Hogan Lovells

Michael S. Heyl

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Biography

Mike Heyl helps medical device companies navigate myriad regulatory and business matters. He guides clients through U.S. Food and Drug Administration (FDA) regulations, requirements, and compliance issues. These issues include FDA's Quality System Regulation (QSR); adverse event reporting; recall reporting requirements; FDA inspections and enforcement actions, such as Warning Letters; defense strategies; and corrective and remedial action plans.

He represents large multinational corporations facing FDA and criminal enforcement, and helps small startups develop and implement postmarket compliance programs. Because he understands FDA's requirements for importing and exporting medical devices, Mike is frequently called on to negotiate the release of detained goods being imported to the United States.

He has assisted in the defense of criminal investigations by the U.S. Department of Justice (DOJ), conducted internal investigations of whistleblower complaints, and prepared strategies for resolving such issues.

Mike also works with device companies in conducting regulatory due diligence and negotiating corporate mergers and acquisitions and initial public offerings (IPOs). He has been involved with numerous transactions ranging from multibillion-dollar acquisitions to the negotiation of supply and distribution agreements.

Languages

English

Practices

Administrative and Public Law

Commercial

Government Relations and Public Affairs

Investigations, White Collar, and Fraud

Marketing and Advertising

Medical Device and Technology Regulatory

Private Equity

Industries

Mike recently became an ISO 9001:2008 certified internal auditor with focus on ISO 13485:2016 and Medical Device Single Audit Program (MDSAP).

Mike is a frequent speaker on regulatory compliance and enforcement issues in the device industry.

Representative experience

Assisted numerous clients to prepare for, defend, and/or respond to domestic and international inspections and enforcement actions.

Assisted a brand name device company with the acquisition of several medical device manufacturers.

Assisted a large multinational corporation with strategy and defense with an FDA enforcement action involving a highly publicized health risk.

Assisted a medium-sized medical device manufacturer in preparing corrective action strategy and drafting a response to an FDA inspection.

Assisted a large company conduct an internal investigation and remediation plan following a whistleblower complaint.

Assisted a medical device manufacturer with a review of promotional materials and remediation strategy following FDA action.

Successfully negotiated the release of devices being detained upon import to the United States.

Assisted a small-sized medical device manufacturer in responding to FDA inspections and grand jury subpoena.

Assisted numerous device manufacturers and companies from other industry sectors in obtaining Emergency Use Authorizations during the COVID-19 pandemic.

Awards and rankings

- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), *Chambers USA*, 2021

Life Sciences and Health Care

Areas of focus

Sales Promotions

Postmarket Compliance and Enforcement Actions

Advertising and Promotion Compliance

In Vitro Diagnostics

Medical Devices

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., The Catholic University of America, Columbus School of Law, magna cum laude, 2002

B.A., University of Delaware, 1993

Bar admissions and qualifications

District of Columbia

Maryland

- U.S. Regulatory Star, *LMG Life Sciences*, 2016-2020
- Shortlisted for Regulatory Attorney of the Year, FDA Medical Device, *LMG Life Sciences*, 2020

Latest thinking and events

- Press Releases
  - Hogan Lovells advises CartiHeal in securing FDA premarket approval for knee implant
- Media Mention
  - 'Where's the patient?': Experts question FDA's final recall guidance *MedTech Dive*
- Hogan Lovells Podcasts
  - Podcast: Talking the cure
- Media Mention
  - FDA identified 28 suppliers unaware of Philips sleep device recall *MedTech Dive*
- News
  - COVID-19 Report for Life Sciences and Health Care Companies
- Insights
  - FDA proposes to conform the Quality System Regulation to the ISO 13485 standard