

Eva F. Yin

PARTNER

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FOCUS AREAS

Advertising, Promotions,
and Marketing

Animal Health

Artificial Intelligence and
Machine Learning

Biotech

Consumer Products and
Services

Corporate

Digital Health

FDA Regulatory, Healthcare,
and Consumer Products

Global Generics

Life Sciences

Medical Devices

Regulatory

EXPERIENCE

Eva Yin, Ph.D., M.P.H., is a partner in Wilson Sonsini Goodrich & Rosati's FDA regulatory, healthcare, and consumer products practice. Her practice includes conducting FDA and healthcare regulatory due diligence for corporate transactions; providing legal counsel to manufacturers regarding FDA approval/clearance for various products—including medical devices, mobile apps, and drugs, FDA compliance, regulation of promotional materials and labeling, and manufacturer compliance under federal and state healthcare laws, e.g., the federal Anti-Kickback Statute (AKS), False Claims Act (FCA), Sunshine Act, state licensing laws, corporate practice of medicine, etc.; reviewing contracts and compliance policies for manufacturers; and providing legal analysis and risk assessment of business models and fee arrangements involving patient assistance programs, healthcare professionals, or hospitals/clinics under federal and state healthcare laws and regulations.

Eva's prior experience also includes patent counseling and patent prosecution for various life sciences and biotechnology companies, freedom-to-operate analysis, non-infringement and invalidity analyses, and legal research for matters involving proceedings before the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office.

Before joining Wilson Sonsini, Eva worked as an associate in the healthcare group of Sidley Austin LLP in San Francisco, where she advised pharmaceutical and medical device manufacturers on healthcare regulatory compliance, risks under the AKS, risks of off-label marketing, and Medicare coverage and reimbursement matters, as well as represented pharmaceutical and medical device manufacturers in government investigations.

CREDENTIALS

Education

- J.D., University of California College of the Law, San Francisco
- M.P.H., Johns Hopkins Bloomberg School of Public Health
- Ph.D., Molecular Biophysics and Biochemistry, Yale University
- B.S., Chemistry and Biology, Emory University

Associations and Memberships

- Member, American Health Law Association
- Member, Food and Drug Law Institute

Honors

- Named winner in *Profiles in Diversity Journal* for the 2023 Asian Leadership Awards
- Recognized as a top author for life sciences by *JD Supra's* "2023 Readers' Choice Awards"

