James N. Czaban
Partner
CHAIR, FDA PRACTICE GROUP

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Jim has extensive experience in government regulation of pharmaceutical, biotechnology, food, medical device and health care related companies.

His practice focuses on counseling such clients on complex regulatory strategies and compliance matters and representing clients in administrative and judicial enforcement actions and other proceedings involving the Food & Drug Administration (FDA), the Federal Trade Commission (FTC), the Drug Enforcement Administration (DEA), the Department of Justice (DOJ) and other federal and state agencies. In recommending Jim as a "Notable Practitioner," Chambers USA referred to his "impressive and well-reputed practice" (2011) and noted that sources praised him as "one of only a few people who really do think outside the box," the lawyer to turn to "if you are looking for innovation and someone to break new ground" (2010).

RELATED SERVICES

- International Trade, Regulatory and Government Affairs
- FDA

RELATED SECTORS

- Life Sciences

A particular emphasis of Jim's practice is navigating the myriad interrelated legal, regulatory and policy issues implicated by competitive pressures within the pharmaceutical industry. Chambers USA reports that clients praise "his ability to propose a creative solution" and characterize him as "practical, responsive and candid." Chambers further notes that he "brings significant FDA expertise to his work advising a range of clients on regulatory matters and he is well versed in representing clients in proceedings with government agencies" (2012). Jim is recognized as a leading authority on the Hatch-Waxman Amendments and the legal and regulatory strategies available to both innovator and generic drug companies.

Jim's clients include a wide range of pharmaceutical, biotechnology, food and medical device companies, as well as banks, venture capitalists and other entities involved with life sciences companies. He guides these clients at all stages of a product’s lifecycle, from product development, marketing applications, advertising and promotional compliance, good manufacturing practices and post-approval safety requirements. He also counsels clients and performs regulatory due diligence in connection with financings, public offerings, mergers and acquisitions, licensing and joint venture agreements involving life sciences companies.

EXPERIENCE

PHARMACEUTICAL PRODUCT DEVELOPMENT

- Provides regulatory counseling regarding: pre-clinical and clinical development strategies; bioequivalence and therapeutic

equivalence standards; Abbreviated New Drug Application (ANDA) and 505(b)(2) New Drug Application (NDA) strategies; product classification and regulatory approval pathways; strategic use of FDA meeting opportunities; dispute resolution; labeling negotiations; and appeals of adverse FDA review decisions

DRUG MARKETING AND PROMOTION

- Served as outside counsel on the promotional review committees of several prominent pharmaceutical companies
- Regularly advises clients on compliance with laws governing drug promotion and marketing practices, including rules enforced by the FDA, the FTC, the Securities & Exchange Commission (SEC) and the Health and Human Services' Office of Inspector General (HHS/OIG)
- Counsels and trains pharmaceutical companies on all manifestations of pharmaceutical marketing and education, including: professional detail aids; managed care marketing; DTC advertising; pharmacy and patient support programs; press releases and other corporate disclosures; medical conference sponsorship; financial relationships with health care practitioners; and the permissible boundaries of the dissemination of "off-label" information for prescription drugs
- Represents companies in response to government investigations of alleged off-label marketing and civil and criminal prosecutions under the False Claims Act, the Stark anti-kickback law, and the Food, Drug and Cosmetic Act

HATCH-WAXMAN

- Handles matters arising under the Hatch-Waxman Amendments, providing strategic advice regarding: regulatory exclusivities; patent listings; patent challenges; patent term extensions; 180-day generic exclusivity; and lifecycle management strategies
- Has served as lead counsel in numerous administrative petition proceedings and judicial challenges arising under Hatch-Waxman

INTERNATIONAL TRADE

- Advised pharmaceutical companies on negotiation and implementation of international trade agreements
- Advises companies on the laws governing the importation and exportation of pharmaceuticals and food products

INTELLECTUAL PROPERTY

- Counsels clients on issues such as Orange Book patent listing requirements and limitations and the role of IP rights in delineating the scope and timing of generic entry
- Assists innovator companies to develop and enforce IP rights via the regulatory process, including by the use of Citizen Petitions, interactions with the FDA's Center for Drug Evaluation and Research (CDER), the Office of Regulatory Affairs, the Office of Generic Drugs and the Office of the Chief Counsel. Antitrust
- Counsels clients in advance of potential pharmaceutical patent settlements and in litigation and investigations involving consummated settlements

CORPORATE

- Provides regulatory counseling and advice in connection with corporate and commercial transactions, all stages of venture financing, and public offerings
- Provides strategic counseling on deal terms (regulatory-based milestones, regulatory responsibilities in joint ventures, defining the scope of licensed rights based on regulatory classifications/fields of use), as well as regulatory due diligence

SECURITIES LAW

- Advises FDA-regulated entities on the regulatory and securities law ramifications of corporate disclosures

