

# WILSON SONSINI

## Georgia C. Ravitz

PARTNER

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### FOCUS AREAS

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Advertising, Promotions,  
and Marketing

Biotech

Consumer Products and  
Services

Digital Health

FDA Regulatory, Healthcare,  
and Consumer Products

FoodTech and AgTech

Global Generics

Life Sciences

Medical Devices

Regulatory

### EXPERIENCE

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Georgia Ravitz is a partner in the life sciences practice of Wilson Sonsini Goodrich & Rosati, where she specializes in FDA regulatory, healthcare, and consumer products innovation and compliance. In particular, she focuses on food and drug law and regulatory policy governing the regulation and promotion of medical devices, pharmaceuticals (including OTCs), health and beauty aids (cosmetics), dietary supplements, vitamins, food and agribusiness, tobacco and e-cigarettes, cannabis, and a wide variety of consumer goods and emerging consumer technologies. She counsels U.S. and foreign manufacturers, distributors, retailers, and importers of regulated products in all phases of their product lifecycle, from innovation through product commercialization and ongoing post-market compliance.

Prior to joining the firm, Georgia was a senior partner in the FDA and advertising practices of Arent Fox in Washington, D.C., where she led the firm's consumer product safety practice. She is a frequent speaker at conferences and events, and a regular contributor to leading trade and consumer media outlets.

### CREDENTIALS

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#### Education

- J.D., Emory University School of Law, 1989
- B.A., Skidmore College, 1985

#### Associations and Memberships

- Member, Advisory Board of the National Women's Law Center
- Member, The Food and Drug Law Institute
- Member, Association of Food and Drug Officials
- Member, Lawyers for Children America

#### Honors

- Honored as a "BTI Client Service All-Star Attorney" in 2019

#### Admissions

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

### INSIGHTS

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#### Select Publications

- Co-author, "Drug Use-Related Software Back in the Spotlight at the U.S. Food and Drug Administration," Wilson Sonsini Alert, October 2, 2023

- 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, "Next Step for Cosmetic Products' Regulatory Makeover," Wilson Sonsini Alert, August 17, 2023
- Co-author, "Lab to Table Dining-Coming Soon to a Kitchen Near You," Wilson Sonsini Alert, June 27, 2023
- Co-author, "FDA Accelerates Approval of Animals with Investigational Intentional Genomic Alterations (IGAs)," Wilson Sonsini Alert, June 5, 2023
- Co-author, "New Reimbursement Rules from Centers for Medicare & Medicaid Services Will Likely Impact Digital Health and Telemedicine," *The Journal of Federal Agency Action*, Vol. 1, No. 2, March-April 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, "A Much-Needed Makeover: Congress Signs Updates to Cosmetic Regulations," Wilson Sonsini Alert, January 17, 2023
- Co-author, "FTC Releases Health Products Compliance Guidance," Wilson Sonsini Alert, January 3, 2023
- Co-author, "DOJ Antitrust, OIG Announce Collaboration to Protect Healthcare Markets," Wilson Sonsini Alert, December 14, 2022
- Co-author, "New Reimbursement Rules Will Likely Impact Digital Health and Telemedicine," Wilson Sonsini Alert, December 2, 2022
- Co-author, "Prescription Drug Provisions in the Inflation Reduction Act of 2022," Wilson Sonsini Alert, August 29, 2022
- Co-author, "California Enacts Strict New Rules on Packaging Materials," Wilson Sonsini Alert, July 6, 2022
- Co-author, "FDA Issues Guidance on Importing Drugs from Canada," Wilson Sonsini Alert, June 22, 2022
- Co-author, "Privacy and Security of Health Information: A Primer for Digital Health Companies," Wilson Sonsini Client Advisory, June 1, 2022
- Co-author, "CDER Launches the ARC Program to Expedite Treatment Options for Rare Diseases," Wilson Sonsini Alert, May 20, 2022
- Co-author, "FDA Warns Companies Illegally Selling CBD and Delta-8 THC Products," Wilson Sonsini Alert, May 11, 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, "FDA Holds Webinar on Draft Transition Plans for COVID-19 Related Medical Devices and Enhances 510(k) Submission Tracker," Wilson Sonsini Alert, February 24, 2022
- Co-author with D. Hoffmeister, 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, D. Hoffmeister, 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, "FDA Grants Historic Approval for Alzheimer's Disease Therapy in Permissive Decision," Wilson Sonsini Alert, June 10, 2021
- Co-author, "FDA Cracks Down on Companies Listing CBD as an Inactive OTC Ingredient," Wilson Sonsini Alert, April 2, 2021
- Co-author, "Forecasting Healthcare Regulatory Developments in a Biden Administration," Wilson Sonsini Alert, February 26, 2021
- Co-author, "FDA Approves First-of-its-Kind Intentional Genetic Alteration in Pigs Intended for Food and Production of Human Therapeutics," Wilson Sonsini Alert, December 18, 2020
- Co-author, "In a Regulatory First, the Singapore Food Agency Approves Eat Just's Cell Cultured Chicken," Wilson Sonsini Alert, December 10, 2020
- Co-author, "HHS Shuts Down FDA's Unapproved Drugs Initiative," Wilson Sonsini Alert, December 1, 2020
- Co-author, "OIG Turns up the Volume on Industry-Sponsored Speaker Programs," Wilson Sonsini Alert, November 20, 2020
- Co-author, "FDA Authorizes First COVID-19 Test for Self-Testing at Home," Wilson Sonsini Alert, November 19, 2020

