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Select Areas of Litigation Practice

- Product Liability
- Agriculture
- Environment, Energy & Natural Resources
- Food, Beverage & Hospitality
- Food, Drug & Device Law
- Healthcare
- Per- and Polyfluoroalkyl Substances (“PFAS”) Issues
- Retail

Education

- Case Western Reserve University School of Law
Cleveland, OH
J.D., 1985
- Berklee College
Boston, MA
B.A., 1980

Michael A. Walsh

Parsons McEntire McCleary PLLC
Shareholder

Mike devotes his practice to counseling clients in FDA regulated industry on issues related to manufacturing, labeling, compliance and transportation. He has extensive experience defending clients in complex administrative law and litigation matters, and has served as national coordinating counsel, regional trial counsel and as local Texas counsel. Mike is the founder of the Texas Food Law Forum, a daylong educational program designed for lawyers and senior executives in the food industry. Mike has practiced in Dallas since 1994. Prior to 1994, he practiced in New York City as a trial lawyer handling a broad range of matters including securities, commercial, real estate, intellectual property, pharmaceutical, toxic tort and environmental contamination matters. He is the author of the law book, *The Supply and Distribution of FDA Regulated Products* published by Thompson Reuters. Mike is a frequent writer and speaker on issues related to compliance and litigation for FDA regulated industry and is regularly published on issues concerning compliance, advertising, labeling, marketing, promotion, social media and the First Amendment.

Mike served for 19 years as chair of his previous firm’s Food, Drug & Medical Device Industry Team, and is the Chair emeritus of the Federation of Defense and Corporate Counsel’s (FDCC) FDA Law Section.

Admission to Practice

- Texas, 1994
- New York, 1985
- U.S. District Courts for the Northern, Southern/Bankruptcy, Eastern, and Western Districts of Texas
- Maryland District Court
- New York Eastern/Bankruptcy and Southern/Bankruptcy District Courts
- U.S. Courts of Appeals for the Second and Fifth Circuits
- Federal District & Bankruptcy Court

Memberships & Affiliations

- Federation of Defense & Corporate Counsel,
Drug Device and Biotechnology Section, Chair emeritus
- Defense Research Institute,
Drug and Device Committee
- State Bar of Texas
- Dallas Bar Association
- New York State Bar Association,
Food and Drug Law Committee
- New York City Bar Association
- American Bar Association, Litigation Section
- Association of Food and Drug Officials,
Laws and Regulations Committee

