# Snell & Wilmer



Daniel S. Wittenberg

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### **Main Bio**

Dan Wittenberg's practice is concentrated on representing manufacturers and distributors of products across a vast array of industry sectors including: life sciences, medical technologies, pharmaceutical, consumer products, appliances, fall protection, food, cosmetics, dietary supplements, healthcare products, heavy equipment, oral and personal care products, power generation and timber. He regularly defends these companies in product liability litigation as well as counsels these businesses on agreements, risk avoidance/management strategies, labeling and marketing materials, instructions for use, as well as recalls and regulatory matters, including those involving the FDA and CPSC. Dan has served as national counsel for major medical device manufacturing concerns and regional as well as local counsel in mass tort cases. He has attained certification as a Global Regulatory Affairs Compliance Professional (GRACP). Dan also works with entities in technology transfer and intellectual property matters including university technology commercialization, litigation, licensing and agreement negotiations. He also represents individuals and companies in commercial litigation. Representative clients also include renewable/clean energy companies, such as a leading manufacturer of solar cells, panels, inverters and imaging detectors, as well as one of North America's largest wind energy companies.

Dan is a Co-Chair of the firm's Pharmaceuticals and Medical Devices Industry Group, is listed in The Best Lawyers in America<sup>®</sup>, Product Liability Litigation – Defendants and named by LMG as a Life Sciences Star. He is Peer Review Rated AV Preeminent in Martindale-Hubble and currently assisting clients throughout the Western United States including Arizona, California, Colorado, Nevada and Utah.

# Representative Experience

## Pharmaceutical, Medical Device, Life Science Companies

- Works extensively with medical technology and healthcare product companies on product liability related issues as well as counsel these businesses on regulatory, risk, compliance and transactional matters
- Vast experience in working with senior management including C-level executives, as well as with business units, sales teams, engineering departments, R&D, quality, regulatory, legal and medical safety representatives in addition to compliance departments
- Counsels companies on labeling, marketing, instructions for use, methods for creation of appropriate internal documentation with an eye towards reducing future risk exposure, as well as in responding to FDA inquiries concerning product lines or complaint trends, general investigations as well in responding to 483s

- Participated on the regional team defending a global pharmaceutical and biotechnology company in mass tort litigation involving diet drugs as well as mass tort litigation involving phenylpropanolamine
- Serves as local counsel in various jurisdictions defending a pharmaceutical company in litigation arising out of professionally labeled OTC products as well as local counsel for a pharmaceutical company in litigation arising out of gadolinium-based contrast agents
- Served as local counsel for a medical device manufacturer in the pain pump litigation and also counsels medical device manufacturers in product recall strategies and risk management issues

#### Medical Device & Pharmaceutical Manufacturers & Suppliers

- Litigated, negotiated and resolved cases involving:
  - o non-surgical transcatheter cardiac defect closure device
  - o biomedical/pharmaceutical grade tubing manufacturer
  - o self-reinforced, resorbable polymer implants for use in orthopedic surgery
  - laser surgical device for aesthetic applications
  - laser ophthalmic devices
  - o generic pharmaceuticals in tardive dyskinesia case
  - o dental anesthetics
  - electrosurgical generator units, electrodes and surgical devices in circumcision, dental and obstetrical oriented cases
  - o cryosurgery devices
  - manual and power wheelchairs
  - durable medical equipment including patient lifts, hospital beds, crutches, canes, walkers and scooters
  - o wheelchair lifts
  - vascular access products
  - infusion therapy devices
  - disposable surgical accessories
  - spinal implant and orthobiologic products
  - home-use electrotherapy products
  - over-the-counter pharmaceutical products

#### Defense of Other Manufacturers

- Forest products
- · Recreational accessories including towing products and bungee cords
- Underground construction equipment
- Heavy equipment
- Industrial gas turbine power system solutions
- Manufacturers of consumer products including appliances for use in and outside of the home

