WILSON SONSINI

Daniel E. Orr

SENIOR COUNSEL

FDA Regulatory, Healthcare, and Consumer Products

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FOCUS AREAS

Biotech

FDA Regulatory, Healthcare, and Consumer Products

Intellectual Property

Life Sciences

Medical Devices

Regulatory

EXPERIENCE

Dan Orr is senior counsel at Wilson Sonsini Goodrich & Rosati, where he brings an insider's perspective to helping clients prevent and solve problems with the U.S. Food & Drug Administration. Dan, a former FDA regulatory counsel, has more than 20 years of experience concerning regulation of drugs, biologics, and medical devices.

At the FDA, Dan developed wide-ranging, national policies for drugs and biologics and solved regulatory problems in a portfolio of products with combined annual sales of over $37 billion. He also served on the agency's exclusivity board and is frequently sought as an expert concerning regulatory exclusivity and FDA-related patent issues.

Dan represents clients before the FDA and in related transactions and litigation, such as life-cycle management, rulemaking and petitions, compliance issues, FDA dispute resolution, and regulatory due diligence.

He is practicing virtually in Pennsylvania, where he is licensed.

CREDENTIALS

Education

- J.D., Vanderbilt University Law School
- M.A., University of Pennsylvania
- B.A., University of Pennsylvania
  With Distinction
- B.S., City University of New York
  Cum Laude

Associations and Memberships

- Editorial Board, *Food and Drug Law Journal,* Food & Drug Law Institute
- Lifetime Member, Food & Drug Administration Alumni Association
- Member, Food and Drug Law Institute

Honors

- FDA Group Recognition Award, Biosimilar Education & Outreach, 2017
- FDA Group Recognition Award, Quality Metrics, 2017
- FDA Group Recognition Award, Approval of Glatopa, First Generic Drug to Copaxone, 2016
- Equal Justice Medal, Legal Services Corporation of New Jersey, 2008

Admissions

- Bar of the District of Columbia
- State Bar of New Jersey
- State Bar of New York

- State Bar of Pennsylvania
- U.S. Supreme Court
- U.S. Patent and Trademark Office

MATTERS

Representative Experience

- Represented a Fortune 500 biopharmaceutical manufacturer before the FDA regarding exclusivity for a biologic with over $6 billion in annual sales.*
- Advised a Fortune 500 client concerning life-cycle management of drugs and biologics acquired in an over $50 billion corporate merger.*
- Counseled multiple national and regional laboratory clients concerning FDA regulation of laboratory developed tests.*
- Represented a Fortune 500 manufacturer in FDA dispute resolution concerning pediatric studies for a biologic with over $1 billion in annual sales.*
- Assisted a publicly traded client in obtaining a Regenerative Medicine Advanced Therapy designation for an orphan designated cell therapy.*
- Assisted a Fortune 500 client in demonstrating clinical superiority to overcome orphan exclusivity held by a competing product.*
- Defended a European pharmaceutical manufacturer in a $110 million suit that claimed the client's manufacturing processes violated the FDA's Good Manufacturing Practice regulations.*
- Advised a publicly traded pharmaceutical manufacturer in obtaining FDA approval to remove a boxed warning from its product label.*
- Counseled a European pharmaceutical manufacturer concerning compliance problems detected during acquisition of two U.S. manufacturing facilities.*
- Obtained dismissal of four state attorney-general investigations against a national medical device manufacturer as preempted by FDA approval.*
- Assisted a Chinese animal drug manufacturer in reconditioning product labels to obtain release from FDA and U.S. Customs detention.*
- Guided three regional physician practice groups concerning the scope of permissible "off-label" promotion for an FDA-approved medical device.*

**Denotes experience at another firm prior to joining Wilson Sonsini.*

INSIGHTS

Select Publications

- "Congress Must Fix the Inflation Reduction Act Before Millions Lose Treatment for Rare Diseases," *Yale Law & Policy Review Inter Alia*, December 2023
- "How to Pick a Winning Patent," 21(2) *UCLA Journal of Law & Tech*, 2017
- "International Discovery Agreements Can Facilitate the Transfer of Data from the European Union," 200 *New Jersey Law Journal* 167, 2010
- Co-Author with C. Guthrie, "Anchoring, Information, Expertise, and Negotiation: New Insights from Meta Analysis, 21(3) *Ohio State Journal on Dispute Resolution* 597, 2006
- Co-Author with J. Ferrigno-Stack, "Childproofing on the World Wide Web," 41 *Jurimetrics Journal* 465, 2001

Select Speaking Engagements

- Discussant, "Regulating on Shifting Sands: Analyzing the Impact of Recent and Upcoming Federal Court Decisions on FDA's Authority," *Food and Drug Law Journal* Symposium, November 2023
- Panelist, "How to Navigate the FDA Approval Process and Other Regulatory Issues," SCBIO, December 2020
- Guest Lecturer, "From Lab to Clinic: Early-Stage Interactions with the FDA," Georgetown University Medical Center, September 2019
- Instructor and Curriculum Advisor, "Introduction to Drugs and Biologics Regulation," Food & Drug Law Institute, 2018-2019 (3 sessions)
- Panelist, "Regulatory and IP Issues for Immunotherapies Including CAR-T and Antibody Technologies," American Intellectual Property Law Association, October 2018
- Instructor, "Introduction to Drug Law," FDA Training Academy, 2014-2016 (3 sessions)