Representative Presentations – Speaking Engagements

- Program Chair, *Food and Drug Law: Compliance, Enforcement and Litigation: What you don't know CAN hurt you!*, State Bar of Texas, October 2019.
- *PFAS Threats, Trends and Theories: Assessing Liability and Allocating Risk*, State Bar of Texas Food and Drug Law Conference - Compliance, Enforcement and Litigation, Austin, Texas, October 2019.
- *Food Labeling: Compelled Speech: The First Amendment Pendulum has Swung – The FDA and the New World Order*, State Bar of Texas Food and Drug Law Conference - Compliance, Enforcement and Litigation, Austin, Texas, October 2019.
- *Cases and Controversies: What is going on in the courts and why does it matter?*, *Perfluorinated Chemicals: Theories and Strategies*, Federation of Defense and Corporate Counsel (FDCC), Annual Meeting, Toxic Tort and Environmental Law, Sun Valley, Idaho, August 2019.
- *Perfluorinated Chemicals Business Risks & Impacts*, American Coatings Association, Webinar, Washington, DC, July 2019.
- *Recent Trends: Industry-Wide Litigation/State AG Actions*, Global Semiconductor Design & Manufacturing Company, Richardson, Texas February 2019.
- Program Chair, *Food Law Basics & Beyond: Critical Information for Those in Food – Related Businesses*, 2018 Food Law Forum, Dallas, Texas, November 2018.
- *Recent Trends: Industry-Wide Litigation/State AG Actions*, 2018 Food Law Forum, Dallas, Texas, November 2018.
- *Litigation Hot Topics*, 2018 Food Law Forum, Dallas, Texas, November 2018.
- *The First Amendment Pendulum Has Swung: The FDA and the New World Order*: 2018 Food Law Forum, Dallas, Texas, November 2018.
- *Opioids: A Prescription for Risk*, State Bar of Texas, Health Law Meeting, Austin, Texas, October 2018.
- *The First Amendment Compelled Speech Doctrine: The Pendulum Has Swung*: The State Bar of Texas Food and Drug Law Conference - Compliance, Enforcement and Litigation, Austin, Texas, October 2019.
- *When business as usual becomes a crisis (grass is GRAS and Crisco is not)*, Global Food Law Current Issues Conference, Michigan State University School of Law, East Lansing, Michigan, June 2018.
- *Prescription Opioids: Controlled Substances, Uncontrolled Litigation*, (program topic and paper) Defense Research Institute (DRI) Drug and Device Litigation, New York, New York, May 2018.
- *The Opioid Crisis: A Prescription for Intense Oversight, Investigations and Litigation* Webinar, American Health Lawyers Association, April 2018.
- *The Opioid Dilemma - Pain and Punishment*, FDCC Winter Meeting, Amelia Island, Florida, February 2018.
- *Tomorrow's Headlines: Litigations, Task Forces, and New Technologies*, Program plan and materials, American Conference Institute (ACI) Summit on Controlled Substances, Washington, DC, January 2018.
- *The Opioid Epidemic: Cases and Controversies*, Pain Management Summit, Reducing the Use of Opioids, Orlando, Florida, December 2017.
- *Employers & Opioids: A Prescription for Risk*, Webcast, Society of Human Resource Management (SHRM) November 2017.
- *The Pendulum Has Swung: Off-Label Use and the New World Order*, In house presentation at annual retreat for large pharma, Chapel Hill, North Carolina, October 2017.
- *Overview of the Opioid Epidemic: Epidemiology, Economics and Strategies*, Retail Industry Leaders Association, Retail Law Conference 2017, Chicago, Illinois, October 2017.

Representative Presentations – Speaking Engagements

- *Industry Liability: From Summers v. Tice to Sugar*, Food Law Basics and Beyond, State Bar of Texas, Austin, Texas, October 2017.
- *Threading the Needle: Navigating Off-Label/ New Use*, ACI FDA Bootcamp, Boston, Massachusetts, September 2017.
- *Drug Device and Biotech: Shifting Political Winds –what does it mean for FDA regulated industry?*, Webcast, FDCC, September 2017.
- *The Opioid Epidemic: Cases and Controversies*, The Institute of Healthcare Executives and Suppliers - Meeting XXX, Frisco, Texas, September 2017.
- *From Farm to Table or Felon to Table - How to Know the Difference: FSMA - what it means for foreign suppliers and US Importers*, 2017 FDCC Annual Meeting; Montreux, Switzerland, July 2017.
- *Food Additives and Ingredients, Imports and Expert, Claims and Claim Substantiation*, National Business Institute Webcast, June 2017.
- *The Food Modernization Act: What Every Texas Lawyer Should Know*, 11th Annual Huffaker Course: Agricultural Law, Lubbock, Texas, May 2017.
- *The Fifth Vital Sign The Opioid Epidemic: Where We Are & Where We Go From Here*, State Bar of Texas Webcast, April 2017.
- *The Marketing Pendulum Has Swung: Civil and Criminal Liability and the New Paradigm*, ACI FDA Bootcamp, New York, New York, March 2017.
- *FDA Naturally Taking a Healthy Look at the Health of Healthy*, Dr. Pepper Snapple, February 2017.
- Program Chair, *The Fifth Vital Sign - Pain & Treatment, The Opioid Epidemic: Where We Are & Where We Go From Here*; Speaker, *Defense Perspective, Product Promotion and Distribution*, 2017 Food & Drug Law Forum, Dallas and San Antonio, Texas, February 2017.
- *Compliance, Labeling, Enforcement & Penalties*, 2017 Annual Conference & Trade Show: FDA & TTB Related Businesses, San Marcos, Texas, February 2017.
- *The Food Safety Modernization Act*, SBOT Webinar, January 2017.
- *Food Law: What Every Texas Lawyer Needs to Know - An Overview of Food Law in Texas*, SBOT Webinar, January 2017.
- *FDA Law: Off-Label Use of Drugs and Medical Devices*, SBOT Webcast, December 2016.
- *Regulatory Changes and the Cost of Compliance/Enforcement Actions*, Collin County Business Forum.
- *The Marketing Pendulum Has Swung Civil and Criminal Liability and the New Paradigm*, ACI FDA Bootcamp, Boston, Massachusetts, September 2016.
- Program Chair, 2016 Food Law Forum.
- *Civil and Criminal Liability and the New Paradigm*, 2016 Food Law Forum, Dallas, Texas, September 2016.
- Moderator, *Analytical Ingredient and Product Testing and The Rise of Litigation*, ABA Section of Litigation Food & Supplements Sixth Annual Workshop, PepsiCo Inc., Purchase, NY, June 2016.
- *Food & Business Law: Start-to-Finish*, National Business Institute Webcast, May 2016.
- *What's Keeping Collin County Business Leaders Up at Night?*, Business & Law Forum, Frisco, Texas, May 2016.
- *FDA Enforcement and Litigation – Food and Drug Law (food, beverages, dietary supplements, drugs (prescription and OTC), biologics, devices, cosmetics, biologics, sunscreens, tobacco)*, Dallas Bar Association, Dallas, Texas, March 2016.
- *Managing the Crisis Before it Happens – Labeling Advertising and Promotion Part I*, ACI FDA Boot Camp, New York, New York, March 2016.
- *FSMA Update, Supply and Distribution and Transportation*, Sysco Corporation Corporate Headquarters, Houston, Texas, December 2016.