REPORTED CASES

- *Merck KGaA v. Integra LifeSciences*, 545 US 193 (2005) (FDA counsel to Merck in favorable 9-0 Supreme Court of the United States decision interpreting the drug development-patent infringement safe harbor provisions of the Hatch-Waxman amendments)
- *Granholm v. Heald*, 544 US 460 (2005) (counsel to amicus curiae WineAmerica in support of successful constitutional challenge to state wine shipment restrictions)
- *Teva Pharmaceuticals v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999) (as appellant); on further appeal, 2000 US App. LEXIS 38667

(D.C. Cir., 2000) (argued two appeals in the DC Circuit successfully challenging FDA's refusal to approve client's generic drug application)

CREDENTIALS

Admissions

- District of Columbia
- New York

Recognitions

- Recognized as a *Life Sciences Star* by the Legal Media Group in the publication of "*LMG Life Sciences 2018."*
- Recognized in the 25th Edition of *Best Lawyers* for his work in FDA law (2019)
- Received 2018 Burton Award for Legal Writing
- Included in *The Best Lawyers in America* directory for FDA Law (2015-2016)
- Received 2011 Burton Legal Writing Award
- Recognized in Who's Who Legal: Life Sciences (2015)
- Named one of DC's "Super Lawyers" for Food & Drugs by *Super Lawyers* magazine (2010-2015, 2017)
- Named a "Life Sciences Star" for outstanding FDA work in Euromoney's LMG Life Sciences (2012-2013, 2015-2016)
- Named by *Lawdragon* as one of "3000 Leading Lawyers in America" (2010-2011)
- Named one of "Washington's Top Lawyers" by *Washingtonian* magazine (2004-2009)
- Listed by *Chambers USA* as one of "America's Leading Lawyers for Business" in Pharmaceutical/Medical Product Regulatory (2009-2012)
- Recommended by PLC Which Lawyer in the Life Sciences Regulatory category (2008-2011)
- Recognized as a "notable practitioner" in the Medical Products Regulatory category by Chambers USA's America's Leading Lawyers (2008), which described him as a "creative and forceful lawyer who is committed to getting results"

Education

- J.D., University of Virginia School of Law
- B.A., University of California at Berkeley

Courts

- Supreme Court of the United States

Memberships

- Legal columnist and member, Editorial Board for the Journal of Precision Medicine
- Bloomberg Law Advisory Board for Pharmaceuticals and Life Sciences
- Food & Drug Law Institute (FDLI)
- Chair, H. Thomas Austern Writing Awards Committee - FDLI Audit Committee

INSIGHTS

Publications

New Acting FDA Commissioner Sharpless: 4 policy issues to watch

9 APR 2019

A look at four pressing, high-profile issues facing the new acting FDA commissioner.

FDA announces major regulatory overhaul initiative

8 SEP 2017

This initiative will be a massive undertaking given the breadth of FDA's regulatory authority over a vast array of products and industries.

Coming soon from FDA? Streamlined safety information in prescription drug television ads

7 SEP 2017
If FDA proceeds, TV may feature even more drug ads, and the advice to “talk to your doctor” will become even more important.

- Co-author, with Sima S. Kulkarni, "The Challenges of Patenting Precision Medicine in the Era of *Mayo* and *Myriad*," *Journal of Precision Medicine,* November 2018
- "For FDA, addressing drug pricing is a matter of doing its job better," *Food and Drug Law Institute*, August/September 2018
- "Deal or No Deal? Legal and Regulatory Considerations in the Business of Precision Medicine," *Journal of Precision Medicine,* March/April 2018
- "Is FDA Regulatory Flexibility an Oxymoron?" *Journal of Precision Medicine,* December 2017
- "FDA's Final MMA Regulations Section-by-Section Redline Guide for Industry ," *FDA and Medical Products Regulatory Practice Group*, December 2016
- Promotion of Precision Medicine Under Imprecise Rules, Advertising and Promotion Conference, September 28, 2016
- Co-author, with A. Claire Frezza, "Food & Drug Law and Regulation Chapter 10: Drugs: INDs and Full NDAs" *Food and Drug Law Institute*, May 26, 2015
- "FDA's MMA Proposed Rules—Section-by-Section Redline Guide for Analysis and Development of Comments to FDA," February 9, 2015
- "FDA Issues REMS-Drug Generic Access Guidance; Antitrust Issues Remain Key Factor," December 5, 2014
- Co-author, with Sonali P. Gunawardhana, "Pushback Prompts FDA To Propose New Food Safety Rules," *Law360*, November 18, 2014
- Co-author, with Sonali P. Gunawardhana, "Public Comments Result in FDA Revising Proposed Food Safety Rules," September 19, 2014
- "FDA's Bold New Policy on NCE Exclusivity for Combination Drugs – Can It Survive Scrutiny?", February 24, 2014
- Co-author, with Sonali P. Gunawardhana, "FDA's "Tentative" Determination Regarding Trans Fat: A Food Safety Assessment," *Food Safety Magazine eDigest*, February 4, 2014
- "Food & Drug Law Chair, Jim Czaban, to Speak at Webinar on *FTC v. Actavis*," July 11, 2013
- Co-author, with Brian H. Pandya, "Reverse Payments After *FTC v. Actavis*: Supreme Court Unsettles Hatch-Waxman Patent Settlements," *Bloomberg BNA's Pharmaceutical Law & Industry Report*, June 28, 2013
- Co-author, with Sonali P. Gunawardhana, "What FSMA Really Tells Us About the Focus of Food Safety Food," *Safety Magazine*, June/July 2013

