WILSON SONSINI

David M. Hoffmeister

RETIRED MEMBER

Corporate

Palo Alto

FOCUS AREAS

Biotech

Corporate

Corporate Governance

Digital Health

FDA Regulatory, Healthcare, and Consumer Products

FoodTech and AgTech

Global Generics

Life Sciences

Medical Devices

HIGHLIGHTS

Representation of Innovative Life Sciences Clients
David was advisor to a wide range of pharmaceutical, biotechnology, medical device, diagnostic, and dietary supplement clients.

Comprehensive Practice
During his career, David advised clients on a variety of regulatory and healthcare issues, including strategies for obtaining FDA product approvals and clearances, recalls, labeling, and claim support for advertising and promotional materials.

A Recognized Practitioner
David was named among the *Daily Journal's* "25 Leading Biotech Attorneys" in California and was recognized as one of the leading food and drug regulatory attorneys in the U.S.

Established Author
David has published many articles about the FDA and pharmaceutical and medical device industries.

EXPERIENCE

David Hoffmeister retired as a partner from Wilson Sonsini Goodrich & Rosati in 2023. He was a senior practitioner in the firm's drug and device regulatory practice as well as the firm's life sciences group. He was named as one of the "25 Leading Biotech Attorneys" in California by the *Daily Journal*, and was recognized as one of the leading food and drug regulatory attorneys in the country.

David has more than 25 years of experience in drug and device regulatory and healthcare law matters. He represented pharmaceutical, biotechnology, medical device, diagnostic, and dietary supplement clients, advising them on a variety of regulatory and healthcare issues, such as strategies for obtaining FDA product approvals and clearances, recalls, labeling, and claim support for advertising and promotional materials. He also conducted numerous internal investigations for pharmaceutical and medical device companies involving fraud and abuse, advertising and promotional practices, and clinical research practices.

Earlier in his career, David was senior counsel for drug and device law at Syntex U.S.A., Inc., where his primary focus was advising senior management on worldwide issues affecting the ability of the corporation and its affiliates to develop, manufacture, and distribute pharmaceutical, device, diagnostic, and over-the-counter drugs in compliance with the Federal Food, Drug, and Cosmetics Act, as well as implementing regulations and applicable state and federal healthcare laws.

CREDENTIALS

Education

- J.D., University of San Francisco School of Law, 1987
- B.S., Business Administration, University of the Pacific, 1982

Associations and Memberships

- Member, Editorial Advisory Board, Thompson FDA Advertising and Promotion Manual
- Member, Food and Drug Law Institute

Honors

- Named among the *Daily Journal's* "25 Leading Biotech Attorneys" in California, 2011
- Selected as a "Highly Recommended Life Sciences Regulatory Attorney in the United States and Silicon Valley," *Global Counsel 3000* (2002-2005 editions)
- AV Preeminent Peer Review Rating, Martindale-Hubbell

Admissions

- State Bar of California
- Various federal courts

CLIENTS

Select Clients

- Align Technology, Inc.
- Becton Dickenson (BD Rx)
- Cutera
- Heidelberg Engineering
- InSound Medical
- Instrumentation Laboratories
- Insulet
- Mylan
- Varian Medical Systems

INSIGHTS

Select Publications

- Co-author, "New Reimbursement Rules Will Likely Impact Digital Health and Telemedicine," Wilson Sonsini Alert, December 2, 2022
- Co-author, "DOJ Civil Division's Consumer Protection Branch Features FDA Enforcement Actions in its First-Ever Annual 'Recent Highlights' Report," Wilson Sonsini Alert, April 25, 2022
- Co-author with G. Ravitz, J. Ravitz, and E. Yin, "Prescription Drug Provisions in the Build Back Better Act," Wilson Sonsini Alert, January 10, 2022
- Co-author with P. Gadiock, G. Ravitz, J. Ravitz, and E. Yin, "FDA Issues Draft Transition Plans for Medical Devices Commercialized Pursuant to EUA or Enforcement Discretion Policy During COVID-19 Emergency," Wilson Sonsini Alert, December 23, 2021
- Co-author, "Employer Vaccination Programs: Wielding Carrots and Sticks," *Daily Journal*, March 22, 2021
- Co-author, "FDA Complete Response Letters," Lexis Practical Guidance, October 16, 2020
- Co-author, "The FDA and Qualified Health Claims: A Case Study," *Daily Journal*, August 12, 2020
- Co-author, "Why FDA's Proposed Food Standard Principles Are Important," *Law360*, June 30, 2020
- Co-author, "Bill Would Bring Drugs That Treat Serious Conditions to Market Faster," *Daily Journal*, June 16, 2020
- Co-author, "FDA, FTC Issue Joint Statements on Efforts to Support Market for Biologics," *Daily Journal*, February 24, 2020
- Co-author with V. Norviel, L. Lieto, G. Ravitz, J. Ravitz, C. Andres, and R. Watkins, "Citizen Petitions are Crucial in Managing A Drug's Life Cycle," *Law360*, November 8, 2019
- Co-author with V. Norviel, J. Galvin, C. Andres, D. Rowe, and D. Knapp, "Cures Revolution May Reshape Pharmaceutical Landscape," *Law360*, June 14, 2018
- Co-author with C. Andres and F. Tian, "Digital Health: FDA Gives Nod to Multiple First-in Class Devices?" *Cyberspace Lawyer*, Vol. 23, Issue 1, January/February 2018
- Co-author with M. Skubatch, C. Andres, D. Van Goor, and I. Dasgupta, "Dietary Supplements And FDA: Potential For Partnership?" *Law360*, March 7, 2018
- Co-author with M. Skubatch, V. Norviel, and C. Andres, "Complying with Expanded Access Policy Drug Laws," *Law360*, February 28, 2017
- Co-author, "The Serious and Immense Impact of a Medical Device Hack," *Law360*, January 12, 2017
- Co-author, Brief for *amici curiae* Amarantus Bioscience Holdings, Inc., Exo Incubator, Inc., and Michael Heltzen in support of petitioner, *Sequenom, Inc. v. Ariosa Diagnostics, Inc., et al.*, On