Representative Presentations – Speaking Engagements

- Program Chair and Moderator, *FDA Labeling*, Food Law Forum, SMU, Dallas, Texas, November 2015.
- *The Drug Supply Chain Act – Summarizing the Act and Its Effect on FDA Practice and in a Master Class on Regulation and Master Class: Dissemination of Off-Label Information*, ACI FDA Boot Camp, September-October 2015.
- Moderator, *The Changing Landscape of GRAS: PHO, GMO and More*, Food Law Forum, San Antonio September 2015.
- *Food Drugs and Rock and Roll: The Evolution of Deference and the First Amendment*, Tsai Talk at SMU Law School, September 2015.
- *Parallel Claims: What they are and where they came from*, FDCC 2015 Annual Meeting, Banff, Alberta, July-August 2015.
- *Dispensers DSCSA Compliance*, Webinar, June 2015.
- Speaker, *Brand-Threatening Recalls - 2015 FSMA update*, Moderator, *Food Recalls – Preparing for the unthinkable*, Moderator, *Brand Threatening Recalls – Reverse Logistics and Environmental Issues*, 2015 Houston Food Law Forum, South Texas College of Law, June 2015.
- *FDA's Regulation of Off Label Promotion and Emerging Issues*, Q1 Productions Webinar, March 2015.
- Co-Presenter, *The Regulation and Dissemination of Off-Label Information*, ACI FDA Bootcamp, New York, New York, March 2015 and San Francisco, California July 2015.
- *The Drug Supply Chain Security Act - Summarizing the Act and Its Effect on FDA Practice*, ACI FDA Bootcamp, New York, New York, March 2015 and San Francisco, California July 2015.
- *Product Safety and Quality Global Compliance Emergency Action Planning Food Safety Modernization Act*, Food Law Forum, February 2015.
- *The Drug Supply Chain Overview of Developments (Where we are, how we got here and what is next)*, DQSA Panel Discussion, PCSC/ASIS/NBSC Educational Conference, February 2015.
- *FDA and Social Media - A New Paradigm for FDA*, Compliance Online Webinar, October 2014.
- *What you need to Know about the Drug Supply Chain Security Act*, FX Conferences Webinar, November 2014.
- *The Drug Supply Chain Security Act - Summarizing the Act and Its Effect on FDA Practice*, ACI FDA Bootcamp, Boston, Massachusetts, September 2014.
- *Use of Statistics in the Courtroom - Views of Two Lawyers and a Scientist*, FDCC 2014 Annual Meeting, White Sulphur Springs, West Virginia, July-August 2014.
- *Social Media for FDA Regulated Industry: Navigating the Web of Rules and Guidance*, Compliance Online Webinar, June 2014.
- Moderator, *Emerging Issues: Surveying the Regulatory and Litigation Horizon 2014*, Section of Litigation Food & Supplements Fourth Annual Workshop, Cargill, Inc., Wayzata, Minnesota June 2014.
- Speaker, *Federal Oversight and Enforcement– The Food Modernization Act and the \$5,000 Egg*, Texas Assisted Living Association, 2014 Spring Conference, San Antonio, Texas, April 2014.
- Speaker, *Regulation and Dissemination of Off-Label Information, Post-Approval Marketing Guidance and Preemption Protocols*, ACI FDA Bootcamp, New York, New York, March 2014.
- Speaker, *Social Media: Using it to Your Advantage and Avoiding Liability*, Food and Drug Law Institute, Food Week 2014, Washington, D.C., February 2014.
- Speaker, *Off-Label Promotion: A Case Study Civil Penalties, Criminal Enforcement and Tort Claims*, ACI, Boston, Massachusetts, September 2013.