#### Commercial Matters

• Defended a publicly traded supplier of oxygen, respiratory and home infusion products in breach of contract action arising out of its acquisition of assets of predecessor entity, as well as in commercial

lease disputes, and contract action arising out of dispute over sales commissions

- Defended a leading independent provider of medical imaging software in breach of contract/licensing agreement dispute
- Defended major issuer in consumer credit card litigation
- Defended a worldwide manufacturer, distributor and servicer of medical devices in breach of contract, express indemnity and declaratory relief action arising out of suppliers' resolution of an independent underlying tort action
- Defended a debt consolidation company in unfair business practices and consumer legal remedies class action
- Negotiated resolution of breach of contract action arising out of dispute over sales commissions on behalf of global industrial laser manufacturer
- Favorably resolved a medical malpractice/elder abuse action against a home health care agency
- Negotiated positive resolution on behalf of a provider of health and medical career training institution arising out of one of its phlebotomy courses

#### Education

- University of Denver College of Law (J.D.)
- University of Colorado (B.A.)

## **Professional Memberships & Activities**

- American Bar Association
  - Litigation Section
    - Co-Chair, Food and Supplements Sub-Committee
    - Co-Chair, Sound Advice
    - Associate Editor, "Litigation News"
      - Columnist, "Business of Litigation"
    - Division Director (2010-2012)
      - Products Liability Committee, Co-Chair (2007-2010)
        - Pharmaceutical Sub-Committee, Co-Chair (2005-2007)
    - Young Advocate Training and Outreach Committee, Co-Chair (2003-2005)
    - Technology Committee, Co-Chair (2002-2004)
  - Young Lawyers Division (1996-2002)
    - Domestic Violence Institute, Project Manager
    - Disaster Legal Services Committee, Chair
    - National Conferences Team, Vice-Chair
    - Northern California District Representative (1996-1998)
- Boulder Economic Council
- Colorado BioScience Association
  - Board of Directors
  - o Government Relations and Public Affairs Committee, Co-Chair

- Defense Research Institute
- Bar Association of San Francisco (1994-1997)
  - o Barristers Club, Treasurer & Board of Directors
- Denver Metro Chamber of Commerce, Healthcare Committee

## **Representative Presentations & Publications**

- "Chatbots and the Business of Law," Author, American Bar Association (May 24, 2023)
- "Environmental, Social, and Business governance: The Business of Law," Author, American Bar Association (February 22, 2023)
- "FDA Clears Lab-Grown Meat for Human Consumption," Author, Snell & Wilmer Product Liability Update Blog (November 17, 2022)
- "FDA Proposes Updated Definition of 'Healthy' for Foods," Author, Snell & Wilmer Product Liability Update Blog (September 28, 2022)
- "FDA Publishes Manual on Complex Product Classification for Generic Development," Author, Snell & Wilmer Product Liability Update Blog (April 25, 2022)
- "The Great Resignation and the Business of Law," Author, Litigation News (Winter 2022)
- "House Passes Bill to Federally Decriminalize Marijuana," Author, Snell & Wilmer Product Liability
  Update Blog (April 1, 2022)
- "Mental Health, Mindfulness and the Business of Law," Author, Litigation News (Spring 2022)
- "FDA Approves Second Booster," Author, Snell & Wilmer Product Liability Update Blog (March 30, 2022)
- "A Deeper Dive into FDA Draft Guidance on the Remanufacturing of Medical Devices," Author, Snell & Wilmer Product Liability Update Blog (March 4, 2022)
- "Food Litigation Is Growing," Author, Litigation News (January 24, 2022)
- "Litigation Finance: Growth Expected After Tough Year," Author, Litigation News (November 15, 2021)
- "FDA Issues Draft Guidance on Remanufacturing," Author, Snell & Wilmer Product Liability Update Blog (June 18, 2021)
- "Brace for the Storm: The Tsunami of Pandemic-Related Litigation," Author, Litigation News (June 2, 2021)
- "The COVID-19 Vaccine Race: With Risks Come Rewards," Author, Litigation News (March 19, 2021)
- "<u>Update on FDA Guidance Pertaining to COVID Variants</u>," Author, Snell & Wilmer Product Liability
  Update Blog (March 16, 2021)
- "Virginia Legalizes Marijuana," Author, Snell & Wilmer Product Liability Update Blog (March 2, 2021)
- "FDA Releases New Guidance for Covid-19 Products," Author, Snell & Wilmer Product Liability Update Blog (February 24, 2021)
- "FDA Provides Coronavirus Testing Update," Author, Snell & Wilmer Product Liability Update Blog (February 18, 2021)
- "<u>Tort Litigation Immunity for COVID-19 Vaccines</u>," Host, CalCurrent Podcast, Episode 29 (January 7, 2021)
- "The Pandemic's Dramatic Effect on the Business of Law," Author, Litigation News (October 2020)

