James C. Shehan

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Life sciences companies look to Jim for innovative legal strategies that minimize risk and move their businesses forward. As a seasoned health care executive and lawyer, he is well-versed in complex regulatory and commercial issues related to drug development, life cycle management, compliance matters, internal investigations, and transactions.

Jim's extensive pharmaceutical and health care industry expertise includes mergers and acquisitions, licensing, litigation, intellectual property, securities, and corporate governance, as well as regulatory issues. Known for his deep knowledge of Food and Drug Administration (FDA) regulatory matters, Jim is a trusted advisor to clients on the development and commercialization of pharmaceutical products, medical devices, and food products. He also has a deep understanding of the emerging field of biosimilars.

Prior to joining Lowenstein Sandler, Jim was of counsel at Hyman, Phelps & McNamara in Washington, D.C. Previously, he was General Counsel and Head of Government Affairs and Quality at Novo Nordisk, one of the most successful global health care companies. During his tenure, Jim oversaw all legal issues, helped establish the company as the market leader in diabetes, and played a key role in the success of several other therapies. Additionally, Jim served as Corporate Counsel at Pfizer, where he advised management on various matters, including the company's compliance with manufacturing, clinical, and laboratory processes. At the start of his career, Jim was an associate in the FDA law group at Sutherland, Asbill & Brennan, and worked at the FDA as a regulatory counsel in the office of the Associate Commissioner for Health Affairs.

A frequent writer and speaker, Jim is sought after for his perspective on the regulatory, legal, and policy challenges shaping the global health care industry. He has spoken at various industry conferences, congressional briefings, and FDA public hearings.

NEWS & INSIGHTS

Publications

- March 19, 2020
  "FDA Guidance on Conducting Clinical Trials During the COVID-19 Pandemic," *Life Sciences Client Alert*
  James C. Shehan
- October 1, 2019
  "New Bill Aims To Drive Insulin Price Reductions," *Biosimilar Development*
  James C. Shehan
- October 24, 2018
  "State Initiatives to Control Drug Prices," *Life Sciences Client Alert*
  James C. Shehan
- February 21, 2017
  "Sparking Discussion and Adding Fuel to the Fire: FDA Discussion Paper on Laboratory Developed Tests (LDTs)," *Life Sciences Client Alert*
  James C. Shehan, Alan Wovsaniker
- January 27, 2017
  "FDA Breaks Medical Product Communications Silence," *Law360*
  James C. Shehan,
- January 24, 2017
  "With a Whisper, Not a Shout, FDA Breaks Silence on Medical Product Communications," *Life Sciences Client Alert*
  James C. Shehan,
- December 14, 2016
  "Changes on the Horizon for Clinical Research and Drug and Device Development: 21st Century Cures Act Becomes Law," *Life Sciences Client Alert*
  Michael J. Lerner, James C. Shehan
- 2016

"Chapter 20, Internal Investigations," *FDA Deskbook: A Compliance and Enforcement Guide (Practising Law Institute)*
James C. Shehan

> October 20, 2016
"US Biosimilars Update - Where We Are and the Road Ahead," *Life Sciences Client Alert*
James C. Shehan

In the Media

> September 4, 2020
Lowenstein's representation of **Traub Capital**, an investment firm specializing in building value in consumer companies using its unique combination of strategic, operational, and financial expertise, in the company's purchase of MANA Products, a premier beauty contract manufacturer based in Long Island City, New York, is noted in the **Global Legal Chronicle**. The Lowenstein deal team included **Michael A. Brosse**, **Lauren M. Troeller**, **Lowell A. Citron**, **Doreen M. Edelman**, **Darren Goodman**, **Ted Hunter**, **Marc S. Kurzweil**, **Gavin J. Rooney**, **Jeffrey M. Shapiro**, **Michael Walutes**, **James C. Shehan**, **Norman W. Spindel**, **Daniel A. Suckerman**, **David Toma**, **Stuart S. Yusem**, **Abbey E. Baker**, **Eric Jesse**, **Stacey C. Tyler**, **Naomi D. Barrowclough**, **Matthew P. Hintz**, **Manali Joglekar**, **Kimberly E. Lomot, Kathleen A. McGee**, **Megan Monson**, **Zachary L. Berliner**, **Christian C. Contardo**, **Mark S. Heinzelmann**, **Amanda C. Lutick**, **Michael T. Melchiorre**, **Joshua A. Rabinovits**, **Stephen Tanico**, **Jenna-Marie Tracy**, Joseph Mignone, and Keith Janowitz. ***View Lowenstein's news announcement about this transaction***.