- Co-author, "The 2020 Election's Impact on CBD and Cannabis," Wilson Sonsini Alert, November 2, 2020
- Co-author, "FDA Issues Proposed Rule Clarifying the Types of Evidence It Considers When Determining the Intended Use of a Product," Wilson Sonsini Alert, October 9, 2020
- Co-author, "FDA Announces Proposed New Rule to Advance Food Traceability," Wilson Sonsini Alert, September 25, 2020
- Co-author, "Administration Issues Executive Order on Medicare Drug Pricing Which Attempts to Impose Price Controls on Drugs Purchased by the Federal Government," Wilson Sonsini Alert, September 14, 2020
- Co-author, "Administrative Notice Limits the FDA's Ability to Regulate Laboratory Developed Tests, Including COVID-19 Tests," Wilson Sonsini Alert, August 26, 2020
- Co-author, "FDA Issues Umbrella EUA for Surgical Masks," Wilson Sonsini Alert, August 20, 2020
- Co-author, "The FDA and Qualified Health Claims: A Case Study," *Daily Journal*, August 12, 2020
- Co-author, "In a Move Designed to Benefit Patients, the President Signs an Executive Order to Pass Drug Manufacturer Rebates Directly to Medicare Part D Patients," Wilson Sonsini Alert, August 11, 2020
- Co-author, "President Signs a 'Buy American for Essential Drugs and Medical Supplies' Executive Order," Wilson Sonsini Alert, August 7, 2020
- Co-author, "Patient Dies, and the FDA Issues Warning Letter to In-Vitro Diagnostic Medical Device Manufacturer," Wilson Sonsini Alert, August 3, 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 Issues Revised EUA for Disposable Filtering Facepiece Respirators Manufactured in China," Wilson Sonsini Alert, June 12, 2020
- Co-author, "FDA Issues Revised EUA for Disposable Filtering Facepiece Respirators (FFRs) Manufactured in China," Wilson Sonsini Alert, May 8, 2020
- Co-author, "FDA Issues Two Product-Specific Guidances for Chloroquine Phosphate and Hydroxychloroquine Sulfate Drug Developers," Wilson Sonsini Alert, April 20, 2020
- Co-author, "FDA and FTC Send Joint Warning Letters to Multiple Companies for 'Selling Fraudulent COVID-19 Products'," Wilson Sonsini Alert, April 16, 2020
- Co-author, "CARES Act Contains Significant New Over-The-Counter (OTC) Drug Provisions," Wilson Sonsini Alert, April 6, 2020
- Co-author, "FDA Issues Guidance on Use of 3D Printing on Medical Devices, Accessories, Components, and Parts," Wilson Sonsini Alert, April 1, 2020
- Co-author, "Discontinuance and Interruptions in Manufacturing During COVID-19," Wilson Sonsini Alert, March 31, 2020
- Co-author, "The CARES Act: A Summary for Technology and Life Sciences Companies," Wilson Sonsini Alert, March 30, 2020
- Co-author, "The CARES Act Brings Changes for Drug and Medical Device Oversight and New Options for Telehealth Services," Wilson Sonsini Alert, March 30, 2020
- Co-author, "FDA's COVID-19 Test Kit Policy Short sighted and Creates Unacceptable Industry Confusion," Wilson Sonsini Alert, March 27, 2020
- Co-author, "FDA Issues Guidance on Clinical Trials During the COVID-19 Pandemic," Wilson Sonsini Alert, March 19, 2020
- Co-author, "FDA Issues 'Immediately in Effect' Guidance to Accelerate Availability of COVID-19 Diagnostic Tests," Wilson Sonsini Alert, March 18, 2020
- Co-author, "FDA and FTC Send Joint Warning Letters to Seven Companies for 'Selling Fraudulent COVID-19 Products'," Wilson Sonsini Alert, March 10, 2020
- Co-author, "FDA Releases Final Guidance: Transition of Previously Approved Drugs to Being 'Deemed Licensed' Biologics," Wilson Sonsini Alert, March 6, 2020
- Co-author, "FDA Releases Table of Gene-Drug Interactions amid Ongoing Clash over Pharmacogenetics Tests," Wilson Sonsini Alert, February 25, 2020
- Co-author, "FDA, FTC Issue Joint Statements on Efforts to Support Market for Biologics," *Daily Journal*, February 24, 2020
- Co-author, "FDA Announces Unprecedented Recall of Dietary Supplements," Wilson Sonsini Alert, February 11, 2020
- Co-author, "FDA Reduces Regulatory Burden for Certain Medical Image Analyzers," Wilson Sonsini Alert, January 31, 2020
- Co-author, "FDA Issues Draft Guidance on Determining Sameness of Gene Therapies," Wilson Sonsini Alert, January 30, 2020
- Co-author, "Court Holds the FDA Cannot Classify an Imaging Agent Medical Device as a Drug," Wilson Sonsini Alert, December 19, 2019
- Co-author, "A Preliminary Evaluation of the RMAT Designation's Effect on Publicly Traded Company Stock Price," Wilson Sonsini Alert, December 16, 2019

