

JON SMOLLEN

Temple University Beasley School of Law, Klein 510
1719 North Broad Street, Philadelphia, PA 19122
(215) 204-7149 (w)
(484) 354-2654 (c)
jon.smollen@temple.edu

PROFESSIONAL EXPERIENCE

TEMPLE UNIVERSITY BEASLEY SCHOOL OF LAW, Philadelphia, PA **2016-present** **Practice Professor of Law and Executive Director, Center for Compliance and Ethics**

Leading academic center dedicated to improving the understanding and practice of compliance across disciplines and industries through educational programming, public-private dialogue and research.

- Teach “Introduction to Compliance” and collaborate with Associate Dean for Academic Affairs to develop compliance course offerings and curriculum.
- Chair Center’s Advisory Board, develop Center’s strategy along with annual plan and budget supported by potential fundraising goals.
- Launch summer compliance fellowship program resulting in student placements at leading technology, financial services, insurance and healthcare organizations.
- Plan and launch programs consistent with Center mission such as FCPA roundtable, careers in compliance panels, U.S. and international executive education and Symposium on 21st Anniversary of *Caremark* decision.
- Co-edit Center’s Compliance & Risk Management e-journal.

ENDO INTERNATIONAL, Malvern, PA **2011 - 2016**

Executive Vice President and Chief Compliance Officer

Member of executive leadership team reporting to CEO with compliance responsibilities for U.S. and international branded pharmaceuticals, generics and medical device businesses.

- Built effective organizational structure across existing and newly acquired businesses and enhance company-wide program.
- Oversaw with General Counsel resolution of civil and criminal investigations and Qui Tam False Claims Act cases related to alleged off-label promotion of U.S. branded pharmaceutical product.
- Negotiated and implemented Corporate Integrity Agreement and Deferred Prosecution Agreement for U.S. branded pharmaceuticals business and lead discussions with Endo’s federal monitor.
- Chaired Global and U.S. Compliance Committees and regularly update Board’s Subcommittee on Compliance.
- Oversaw enhancements and implementation of policies, procedures, effective training and communication programs, internal investigations and promotional and non-promotional monitoring programs across Endo.
- Enhanced global anti-bribery program to address promotional activities and other direct or indirect interactions with foreign government officials in numerous countries.
- Conducted due diligence on acquisitions and lead compliance integrations in the U.S. and internationally.

SIEMENS, Malvern, PA **2010-2011**

Vice President and Chief Compliance Officer, Siemens Healthcare USA

Member of U.S. executive management team with compliance responsibility for Siemens Healthcare in the U.S including laboratory diagnostic, health IT and diagnostic imaging and therapy businesses.

- Chair Compliance Committee and regularly report to executive management on issues and initiatives.
- Served as a trusted advisor to business partners and management on compliance and emerging trends.
- Represented Siemens with external constituencies to position the company as a compliance leader.
- Oversaw internal investigations, promptly resolved compliance issues and implemented an effective communication and training program focused on company policies and a values based approach.

- Directed timely reporting of transparency and disclosure reports to various state authorities and implementation of federal transparency requirements.

WYETH, Collegeville, PA**2002-2010****Vice President, Commercial Excellence & Compliance, Wyeth Consumer Healthcare (2009-2010)**

Member of executive management team reporting to President for Wyeth Consumer Healthcare. Established and led function to develop self-regulatory program tailored to OTC, dietary supplement and cosmetic business.

- Redesigned divisional governance teams and established cross-functional and global category teams.
- Established U.S. and global policies for promotional and marketing practices and enhanced internal processes to develop promotional claims and ad copy.
- Chaired Executive Copy Clearance Committee and served on Global Compliance and Continuity Committee.
- Created awareness and training programs to address proactively existing and emerging requirements.
- Revised commercial practices to support appropriate interactions with health care professionals and patient organizations.

Senior Division Counsel, Wyeth Pharmaceuticals (2006-2008)

Advised executive management and operating units on regulatory inspections, product recalls, contractual and litigation matters, compliance issues and internal investigations.

- Enabled timely product approvals and ongoing product supply through successful resolution of FDA Warning Letter at critical U.S. manufacturing facility.
- Developed corporate positions on proposed federal and state legislation on import safety and anti-counterfeiting and served on PhRMA and BIO task forces.
- Designed global anti-counterfeiting strategy and implementation plans with executive management to address emerging product security requirements in U.S. and Europe.
- Resolved potential government intervention in Qui Tam False Claims Act case involving \$2.4B vaccine product.
- Drafted and reviewed inspection responses and communications to FDA, European Medicines Agency, Irish Medicines Board and UK Medicines and Healthcare Products Regulatory Authority.

Chief Privacy Officer, Wyeth (2002-2006)

Established corporate privacy program by securing management approval for new function designed to ensure adherence to global privacy laws and to enhance trust with physicians, patients and consumers. Reported at least annually to executive management teams.

- Led effort to certify U.S. operations to E.U.-U.S. Safe Harbor and affiliates in more than 50 countries to global privacy policies.
- Established and led global function and collaborated with privacy coordinators for more than 50 countries through implementation tools, annual certification process and audit program.
- Developed and launched training programs in 17 languages to educate 52,000 member workforce.
- Chaired global committees on privacy and served on e-commerce governance committee.
- Advised sales, marketing, R&D, pharmacovigilance and human resources on E.U. Data Directive, FTC Act, HIPAA and other federal, state and international privacy laws.
- Managed outside counsel in multi-country projects and successfully resolved privacy class action litigation.
- Earned Wyeth public recognition among U.S. physicians as one of the most trustworthy pharmaceutical companies for privacy.

