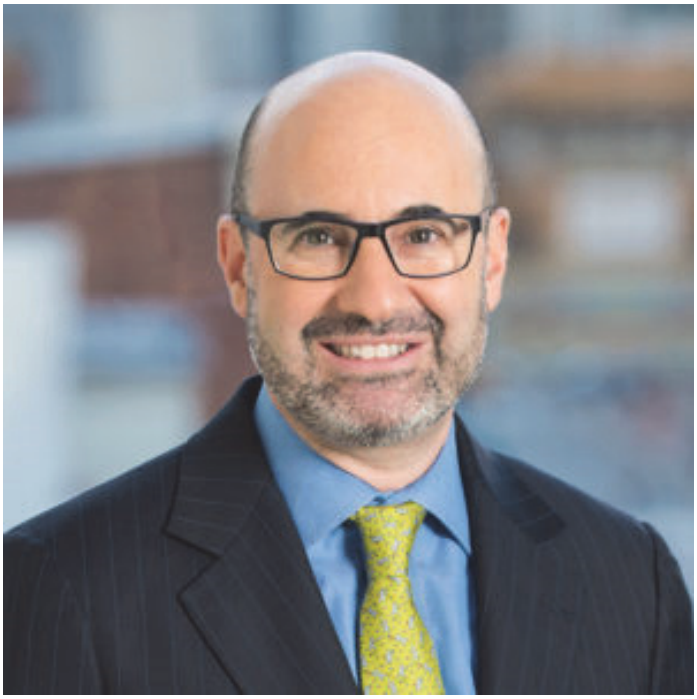
Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Jeff Francer		
2. Your Title: Senior Vice President & General Counsel		
3. The Entity(ies) You are Representing: Association for Accessible Medicines (AAM)		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** X
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2015. Only grants, contracts, or payments related to the subject matter of the hearing must be listed. N/A		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature: [redacted] **Date:** 3/19/18

aam
Association for Accessible Medicines

Your Generics and Biosimilars Industry



Jeff Francer

Senior Vice President and General Counsel

Association for Accessible Medicines (AAM)

Jeff Francer is Senior Vice President and General Counsel of the Association for Accessible Medicines, where he leads legal and international trade advocacy.

Jeff served as Associate Chief Counsel of the Food and Drug Administration from 2003 to 2005, where he advised agency leaders on issues involving the regulation of drugs and biologics including clinical investigation, manufacturing, promotion, enforcement and legislative matters. After leaving the FDA, Jeff served as Associate General Counsel, U.S. Compliance Officer, and Chief Privacy Officer of Biogen Idec, Inc. At Biogen Idec, he was the primary in-house counsel on FDA issues, fraud and abuse prevention and patient privacy. Jeff was also responsible for overseeing the U.S. corporate compliance program.

Immediately prior to joining AAM, Jeff served as Vice President and Senior Counsel of the Pharmaceutical Research and Manufacturers of America (PhRMA) where he was the principal counsel to the association on issues relating to the research, development and regulation of medicines in the U.S. and globally.

Mr. Francer received his A.B. in Public Policy and Economics from Brown University, his M.P.P. from Harvard University, and his J.D. from the University of Virginia.

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

ASSOCIATION FOR ACCESSIBLE MEDICINES (AAM), WASHINGTON, DC
Senior Vice President and General Counsel, November 2016 – Present

- Serve the Association, its Board of Directors, and its senior leadership team by managing all legal analysis, counseling, and advocacy for the nation's principal trade association representing generic drug and biosimilar manufacturers.
- Support the policy advocacy of the Association by assessing the legal impact of proposed laws, regulations, and agency guidances impacting the generic drug and biosimilar industry, including FDA regulatory, intellectual property, competition, and pricing law.
- Litigate on behalf of, counsel, and defend the Association with respect to all legal claims and investigations.
- Lead international trade advocacy; appointed to U.S. Department of Commerce Industry Trade Advisory Committee on Intellectual Property Rights (ITAC-15).

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), WASHINGTON, DC
Vice President and Senior Counsel, June 2013 – November 2016
Assistant General Counsel, October 2007 – June 2013

- Served as principal counsel to the association and member companies on legal and regulatory issues relating to the research, development, manufacturing, and marketing of medicines in the US and globally.
- Managed in-house and outside legal advocacy on FDA regulatory and legislative advocacy on a wide range of issues affecting the biopharmaceutical industry including clinical development of new medicines, drug safety, product labeling, data sharing, marketing issues, and enforcement.

- Represented the biopharmaceutical industry in negotiations with the FDA regarding the Prescription Drug User Fee Act (PDUFA) and Biosimilar User Fee Act (BsUFA).
- Led committees that drafted and revised PhRMA's *Code on Interactions with Healthcare Professionals*, *Principles for Responsible Clinical Trial Data Sharing*, *Clinical Trial Principles*, and *Guiding Principles on Direct-to-Consumer Advertising*.

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.
- Lead business unit counsel during major product re-launch. Reviewed pricing materials, labeling changes, press releases, promotional materials, and sales training.
- Prepped company speakers for FDA Advisory Committee and edited briefing documents.

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.
- Assisted in litigation and enforcement actions 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, responses to FDA warning letters, drug marketing, and clinical trial compliance.
- Managed teams of attorneys in a substantial product liability defense matter.
- 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

- *Embracing 21st Century Information Sharing: Defining a New Paradigm for the Food and Drug Administration's Regulation of Biopharmaceutical Company Communications with Healthcare Professionals,* 70 FOOD & DRUG L.J. 143 (2015) (with James M. Spears and Natalie A. Turner).
- *Ethical Pharmaceutical Promotion and Communications Worldwide: Codes and Regulations,* 9 PHILOSOPHY, ETHICS, AND HUMANITIES IN MED. 7 (2014) (with Jose Zamarriego Izquierdo et. al).
- *Preparing for Responsible Sharing of Clinical Trial Data,* 369 N. ENGL. J. MED. 1651 (2013) (with Michelle M. Mello et. al).
- *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, Supreme Court of the United States, U.S. District Court for the District of Columbia.