Michael M. Gaba

FOOD & DRUG VICE CHAIR
he / him / his

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Michael Gaba provides strategic FDA regulatory, Medicare policy, and federal relations counsel to an array of companies developing a variety of products in the life sciences space, whether traditional medical devices, digital health-based products, biotechnologies, biologic-device combinations, or pharmaceuticals. His primary goal is to bring companies to market and then help them remain there in the most efficient and effective manner possible.

Working as an extension of each company's legal and business teams, Michael draws on nearly 30 years of experience to navigate the FDA pre-market regulatory pathways, counsel companies on FDA post-market compliance matters, and resolve Medicare coverage, coding, and reimbursement disputes with the Centers for Medicare and Medicaid Services. By using his FDA and CMS experience during the product development phase, Michael is able to help maximize companies' opportunities to be appropriately compensated in the proper treatment venues, whether a physician's office, hospital outpatient or inpatient departments, ambulatory surgical centers or home care.

During the COVID-19 pandemic, Michael provided strategic FDA counsel to many medical device and diagnostic companies, including several first-time entrants to the medical device space, helping them obtain emergency use authorizations from the FDA, and advising them on how to comply with FDA's pandemic-focused enforcement discretion policies. Michael continues to advise these companies on transitioning to full FDA compliance in the post-pandemic environment.

There are times when federally-regulated life science companies and the patients they serve would benefit from changes to public policy, Michael works with members of Congress and Executive Branch officials to develop, enact and implement these policy changes.

Education

- The George Washington University Law School (J.D., 1986)
- Franklin & Marshall College (B.A., 1983)
    - Government

Capabilities

- Digital Health
- Federal Government Policy/Lobbying
- Food, Drug & Device
- Medical Devices
- Laboratories
- Life Sciences
- Pharmacy
- Post Chevron Educational Resources & Updates

Bar Admissions

- Maryland, 1987
- District of Columbia, 1988

Court Admissions

- U.S. District Court for the District of Columbia
- State of Maryland

Memberships

- American Health Law Association
- Maryland Bar Association
- District of Columbia Bar Association
- Food and Drug Law Institute

Recognition

- Ranked in *Chambers USA: America's Leading Lawyers for Business*, Healthcare Pharmaceutical/Medical Products Regulatory, District of Columbia, 2007-2014, 2021-2025
- Selected for inclusion in *Best Lawyers in America*® for Health Care Law, 2014-2026
- FDAnews Medical Device Conferences Advisory Board Member, 2017-present
- AdvaMed, Medical Technology Learning Institute Advisory Council, 2015-present
- Food & Drug Law Institute, Food & Drug Law Journal Editorial Advisory Board, 2009--2013
- Bloomberg BNA Medical Devices Law & Industry Report Advisory Board, 2007-2018
- Food & Drug Law Institute, H. Thomas Austern Writing Awards Committee, 2006--2010

Matters

- Obtained release of detained imported VTM test kits intended for use during the COVID-19 pandemic by persuading FDA that the product was eligible for entry under the agency's enforcement policy.
- Negotiated a rapid medical device review with the FDA resulting in the clearance of an amendment to a 510(k) and a follow-on Special 510(k) within 80 days of starting the project.
- Advised clients producing Personal Protective Equipment for use during the COVID-19 pandemic on how to obtain an Emergency Use Authorization or comply with FDA enforcement policies.
- Negotiated a 510(k) pathway with the FDA for a first of its kind medical device, avoiding the de novo process, and resulting in a 510(k) clearance.
- Successfully appealed an FDA rejection of a clinical trial design for a PMA supplement to enable the medical device company to embark upon its study, leading the FDA to issue guidance to redefine the proper balance between pre-market and post-market data requirements.

Publications

January 15, 2026
Industry Says FDA Loosening Regs On Wearable And Digital Products Is Good For Innovation
Quoted, Medtech Insight

January 8, 2026
FDA's new general wellness guidance is no dramatic overhaul
Quoted, BioWorld

January 8, 2026
Ringing in the New Year with Digital Health: FDA Updates Guidance Documents on Clinical Decision Support Software and General Wellness Products

January 8, 2026
Polsinelli Life Sciences Spotlight - Volume 3 - Turning Insight into Action: A Life Sciences Playbook for 2026

October 8, 2025
Are Medical Device Manufacturers Exempt from FDA's Push for "Radical Transparency"?
Author, AAMI

April 14, 2025
Using AI in hospitals: the HIPAA hurdle
Quoted, Medical Technology

April 1, 2025
In Landmark Ruling, Eastern District of Texas Strikes Down FDA's Final Rule Regulating Laboratory Developed Tests

March 13, 2025
In-House Influence Podcast
Co-Host, In-House Influence Podcast, Washington, D.C.

February 19, 2025
MAHA Commission expected to impact approach to medications, vaccines, research
Quoted, McKnights Senior Living

February 11, 2025
CISA and FDA Sound Alarm on Backdoor Cybersecurity Threat with Patient Monitoring Devices

February 6, 2025
Generative Artificial Intelligence Leveraged to Deliver Healthcare - Legal Risks and Issues

January 8, 2025

Polsinelli Life Sciences Spotlight - Volume 1 - Looking Back, Moving Forward: A Year in Life Sciences

August 7, 2024
Top Questions Health Care Providers Should Consider in a Post-Chevron World – A Polsinelli Round Table Discussion

July 29, 2024
Challenges to LDT Final Rule Continue as Rule Goes into Effect

May 6, 2024
FDA Finalizes Rule Regulating Laboratory Developed Tests

February 27, 2024
FDA 2023-24: A Look Back & A Peek Forward
A Curated FDA Review

July 31, 2023
Triaging Health Risks in the Cosmetic World: FDA Says Let's Start with Tattoo Inks

August 9, 2022
Medical Device Premarket Review Pathways and FDA Mechanisms for Expedited Review
Presenter, FDA News

June 24, 2022
Strategically Managing Health Care Policy: The Food and Drug Administration: Policy and Process
Presenter, The Washington Campus MBA Health