

## Nina M. Gussack

Senior Counsel

Philadelphia

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A nationally recognized leader of the pharmaceutical and medical device defense bar, Nina Gussack is sought after for her ability to find effective strategies to resolve the hardest and most complex of cases.

### OVERVIEW

Nina's trial practice is concentrated in civil litigation, with a primary emphasis in the defense of pharmaceutical and medical device companies regarding marketed products, investigational new drugs, medical devices, and over-the-counter drug products. Nina serves as national coordinating and trial counsel and as regional counsel in pharmaceutical litigation, including class actions and multidistrict litigation.

Nina also represents pharmaceutical manufacturers, consultants, and academic institutions in civil and criminal actions in related complex litigation involving health care fraud and abuse, and the defense of individual and class actions. She has conducted internal corporate investigations, audits, and negotiations with government agencies, as counsel to pharmaceutical companies in grand jury proceedings and multistate investigations. Her practice includes counseling regarding regulatory issues governing clinical trials and compliance in promotional activities, as well as Lanham Act claims in the pharmaceutical industry.

She is the recipient of numerous awards and high national rankings from legal publications, including being named to the "Top 10 Female Litigators" in the U.S. by *Benchmark Litigation*, based on receiving "the most robust and vocal 'best in class' nominations" by peers and clients. Nina also was named by the national legal newswire *Law360* as one of the "10 Most Admired Product Liability Attorneys" in the country; has been listed in *Best Lawyers in America* for Product Liability Litigation – Defendants every year since 2013; and was honored by *LMG Life Sciences* as Life Sciences Lawyer of the Year in 2015. She also is a member of the LMG Life Sciences Hall of Fame and has been selected as a Life Sciences Star by *LMG Life Sciences* every year since 2012.

Nina is a frequent writer and lecturer on medical, pharmaceutical, and medical device issues, and has given presentations at ACI, PhRMA, DRI, Drug Information Association (DIA), Food and Drug Law Institute (FDLI), and American Law Institute-American Bar Association (ALI-ABA) programs on fraud and abuse issues, federal preemption, off-label promotion, minimizing civil liability risks during pendency of a government investigation, clinical trials, Daubert challenges, informed consent, and risk management in the pharmaceutical industry. She also is a member of the Steering Committee of the Emory Law Institute for Complex Litigation and Mass Tort Claims, which supports the judiciary and the bar by advancing the understanding of new developments and trends in the resolution of mass claims within and outside of litigation.

Nina is a fellow of The Pepper Center for Public Service. The Pepper Center draws on the talents of the firm's retired partners and senior attorneys to wrestle with tough problems facing our communities. Through the center, these attorneys study, analyze, and work to resolve problems that affect the lives of people in our communities.

## REPRESENTATIVE MATTERS

- Lead MDL counsel for numerous pharmaceutical and medical device manufacturers.
- National trial counsel for litigation involving antipsychotic medication.
- Counsel for various pharmaceutical entities conducting internal investigations and defending against parallel, federal and state, criminal and civil investigations.
- Lead trial counsel in state attorney general actions alleging consumer fraud/unfair trade practices.
- National trial counsel for litigation involving diabetes medication.
- Lead counsel to an academic institution and clinical investigators in civil litigation, governmental investigations, a congressional investigation, and FDA CBER regulatory proceedings arising from a gene therapy clinical trial.
- National counsel for medical device and pharmaceutical manufacturers in litigation preparation for high-risk products, including review, analysis, and strategic guidance regarding regulatory inquiries, clinical trials, prepublication review of medical literature, marketing and DTC materials, consumer complaints, payor issues, research and development, and sales and marketing activities.
- Trial counsel to pharmaceutical companies in Lanham Act litigation.
- National counsel in litigation for a number of companies regarding clinical trial adverse events.
- National trial counsel for litigation involving over-the-counter surgical preparation product.
- Counsel for litigation involving cardiovascular medical devices.