> May 7, 2020
Lowenstein's representation of **Delcath Systems, Inc.** in an underwritten public offering of shares and warrants is noted in the **Global Legal Chronicle**. The Lowenstein deal team included **John D. "Jack" Hogoboom**, **Robert J. Paradiso**, **Brian A. Silikovitz**, **James C. Shehan**, **Sarah P. Cole**, **Michael T. Melchiorre**, **Erica Perlmutter**, and **Kristin V. Taylor**. ***View Lowenstein's news announcement about this transaction***.

> December 16, 2019
James C. Shehan is quoted in the **Pink Sheet** regarding Sarepta Therapeutics Inc.'s decision to not publicly disclose its submission of a formal dispute resolution request appealing the FDA's rejection of the drug Vyondys 53. Shehan notes that the legal standard for determining whether information such as this must be disclosed is how material is it to an investor's buy or sell decision and that, because companies don't often win formal dispute resolutions with the FDA, Sarepta's decision to not disclose the appeal's existence could be legally permissible. *(subscription required to access article)*

> November 9, 2019
Lowenstein's representation of **W2O**, the leading independent provider of analytics-driven, digital-first marketing communications to the health care sector, in the acquisition of Arcus Medica, a recognized leader in medical and scientific communications, highlighted in the **Global Legal Chronicle**. The Lowenstein deal team included **David L. Goret**, **Marita A. Makinen**, **Andrew P. Erdmann**, **Matthew Tippy**, **Eugene R. Cheval**, **Tracy F. Buffer**, **Michael Walutes**, **Sophia Mokotoff**, **Megan Monson**, **Matt Savare**, **Bryan Sterba**, **Mary J. Hildebrand**, **Manali Joglekar**, **Carly S. Penner**, **Amy Komoroski Wiwi**, and **James C. Shehan**. ***View Lowenstein's news announcement about this transaction***.

> October 3-7; November 8, 2019
Lowenstein's representation of NexPhase Capital in its investment in Popcornopolis was reported in ***Business Wire,*** the ***Valdosta Daily Times***, ***Bloomberg Law – Big Law Business***, ***The Tullahoma Tennessee News,*** **Mergers & Acquisitions**, and the **Global Legal Chronicle**. The Lowenstein team included **Christopher C. Henry**, **Michael Walutes**, **Matt Savare**, **Vanessa A. Ignacio**, **Julie Levinson Werner**, **James C. Shehan**, **Eric Jesse**, **Sabrina Cua**, **Bryan Sterba**, **Megan Monson**, and **Lauren M. Troeller**. ***View Lowenstein's news announcement about this transaction***.

> November 4, 2019
James C. Shehan is quoted in ***The Center for Biosimilars*** in an article discussing the nomination of Stephen Hahn to be the next FDA commissioner and whether his selection would mean continued advancement for biosimilars, as was the case during Scott Gottlieb and Ned Sharpless's tenures. Shehan notes a major shift in the U.S. market's need for biosimilars, with Gottlieb's time as commissioner representing a "quantum leap in terms of activism."

> July 10, 2019
James C. Shehan, Chair of Lowenstein's **FDA Regulatory practice**, comments in ***Law360*** on the D.C. federal court ruling that struck down the Trump administration rule requiring drug prices to be disclosed in TV ads. U.S. District Judge Amit P. Mehta found that there was no basis in either statute or legislative history to support the authority of Department of Health and Human Services (DHHS) to make such a rule. Shehan notes the judge's "powerful argument" that if DHHS's general powers were extended to include the authority to force price disclosure in commercials, "it could also use that authority" to regulate many other subjects not identified in the law, "like medical school tuition rates or hospital executive compensation." *(subscription required to access article)*

> June 9, 2019
James C. Shehan, Chair of Lowenstein's **FDA Regulatory** practice, is interviewed on the "Not So Different" podcast by the ***Center for Biosimilars*** on the FDA's recently released final guidelines on demonstrating interchangeability, which Shehan knows well because he helped craft the sections of the Biologics Price Competition and Innovation Act that govern interchangeability. He also addresses the upcoming transition of insulin to its regulation as a biologic instead of as a drug, and the possibility of it being categorized as an interchangeable one day.

> May 1; May 25, 2019
Morningstar Inc., Yahoo Finance, BioSpace, Cision PR Newswire, Chain Drug Review, and the **Global Legal Chronicle** note Lowenstein Sandler as counsel to Crown Laboratories, Inc. and Hildred Capital Partners LLC in Crown's acquisition of the North American distribution rights to Keri from GlaxoSmithKline plc (NYSE: GSK). (Lowenstein deal team: **Herschel S. Weinstein**, **Sam E. Khan**, **Mitchell McDonald**, **James C. Shehan**, **Matthew P. Hintz**, **Michael A. Buxbaum**, **Matthew Tippy**, **Erica Perlmutter**, **Jeffrey M. Shapiro**, and **Jack Sidorov**.) **View Lowenstein's news announcement about this transaction.**

> April 8, 2019
A video interview with **James C. Shehan**, Chair of Lowenstein's **FDA Regulatory** practice, on the FDA's new approach to citizen petitions aimed at delaying market entry of

products, was published on the **CenterForBiosimilars.com**. Shehan explains that the agency has issued more details on the criteria it will use in deciding whether a petition's primary purpose is to delay generic competition.