Representative Presentations – Speaking Engagements

- Speaker, *Labeling, Social Media, and the First Amendment*, DRI Product Liability Conference, Maryland, April 2013.
- Panelist, *Post-Approval Marketing Guidance and Preemption Protocols Master Class*, ACI FDA Boot Camp, New York, New York, March 2013.
- Speaker, *Basic Training in Core Regulatory Concepts for Life Sciences Lawyers, Business Executives and Policy Analysts*, ACI FDA Bootcamp, Boston, Massachusetts, September 2012.
- Speaker, *The FDA and Medical Products: Practices and Proposals for Internet and Social Media*, DRI, July 2012.
- Speaker, *ABA 2012 Food and Supplements Seminar*, American Bar Association Section of Litigation, Sara Lee Corporation, Chicago, Illinois, 2012.
- Speaker, *Master Class, Off-Label Promotion - Regulation and Dissemination*, ACI FDA Bootcamp Master Class, Boston, Massachusetts, September 2011 and New York, New York, March 2012.

Publications

- *PFAS: Ubiquitous and Persistent Chemicals - Assessing Liability and Allocating Risk: Applying Lessons Learned in Industry-Wide Litigation*, Texas Environmental Law Journal, Vol. 49, Issue 2 (November 2019)
- *Compelled Speech and the First Amendment: The Pendulum Swings for FDA Regulated Industry*, State Bar of Texas, Food and Drug Law Conference - Compliance, Enforcement and Litigation, Austin, Texas, October 18, 2019
- *Food and Drug Law: PFAS Threats, Trends and Theories - Assessing Liability and Allocating Risk*, State Bar of Texas, Food and Drug Law Conference - Compliance, Enforcement and Litigation, Austin, Texas, October 18, 2019
- *PFAS: Ubiquitous and Persistent Chemicals: Assessing Liability and Allocating Risk*, Federation of Defense and Corporate Counsel, August 2019
- *The Opioids Dilemma: Pain and Punishment Industry-Wide Liability*, Defense Research Institute, Drug and Medical Device, May 2018
- *Industry-Wide Liability – A case study when an ingredient goes from safe to unsafe*, State Bar of Texas October 12, 2017
- [Product Liability Cases To Watch: Midyear Report](#), Law 360, June 30, 2017
- [Is Restaurant Menu Labeling On ACA Chopping Block?](#), Law 360, January 6, 2017.
- [First Amendment in Flux: Supreme Court Clarification Needed on Compelled Commercial Speech](#), Legal Background – Vol 31, #22 Washington Legal Foundation, September 30, 2016.
- [Sanitary Transportation of Food: Contracts and the New Rules](#), Food Safety Magazine, June/July 2016.
- [J&J Ultramet Verdict Is Too Much Green](#), Law 360 (April 12, 2016).
- [What Misbranding Means for Restaurants and Retail Food Stores](#), Food Safety Magazine (April/May 2015)
- [Vt. GMO Labeling Act Is Unnatural And Unconstitutional](#), Law 360, Food and Beverage, Expert Analysis (October 8, 2015)
- [Parallel Claims, the First Amendment and FDA's Permissive View of Private Enforcement](#), Defense Research Institute, Drug and Medical Device Committee Journal For the Defense (Fall 2015)
- [Parallel Claims State Law Tort Claims for Violating the Food Drug and Cosmetic Act](#), Submitted FDCC 2015 Annual Meeting, The Fairmont Banff Springs Hotel – Banff, Alberta (July 25 through August 1, 2015)
- [The Supply and Distribution of FDA-Regulated Products](#), Law Book, Thompson Reuters (Fall 2014)
- [The FDA and the Practice of Medicine: The Hidden Price of Lowest-cost Drugs](#), M.D. News (October 2, 2014)