- Co-author, "Despite Easy Confirmation, Difficult Issues Lie Ahead for New FDA Commissioner Stephen Hahn," Wilson Sonsini Alert, December 13, 2019
- Co-author, "FDA Declares CBD Is Not GRAS and Signals That It Will Maintain Its Deliberate Approach," Wilson Sonsini Alert, November 26, 2019
- Co-author with V. Norviel, L. Lieto, D. Hoffmeister, J. Ravitz, C. Andres, and R. Watkins, "Citizen Petitions are Crucial in Managing A Drug's Life Cycle," *Law360*, November 8, 2019
- Co-author, "FDA Issues Final Guidance on Citizen Petitions and Stay of Action Petitions Subject to FDCA Section 505(q)," Wilson Sonsini Alert, November 4, 2019
- Co-author, "FDA Issues Final Guidance on PDUFA Waivers, Reductions, and Refunds," Wilson Sonsini Alert, October 18, 2019
- Co-author, "Delaware Court Notes Significance of Director Oversight of 'Mission Critical' Operations," Wilson Sonsini Alert, October 9, 2019
- Co-author, "FDA Issues Warning Letter for Refusal to Permit Inspection: Important Takeaways for Startups and Drug and Device Manufacturers," Wilson Sonsini Alert, October 7, 2019
- Co-author, "Microbes and Medical Foods: A Growing Area of Commercial Importance," Wilson Sonsini Alert, September 25, 2019
- Co-author, "Senate Majority Leader Intensifies Pressure on FDA to Expedite Cannabis Guidance," Wilson Sonsini Alert, September 19, 2019
- Co-author, "Congressional Committee Targets Private Equity Firms on Medical Billing Practices," Wilson Sonsini Alert, September 18, 2019
- Co-author, "FDA Finalizes Guidance on Special 510(k) Pathway," Wilson Sonsini Alert, September 16, 2019
- Co-author, "Administration Again Seeks Lower Drug Prices," Wilson Sonsini Alert, August 23, 2019
- Co-author, "FDA Issues First FSVP Warning Letter," Wilson Sonsini Alert, August 19, 2019
- Co-author, "CMS Makes CAR T-Cell Cancer Therapy Available," Wilson Sonsini Alert, August 14, 2019
- Co-author, "CMS Releases 2020 Payment and Policy Proposals," Wilson Sonsini Alert, August 8, 2019
- Co-author, "FDA Suspends Texas-Based Seafood Producer Registration," Wilson Sonsini Alert, August 5, 2019
- Co-author, "FDA Issues Cannabidiol Marketing Warning," Wilson Sonsini Alert, August 1, 2019
- Co-author, "FDA Prioritizes Review of Generic Drugs to Treat Opioid Overdose," Wilson Sonsini Alert, July 11, 2019
- Co-author, "Companies with New Cancer Drug Candidates: Plan Now for August 2020," Wilson Sonsini Alert, June 28, 2019
- Co-author, "FDA Updates Paragraph IV Certification to Spur Development Investment," Wilson Sonsini Alert, June 25, 2019
- Co-author, "FDA Target of Executive Order on Agricultural Biotech," Wilson Sonsini Alert, June 24, 2019
- Co-author, "FDA Launches Experimental Cancer Drug Project," Wilson Sonsini Alert, June 7, 2019
- Co-author, "CMS Proposes New Payment Pathway for Medical Devices," Wilson Sonsini Alert, April 30, 2019
- Co-author, "DOJ Takes Down \$1.2 Billion Healthcare Fraud Scheme," Wilson Sonsini Alert, April 12, 2019
- Co-author, "FDA Steps Toward Allowing CBD in Food, Beverages, and Supplements," Wilson Sonsini Alert, April 12, 2019
- Co-author, "Two Major Retailers Set to Sell CBD-Containing Products," Wilson Sonsini Alert, April 8, 2019
- "Anti-Aging Products Are Not Drugs! Does the Withdrawal of Import Alert 66-38 Signal a Change of Heart at the US Food and Drug Administration?" *Happi Magazine*, February 6, 2018
- "Cosmeceutical Claims May Be Headed into FDA's Radar," *The Tan Sheet* 8, August 10, 2009
- "Less Tolerant FDA May Flex Enforcement Muscles on Cosmeceuticals - Lawyer," *The Rose Sheet* 5, July 6, 2009
- Articles for Happi Magazine, a well-known publication for the household, chemical, and personal products industry. Some of the articles Georgia has written include: "Here's a Better Way to Substantiate Claims," "Will FDA Put the Heat on Salon Suppliers?" and "Should Your AHA Cream Carry a Warning Label?"