- "Clarifying the Difference Between Medical Device Servicing and Remanufacturing," Co-Presenter, DRI Webinar (July 31, 2020)
- "Data Privacy: More Than Just 'The New Black'," Author, Litigation News (Spring 2020)
- "Colorado Companies That Have Achieved FDA Regulatory Milestones" Moderator, Medical Device Symposium, Colorado BioScience Association, Westminster, CO (March 4, 2020)
- "The Vaping Market Is Igniting," Author, Litigation News (Winter 2020)
- "Potential Health Risks & Regulatory Hurdles Associated with Cannabis & Its Concentrates," Speaker, Environmental & Energy, Mass Torts, and Products Liability Litigation Committees' Joint Regional CLE Program, Snowmass Village, CO (January 29, 2020)
- "Multidistrict Litigation: Dominating the Federal Docket," Author, Litigation News (Fall 2019)
- "Clarifying the Difference Between Medical Device Servicing and Remanufacturing," Co-Author, DRI's For the Defense (September 2019)
- "Class Action Spending Reaches 10-Year High," Author, Litigation News (September 2019)
- "Alternate Legal Service Providers: A Booming Market," Author, Litigation News (June 2019)
- "Advising on Cannabis Products, Including Development of State Bar Rules," Moderator, Ninth Annual Food & Supplements Workshop, The Kraft Heinz Company, Chicago, IL (May 21, 2019)
- "The Grass Grows Greener for the Cannabis Legal Market, Despite Risks," Author, Litigation News (April 2019)
- "Leaders in MedTech Panel Discussion," Moderator, Medical Device Symposium, Colorado BioScience Association, Westminster, CO (March 7, 2019)
- "Trade Secret Litigation Continues to Soar," Author, Litigation News (October 2018)
- "Blockchain: Technology Rockin' the Legal Industry," Author, Litigation News (September 2018)
- "The SEC's Whistleblower Program: A Growing Legal Cottage Industry," Author, Litigation News (May 2018)
- "Dietary Supplement Labeling," Author, ABA Section of Litigation Products Liability Committee Practice Pointer (April 2018)
- "Life Sciences: The Intersection of Professional Liability & Products Liability," Panelist, 2018 PLUS Healthcare and Medical PL Symposium (March 2018)
- "The Intersection of Medical Malpractice and Product Liability Cases Unintended Consequences of Damage Caps," Author, 2018 PLUS Healthcare and Medical PL Symposium (March 2018)
- "Data Analytics: A New Arrow in Your Legal Quiver," Author, Litigation News (Winter 2018)
- "Increasing Ransomware Attacks Serve as a Reminder to Consider Cyber Insurance," Author, Litigation News (Fall 2017)
- "FDA Makes Gene Therapy Available for First Time in USA," Author, Product Liability Update (September 2017)
- "A Brief Look at the European Union's New Medical Device and In Vitro Diagnostic Regulations," Co-Author, ABA Products Liability Litigation Newsletter (August 2017)
- "Corporate Clients Demand More Diversity from Law Firms," Author, Litigation News (Summer 2017)
- "Boulder's Research & Commercialization Imperative," Moderator, Boulder Economic Summit, Boulder, CO (May 2017)
- "Senate Confirms New FDA Commissioner," Author, Product Liability Update (May 2017)