Publications

- [It's Not Fair! Combating Competitors' Dishonest Marketing Tactics](#), Pharmaceutical Compliance Monitor (September 24, 2014)
- [Parallel Claims: Who, What, When, Where and Why](#), Defense Research Institute, Drug and Medical Device, The Defense Research Institute, For The Defense™ (September 2014)
- [Use of Statistics in the Courtroom - Views of Two Lawyers and a Scientist](#), FDCC 2014 Annual Meeting, The Greenbrier – White Sulphur Springs, West Virginia (July, 2014)
- [The Preemption Pendulum: Medical Products and Parallel Claims](#), LAW360 Expert Analysis (June 2014)
- [Emerging Issues: The Manufacturer's Dilemma - The Internet, The Constitution And The Government's Regulation Of The Words We Say](#), ABA Section of Litigation Food & Supplements, Fourth Annual Workshop, Cargill, Incorporated, Minneapolis, MN (June 5, 2014)
- [Allergan v Athena: Medical Products and the Alchemy of Parallel Claims](#), Federal of Defense and Corporate Counsel, Drug Device and Biotech, Vol. 2, Issue 1, (Spring 2014)
- [New Tort Theory Emerging](#), Texas Lawyer (January 2014)
- [The Doctrine of Parallel Claims](#), New Jersey Law Journal - Personal Injury (Mar. 30, 2014)
- [Parallel Claims: Federal Courts Pave New Path for Medical Product Liability Claims – New Tort Theory Emerges](#), Texas Lawyer (28 Jan. 2014)
- *Net Impression: FDA's Old World Approach to a New World Opportunity (FDA's regulation of social media)*, [Inside the Minds: Recent Developments in Food and Drug Law](#), 2014 ed., West, Thompson Reuters Food and Law Book (Nov. 2013)
- *Prosecution of Off-Label Promotion: The Road from Carte Blanche to Strict Scrutiny*, [Navigating Recent Off-Label Promotion Developments Understanding Government Regulations and the Potential Impact of Noteworthy Cases](#), West, Thomson Reuters/Aspatore "Special Report" (Nov. 2013)
- [The Pharmacy Compounding Quality Act of 2013: Something Old, Something New, Something Borrowed and Something Missing](#), Health Industry Online (20 Nov. 2013)
- [The First Amendment And The Emerging Tort Of Off-Label "Promotion,"](#) Washington Legal Foundation (April 2013)
- [US v. Caronia: Just in Time for the Holidays, a Gift You May Not Be Able to Return - the Tort of Off-Label Promotion](#), Volume 21, Issue 1, DRI (January 2013)
- [Inside the Minds: Recent Developments in Food and Drug Law](#), 2013 ed., West Thompson Reuters Food and Law Book (Nov. 2012)
- [A Closer Look at Dietary Supplement Labels](#), LAW360 HealthLaw and Products Liability, (Oct. 2, 2012)
- Paper: [The First Amendment and FDA's Regulation of Dietary Supplements](#), Presented at the American Bar Association 2012 Section of Litigation seminar Food and Supplements, Sara Lee Corporation, Chicago, (2012)
- [FCC v. Fox: The Supreme Court finds fleeting indecency standards unconstitutionally vague but avoids First Amendment issue](#), Trial and Error: The Appellate Blog, (June 25, 2012)
- [FDA and Social Media - Data Smog, Digital Strangers and FDA's Road Not Taken](#), RX for the Defense: The Newsletter of the Drug & Medical Device Committee. Volume 20, Issue I (5 April 2012)
- [Off-Label Promotion and the First Amendment](#), The Defense Research Institute, For The Defense™ (December 2011)
- [How Many Supreme Court Justices Does It Take To Remove Crayons From The Free Speech Crayon Box?](#), IP Frontline (18 Nov. 2011)

