

ZACHARY A. ROTHSTEIN

1301 Pennsylvania Ave, NW, Suite 400, Washington, DC, 20004

PROFESSIONAL EXPERIENCE

ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED)

Washington, D.C.

Executive Director, AdvaMedDx

July 2022-Present

- Lead Division with membership of more than 70 *in vitro* diagnostic test manufacturers, including a 24-person Board of Directors made up of CEOs and General Managers.
- Direct US and global policy, advocacy, communications, regulatory, payment and legislative strategy and operations of AdvaMedDx by leading a multidisciplinary team of experts.
- Work with the Board of Directors, member companies, and the AdvaMed organization to develop and implement strategies to advance AdvaMedDx member's public policy interests.
- Develop a 5-year strategic plan in consultation with the Board of Directors and lead the implementation and execution of the strategic plan.
- Establish partnerships with allied organizations to coordinate and align the strategic plan and related policy work of the industry at the domestic and global level.
- Serve as the AdvaMedDx representative at the global organization and trade association level.

Senior Vice President and Department Deputy, Technology & Regulatory Affairs

June 2021-July 2022

Vice President, Technology & Regulatory Affairs

June 2018 – June 2021

Associate Vice President, Technology & Regulatory Affairs

April 2015 – June 2018

General Duties:

- Lead, and collaborate with, association members to develop consensus regulatory policy positions of the medical device industry in response to existing and proposed regulations, laws, and legislation through developing comments, policy documents, legislative text, and advocacy strategies.
- Advocate on behalf, and in support, of industry priorities in meetings before domestic and international regulators and lawmakers (including China, Japan, South Korea, India, Canada, the United Kingdom, European Commission, and World Health Organization (WHO)) and at public events and conferences.
- Provide strategic advice to members for legal and regulatory matters related to domestic and international medical device regulations.
- Represent AdvaMed and the medical device industry throughout all meetings and discussions concerning the fifth Medical Device User Fee Agreement (MDUFA V), commitment letter, and implementing legislation, and provide regular updates and briefings to members and the AdvaMed Board of Directors.
- Named as a member of the WHO's Digital Health Roster of Experts.

Special Assignments:

- Established, grew, led, and directed the operation and efforts of the AdvaMed Center for Digital Health and managed the Executive Leadership Group (ELG); worked with the ELG and across AdvaMed departments to develop and implement the industry's digital health strategy and policy agendas.
- Worked directly with the General Counsel to establish and build-out AdvaMed's COVID-19 Action Team; coordinated across all AdvaMed departments on matters related to the medical device industry's response to COVID-19, including leading multiple workstreams on COVID-19 advocacy, policy development and establishment of industry forums and tools; developed, grew and maintained partnerships with Federal agencies, the Administration, other associations and private sector partners to coordinate and promote industry's response to COVID-19.
- Created, launched and managed the operations of the MedTech Cybersecurity Information Sharing and Analysis Organization (ISAO), an entity that enables medical device companies to securely and confidentially share cybersecurity threat information.

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SAMSUNG ELECTRONICS

Deputy Senior Counsel, Public Policy and Medical Devices

Washington, D.C.

June 2013 – April 2015

- Acted as sole attorney for, and provided strategic advice to, Samsung Electronics' global business units and Chief Medical Officer with respect to laws and regulations affecting digital health, Health IT, medical imaging equipment, and other medical device products through all stages of product development.
- Engaged with domestic and international medical device regulators to negotiate go-to-market strategies for new products and those in development.
- Planned and executed global healthcare legal, regulatory and legislative policy objectives; provided detailed analysis of, and identified potential market opportunities arising from, proposed and pending domestic and international legislative and regulatory matters.
- Served on the Board of Directors for the Consumer Technology Association (CTA) Health and Fitness Technology Division, and the Personal Connected Health Alliance (formerly Continua).

MORGAN, LEWIS & BOCKIUS LLP

Associate Attorney, FDA Practice Group

Washington, D.C.

September 2012 – June 2013

- Counseled clients on legal and regulatory matters involving medical devices, drugs, foods, dietary supplements, cosmetics, and consumer products.
- Advised and represented clients in enforcement proceedings and product recalls before the Food and Drug Administration (FDA), Federal Trade Commission (FTC), and Consumer Product Safety Commissions (CPSC).
- Reviewed product labels, advertising, and promotional materials for compliance with FDA and FTC requirements; assisted clients with labeling and advertising substantiation.

K&L GATES LLP

Associate Attorney, FDA Practice Group

Washington, D.C.

March 2012 – September 2012

- Practice group moved to Morgan Lewis; same job duties.

KELLER AND HECKMAN LLP

Associate Attorney, FDA and Consumer Product Safety Practice Groups

Washington, D.C.

August 2010 – March 2012

Law Clerk

December 2009 – May 2010

Summer Associate

June 2009 – August 2009

- Counseled clients on domestic and international health, science and product liability issues.
- Assisted businesses in designing and strengthening risk management and compliance strategies under U.S. and international administrative and regulatory laws.
- Advised clients in enforcement proceedings and product recalls before the FDA, FTC and CPSC.
- Drafted and negotiated complex transactional documents.

EDUCATION

THE CATHOLIC UNIVERSITY OF AMERICA, COLUMBUS SCHOOL OF LAW, Washington, D.C.

Juris Doctor; Certificate in Communications Law Studies

- *Class Recipient*, Law School Alumni Society Award
- *2009 National Telecommunications Moot Court Competition*, Overall Winner and Best Brief
- *Catholic University Law Review*, Note and Comment Editor
- *Catholic University Moot Court Association*, President
- *Communications Law Student Association*, Vice President

INDIANA UNIVERSITY, Bloomington, Indiana

- Bachelor of Arts; Double Major in Political Science and Criminal Justice

LICENSURES

- Virginia State Bar; District of Columbia Bar