## AWARDS

- Named to the *City & State Pennsylvania's* "The 2022 Impact 50" list (2022)
- Listed in *Lawdragon 500 Leading Litigators in America* (2023)
- *Pennsylvania Super Lawyers* (2004-2021)
- Highly rated at the national level for product liability litigation in *Chambers USA: America's Leading Lawyers for Business*, which researches the reputation of leading lawyers across the U.S.
- Named by the national legal newswire *Law360* as one of the "10 Most Admired Product Liability Attorneys" in the country (September 2010)
- *Best Lawyers in America®*: Product Liability Litigation – Defendants (2013-2026)
- Selected as Product Liability Lawyer of the Year by LMG Life Sciences (2015)
- Inducted into the LMG Life Sciences Hall of Fame (2015)
- Selected as a Life Sciences Star in *LMG Life Sciences* (2012-2019)
- *Legal 500 United States* for Product Liability Litigation (2013-2022, 2024)
- Named to *Lawdragon's 500 Leading Lawyers in America* every year since its inception in 2005
- Listed in *Benchmark Litigation* as a litigation star in the United States and as a local litigation star in Pennsylvania; named to "Top 100 Trial Lawyers" (2017-2018); "Top 10 Female Litigators" (2016-2018); *Benchmark: Top 250 Women in Litigation* (2012-2018)
- Listed in the life sciences and product liability sections of *Who's Who Legal: The International Who's Who of Business Lawyers*, is listed in *Who's Who Legal 2017*, *Who's Who Legal: Product Liability Defence 2017* and *Who's Who Legal: Life Sciences* 2015, 2018, and 2019, and is listed in *The International Who's Who of Liability Defense Lawyers* in the area of product liability defense
- Selected for *The Legal Intelligencer's* Lifetime Achievement Award, which recognizes "noteworthy individuals...who have helped to shape the law in Pennsylvania" (2014)

- Received the Rainmaker Award from the Transformative Leadership Awards Committee and *Inside Counsel* magazine, in recognition of her success as a business generator and her leadership in promoting the advancement of women in the profession (2013)
- Recognized as a “Best of the Bar” honoree by the *Philadelphia Business Journal* (2017)

## TOP AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Fraud + Abuse Litigation + Investigations
- Health Care + Life Sciences
- Pharmaceutical + Medical Device Litigation + Counseling

## ALL AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- False Claims Act + Other Whistleblower Actions
- Fraud + Abuse Litigation + Investigations
- Health Care + Life Sciences
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability
- State Attorneys General
- White Collar Litigation + Investigations

## PROFESSIONAL/COMMUNITY INVOLVEMENT

- Chair, Finance Committee, Board of American Foundation for Suicide Prevention
- Board member, WHYY

## EDUCATION AND CERTIFICATIONS

### EDUCATION

- Villanova University Charles Widger School of Law, J.D., *magna cum laude*, member, *Villanova Law Review*
- University of Pennsylvania, M.S., *magna cum laude*, secondary education
- University of Pennsylvania, B.A., history

### BAR ADMISSIONS

- Pennsylvania
- New York

### COURT ADMISSIONS

- U.S. Court of Appeals, Fourth Circuit
- U.S. District Court, District of Columbia

- U.S. Court of Appeals, Eighth Circuit
- U.S. District Court, Southern District of Indiana
- U.S. Court of Appeals, Second Circuit
- U.S. Court of Appeals, Seventh Circuit
- U.S. Court of Appeals, Sixth Circuit
- U.S. Court of Appeals, Third Circuit
- U.S. District Court, Eastern District of Pennsylvania

## **SPEAKING ENGAGEMENTS**

- Speaker, “COVID-19: A Year Later. Where Do We Go From Here?,” Troutman Pepper, March 23, 2021.

## **MEDIA COMMENTARY**

- Profiled and interviewed, “Best Law Firm Mentors 2023: Nina M. Gussack,” *The Legal Intelligencer*, June 11, 2023.