Publications

- [*The Truth Is Out There, But Not Always On The Label*](#), LAW360 HealthLaw and Products Liability (16 Nov. 2011)
- [*You Cannot Sue for What They Cannot Do*](#), LAW360 HealthLaw and Products Liability (25 Oct. 2011)
- [*Federal Preemption of Failure to Warn Claims against Generic Drug Manufacturers*](#), Health Industry Online (27 June 2011)
- [*Bill Summary: The Food Safety Modernization Act of 2010*](#), Client Alert (26 Jan. 2011)
- [*MTBE and the City of New York Trial*](#), ALFA International Products Liability Perspectives, Volume 2, Issue 3 (Fall 2009)
- [*MTBE - What It Is and Where It Is Going*](#), ALFA International Products Liability Perspectives, Volume 2, Issue 4 (Summer 2009)
- [*You Can't Heed What You Don't Read - U.S. Supreme Court - Wyeth v. Levine*](#), Health Industry Online Newsletter (19 March 2009)
- [*As Supplement Sales Soar, So Does The Potential For Product Misuse. Texas Lawyer*](#) (2 Dec. 2002)
- [*MTBE or Not MTBE, that is the question in Texas. Texas Lawyer*](#) (13 Nov. 2000)

Food and Drug Law Blogs and Alerts

- [*The Trump Administration's Proposal to Reorganize the FDA*](#), Clark Hill Alerts, (June 25, 2018)
- [*FSMA: What Every Food Industry Executive Should Do & Why*](#), Food and Drug Law Blog, (June 23, 2017)
- [*Opioids: A Prescription for Liability Opioids: A First For The FDA*](#), Food and Drug Law Blog
- [*FDA Deadline Extension: Agricultural Water Standards Compliance*](#), Food and Drug Law Blog, (June 7, 2017)
- [*DELAYED: The FDA's Intended Use Rule Law Blog*](#), Food and Drug Law Blog, (March 21, 2017)
- [*FDA Provides a Healthy Extension to Comment on Healthy*](#), Food and Drug Law Blog (December 30, 2016)
- [*FTC Finds "All Natural" and "100% Natural" Claims False and Misleading*](#), Food and Drug Law Blog (December 15, 2016)
- [*FDA Final Rule on the Submission of Import Data*](#), Food and Drug Law Blog (December 5, 2016)
- [*Drug Law: Off-Label Use – a Paradigm Shift and a Moral Imperative*](#), Food and Drug Law Blog (October 21, 2016)
- [*Will the Election Affect the Menu Labeling Rule Section of the ACA?*](#), Food and Drug Law Blog (October 10, 2016)
- [*FDA's Off-Label Hearing Set for the Day after the 2016 Election*](#), Food and Drug Law Blog (September 6, 2016)
- [*FDA is KIND about Healthy and Tasty*](#), Food and Drug Law Blog (May 11, 2016)
- [*Sanitary Food Transportation: New Rules May Require a Fresh Look*](#), Food and Drug Law Blog (April 25, 2016).

