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Mark C. Levy

MEMBER

Mark Levy is a litigator and trial attorney who has spent most of his career defending manufacturers of consumer products in heavily regulated industries in civil claims brought by private plaintiffs as well as both civil and criminal charges initiated by federal, state, and local law enforcement agencies. Mark regularly handles matters involving threatened or actual enforcement actions undertaken by agencies, commissions, and departments of the United States such as the Food and Drug Administration ("FDA"), Federal Trade Commission ("FTC"), Environmental Protection Agency ("EPA"), Department of Defense ("DOD"), and Consumer Product Safety Commission ("CPSC") as well as matters initiated by the various state enforcement agencies including state attorneys general.

As an outgrowth of his experience with these government agencies, Mark regularly provides risk-management counseling and regulatory advice to businesses that manufacture and sell products for consumer use. This includes developing, expanding, and implementing corporate compliance programs and assessing the risks of litigation in complex, multi-party litigation.

Mark has also conducted internal investigations, from routine to serious, for dozens of companies in the pharmaceutical, medical device, oil and gas, sports apparel, services, retail goods and manufacturing industries.

After graduating law school, Mark served as law clerk to the Honorable James T. Giles, United States District Court for the Eastern District of Pennsylvania.

REPRESENTATIVE MATTERS

- **Regulatory Enforcement | FDA and state agencies:** Represented manufacturers and distributors in enforcement actions arising from alleged failure to comply with regulatory requirements including those related to clinical trials, regulatory submissions, registration, marketing and labeling, and manufacturing practices.
- **Regulatory Enforcement | FTC and state agencies:** Represented consumer goods manufacturers in responding to federal and state enforcers related to alleged false or misleading advertising/labeling claims including "green claims" and "health claims."
- **Regulatory Enforcement | CPSC:** Represented consumer goods manufacturers, box store retailers and on-air retailers in

PRACTICE AREAS:

Product Liability

Life Sciences

White Collar Defense & Internal Investigations

Commercial Litigation

STATE ADMISSIONS:

Pennsylvania

Massachusetts

EDUCATION:

J.D., Villanova University School of Law; Managing Editor, *Villanova Law Review*

B.A., Wesleyan University

reporting and responding to the CPSC.

- **Regulatory Enforcement | Environmental:** Represented former railroad in one of the largest state investigations into alleged violations of environmental laws; represented contractors in state and federal investigations arising from construction of Revolution and Mariner East Pipelines; represented glass manufacturer in nationwide state and EPA matters.
- **Regulatory Enforcement/Proposition 65:** Represented manufacturers and sellers of products in allegations by private enforcers under California's Proposition 65.
- **Investigations | Pharmaceutical/Medical Products:** Internal investigations for medical device pharmaceutical, nutraceutical and cosmetic manufacturers on alleged illegal marketing practices including off-label use.
- **Investigations | Government Contracts:** Conducted investigation for waste handling company involving minority contracting issues; Conducted investigation involving billing and mishandling of classified information under various DOD contracts.
- **Investigations | Environmental:** Conducted investigations for hospitality industry company and transportation company arising from waste disposal issues.
- **Compliance | Compliance Programs:** Represented medical device manufacturers in developing compliance programs to address recent areas of government enforcement; assisted international aid/health program in revisions to its global compliance program (American Red Cross).
- **Compliance | Recalls:** Represented medical device, cosmetic, food, specialty oil producer and retailers in evaluating and responding to voluntary and mandatory recalls.
- **Trial | Government Contracting:** Represented largest public service provider in United Kingdom in arbitration over the provision of services related to the reconstruction of Iraq.
- **Trial | Pharmaceutical/Medical Products:** Represented pharmaceutical and medical device manufacturers in defense of mass tort claims, class action suits and product liability actions as well as commercial litigation arising from contractual disputes.
- **Trial | Products Liability/Environmental:** Represented oil and gas producers in products liability cases as well as individual executive of oil and gas company charged under the Park Doctrine.