- "The Virtual Practice of Law," Author, Litigation News (Spring 2017)
- "Post-market Cybersecurity Management in Medical Devices," Presenter, Webinar, Marsh Mid-Atlantic (March 2017)
- "Colorado BioScience Policy Update," Featured Speaker, BioScience Day at the Capitol, Denver, CO (March 2017)
- "Hot Topics in Life Science Litigation," Featured Speaker, Medmarc Annual Brokers Meeting, Las Vegas, NV (February 2017)
- "One in, Two Out: Potential FDA Uncertainty for Medical Device and Pharmaceutical Companies," Author, Product Liability Update (January 2017)
- "Leveraging Partnerships for Success," Moderator, Medical Device Symposium, Broomfield, CO (January 2017)
- "Rise of the Machine: Artificial Intelligence in the Practice of Law," Author, Litigation News (Winter 2017)
- "Benefiting From FDA's Medical Device Risk-Benefit Guidance," Co-Author, Law360 (July 25, 2016)
- "Cybersecurity: What Life Sciences Companies Need to Know to Defend Themselves Against the Inevitable," Co-Presenter, Medmarc Loss Control Webinar Series (June 29, 2016)
- "What's The Big Deal About US Biosimilar Approval?" Author, Law360 Life Sciences (April 27, 2016)
- "Biologics, Biosimilars and Product Liability Risk Considerations," Featured Speaker, Chicago, IL (March 2016)
- "Hello 'Proportionality,' Goodbye 'Reasonably Calculated': Reinventing Case Management and Discovery Under the 2015 Civil Rules Amendments," Regional Chair, Denver, CO (March 2016)
- "A View from the Inside: Practice Pointers from In-House Counsel," Contributing Editor, Products Liability Newsletter (February 2016)
- "Colorado BioScience Policy Update," Featured Speaker, BioScience Day at the Capitol, Denver, CO (February 2016)
- "Product Liability Year In Review," Featured Speaker, Environmental, Mass Torts & Products Liability Litigation Joint CLE Seminar, Park City, UT (January 2016)
- "50-State Survey Chemical Exposure Claims," Contributing Co-Author, ABA Section of Litigation (August 2015)
- "Going In-House: An Interview on Making the Move," Moderator, ABA Section of Litigation, Sound Advice Podcast (August 2015)
- "FDA Issues Final Guidance on Intent to Exempt Certain Medical Devices from Premarket Notification Requirements," Author, Product Liability Update (July 2015)
- "Adopting a Safety Policy and Assembling a Safety Team," Author, Litigation 360 (June 4, 2015)
- "Minimizing Clinical Trials Liability: Ensuring Effective Informed Consent Documents," Featured Presenter, Medmarc Insurance Webinar (May 27, 2015)
- "Collaborative Arrangements in Commercializing Devices and Diagnostics," Moderator, Colorado BioScience Association Spring Industry Symposium, Broomfield, CO (May 13, 2015)
- "Going In-House: An Interview on Making the Move," Moderator, ABA Section of Litigation, Sound Advice (May 2015)
- "FDA Issues Draft Guidance on Distributing New Risk Information for Approved Drugs and Biologics,"
  Author, Product Liability Update (2014)