Food and Drug Law Blogs and Alerts

- [Two Cases: Wineries and Regulators Are a Unique Blend](#), Food and Drug Law Blog (April 19, 2016)
- [\\$500 Million Verdict in J&J Ultramet Case: Too Much Green, Even For St. Patrick's Day](#), Food and Drug Law Blog (March 22, 2016).
- [Restaurant Menu Calorie Count Compliance Stayed Indefinitely](#), Food and Drug Law Blog, (March 18, 2016).
- [Conte Revisited: Innovator Liability for A Generic Manufacturer's Product](#), Food and Drug Law Blog, (March 14, 2016).
- [DOJ's Yates Memo: Focus on the Individual in Cases of Corporate Wrongdoing](#), Food and Drug Law Blog, (October 13, 2015)
- [Vermont is "naturally" genetically modified](#), Food and Drug Law Blog, (September 22, 2015)
- [The Titanic is Sinking: Caronia, Amarin and now Pacira v FDA](#), Food and Drug Law Blog, (September 20, 2015)
- [The FDA is getting PCOI: New FSMA Rules Issued](#), Food and Drug Law Blog, (September 14, 2015)
- [Amarin/Caronia: What Lies Ahead for Tort Preemption?](#) Food and Drug Law Blog, (August 11, 2015)
- [D'oh! Is the FDA Banning Donuts?](#), Food and Drug Law Blog (June 16, 2015)
- [Parallel Claims – the Government's Position revealed in Allergan v Athena](#), Food and Drug Law Blog, (June 9, 2015)
- [Drug Supply Chain – July 1, 2015 Deadline for Dispensers](#), Food and Drug Law Blog (May 19, 2015)
- [For Whom the Blue Bell Tolls: Blue Bell Takes a Major Step Forward](#), Food and Drug Law Blog, (May 14, 2015)
- [Trying to Infuse® Common Sense into Parallel Claims and Off-Label Promotion](#), Food and Drug Law Blog, (May 11, 2015)
- [FDA's Mandatory Recall Draft Guidance: What, When, Why, How and Who Pays!](#), Food and Drug Law Blog, (May 7, 2015)
- [Purity or Purely Political: New York AG's Dietary Supplement Science Fiction Feeding a Class Action Frenzy](#), Food and Drug Law Blog, (February 6, 2015)
- [FDA's Social Media Oversight: An Ounce of "Cure" is Worth a Pound of Enforcement](#), Food and Drug Law Blog, (February 1, 2015)
- [Genetically Modified Corn - a Litigation Commodity](#), Food and Drug Law Blog, (January 19, 2015)
- [From Mayday! to May Day: FDA Extends Enforcement Deadline for DSCSA Track and Trace Compliance until May 1, 2015](#), Food and Drug Law Blog, (December 30, 2014)
- [Drug Wholesaler and Third-Party Logistics Provider Licensing and Reporting: FDA issues Guidance Documents](#), Food and Drug Law Blog, (December 18, 2014)

