

Andrew E. Kantra

Partner

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Andy is sought out by pharmaceutical, medical device, and other health sciences clients for his regulatory knowledge and skill at risk evaluation and data interpretation. 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, regulatory counseling, and mediations of matters involving marketed products and clinical trials.

He has defended wrongful death and personal injury actions involving marketed and investigational products, extensive expert witness work, analysis of medical literature, dispositive motion practice, and deposition preparation of company witnesses. He has led Daubert challenges to experts in varied litigations and conducted Science Day programs for federal and state courts. He also conducts internal corporate investigations.

Andy counsels pharmaceutical and device companies on research and development procedures, adverse event reporting and analysis, compliance with FDA regulations and consistency with ICH and CIOMS guidance, and master services agreements; and conducts risk assessments of investigational and marketed pharmaceuticals. He also counsels clients on clinical trial-related injuries. He has evaluated the promotional claims for medical devices and medicines. He provides prophylactic counseling to clients with respect to FDA regulatory requirements regarding Good Manufacturing Practices, Good Laboratory Practices, Good Clinical Practices, clinical trials, labeling, risk management plans, private payor communications, and advertising and other promotional activities.

Andy helps a wide range of clients respond to inquiries and notices from FDA (including warning letters and label change requests) and foreign regulatory agencies; identifies potential litigation risks in proposed protocols, informed consent documents, regulatory submissions, scientific disclosures, medical letters, press releases, stand-by statements, website content, social media, and investor relations presentations; and conducts due diligence analysis of contract research organizations and biotechnology companies. He also evaluates potential litigation risks associated with clinical trials conducted outside the United States.

He 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

- In 1996, received the Craig M. Perry Community Service Award from the Young Lawyers Division of the Philadelphia Bar Association
- *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

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