Events

Previous

The More Things Change: Improvement Patents, Drug Modifications, and the FDA

19 OCT 2018

Promotional Compliance and Liability Risks Beyond FDA

17 OCT 2018

Clarifying the Clinical Trial Process for Drugs and Biologics

27 SEP 2018
Boston

- "Top 10 Compliance Tips for Healthcare Communications Companies," Post-election Conference on Healthcare Policy, Coalition for Healthcare Communication, January 3, 2019
- American University Washington College of Law and the Food and Drug Law Institute conference, FDA: Past, Present, and Future. Speaking on the topic "The More Things Change: Improvement Patents, Drug Modifications, and the FDA," October 19, 2018
- FDLI's Annual Advertising and Promotion Conference, moderating and speaking on the panel titled: "Promotional Compliance and Liability Risks Beyond FDA," October 17, 2018
- American Conference Institute's FDA Boot Camp (Boston), speaking on "Clarifying the Clinical Trial Process for Drugs and Biologics," September 27, 2018
- American Conference Institute's 32nd FDA Boot Camp, September 26–28, 2018
- "Drug Pricing for the Food and Drug Community," Food and Drug Law Institute (FDLI) Webinar, July 17, 2018
- Food Law Panel, Food Law at Virginia Association (FLAVA), University of Virginia School of Law, February 8, 2018
- "Is Regulatory Agility an Oxymoron?" Precision Medicine Leaders Summit, August 2017
- Minimizing the Uncertainty Surrounding the Pathway: Insights Into USFDA's Current Initiatives Regarding the First Wave of Biosimilars Applications, ACI's Summit on US Biosimilars, April 21, 2015
- Delving into the Mechanics of the USFDA Biosimilars Approval Process and Section 351(k) Applications Under the Pathway, ACI's Summit on US Biosimilars, April 20, 2015
- Hatch-Waxman and BPCIA: Overview of Biosimilars and Life Cycle Planning for Drugs and Biologics, ACI's 24th FDA Boot Camp, March 11, 2015
- Public Health: The Policy Issue Permeating the Regulatory Landscape FDLI's *Europe v. U.S. Food, Drug, Device, & Tobacco Regulation & Policy*: Emerging Issues and Comparative Analysis, November 14, 2014
- The Nature of the Approval Process, ACI's 23rd FDA Boot Camp, September 18, 2014
- Common Mistakes to Avoid and Practical Strategies for Increasing Your Likelihood of Approval for Your Next IND/ NDA or 510(K), FDA Intensive, November 18, 2013
- The Nuts & Bolts of Patents and the Drug Approval Process, ABA Webinar, November 14, 2013
- Hatch-Waxman Patent Settlements in the Aftermath of *FTC v. Actavis*, Bloomberg BNA Webinar, July 16, 2013
- Panel and Q&A on Key Legal Issues Barclays Select Series 2013: Generic Pharmaceuticals Symposium, January 18, 2013

- Factoring Orphan Drugs Into Your Broader Patent Portfolio and Life Cycle Strategies, ACI's Orphan Drugs and Rare Diseases Conference, November 29, 2012

NEWS

DLA Piper advises Gener8 in its acquisition by Sverica Capital Management

21 SEP 2018

DLA Piper represented Gener8, LLC, a designer and manufacturer of life science instrumentations and medical devices headquartered in Sunnyvale, California, in its acquisition by private equity firm Sverica Capital Management LP.

DLA Piper attorney wins Burton Award for legal writing

24 MAY 2018

DLA Piper is proud to announce that Chair of the FDA Practice group, James Czaban, was recognized with a 2018 *Law360* Distinguished Legal Writing Award by the Burton Awards for Legal Achievement.

DLA Piper lawyers and practices were highlighted in the 2017 directory of Who's Who Legal

22 DEC 2017

DLA Piper is pleased to announce *Who's Who Legal* designated us as both the Real Estate Firm of the Year and the Franchise Firm of the Year for 2017.