Jeffrey Keith Francer

Education

UNIVERSITY OF VIRGINIA, SCHOOL OF LAW, CHARLOTTESVILLE, VA
J.D., 1999

Honors and Activities:

- Symposium Editor, *Virginia Journal of Social Policy & the Law*
- Bracewell & Patterson Oral Advocacy Award for First-Year Moot Court, 1997
- Public Interest Summer Fellowship, 1997

HARVARD UNIVERSITY, JOHN F. KENNEDY SCHOOL OF GOVERNMENT, CAMBRIDGE, MA
M.P.P., 1998

Honors and Activities:

- Kennedy Fellow
- Teaching Assistant, Professor Roger Porter
- Thesis, FOOD SAFETY: ENHANCING A FRAGMENTED REGULATORY SYSTEM (1998), *cited in* NATIONAL ACADEMY OF SCIENCES, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION (1998).

BROWN UNIVERSITY, PROVIDENCE, RI
A.B., Public Policy (Honors) and Economics, 1993

Honors and Activities:

- Phi Beta Kappa
- Rose Writing Fellow
- Emergency Medical Technician, Brown EMS

MILTON ACADEMY, MILTON, MA, 1989

Experience

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), WASHINGTON, DC
Assistant General Counsel, October 2007 – Present

- Provide counsel and advocacy on a wide range of legal, regulatory, and policy issues for the pharmaceutical industry trade association and its member companies.
- Principal attorney responsible for representing and advising the association and member companies on FDA regulatory and legislative issues including clinical development of new medicines, drug safety, product labeling, data sharing, marketing issues, and enforcement
- Counsel committees that draft and revise PhRMA's *Code on Interactions with Healthcare Professionals*, *Clinical Trial Principles*, and *Guiding Principles on Direct-to-Consumer Advertising*. Advocate on behalf of industry ethical business standards with stakeholders and the media.

BIOGEN IDEC INC., CAMBRIDGE, MA

Associate General Counsel and U.S. Compliance Officer, February 2006 – October 2007
Acting Chief International Compliance Officer, July 2007 – October 2007

- Primary in-house counsel providing advice on FDA issues, fraud and abuse, and HIPAA. Provided counsel regarding approval, enforcement, and regulatory issues for all marketed products.
- Managed U.S. corporate compliance program.
- Supervised international compliance activities and approximately 30 compliance officers in Europe, Asia, and Latin America. Conducted Foreign Corrupt Practices Act training for international distributors in high risk markets.
- Served as Chief Privacy Officer, responsible for company-wide HIPAA and privacy compliance.

Assistant General Counsel, Corporate, December 2005 – February 2006

- Primary in-house counsel providing advice on FDA issues, fraud and abuse, and privacy.
- Responsible for overseeing the U.S. compliance program for U.S. businesses and acted as international compliance officer during 2007. Led major overhaul of compliance policies and global training system..
- Prepped company speakers for FDA Advisory Committee and edited briefing documents.
- Reviewed labeling changes, press releases, promotional materials, and sales training.

U.S. FOOD AND DRUG ADMINISTRATION, ROCKVILLE, MD
Associate Chief Counsel, June 2003 - April 2005

- Advised senior FDA and HHS leaders on drug and biologics regulation, on issues including: clinical trials, emergency preparedness, manufacturing, safety issues, and marketing and advertising.
- Reviewed and approved FDA enforcement actions relating to criminal and civil violations.
- Worked with other Federal agencies including DoJ, SEC, and FTC.
- Assisted in the development and implementation of the Project BioShield Act of 2004 and the issuance of the FDA's first emergency use authorization under the act to facilitate use of anthrax vaccine for U.S. military personnel in the Middle East.
- Represented FDA in clinical investigator disqualification matters involving clinical trial compliance.
- Reviewed and drafted proposed legislation, regulations, guidances, and contracts on behalf of the agency.

ARNOLD & PORTER, WASHINGTON, DC
Associate, June 2000 - June 2003
Summer Associate, May - August 1999

- Advised pharmaceutical and medical device manufacturers in resolving FDA issues, including: enforcement litigation, response to FDA warning letters, drug marketing, and clinical trial compliance.
- Provided legislative advocacy and drafting for bioterrorism legislation after 9/11.
- Managed teams of attorneys in substantial product liability defense matter.
- Drafted and coordinated submission of comments on behalf of over 20 companies during the creation of the HHS Compliance Program Guidance for Pharmaceutical Manufacturers.
- Successfully litigated *pro bono* child custody case in D.C. Superior Court.
- Elected by peers to Committee of Associates, representing associates with firm management.

FRIED, FRANK, HARRIS, SHRIVER & JACOBSON, WASHINGTON, DC
Summer Associate, June - August 1998

- Participated in internal corporate investigations involving alleged financial fraud.
- Drafted discovery requests and litigation filings.

U.S. SECURITIES AND EXCHANGE COMMISSION, WASHINGTON, DC
Summer Honors Program, Division of Enforcement, May - August 1997

- Investigated cases of alleged insider trading and financial fraud, including taking formal and informal enforcement depositions.

- Drafted action memoranda for commissioners for several SEC enforcement investigations.

MORGAN STANLEY & CO. INCORPORATED, NEW YORK, NY
Financial Analyst, Public Finance, July 1993 - July 1995

- Served health care clients by providing analytical support for financings and mergers.
- Performed debt modeling, credit analysis, and evaluation of securities disclosures.

U.S. SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, WASHINGTON, D.C.
Intern, May-August 1991, 1992

- Assisted Senator Kennedy and committee counsel in FDA oversight and Committee investigations.
- Participated in legislative drafting sessions and preparation for congressional hearings on wide range of food and drug issues and FDA budgetary needs, including the original PDUFA legislation.

Publications

- *Communicating the Benefits and Risks of Medicines Responsibly Using the Internet and Social Media Tools* (chapter), in Food and Drug Law Institute, USING SOCIAL MEDIA IN FDA-REGULATED INDUSTRIES: THE ESSENTIAL GUIDE (Carrie Dooher, ed. 2010).
- *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61 (2000) (with Richard A. Merrill).
- *Frankenstein Foods or Flavor Savers?: Safety and Labeling Issues in the Regulation of Agricultural Biotechnology in the United States and European Union*, 7 VA. J. SOC. POL'Y & L. 257 (2000).

Bar Affiliations

District of Columbia, Massachusetts, U.S. District Court for the District of Columbia.