> March 6-9, 2019

James C. Shehan is quoted in **CenterForBiosimilars.com,** ***BioPharma Dive*****,** and ***Modern Healthcare*** discussing what the biosimilars industry will look like once FDA Commissioner Scott Gottlieb, MD steps down this April. Shehan notes that Gottlieb represented "a quantum leap in terms of activism" and "has gotten far and away the highest job marks of any commissioner we've seen, particularly when you consider that he has gotten respect across the board, which is unusual", further noting the change in approach to the biosimilars market Gottlieb has taken during his tenure at the FDA resulting in a more competitive drug market. Shehan observes that Gottlieb's legacy will encourage his successors to "be more communicative with the public and more willing to take a role in some of the great public health controversies", he further provides that the industry's concern is rooted in the uncertainty of who the next commissioner will be and if he or she will be able to keep this positive action going.

> January 25, 2019

James C. Shehan is quoted in an article discussing high drug prices and Congressional activity aimed at driving down rising costs. In ***The American Journal of Managed Care***, his interview with *The Center for Biosimilars* is referenced, with Shehan commenting that the U.S. Congress has been "all talk and no action" for the last decade. States, however, Shehan notes, have taken concrete action on drug pricing, with almost every state having considered some kind of proposal and a number of laws enacted.

> January 24, 2019

The PE Hub Network, **The Deal**, and ***Law360*** (**December 12, 2018**; **January 24, 2019**) note Lowenstein Sandler as lead counsel to Cerberus Capital Management, L.P. in its acquisition of Sparton Corporation (NYSE: SPA). (Lowenstein deal team: **Marita A. Makinen**, **Robert G. Minion**, **Jeffrey Blumenfeld**, **Mary J. Hildebrand**, **Nicholas G. Mehler**, **Christine Osvald-Mruz**, **Matt Savare**, **Jeffrey M. Shapiro**, **James C. Shehan**, **Michael Walutes**, **Jack Sidorov**, **Norman W. Spindel**, **Stuart S. Yusem**, **Manali Joglekar**, **Sabrina Cua**, **Allison Gabala**, **Megan Monson**, **Alex H. Rosenthal**, **Bryan Sterba**, **Matthew Tippy**, **Lauren E. Killeen**, and **Lauren M. Troeller**.) *(subscription required to view certain content)* ***View Lowenstein's news announcement about this transaction.***

> November 30 - December 3, 2018

Business Wire, **MarketWatch**, **Pharmaceutical Business Review**, **Cosmetics Technology**, **ABF Journal**, **Cision PR Newswire**, and the ***Tullahoma News*** note Lowenstein Sandler as counsel to Crown Laboratories, Inc. (Crown Laboratories) and Hildred Capital Partners, LLC in Crown Laboratories' acquisition of the North American distribution rights of five OTC consumer brands from GlaxoSmithKline plc (NYSE: GSK). (Lowenstein deal team: Herschel S. Weinstein, **Sam E. Khan**, **Mitchell McDonald**, **Sunita Patel**, **James C. Shehan**, **Matthew P. Hintz**, **Sofia Kopelevich**, **Michael A. Buxbaum**, Nicholas Gonski, **Matthew Tippy**, **Jeffrey M. Shapiro**, and **Jack Sidorov**. ***View Lowenstein's news announcement about this transaction.***

> October 29-December 27, 2018

Reuters, **Axios**, **The PE Hub Network**, ***Food Processing Technology*** (**October 31, 2018**; **November 2, 2018**), **Global Legal Chronicle**, and **just-food.com** note Lowenstein Sandler as counsel to Traub Capital LLC in its acquisition of Signature Brands from The Hero Group. (Lowenstein deal team: **Michael A. Brosse**, **Michael J. Mueller**, **Sabrina Cua**, **Justin Gindi**, **Lowell A. Citron**, **Theodore C. Sica**, Nicholas Gonski, **Michael Walutes**, **Nicholas G. Mehler**, **Matthew P. Hintz**, **Sofia Kopelevich**, **Darren Goodman**, **Megan Monson**, **Eric Jesse**, **James C. Shehan**, **Stuart S. Yusem**, and **Mitchell McDonald**.) ***View Lowenstein's news announcement about this transaction.***

> October 15, 2018

James C. Shehan is quoted in ***Law360*** in an article discussing the Administration's proposed regulation forcing disclosure of drug prices in TV ads. Shehan notes that the proposal pushes the limits of existing legal authority.

