SCOTT M. LASSMAN

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PROFESSIONAL EXPERIENCE

Lassman Law+Policy
Expert Witness, 2025 – Present
Provide expert witness services based on over 33 years working as an attorney specializing in FDA law and policy.

Principal, 2019 – 2025
Founder of boutique law firm specializing in FDA regulatory law and policy, including strategic advice, counseling, administrative advocacy, and litigation on civil and criminal matters concerning pharmaceuticals, biological products, and medical devices. Areas of specialty include Hatch-Waxman lifecycle management, biologics and biosimilars, drug and device approvals, advertising and promotion, clinical trial requirements, internal investigations, citizen petitions, and FDA policy and legislation.

Goodwin Procter
Partner, 2016 – 2019
Chair of the FDA Practice Group. Practice focused on FDA regulatory law, including strategic advice, counseling, administrative advocacy, and litigation on civil and criminal matters concerning pharmaceuticals, biological products, and medical devices.

Kleinfeld, Kaplan and Becker
Partner, 2009 - 2016; 1999 - 2003
Associate, 1994 - 1999
Practice focused on FDA regulatory law, including strategic advice, counseling, administrative advocacy, and litigation on civil and criminal matters concerning pharmaceuticals, biological products, and medical devices.

Wilmer, Cutler, Pickering, Hale & Dorr
Partner, 2007 – 2009
Served as Co-Chair of the FDA practice group of a major, international law firm handling FDA regulatory and policy issues.

PhRMA (Pharmaceutical Research and Manufacturers of America)
Senior Assistant General Counsel, 2005 - 2007
Assistant General Counsel, 2003 – 2005
Handled a wide variety of FDA regulatory and legislative issues for the trade association, including Hatch-Waxman reform, drug safety, direct-to-consumer advertising, citizen petition reforms, and reauthorization of the Prescription Drug User Fee Act (PDUFA). Recipient of the PhRMA Board of Directors Exceptional Service Award in 2007.

Hogan & Hartson
Associate, 1991 - 1994
Practiced FDA law with primary emphasis on medical device matters and FDA enforcement actions.

Amgen Exhibit 1024
Amgen v. BMS

EDUCATION

University of Virginia School of Law
J.D., 1991
Order of the Coif; Virginia Law Review

University of Texas at Austin
M.A., Philosophy, 1988 (University Fellowship)

Yale University
B.A. (with honors), 1985

RECOGNITION

LMG Life Sciences Star (2016 – 2024)
- FDA Regulatory Attorney of the Year, Shortlist (2017, 2018)
- Regulatory Firm to Watch, Shortlist (2019) (Lassman Law+Policy)

Chambers USA, Healthcare: Pharmaceutical/Medical Products Regulatory (DC) (2017 - 2024)

Best Lawyers in America, Administrative and Regulatory Law; FDA Law (2010 – 2024)

Best Law Firms in America, Administrative and Regulatory Law; FDA Law (2020 - 2024)

Who's Who Legal: The International Who's Who of Life Sciences Lawyers (2008, 2014 - 2024)

Who's Who Legal: Thought Leaders – Life Sciences (2023)

Who's Who Legal: The International Who's Who of Healthcare Lawyers (2020 - 2021)

SuperLawyers, FDA Law (2013 – 2017, 2020 – 2024)

The Legal 500, Healthcare: Life Sciences (2017)

PUBLICATIONS

Chapter 2: Tips for Smooth Interactions on New Drugs and Abbreviated Applications, How FDA Really Works: Insights from the Experts (2022), Food and Drug Law Institute (co-author)

Chapter 3: The FDA Approval Process for Biosimilar and Interchangeable Biological Products, Guide to Biosimilars Litigation and Regulation in the U.S. (2019-2020 edition), Goodwin, Thomson Reuters (co-author)

Criticism of FDA Citizen Petitions Is Often Misguided, Law360 Expert Analysis-Opinion (Nov. 20, 2017).

Clinical trial transparency, a reassessment of industry compliance with clinical trial registration and reporting requirements in the United States, Lassman SM, Shopshear OM, Jazic I, et al. *BMJ Open* 2017;**7:**e015110. doi: 10.1136/bmjopen-2016-015110.

Chapter 6: Food and Drug Administration Amendments Act of 2007 and the Growth of FDA Enforcement Authority, Practising Law Institute Pharmaceutical Compliance and Enforcement Answer Book, Scott Lassman (edited by Howard Dorfman) (2014 - 2024).

Chapter 8: Postmarket Considerations, Practising Law Institute Medical Devices Law and Regulation Answer Book 2013, Thomas O. Henteleff, Kinsey Reagan, Scott M. Lassman (edited by Suzan Onel and Karen M. Becker) (2013 - 2018).

Transparency and Innuendo: An Alternative to Reactive Over-Disclosure, Scott M. Lassman, Journal of Law and Contemporary Problems, Vol. 69, No. 3, pp. 69-84 (2006).

Pharmaceutical Supply Chain Security: A View From the Pharmaceutical Research and Manufacturers of America, Alan Goldhammer and Scott M. Lassman, Journal of Pharmacy Practice, 19:239, 2006.

Innovating Within the OTC Monograph System, Thomas O. Henteleff and Scott M. Lassman, Regulatory Affairs Focus, page 23 (March 2000).

Product Liability Implications of Regulatory Compliance or Noncompliance, Alan Kaplan, Bonnie Beavers, Scott Lassman & Millicent Yim, *Cosmetic Regulation in a Competitive Environment*, 2000 (ed. Norman Estrin).

GATT Implementation and Generic Drug Approval, Peter O. Safir and Scott M. Lassman, Food and Drug Law Journal, Volume 51, Number 2, Page 295 (1996).

U.S. Device Tracking Regulations, Jonathan Kahan and Scott Lassman, Regulatory Affairs Journal, Volume 2, Number 2 (May 1994).

BAR MEMBERSHIPS

District of Columbia
Maryland

PROFESSIONAL ASSOCIATIONS

American Bar Association
Maryland State Bar Association

PRIOR TRIAL AND/OR DEPOSITION TESTIMONY (LAST 4 YEARS)

In Re Actos Antitrust Litigation, Master File No. 1:13-CV-9244-RA-SDA (S.D.N.Y.)

Puma Biotechnology, Inc. and Wyeth LLC v. AstraZeneca Pharmaceuticals LP and AstraZeneca AB, Civ. Action No. 21-1338 (MFK) (D. Del.)

Celltrion, Inc. v. Chugai Seiyaku Kabushiki Kaisha, Genentech, Inc. and Hoffman-La Roche Inc., IPR 2022-00578 and IPR 2022-00579, before the Patent Trial and Appeal Board

Value Drug Company v. Takeda Pharmaceuticals U.S.A., Inc., Par Pharmaceutical Inc., Watson Laboratories, Inc., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., and Amneal Pharmaceuticals LLC, Civ. Action No. 21-3500 (E.D.Pa.)

Zydus Pharmaceuticals, Inc., and Cadila Healthcare Limited v. Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc., Civ. Action No. 18-01994 (FLW)(TJB) (D.N.J.)

Shire Viropharma Incorporated v. CSL Behring LLC and CSL Behring GmbH, Civ. Action No. 12-00414-MSG (D. Del.)