

Andy J. Miller Counsel

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Andy focuses on the intersection of litigation and regulatory issues within the health care industry.

OVERVIEW

Andy handles complex multiparty and multidistrict cases, while also navigating regulatory landscapes, including FDA, ACA, 340B, and HIPAA compliance. He has an extensive background in litigation and regulatory compliance.

Andy served in the National Complex Litigation and Investigations Division of the U.S. Department of Health and Human Services, where he managed high-profile cases across its litigation and regulatory portfolio. He was appointed by the HHS secretary as one of only six individuals to serve as a panel member on the newly formed 340B Administrative Dispute Resolution Board to adjudicate disputes between covered entities and manufacturers. Andy was also a special attorney for the Commercial Litigation Branch, Civil Division of the U.S. Department of Justice.

Andy also represents clients in antitrust actions related to pharmaceutical products, including actions involving reverse payments, product hopping, and REMS. During law school, he served as a research assistant for Professor Herbert Hovenkamp, a renowned expert in antitrust law.

REPRESENTATIVE MATTERS

- Coordinated HHS's response to several cases filed near-contemporaneously in multiple district courts nationwide challenging regulations related to aspects of the Affordable Care Act.
- Investigated and conducted enforcement actions related to HIPAA violations.
- Represented the U.S. in a patent infringement case brought against a pharmaceutical manufacturer for infringement of several U.S. patents related to the use of emtricitabine and tenofovir or a tenofovir prodrug for pre-exposure prophylaxis for the prevention of HIV.

TOP AREAS OF FOCUS

- FDA Regulatory + Risk Management Counseling
- Health Care Litigation

• Health Care Regulatory

ALL AREAS OF FOCUS

- Antitrust
- Artificial Intelligence
- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences Intellectual Property
- Health Care Litigation
- Health Care Regulatory
- Intellectual Property
- Litigation + Trial

PROFESSIONAL/COMMUNITY INVOLVEMENT

Board of directors, Chicago Volunteer Legal Services (CVLS)

PROFESSIONAL EXPERIENCE

- Attorney, National Complex Litigation and Investigations Division, U.S. Department of Health and Human Services, Office of the General Counsel
- Special attorney, Commercial Litigation Branch, Civil Division, U.S. Department of Justice

EDUCATION AND CERTIFICATIONS

EDUCATION

- University of Iowa College of Law, J.D., senior articles editor, Iowa Law Review, 2008
- Harvard University, M.A., 2004
- Emory University, M.A., 2003
- University of Missouri-Kansas City, B.A., with honors

BAR ADMISSIONS

• Illinois