PROFESSIONAL AFFILIATIONS

- Food and Drug Law Institute ("FDLI"), Medical Products Committee, Medical Devices Committee, Advertising and Promotion Conference Committee, and Enforcement Conference Committee
- Philadelphia Bar Association Federal Courts Committee
- Philadelphia Bar Association Judicial Evaluation Committee, Investigatory Panel Member/Team Leader
- Philadelphia Volunteers for the Indigent Program, Past President and Board Member

- Villanova University J. Willard O'Brien American Inn of Court, Member

COMMUNITY INVOLVEMENT

- Planning Commission, East Goshen Township, PA (2019-Present)

AWARDS AND RECOGNITION

- Selected for inclusion as The Best Lawyers in America 2023 and 2024 for Commercial Litigation
- American Bar Foundation, Fellow
- Selected for inclusion in *Pennsylvania Super Lawyers*
- Attained an AV® Preeminent™ rating from Martindale-Hubbell
- Named multiple times to the First Judicial District (Philadelphia) Pro Bono Honor Roll

NEWS AND INSIGHTS

PUBLICATIONS

- **Article:** "FTC provides companies a valuable opportunity to comment on updates to its "Green Guides"" Westlaw Today, February 2023.
- **Article:** "Preparing for when the government comes knocking," Eckert Seamans' Construction Law Update, Spring 2014.
- **Article:** "Developments in Enforcement of Off Label Promotional Activities," Food and Drug Law Institute Update, September /October 2012.
- "The Responsible Corporate Officer Doctrine – The Doctrine No Longer Sleeps for Drug and Device Companies," Food and Drug Law Institute Update, July/August 2010.
- **Book:** "Off-Label Communications: A Guide to Sales and Marketing Compliance: Fourth Edition," The Food and Drug Law Institute.
- **Book:** "Off-Label Promotion: Government Theories of Prosecution and Facts that Drive Them," Food and Drug Law Journal, Volume 65, Number 3.
- **Book:** "Defending a Pharmaceutical, Medical Device, or Biotechnology Client in a Government Investigation: Key Issues for Clients and Attorneys, Agencies in Food and Drug Law," Aspatore Books.
- **Book:** "Compliance Training Handbook for Medical Device Sales Representatives," ePharmaceuticals.

MEDIA COVERAGE

- "Cleaning co. entitled to $3.2M over 'ghost employee' scheme," Rhode Island Lawyers Weekly, June 2023.
- "Spoliation of Evidence Yields Default Judgment," Rhode Island Lawyers Weekly, August 2022.

SPEAKING ENGAGEMENTS

- “Violations, Enforcement, and International Issues,” presenter, Food and Drug Law Institute course, Introduction to Biological Products, Including Vaccines, Biosimilars, Cell and Gene Therapies, and Other Advanced Therapies, October 19, 2023.
- “DTC Without Borders: Global Promotion and Compliance with non-DTC Countries,” presented at the Food and Drug Law Institute (“FDLI”)’s Advertising & Promotion for Medical Products Conference, on October 13, 2022.
- “Inter-Agency Enforcement Updates and Priorities,” moderator, Food and Drug Law Institute Advertising and Promotion Conference, October 2021.
- “Violations, Enforcement, and International Issues,” co-presenter, Food and Drug Law Institute course, Introduction to Drugs, Biologics and Biosimilars Law and Regulation, August 2020.
- “FSMA Enforcement Actions Begin: Trends and Unanswered Questions,” presented at the Food and Drug Institute’s Enforcement Litigation, and Compliance Conference, December 2019.
- “Medical Product Off-Label Use and Marketing: How to Conduct an Internal Investigation,” FDA News Webinar, October 2019.
- “How is 3D Printing Revolutionizing the Medical Device Industry?” panelist, Food and Drug Law Institute’s Conference on Medical Devices: FDA Regulation in the Era of Technology and Innovation, San Francisco, June 2019.
- “Machine Learning, AI, and Digital Health” panel presenter, as part of the Food and Drug Law Institute’s Annual Conference in Washington, D.C., on May 2-3, 2019.
- “Inspections in the FSMA Environment,” presented at the FDA Food Enforcement and Compliance Conference, April 2018.
- “Compliance Issues with the Food Safety Modernization Act Enforcement,” presented at the Litigation and Compliance Conference for the Drug, Device, Food and Tobacco Industries, December 2017.
- “Meeting the Challenge: Managing Internal Investigations in Today’s Regulatory Framework and Pro-Enforcement Environment,” co-presented with Richard Wiedman, Eckert Seamans’ Continuing Legal Education Seminar.