> October 10, 2018

StreetInsider.com, **MarketWatch**, **RTTNews**, **The Advocate**, **Markets Insider**, and **Seeking Alpha** highlight Lowenstein client Compassionate Care Hospice's entering a definitive agreement to be acquired by Amedisys, Inc. (Lowenstein deal team: **Marita A. Makinen**, **Annie Nazarian Davydov**, **James C. Shehan**, **Michael Walutes**, **Michael N. Gooen**, **Darren Goodman**, **Sophia Mokotoff**, **Jack Sidorov**, and **Scott Siegel**.) ***View Lowenstein's news announcement about this transaction.***

> September 6, 2018

Pink Sheet quotes **James C. Shehan** in an article reporting pharmaceutical company Sanofi's settlement with the U.S. Securities and Exchange Commission for violating the Foreign Corrupt Practices Act (FCPA). The article notes that this settlement follows a relatively quiet period for FCPA settlements. Shehan attributes the lack of FCPA enforcement activity to the fact that "there are fewer easy cases out there for prosecutors to go after," that there can be a long period between the alleged violation and resolution of the case, and that companies have generally become more compliant with the law. *(subscription required to access article)*

> August 10, 2018

Law360 interviews with **James C. Shehan** on a broad range of issues, including: critical skills for being a successful FDA lawyer, a move to streamline the FDA's approval process, patent litigation involving biosimilars, FDA updates to off-label promotion guidance, a push in favor or competition and generics, and understanding why the FDA has reduced the number of warning and untitled letters for promotional issues. *(subscription required to access article)*

> July 10, 2018

Law360 quotes **James C. Shehan** in an article discussing the likelihood of an increase in litigation against U.S. Food & Drug Administration (FDA) policies should the Hon. Brett Kavanaugh of the U.S. Court of the Appeals for the District of Columbia Circuit be confirmed to the U.S. Supreme Court. Judge Kavanaugh has criticized the Supreme Court's **Chevron doctrine**, which mandates judicial deference to reasonable administrative agency interpretations of ambiguous federal laws, as enabling agencies to "stretch the meaning of statutes." Shehan predicts that a shift by the Court on ***Chevron*** will spark more lawsuits against the FDA. He notes that while ***Chevron*** may still inspire judicial deference in cases involving complex scientific matters, any lessening of deference more generally would diminish the FDA's authority. *(subscription required to access article)*

> June 16, 2018

Modern Healthcare quotes **James C. Shehan** in an article profiling U.S. Food and Drug Administration commissioner Dr. Scott Gottlieb's positive performance to date. Shehan states that Gottlieb is "the most prominent FDA commissioner in terms of getting out in front of the public" and that he is garnering approval from both the public and the pharmaceutical industry.

- April 19, 2018
  Modern Healthcare quotes **James C. Shehan**, Head of Lowenstein's FDA Regulatory Practice, on how the FDA's new Medical Device Safety Action Plan will fill gaps in device regulation and may portend further FDA action in other areas.
- January 20, 2018
  James C. Shehan, Head of Lowenstein's FDA Regulatory Practice, is quoted in ***Modern Healthcare*** regarding the security of medical devices pertaining to health systems, noting the lack of absolute security in the electronic world.
- January 19, 2018
  James C. Shehan comments in ***Law360*** on the FDA's 2017 enforcement statistics showing a continued drought of drug promotion enforcement.
- December 6, 2017
  James C. Shehan is quoted in ***Modern Healthcare*** regarding the FDA's final guidance on 3-D printed medical devices and how it will spur innovation.
- February 15, 2017
  Jim Shehan comments in **Reuters** on Trump administration proposals for FDA deregulation.
- January 20, 2017
  Jim Shehan comments in **Law360** on the deluge of bold policy statements made by the FDA during the final days of the Obama administration.
- September 19, 2016
  In **Bloomberg Law**, **Jim Shehan** comments on the importance of maintaining contacts for GCs returning to law firms.
- September 19, 2016
  In **Bloomberg Law**, **Jim Shehan** comments on the importance of maintaining contacts for GCs returning to law firms.

SPEAKING ENGAGEMENTS

- Panelist, **Next Generation Orphan Drug Incentives,** BIO, Webinar, June 8, 2020
- Speaker, **Lowenstein Sandler and ACC New Jersey's 5th Annual Cyber Day,** Lowenstein Sandler; ACC New Jersey, Roseland, NJ, October 3, 2019

EDUCATION

- Georgetown University Law Center (J.D. 1985)
- Columbia College, Columbia University (B.A. 1982), Biology, French Concentration

ADMISSIONS

- New York
- District of Columbia