## Select Speaking Engagements

- Co-presenter, "Introduction to Advertising and Promotion for Medical Products," Food and Drug Law Institute, November 1, 2023

- Moderator, “FDA Regulation of Xenotransplantation for Medical Use,” [Food and Drug Law Institute Annual Conference](#), May 18, 2023
- Co-presenter, “Introduction to Medical Device Law and Regulation, Promotion and Advertising,” Food and Drug Law Institute/Center for Devices and Radiological Health, December 9, 2022
- Co-presenter, “Introduction to Medical Device Law and Regulation, Promotion and Advertising,” Food and Drug Law Institute/Center for Devices and Radiological Health, August 10, 2022
- “An Introduction to the Regulation of Promotion and Advertising for Medical Devices,” Food and Drug Law Institute’s Introduction to Medical Device Law and Regulation, November 18, 2021
- “The Regulation of Cosmetics,” Food and Drug Law Institute’s Introduction to Food Law and Regulation, March 18, 2021
- “Regulatory and Start-Up Considerations for Early-Stage Companies,” Future Food-Tech Conference, March 11, 2021
- “Path to Regulatory Approval – A New Era?” Edison Open House: Global Healthcare, January 19, 2021
- “Georgetown FDLI Lunch & Learn: CBD Regulation,” Food and Drug Law Institute, October 30, 2020
- “Regulatory Changes Impacting the Commercialization of Cannabis—Insights About FDA,” CiConnect CannaMed/Tech, May 1, 2019
- “Implementing Successful Strategies for the Substantiation of Environmental Claims,” ACI’s 2nd Annual Legal, Regulatory, and Compliance Forum on Advertising Claims Substantiation, New York, New York, February 1, 2019
- “The Foundation of Beauty: Cosmetics and Personal Care Products Law and Regulation 101,” 6th Annual Legal, Regulatory, and Compliance Forum on Cosmetics and Personal Care Products, New York, New York, March 28-29, 2019
- “Food and Drug Law Institute’s In-House Training Course,” FDA’s Center for Food Safety and Applied Nutrition, College Park, Maryland, August 8, 2018
- Product Recall Webinar, The Knowledge Group, June 14, 2018
- FDA Regulatory Session, Happi Anti-Aging Conference, New York, New York, May 15-16, 2018
- “Medical Product Advertising & Promotion, Social Media Dos and Don’ts” Webinar, FDAnews, January 24, 2018
- “FDA Regulatory Issues Impacting the Anti-Aging Category,” Happi Anti-Aging Conference, New Brunswick, New Jersey, November 29-30, 2017
- “Organic Food Claims: How Best to Defend Against Allegations of Economic Fraud from an FDA and USDA Perspective,” ANA/BAA Marketing Law Conference, Chicago, Illinois, November 13-15, 2017
