Andrew E. Kantra

Partner

Philadelphia

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Andy is sought out by pharmaceutical, medical device, and other health sciences clients for his skill at risk evaluation, data interpretation, and work with experts, especially in the context of clinical trials. His strategic analysis of scientific and medical issues has been critical to success in many high-profile cases.

OVERVIEW

Andy focuses his practice on the representation of pharmaceutical clients in multidistrict litigation, state-coordinated proceedings and individual cases involving investigational products in clinical trials and marketed products.

In defending wrongful death and personal injury actions, he draws on his experience with expert witnesses and his ability to understand and explain complex medical concepts to lead the science component of litigation. He has successfully challenged and defended experts in varied litigations and conducted Science Day programs for federal and state courts. His work crosses multiple therapeutic areas, including endocrinology, epidemiology, gastroenterology, infectious diseases, immunology, neurology, oncology, psychiatry, teratology, and toxicology.

Andy's litigation insights help clients identify and manage risk associated with clinical trials, prophylactically or in real time with ongoing litigation or government investigations. He advises on research and development policies and procedures, adverse event reporting and analysis, study protocols, informed consent documents, clinical holds, clinical study reports, scientific disclosures of data, compliance with FDA regulations and consistency with ICH and CIOMS guidance (*e.g.*, Good Clinical Practices; Good Laboratory Practices; Good Manufacturing Practices), and FDA warning letters. For marketed products, he counsels clients on FDA regulatory requirements regarding payor communications and promotional activities. He also conducts internal corporate investigations.

Andy applies his litigation experience to other related matters, such as business disputes between clinical trial sponsors and clinical research organizations and securities fraud matters involving investigational products.

Andy has spoken on legal risks in the clinical trial setting at the Biotechnology Industry Association's annual convention, and on risk evaluation of contract research organizations at the Practising Law Institute and to the Tort and Insurance Practice Section of the American Bar Association. Additionally, he is a contributing author to the "Drug and Medical Device Product Liability Desk Book." He has been a guest lecturer at the University of Pennsylvania on epidemiology and admissibility of evidence from expert witnesses.

AWARDS

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- Craig M. Perry Community Service Award from the Young Lawyers Division of the Philadelphia Bar Association (1996)
- *Legal 500 United States* for Product Liability Litigation (2016-2019)

TOP AREAS OF FOCUS

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

ALL AREAS OF FOCUS

- Digital Health
- FDA Regulatory + Risk Management Counseling
- Health Care + Life Sciences
- Litigation + Trial
- Pharmaceutical + Medical Device Litigation + Counseling
- Product Liability

PROFESSIONAL/COMMUNITY INVOLVEMENT

- Active in litigating pro bono matters, including representation of Alabama death row inmate and Pennsylvania inmate sentenced to life in prison without parole at the age of 15
- Serves as a volunteer for a men's homeless shelter known as Wintershelter

PROFESSIONAL EXPERIENCE

- Pro bono representation of Alabama death row inmate and Pennsylvania inmate sentenced to life in prison without parole at the age of 15.
- Volunteer at a men's homeless shelter (Wintershelter)

EDUCATION AND CERTIFICATIONS

EDUCATION

- New York University School of Law, J.D., 1986
- Yale University, B.A., 1983

BAR ADMISSIONS

- Pennsylvania

COURT ADMISSIONS

- Supreme Court of the United States
- U.S. Court of Appeals, Third Circuit

- U.S. Court of Appeals, Eighth Circuit
- U.S. District Court, Eastern District of Pennsylvania

CLERKSHIPS

- Hon. Joseph S. Lord, III, U.S. District Court, Eastern District of Pennsylvania, 1989-1991