Admissions

- State Bar of California
- State Bar of Washington

- U.S. Patent and Trademark Office

INSIGHTS

Select Publications

- Co-author, "California Prepares First-of-Its-Kind Food Additive Ban in the United States," Wilson Sonsini Alert, September 18, 2023
- Co-author, "FDA Cracks Down on Unapproved Eye Products," Wilson Sonsini Alert, September 18, 2023
- Co-author, "HHS Names the First 10 Drugs for Medicare Price Negotiation," Wilson Sonsini Alert, September 5, 2023
- Co-author, "Federal Circuit Affirms Jazz Pharmaceutical's Risk Evaluation and Mitigation Strategy patent Is Not Listable in Orange Book," Wilson Sonsini Alert, March 13, 2023
- Co-author, "Not Waiting for the Cows to Come Home, the FDA Issues Guidance for Labeling of Plant-Based Milk Alternatives," Wilson Sonsini Alert, February 24, 2023
- Co-author, "2022-2023 Medical Product and Service Regulatory Initiatives," Wilson Sonsini Alert, February 10, 2023
- Co-author, "Biden Administration's End to COVID-19 Public Health Emergency to Impact Devices Under Enforcement Discretion," Wilson Sonsini Alert, February 9, 2023
- Co-author, "FTC Releases Health Products Compliance Guidance," Wilson Sonsini Alert, January 3, 2023
- Co-author, "New Reimbursement Rules Will Likely Impact Digital Health and Telemedicine," Wilson Sonsini Alert, December 2, 2022
- "OIG Special Fraud Alert Lists Suspect Characteristics in Telemedicine and Telehealth Arrangements," Wilson Sonsini Alert, August 1, 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 D. Hoffmeister, G. Ravitz, and J. Ravitz, "Prescription Drug Provisions in the Build Back Better Act," Wilson Sonsini Alert, January 10, 2022
- Co-author with P. Gadiock, D. Hoffmeister, G. Ravitz, and J. Ravitz, "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, "Biden Administration Inks Bills to Increase Drug Competition," Wilson Sonsini Alert, June 4, 2021
- Co-author, "From the PTO to the FDA: What to Consider When Branding Clinical Trials," *The Intellectual Property Strategist*, Vol. 27, No. 5, February 2021
- Co-author, "Employer Vaccination Programs: Wielding Carrots and Sticks," *Daily Journal*, March 22, 2021
- Co-author, "From the PTO to the FDA: What to Consider When Branding Clinical Trials," *The Intellectual Property Strategist*, Vol. 27, No. 5, February 2021
- "2020 Health Care Fraud Takedown Focuses the Spotlight on Telehealth," Wilson Sonsini Alert, November 6, 2020
- "Basics of the PREP Act and Liability Immunity for COVID-19 Countermeasures," Wilson Sonsini Advisory, July 13, 2020
- "GMP Considerations for Pharmaceutical Manufacturers with Employees Who Test Positive for COVID-19," Wilson Sonsini Alert, July 13, 2020
- Co-author with P. Gadiock, "How to Incorporate FDA into Your R&D," *Digital Health Report*, Q1 2020
- Co-author, "FDA Issues Guidance on Clinical Trials During the COVID-19 Pandemic," Wilson Sonsini Alert, March 19, 2020
- Co-author, "HHS Announces Overhaul of Kickback and Stark Rules," WSGR Alert, October 17, 2019
- Co-author, "CMS Releases Key 2020 Payment and Policy Proposals," WSGR Alert, August, 8, 2019
- Co-author with D. Hoffmeister, J. Ravitz, G. Ravitz, and P. Gadiock, "Navigating the U.S. Healthcare Regulatory Landscape for Wearable Devices," *The Life Sciences Report*, Summer 2019
- Co-author, "CMS Proposes New Add-On Payment Pathway for Breakthrough Medical Devices," WSGR Alert, April 30, 2019
- Co-author, "DOJ Takes Down \$1.2 Billion Healthcare Fraud Scheme Involving Telemedicine, DME Companies, and Medical Professionals," WSGR Alert, April 12, 2019
- Co-author, "HHS Releases Proposed Rule That Could Significantly Impact Drug Manufacturers, PBMs, and Other Stakeholders," WSGR Alert, March 12, 2019
- Co-author with D. Hoffmeister, "AdvaMed Updates Its 'Code of Ethics on Interactions with U.S. Health Care Professionals,'" WSGR Alert, February 13, 2019
- Co-author, "FDA Issues Draft Guidance on Breakthrough Devices Program," WSGR Alert, November 13, 2017

- Co-author with V. Norviel, D. Hoffmeister, S. Silber, and C. Andres, "A Look at the Legality Behind Daraprim's Price Spike," *Law360*, September 30, 2015
- Co-author with A. Spencer and W. Sarraile, "Tracking HIPAA Liability Trends At The State Level," *Law360*, December 10, 2014
- Co-author with S. Bailey, C. Innis, M. Ciubotaru, S. Kamtekar, T. Steitz, and D. Schatz, "Structure of the RAG1 nonamer binding domain with DNA reveals a dimer that mediates DNA synapsis," 16(5) *Nature Structural & Molecular Biology* 499-508, 2009
- Co-author with T. Tishgarten, K. Faucher, R. Dluhy, T. Grant, G. Fischer von Mollard, T. Stevens, and L. Lipscomb, "Structures of yeast vesicle trafficking proteins," 8(11) *Protein Science* 2465-73, 1999

Select Speaking Engagements

- Speaker, "BBA Webinar: Health Law Regulatory Hot Topics," Boston Bar Association, February 16, 2023