- “Navigating Key Regulatory Agencies for the Food Industry: Comprehending the Jurisdiction, Function, Organization, and Interplay of the FDA, USDA, FTC, and Local Health Agencies,” ACI Food Law and Regulation Boot Camp, Chicago, Illinois, November 13-15, 2017
- “The Regulation of Cosmetics,” Food and Drug Law Institute Introduction to Food, Dietary Supplement, and Cosmetic Law and Regulation, August 15, 2017
- “Labeling in the Context of Social Media and Omnichannel Presence,” Cosmoprof, Las Vegas, Nevada, July 9, 2017
- “Navigating Advertising and Labeling Requirements for Cosmetics,” Cosmoprof, Las Vegas, Nevada, July 9, 2017
- “Made in USA” Presentation, BAA Marketing Law Conference, Chicago, Illinois, November 9, 2016
- “‘Made in USA’ Claims – FTC & California Perspectives,” BAA Marketing Law Conference, Chicago, Illinois, November 9, 2016
- “FDA Interface,” BAA Marketing Law Conference, Chicago, Illinois, November 9, 2016
- “FDA Regulatory Roundtable,” Happi Anti-Aging Conference, New Brunswick, New Jersey, September 21, 2016
- “Reprocessing of Reusable Devices,” Food and Drug Law Institute Annual Conference, Washington, D.C., May 5, 2016
- “Beauty Devices vs. Medical Devices: Understanding the Differences and Minimizing Legal and Regulatory Risks,” ACI Legal, Regulatory, and Compliance Forum on Cosmetics & Personal Care Products, New York, New York, March 7, 2016
- “Obtaining Clarity in Chemical and Environmental Safety Issues: Developing Strategies to Ensure Ingredient Safety and Substantiate Testing Protocols,” ACI Cosmetics Conference, New York, New York, March 24, 2015
- “FDA Regulatory Roundtable,” Happi Anti-Aging Conference, New Brunswick, New Jersey, September 11, 2015
- “FDA Overlap – Health & Wellness,” BAA Marketing Law Conference, Chicago, Illinois, November 7, 2014

- "FDA Regulatory Roundtable," Happi Anti-Aging Conference, New Brunswick, New Jersey, September 17, 2014
- "FDA Enforcement/Compliance: Recent Trends Related to Beauty/Personal Care Products," HBA Global Expo and Conference, New York, New York, June 11, 2014
- "Health, Cosmetic, and Luxury Marketing Issues and Claims," BAA Marketing Law Conference, Chicago, Illinois, November 20, 2013
- "FDA Roundtable on Anti-Aging Cosmetics," Happi Anti-Aging Conference, New Brunswick, New Jersey, October 30, 2013
- "Keeping Updated with the FDA: Your Ticket to Staying Out of Hot Water," HBA Global Expo & Conference, New York, New York, June 20, 2013
- "Product Labeling: Federal, State and Beyond – California's Proposition 65," ICPHSO ABA Law Day, Orlando, Florida, March 19, 2011
- "Analysis of Recall Law & Procedures," ICPHSO ABA Law Day, Orlando, Florida, February 25, 2011
- "Properly Building Your Regulatory Business Infrastructure," Global Regulations for Cosmetics Conference, June 2017