- "FDA Issues New Draft Guidance on Medical Device Data Systems," Author, Product Liability Update (2014)
- "Summary of FDA's Final Guidance on Dear Health Care Provider Letters," Co-Author, Product Liability Update (2014)
- "New FDA Guidance on Mobile Medical Apps," Presenter, ABA Section of Litigation Roundtable (2014)
- "Regulatory Strategies for Medical Device, Diagnostic and Pharmaceutical Companies," Moderator, Current Issues in Pharmaceutical and Medical Device Litigation & Policy, NovoNordisk, Inc., Princeton, NJ (2013)
- "Positioning Your Company for Funding," Moderator, Seventh Annual Medical Device Symposium, Westiminster, CO (2013)
- "Overview of New FDA Guidance on Regulation of Mobile Medical Apps," Co-Author, ABA Section of Litigation, Products Liability Committee News & Developments (2013)
- "Summary of FDA Guidance on Mobile Medical Apps," Co-Author, Snell & Wilmer Product Liability Update (2013)
- "Food and Drug Litigation Strategies, Leading Lawyers on Building Strong Defenses and Adapting to Evolving FDA Regulations," Contributing Chapter Author, Aspatore (2013)
- "Colorado BioScience Legislative Briefing for Jared Polis," Presenter, Rocky Mountain Innosphere, Ft. Collins, CO (2013)
- "CEO Roundtable with Congressman Doug Lamborn," Participant, Depuy Synthes, Monument, CO (2013)
- "Colorado BioScience Legislative Briefing," Presenter, Somalogic, Boulder, CO (2012)
- "CEO Roundtable with Senator Mark Udall," Presenter, Denver Metro Chamber of Commerce, Denver, CO (2012)
- "CEO Roundtable with Congressman Cory Gardner," Presenter, Amgen, Longmont, CO (2012)
- "CEO Roundtable with Congressman Ed Perlmutter," Presenter, Terumo BCT, Lakewood, CO (2012)
- "Judge, Jury and Executioner: Liability When Acting as Supplier & Tester/Inspector," Presenter, ERAI Executive Conference, Las Vegas, NV (May 17-18, 2012)
- "Sales Representative Liability Issues," Moderator, Current Issues in Pharmaceutical Litigation & Policy, GlaxoSmithKline, Philadelphia, PA (2011)
- "Industry Trends in the Current Regulatory Environment," Moderator, Fifth Annual Medical Device Symposium, Westminster, CO (2011)
- "Plaintiff's Medical Care and Treatment—Discovery and Evidentiary Issues," Contributing Editor, American Bar Association (2011)
- "Contractual Risk Transfer, Best Practices and Considerations: Indemnification, Recalls and Clinical Trials," Featured Speaker, TechAssure Member Conference, San Francisco, CA (2010)
- "Recall Provisions in Contracts: Important Factors and Considerations" (2010)
- "Clinical Trial Agreements: Four Fundamental Factors" (2010)
- Seminar Organizer, Third Annual Medical Device Symposium, Colorado Bioscience Association, Westminster, CO (2009)