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, No. 15-1182
- Co-author, Brief for *amici curiae* Population Diagnostics, Inc., Avant Diagnostics, Inc., Personalis, Inc., Linda Bruzzone, and Erin Marie Mading in support of petitioner, *Sequenom, Inc. v. Ariosa Diagnostics, Inc., et al.*, On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit, No. 15-1182
- Co-author with D. Van Goor and C. Andres, "How Pharma Companies Can Lessen the Risk of Government Action," *Law360*, February 9, 2016
- Co-author with V. Norviel, P. Girinath, C. McAndrew, and C. Andres, "FDA Developments in 2015 and What's to Come in 2016," *Law360*, January 11, 2016
- Co-author with V. Norviel, C. Aronin, D. Rowe, and C. Andres, "The Retrospective Approach to Companion Diagnostics," *Law360*, October 8, 2015
- Co-author with V. Norviel, S. Silber, E. Yin, and C. Andres, "A Look at the Legality Behind Daraprim's Price Spike," *Law360*, September 30, 2015
- Co-author with V. Norviel, M. Hostetler, P. Girinath, D. Van Goor, and C. Andres, "Overcoming Restriction Requirements On Pharma Patents," *Law360*, August 4, 2015
- Co-author with V. Norviel, D. Carsten, and C. Andres, "Amarin Decision Opens Door to Longer Exclusivity Periods," *Law360*, June 12, 2015
- Co-author with V. Norviel, D. Rowe, and C. Andres, "The Rise Of Companion Diagnostics In Personalized Medicine," *Law360*, June 5, 2015
- Co-author with C. Andres, "An In-Depth Look at the Personal Care Products Safety Act," *Law360*, May 5, 2015
- Co-author with C. Andres, "'Cosmeceutical' Classification in Regulatory Crosshairs," *Law360*, April 8, 2015
- Co-author with V. Norviel and C. Andres, "FDA Regulation in Clinical Labs," *Clinical Lab Products*, Vol. 45, No. 3, March 2015
- Co-author with V. Norviel, S. Liu, P. Girinath, and C. Andres, "There's a Lot to Like About Hamburg's Legacy at the FDA," *Law360*, February 9, 2015
- Co-author with V. Norviel, L. Lieto, T.J. Noh, M.C. Easterday, P. Girinath, and C. Andres, "Reflections on the Remarkable Rise of Orphan Drugs," *Law360*, January 28, 2015
- Co-author with V. Norviel, J. Guise, P. Munson, D. Carsten, S. Williams, R. Torczon, P. Girinath, and C. Andres, "A Good Opinion Is Worth Its Weight in Gold: Take-Home Lessons for Generic Pharmaceutical Companies to Minimize the Risk of Fee Shifting and Sanctions in the Wake of *Highmark* and *Octane Fitness*," Generic Pharma Litigator, January 28, 2015
- Co-author with V. Norviel and C. Andres, "FDA Takes Another Step Toward Regulating LDTs," *Law360*, October 9, 2014
- Co-author with V. Norviel, J. Guise, P. Munson, S. Williams, D. Carsten, R. Torczon, C. Andres, and P. Girinath, "Takeaways for Generics After Octane and Highmark," *Law360*, September 15, 2014
- Co-author with V. Norviel, R. Torczon, P. Girinath, and C. Andres, "Despite GAIN Act, Antibiotic Patents Face Setbacks," *Daily Journal*, August 27, 2014
- Co-author with V. Norviel, P. Girinath, and C. Andres, "USPTO Rules Will Set Back Antibiotic Drug Development," *Law360*, May 23, 2014
- Co-author with V. Norviel, S. Elamrani, P.R. Munson, and C. Andres, "New Exclusivity for Fixed-Dose Drugs Will Help Small Firms," *Law360*, April 28, 2014
- "Research Grants and Fraud Laws: The Need to Separate Sales and Science," *Legal Backgrounder*, Vol. 18, No. 29, Washington Legal Foundation, July 2003
- Co-author. "In The Eye of the Storm: Tips for Managing an FDA Recall," *Legal Backgrounder*, Vol. 17, No. 37, Washington Legal Foundation, September 2002
- "FDA Guidance Needed on Internet Advertising and Promotion of Drugs and Medical Devices," *Update*, Issue 4, Food and Drug Law Institute, August 2000

Select Speaking Engagements

- Speaker, "Off-label Promotion – Minimizing the Risk," FX Conferences, October 16, 2015
- "Gaining Control When a Badge Walks through the Door," Food and Drug Law Institute, Advanced Enforcement Conference, Washington, D.C., June 2001
- "Marketing in the 21st Century, The Changing Legal and Regulatory Landscape," Keynote Speech, Medical Marketing Association National Conference, Scottsdale, June 2000
- "The Need to Implement a Product Recall Policy," Food and Drug Law Institute Recall Conference, Irvine, California, March 1999
- "The Food and Drug Administration Modernization Act of 1997, An Overview," Ernst & Young Life Sciences Conference, Tel Aviv, Israel, 1998