Cassie Scherer

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Profile

Results-driven with a proven track record in navigating complex regulatory landscapes and shaping impactful and fit-for-purpose regulatory policy. Adept at designing and executing policy and advocacy initiatives that promote innovation and compliance. Skilled in educating internal teams on evolving digital health policies and regulation. Established connections with key stakeholders in government agencies and industry associations. Client-focused and driven to deliver for internal and external clients. Experienced in leading teams and fostering a collaborative and informed work environment.

Career Experience

Medtronic, Washington, DC **2016 – Present**
Senior Director of U.S. Regulatory and Global Digital Health Policy, 2022-Present
Director of Digital Health Policy and Regulatory Strategy, 2021-2022

Develop and implement global digital health regulatory strategy to drive innovation. Provide strategic guidance to leadership on emerging digital health trends by anticipating regulatory challenges and opportunities to drive business growth and maintain a competitive edge in the market.

- Lead cross-functional working groups, including Regulatory, Quality, Government Affairs, Legal, R&D and Clinical in providing comments to legislation, regulations and guidance and ensure successful implementation of new and evolving requirements.
- Developed and launched Medtronic position papers on critical artificial intelligence (AI) issues and Medtronic's AI ethical guidelines to demonstrate Medtronic's commitment to developing AI-enabled technologies responsibly.
- Analyze impact of new and changing regulatory policy to Medtronic and provide emerging issue briefings to senior leadership.
- Interact with global regulatory authorities directly and indirectly through industry associations to educate and influence on medical device policy and regulation.
- Established and maintain relationships with key stakeholders, including regulators and industry associations, to influence and shape digital health policies. Examples include serving as a co-lead with U.S. Food and Drug Administration (FDA) on the Medical Device Innovation Consortium Digital Health Program and as an industry representative for the International Medical Device Regulators Forum Software as a Medical Device Working Group.
- Effectively educate internal teams on evolving digital health policies.

Senior Principal Legal Counsel, Enterprise Legal Regulatory, 2016-2021

Provided counsel to corporate functions, Medtronic businesses, and global regions on managing risk and developing compliant regulatory strategies regarding the total product lifecycle of medical devices, including design, regulatory submissions, clinical data and marketing and promotion.

- Provided strategic advice to business units on issues relating to FDA 510(k) premarket notifications and premarket approval applications, including review of pre-submissions and counsel on communications with the Center for Devices and Radiological Health (CDRH).
- Led cross-functional groups, developed internal policy, and conducted trainings to provide knowledge throughout Medtronic on FDA legal and regulatory issues affecting Medtronic, such as issues relating to medical device advertising and promotion and FDA import issues.
- Partnered with Corporate Regulatory, Government Affairs and AdvaMed to comment on key FDA guidances and regulations and to impact draft legislation.
- Counseled internal clients on compliance with FDA laws and regulation, including regulation of advertising and promotion, digital health products, labeling, 510(k) modifications, and quality systems.

Covington & Burling LLP, Washington, DC **2014 – 2016**
Special Counsel

Provided advice to medical device and pharmaceutical clients on premarket and postmarket FDA regulation of innovative technologies, such as software and mobile application products, companion diagnostics, and combination products.

- Collaborated with client decision-makers to develop optimal strategies for interacting with FDA, including strategies for clinical development and premarket review of medical devices.
- Advised on compliance with postmarket requirements and actions, including advertising and promotion restrictions, quality system requirements, and responding to FDA warning letters.

- Prepared clients for meetings with FDA, assisted in developing submissions to FDA, such as IDE applications and pre-submission briefing documents, and initiated and facilitated meetings with key FDA personnel.
- Counseled companies on clinical trial agreements and informed consents.
- Conducted M&A regulatory due diligence for pharmaceutical and medical device companies.

Food and Drug Administration, Silver Spring, MD 2009 – 2014

Director for Strategy and Regulatory Operations, Office of Center Director, CDRH, 2013-2014
Policy Advisor, CDRH, 2012-2013

Advised and consulted CDRH leadership on legal and policy matters related to emerging medical device issues. Developed and implemented new CDRH regulations and policy.

- Managed program, regulatory and policy analysts in developing medical device policy and drafting regulations and key FDA guidance documents, including FDA's General Wellness guidance.
- Analyzed and reviewed potential impact of proposed legislation on CDRH programs, formulated legislative proposals to support mission critical goals, and prepared responses to Congressional inquiries related to CDRH matters.
- Managed the implementation of the provisions of the Food and Drug Administration Safety and Innovation Act of 2012 relating to medical devices and formulated FDA legislative-related deliverables, such as regulations and reports.
- Provided regulatory counsel on responses to appeals from medical device manufacturers to CDRH's Office of the Center Director.

Associate Chief Counsel, Office of Chief Counsel, 2009-2012

Provided legal advice to FDA on issues relating to medical devices and radiation-emitting products, including advising and supporting CDRH with respect to issues relating to the humanitarian device exemption program, medical device reporting, and patient safety organizations.

- Assisted CDRH on development of responses to citizen petitions and congressional inquiries.
- Counseled FDA on issues relating to medical device safety issues and FDA premarket and postmarket actions, including development of guidances and issuance of FDA warning letters.
- Selected as Special Assistant to the General Counsel of Department of Health and Human Services. Provided legal support to the National Institutes of Health, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services.

Additional Experience

Latham & Watkins, Associate, Health Care and Life Sciences Group, Washington, DC 2006 – 2009

- Counseled pharmaceutical manufacturers, medical device companies, and hospitals on health care regulatory matters such as compliance with FDA regulations, federal and state fraud and abuse laws, and the Health Insurance Portability and Accountability Act (HIPAA).
- Assisted pharmaceutical and medical device companies with initiating, managing, and completing large-scale, international clinical trials by drafting and negotiating clinical trial agreements, contracting with and managing clinical research organizations, and developing FDA regulatory strategy.
- Conducted regulatory diligence and drafted purchase and merger agreements in connection with mergers and acquisitions and joint ventures for medical device, pharmaceutical, and biotechnology companies.
- Drafted U.S. Securities and Exchange Commission disclosure statements for medical device companies and pharmaceutical manufacturers concerning federal and state fraud and abuse, HIPAA, and FDA laws.

Education

Juris Doctor | University of Virginia School of Law, Charlottesville, VA

Bachelor of Arts, English | University of Pennsylvania, Philadelphia, PA

- Summa cum laude, with Honors; Phi Beta Kappa

Certificates

Bar Admission | District of Columbia