Hogan Lovells

Postmarket Compliance and Enforcement Actions

It's a reality that medical devices intended to help patients can sometimes cause harm or malfunction. When that happens, how is your company prepared to deal with applicable regulatory requirements?

Hogan Lovells helps companies navigate the complex framework of reporting adverse events to regulatory bodies and governmental agencies related to the use of their devices. Our wealth of experience in this nuanced area allows us to help determine whether an event is reportable and to develop strategies that ensure adverse events are handled effectively, consistently, and in compliance with the law, while in certain instances seeking to develop alternative reporting approaches to streamline regulatory requirements.

We are also able to assist companies in developing remediation strategies and improvement plans where warranted.

Representative experience

We establish regulatory training programs to educate internal units of major medical device and combination product companies about adverse event reporting requirements and procedures.

We have assisted clients in responding to enforcement actions related to inadequate adverse event reporting and helped develop procedures to protect against future enforcement.

Contacts

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Practices

Medical Device and Technology Regulatory

Helped clients conduct retrospective reviews of their files to assess their obligations in submitting Medical Device Reports to the FDA and bring their reporting up to date.

Latest thinking and events

News

FDA warns over use of robotically-assisted surgical devices

News

After a long and winding road, FDA finalizes much-debated "intended use" rule

News

"Remanufacturing" or "Servicing"? New FDA guidance clarifies distinction for medical devices

News

Domestic sourcing guidance issued to help American businesses compete

News

First company receives FDA violation notice for ClinicalTrials.gov submission omission

News

HHS withdraws proposal to exempt 84 medical device types from FDA 510(k) process