Hogan Lovells

Advertising and Promotion Compliance

Our lawyers help companies balance legal compliance with their business objectives helping them to navigate the current environment, highlighted by evolving U.S. Food and Drug Administration (FDA) and EU Member States laws. From regulations and policies governing medical device labeling, advertising and promotion; to the ever-expanding types of media platforms available to companies to promote their devices, the Internet to social media; and ongoing, steady government enforcement.

We advise clients on all aspects of product promotion, from what constitutes permissible discussion of investigational devices to the scope of allowable promotion of cleared, approved, and CE marked devices. We help clients craft promotional strategies that benefit their business while complying with the requirements of the Federal Food, Drug and Cosmetic Act (FDC Act) and FDA regulations, as well as intersection U.S. Federal Trade Commission (FTC) regulations and health care laws, such as anti-kickback statutes and the False Claims Act.

We also counsel on the nuanced and evolving aspects of this area, including First Amendment challenges of FDA and EU restrictions on off-label promotion; avenues for the dissemination of off-label information; the extent to which a manufacturer can be held

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Practices

Medical Device and Technology Regulatory

responsible for third-party materials on traditional and newer media platforms; and the regulation of social media as a marketing tool.

Our services are wide ranging, and include reviewing product promotional materials and programs for compliance with FDA and, when appropriate, FTC, the U.S. Department of Justice (DOJ), and international regulations.

Representative experience

Conduct internal investigations of promotional practices.

Conduct one-off reviews or wholesale audits of promotional materials and activities on traditional and alternative media platforms.

Sit on clients' standing promotional review committees (PRCs).

Conduct salesforce trainings on FDA requirements and expectations with respect to advertising and promotion.

Conduct advertising and promotional trainings for every size of device firm, and for every level within these firms, from C-suite to sales representatives, to lay the groundwork for effective and compliant marketing.

Work with clients to develop SOPs governing the review and approval of promotional materials.

Counsel clients on the inter-relationships between FDA requirements and health care laws to assist these companies in developing and implementing corporate policies and procedures aimed at compliance.

Conducted a corporate investigation of sales and marketing practices, and advised senior managers and corporate boards on the risks and benefits of strategies and tactics.

Conducted internal investigations and compliance audits to ensure that promotional activities did not violate the Federal Food, Drug, and Cosmetic Act.

Review client websites and sit on Promotional Review Committees to assess regulatory risk from proposed promotional strategies and recommend revisions to mitigate risk in delivering key marketing messages.

Assist clients in assuring compliance with European Union and member state requirements and streamlining U.S. and OUS marketing procedures and practices to ensure global compliance.

Latest thinking and events

News

After the Public Health Emergency: FDA plans to revise COVID-19 EUA policies

News

CMS issues initial guidance on Drug Price Negotiation Program

News

The False Claims Act Guide: 2022 and the road ahead

Insights and Analysis

U.S. FDA regulatory insights: the seemingly shifting landscape of clinical decision support

News

Major regulatory changes in pharmaceutical laws and regulations in Spain for 2023

Insights and Analysis

Life Science Law Update – Key developments for pharma and device companies in EU and EU Big Five