Hogan Lovells

Jennifer Agraz Henderson

Partner
Washington, D.C.

Phone
+1 202 637 5783

Fax
+1 202 637 5910

Email
jennifer.henderson@hoganlovells.com

Biography

Jennifer Henderson's extensive background in the health industry lets her strategically navigate U.S. Food and Drug Administration (FDA) regulatory matters for medical device companies – both premarket and postmarket. She helps medical device manufacturers obtain FDA clearance for innovative devices. Be it investigational device exemptions (IDEs), 510(k)s, de novo petitions, or premarket approvals (PMAs), she assists clients in all matters pertaining to premarket submissions.

As the industry has evolved, so has Jennifer's practice. She is well versed in the areas of FDA regulation of mobile health, medical apps, medical software, combination product jurisdictional issues, clinical trial conduct, Bioresearch Monitoring matters, medical device appeals, and conducting regulatory due diligence.

A key piece of Jennifer's practice is the advertising and promotion of medical devices, from traditional media platforms like print and TV ads to global websites and social media platforms. She helps clients in comprehensive audits of promotional materials and provides strategic advice regarding development of marketing strategies and procedures and policies. Jennifer is frequently asked to provide in-house training on advertising and promotional issues. She has also

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

authored numerous articles on medical device regulation, advertising and promotion issues, and mobile health.

Jennifer learned the ins and outs of the industry at the Center for Integration of Medicine & Innovative Technology (CIMIT), a nonprofit consortium of the Harvard Medical Institutions and the Massachusetts Institute of Technology (MIT), dedicated to medical product innovation and development. She also held several academic positions, including Research Fellow and research associate, at Massachusetts General Hospital, as well as Instructor in Dermatology at Harvard Medical School.

Representative experience

Counsel to a U.S. publicly traded software company in the cross-border sale of a business unit.

Helped client obtain a favorable outcome on appeal for a resorbable mesh with antibiotic coating in a contested 510(k) notice.

Conducted full-day bioresearch monitoring training for global imaging device company.

Conducted comprehensive audit of advertising and promotional materials and policies for global device firm, including updating relevant SOPs.

Conducted comprehensive audit of device modifications for global orthopedic firm, including updating SOPs and developing remediation plan.

Awards and rankings

- Healthcare: Life Sciences, *Legal 500 US*, 2018

Latest thinking and events

- Hogan Lovells Publications
  - Clarifying clinical decision support: FDA overhauls guidance to focus on risk *Medical Device Alert*

Areas of focus

Advertising and Promotion Compliance

Combination Products, FDA Jurisdictional Issues, FDA Postmarket Compliance Issues

Medical Devices

Digital Health

Education and admissions

Education

M.P.H., Boston University School of Public Health, 2002

J.D., Boston University School of Law, 2001

B.A., Middlebury College, 1996

Memberships

RAC (US) Certification, Regulatory Affairs Professionals Society, 2005

Bar admissions and qualifications

District of Columbia

Massachusetts

- Hogan Lovells Publications
  - FDA issues draft guidance on providing regulatory submissions in electronic format *Medical Device Alert*
- Hogan Lovells Publications
  - FDA announces new expedited program for devices expected to significantly improve the safety of existing technologies *Medical Device Alert*
- Hogan Lovells Publications
  - FDA releases four final guidances on the 510(k) program; Special 510(k) guidance confirms new approach to eligibility and broader potential for IVDs *Medical Device Alert*
- Hogan Lovells Publications
  - Final guidance provides additional clarity to the Humanitarian Device Exemption program *Medical Device Alert*
- Hogan Lovells Publications
  - De Novo requests: FDA releases updated RTA checklist *Medical Device Alert*