
Focus On Regulation

Hogan Lovells Publications

Telehealth promises faster, more convenient access to health care services
Life Sciences and Health Care Videos

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In the midst of government shutdown, FDA pushes ahead with moving target.

A directory of our U.S. government and agency experience

Areas of focus

Adverse Event Reporting
Vigilance Reporting

Advertising and Promotion Compliance

Advisory Panel Preparation

Clinical Trials

Combination Products, FDA Jurisdictional Issues, FDA Postmarket Compliance Issues

In Vitro Diagnostics

Premarket Review

Unique Device Identifiers

510(k) modernization
Medical Device Alert

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MDR single report exemption and ASRs: Coming to an end for most reporters
Medical Devices Alert