FEDERAL TRADE COMMISSION, Washington, DC**1997-2002****Attorney Advisor, Commissioner Thomas B. Leary (1999-2002)**

Advised FTC Commissioner on consumer protection matters including advertising, e-commerce, privacy, lending and consumer credit issues. Served as representative to industry, government officials, agency staff and the public.

- Reviewed and advised on enforcement actions and settlements under the FTC Act, Fair Credit Reporting Act, Children's Online Privacy Protection Act and the Telemarketing Sales Rule.

- Reviewed agency policy initiatives and Congressional testimony on consumer protection issues including Internet privacy, online behavioral advertising, identity theft and e-commerce.

Staff Attorney, Bureau of Consumer Protection (1997-1999)

Initiated investigations, led enforcement actions and supported development of agency policy.

- Served as trial counsel in *FTC vs. Trans Union*, precedent setting action prohibiting resale of consumer report information for target marketing purposes.
- Initiated investigation and served as lead litigation counsel in *FTC vs. Touch Tone Information*, first action against information brokers and the practice of pretexting.
- Organized agency workshop on *U.S. Perspectives on Consumer Protection in the Global Electronic Marketplace* involving government, industry and consumer advocates.

**U.S. DISTRICT COURT JUDGE JAMES P. JONES,
WESTERN DISTRICT OF VIRGINIA, Abingdon, VA**

1996-1997

Judicial Clerk

Drafted bench memoranda and judicial opinions.

SQUIRE, SANDERS & DEMPSEY, Washington, DC

1995-1996

Associate

Drafted pleadings and legal memoranda for various litigation and regulatory matters and provided client counseling.

EDUCATION

UNIVERSITY OF VIRGINIA SCHOOL OF LAW, Charlottesville, VA

J.D., 1995 – Member, Articles Review Board, *Virginia Journal of International Law*

COLUMBIA UNIVERSITY, SCHOOL OF INTERNATIONAL AND PUBLIC AFFAIRS, New York, NY

M.A., 1992 – International Political Economy and Human Rights and International Law

Dean's Fellowship (1991-92)

Ford Foundation Grant (1991)

GEORGETOWN UNIVERSITY, Washington, DC

B.A., 1988 – *Cum laude*, History

Honors thesis, *Red Fascism, Harry Truman and the Origins of the Cold War*

Edinburgh University (1986-87)

SPEAKING, PUBLICATIONS AND PRESENTATIONS

- *Careers in Healthcare Compliance*, Summit on Emerging Careers for Law Grads, National Association for Law Placement (June 2019)
- *Overcoming ERM Challenges Today*, Temple Fox School of Business Annual Enterprise Risk Management Conference (May 2019)
- *Fostering a Culture of Ethics and Compliance*, 19th Annual Pharmaceutical and Medical Device Compliance Congress (November 2018)
- *Introduction to the Caremark Decision at 21: Corporate Compliance Comes of Age – What Does the Future Hold*, 90 TEMP. L. REV. 597 (Summer 2018)
- *Leveraging Data Analytics to Bridge Management, Legal and Compliance*, 15th Annual Pharmaceutical Congress (April 2018)
- *Two Years After Yates: What Does Cooperation and Individual Accountability Really Look Like?*, 2017 White Collar Practice Seminar, Pennsylvania Association of Criminal Defense Lawyers (November 2017)

- *Compliance Messaging: Using Behavioral Economics to Improve Message Stickiness*, 18th Annual Pharmaceutical and Medical Device Compliance Congress (November 2017)
- “*Caremark’s Impact on the Legal Profession and the Rise and Future of the Modern Compliance Officer*, The Caremark Decision at 21: Corporate Compliance Comes of Age,” 2017 Temple Law Review Symposium (October 2017)
- *Yates Memo: A Lawyer’s Professional Responsibility*, Food and Drug Law Institute Webinar (December 2016)
- *Global Anti-Bribery Laws, Mergers and Acquisitions, Internal Investigations and Global Compliance Programs*, All China Lawyers Association (November 2016)
- *Tactical Strategies in Negotiating with OIG*, 17th Annual Pharmaceutical and Medical Device Compliance Congress in Washington, D.C. (October 2016)
- *Chief Compliance Officer Panel - Current Trends in Ethics and Compliance Law*, Temple University Beasley School of Law (April 2016)
- *Mergers and Acquisitions – Compliance Implications and Concerns for Merging Cultures*, 16th Annual Pharmaceutical and Medical Device Compliance Congress in Washington, D.C. (March 2015)
- *The Art and Science of Compliance*, Duane Morris Compliance and Risk Professionals Education Series (October 2014)
- *Strategies for Dispute Resolution and Disputes Processes*, 2014 Pharmaceutical Compliance Congress (January 2014)
- *Practical Reflections on the Roles of Legal and Compliance – Similarities and Differences*, Ethics & Compliance CLE (December 2013)
- *Compliance Strategies for Small to Mid-Sized Companies*, 2013 Pharmaceutical Compliance Congress (January 2013)
- *Privacy Regulation of the Pharmaceutical Sector*, 4th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (November 2003)

BAR MEMBERSHIPS AND PROFESSIONAL ASSOCIATIONS

Admitted in Massachusetts (1996) and District of Columbia (1997)

Member, Board of Directors, Astella Pharma US, Inc. (2019–present)

Member, Research Advisory Board, International Association of Privacy Professionals (2019-present)

Board Member, International Pharmaceutical Privacy Consortium (2003-2006)