- "Indemnification Agreements and Contractual Risk Transfer for Life Science Companies," Featured Speaker, Chubb Life Sciences Producer Forum, Inverness, CO (2009)
- "Consumer Class Actions 50 State Survey," Contributing Author, American Bar Association (2009)
- Seminar Organizer and Panel Moderator, Second Annual Medical Device Symposium, Colorado Bioscience Association, Westminster, CO (2008)
- "Reducing Exposure to Lawsuit Liability in Life Science Product Cases: Litigation Readiness in the Electronic Age," Featured Speaker, Denver, CO (2007)
- "Update on Punitive Damage Claims: A Fifty-State Survey," Contributing Author, American Bar Association (2007)
- "Beyond the Preemption Preamble: A Practical Analysis of the New FDA Labeling Requirements,"
  Moderator, Current Issues in Pharmaceutical Litigation & Policy, Kenilworth, NJ (2006)
- "'Off Label' Is 'In,' The Growing Trend of Pharmaceutical Prescriptions for Non-FDA Approved Purposes," Co-Author, American Bar Association (2006)
- "The Good, The Bad, and The Ugly: A Product Liability Year In Review 2005," Featured Speaker, American Bar Association's Litigation Section's Joint CLE, Beaver Creek, CO (2006)
- "Establishing and Maintaining the In-House Counsel Relationship," Moderator, American Bar Association Annual Meeting, Chicago, IL (2005)
- "Litigation Defense Strategies in Medical Product Design," Panelist, Denver, CO (2005)
- "The Use of Toxicology in Tort Litigation, A Survey of Federal & State Jurisdictions," Contributing Author, American Bar Association (2004)
- "Hot Topics in Medical Device Litigation," Panelist, The Seventeenth Medical Device Seminar, Santa Fe, NM (2004)
- "California's Unfair Competition Laws," Featured Speaker, Current Issues in Pharmaceutical Litigation & Policy, Philadelphia, PA (2003)
- "Standard for Design Defects A State by State Survey," Contributing Author, American Bar Association (2003)
- "Hot Topics In Products Liability Law," Moderator, American Bar Association Annual Meeting, San Francisco, CA (2003)
- "The Use of Epidemiology in Tort Litigation: A Summary of Federal & State Jurisdictions," Contributing Author, American Bar Association (2003)
- "Post Sale Duty to Warn," Contributing Author, A Monograph Prepared by the ABA Section of Litigation's Product Liability Committee, American Bar Association (2003)
- "The Young Litigator's Toolkit," Co-Moderator, ABA Section of Litigation's Annual Meeting, Houston, TX (2003)
- "The Battle Over the Role of Epidemiology in Proving General Causation: Word From the Front," Co-Moderator, Current Issues in Pharmaceutical Litigation & Policy, Bridgewater, NJ (2002)
- "The Battle Over the Role of Epidemiology in Proving General Causation: Word From the Front," Author, Product Liability Newsletter, Vol. 13, No. 2, American Bar Association (2002)
- "Discovery In Products Liability Actions," Author, Dri Young Lawyers' Form Book 2002, II.A-1 II.A-40, DRI (2002)
- "Terminating the Product Franchise," Co-Author, ABA Section Of Litigation Section Annual Meeting, Program Materials, pp. 47-52, Boston, MA (2002)

- "Product Liability Primer," Featured Speaker, Global Quality Council Meeting, Sunrise Medical, Inc., Fresno, CA (2000)
- "The Role of the Sales Representative in Products Liability Claims," Featured Speaker, Sunrise Medical, Inc.'s National Sales Meeting, Interlocken, CO (1999)
- "Design Defense Strategies," Featured Speaker, Sunrise Medical, Inc.'s Growth Conference, Denver, CO (1999)
- "Hot Potatoes, Proving It's Not Your Product," Featured Speaker, DRI Products Liability Seminar, New Orleans, LA (1998)

## **Professional Recognition & Awards**

- The Best Lawyers in America®, Product Liability Litigation Defendants (2013-2024)
- Who's Who Legal: Life Sciences (2024)
- LMG Life Sciences Star (2012-2018)
- Global Regulatory Affairs Compliance Professional (GRACP)
- Medmarc Insurance Company's Defense Attorney of the Year (1997)

## **Community Involvement**

- American Lung Association, Colorado, Board of Directors (2010-2015)
- Colorado BioScience Political Action Committee
  - o Founding Member
  - Board of Directors
- WOW! Children's Museum, Board of Directors (2007-2015)

# **Previous Professional Experience**

- Gordon & Rees, LLP, Partner, San Francisco, California
- Wright Robinson Osthimer & Tatum, Shareholder, San Francisco, California

#### **Bar Admissions**

- California
- Colorado
- · District of Columbia
- Washington

#### **Court Admissions**

- District of Columbia Court of Appeals
- Supreme Court of California
- Supreme Court of Colorado
- Supreme Court of Washington
- United States Court of Appeals, Ninth Circuit
- United States District Court, District of Arizona
- United States District Court, District of Colorado
- United States District Court, Northern District of California

- United States District Court, Western District of Washington
- United States Supreme Court