Food and Drug Law Blogs and Alerts

- [Whole Foods' Greek Yogurt: Federal Labeling Requirements and Class Actions](#), Food and Drug Law Blog, (December 17, 2014)
- [The Drug Supply Chain Initial Standards for Interoperable Exchange](#), Food and Drug Law Blog, (December 1, 2014)
- [Restaurants & Retail Food Stores: the FDA is on its Way; Misbranding is a Crime](#), Food and Drug Law Blog, (November 26, 2014)
- [FDA Releases Guidance on Medical Device Cybersecurity](#), Food and Drug Law Blog, (October 9, 2014)
- [FDA's "Mid Course Corrections" For Correcting Third-Party Content and Using Twitter](#), Food and Drug Law Blog, (September 30, 2014)
- [How you Source Drugs and Criminal Liability](#), Food and Drug Law Blog (September 12, 2014)
- [News Break: New York to Remain the "Big" Apple](#), Food and Drug Law Blog (July 2, 2014)
- [FDA and the Lanham Act: Things Did Not Go Better With Coke](#), Food and Drug Law Blog (April 29, 2014)
- [FDA - Supply and Distribution Information Sharing](#), Food and Drug Law Blog (April 23, 2014)
- [Zohydro and Mass Usurpation](#), Food and Drug Law Blog (April 18, 2014)
- [The FTC and Free Speech: POM v. FTC - The American Hustle - It takes two to tango with the FTC: two randomized control trials that is](#), Food and Drug Law Blog (March 20, 2014)
- [Drug Importation: FDA Announces the Start of the Secure Supply Chain Pilot Program](#), Food and Drug Law Blog (February 26, 2014)
- [Boats, Planes, Trucks and Trains: FDA Proposes New Transportation Sanitary Rule](#), Food and Drug Law Blog (11 Feb. 2014).
- [Food Law: What Deference Does It Make? The Fifth Circuit And How To Cook A \\$5,000 Egg](#), Food and Drug Law Blog (16 Jan. 2014).
- [FDA Issues Draft Guidance on the Internet and Social Media](#), Food and Drug Law Blog (14 Jan. 2014).
- [Allergan v Athena: Medical Products Liability and Parallel Claims](#), Food and Drug Law Blog (10 Jan. 2014).
- [FDA Reveals Oversight Plan For Traditional Pharmacy Compounding](#), Food and Drug Law Blog (5 Dec. 2013).
- [The Food Industry And No Fault Crimes - Criminal Liability For the Conduct of Others](#), Food and Drug Law Blog (27 Nov. 2013).
- [BIG PHARMA\(cies\) are Drug Manufacturers: The Pharmacy Compounding Quality Act of 2013](#), Food and Drug Law Blog (25 Nov. 2013).
- [WHEN LABELING AND EDUCATION ARE NOT ENOUGH, DECLARE IT ILLEGAL](#), Food and Drug Law Blog (8 Nov. 2013).
- [Dear Doctor: Big Changes Are Being Effected - The 4th Branch of Government to the Rescue of Tort Claimants](#), Food and Drug Law Blog (8 Nov. 2013).

Food and Drug Law Blogs and Alerts

- [The Off-Label Conundrum: The DOJ Blows the Whistle and Defendants Deny the Foul](#), Food and Drug Law Blog (6 Nov. 2013).
- [FDA Regulation of Medical Apps – Don't Worry Be Appy](#), Food and Drug Law Blog (29 Oct. 2013).
- [FDA to Set Safety Limits for Potential Toxic Elemental Impurities in Approved Drugs](#), Food and Drug Law Blog (22 Oct. 2013).
- [The Proposed Pharmacy Compounding Quality Act of 2013 Something Old, Something New, Something Borrowed and Something Missing](#), Food and Drug Law Blog (10 Oct. 2013).
- [FDA and Food Safety: Arsenic in Apple Juice!](#), Food and Drug Law Blog (8 Aug. 2013).
- [Restaurant Menu Labeling – Get Ready, The FDA Is Coming.](#), Food and Drug Law Blog (9 July 2013).
- [Consumers, Upset Because You Can't Sue? Blame Congress](#), Food and Drug Law Blog (26 June 2013).
- [FDA and Social Media: the FDA speaks](#), Food and Drug Law Blog (10 June 2013).
- [FDA Regulatory Compliance - Contract Manufacturing and Quality Management Agreements](#), Food and Drug Law Blog (3 June 2013).
- [PRIOR NOTICE OF IMPORTED FOOD: FDA FINALIZES RULE](#), Food and Drug Law Blog (30 May 2013).
- [FDA Marketing: PAR v US – “Pay no attention to the man behind the curtain” - Why is the Government Trying to Strike its Own Statements from the Public Record?](#), Food and Drug Law Blog (20 March 2013).
- [Off-Label March Madness: One Loss, One Win and One Tie \(Caronia, Harkonen and PAR\)](#), Food and Drug Law Blog (12 March 2013).
- [Fines, Detentions and Arrests](#), Food and Drug Law Blog (22 Feb. 2013).
- [Food Labeling – FTC Fumbles the First Amendment](#), Food and Drug Law Blog (25 Jan. 2013).
- [Drugs are not Lawnmowers](#), Food and Drug Law Blog (15 Jan. 2013).
[The Tort of Off-Label Promotion: US v Caronia - Just in Time for the Holidays, a Gift You May Not be Able to Return](#), Food and Drug Law Blog (2 Jan. 2013).
- [Off-Label Promotion and the First Amendment: How a \\$25 Fine and 100 Hours of Community Service Sank the Titanic](#), Food and Drug Law Blog (5 Dec. 2012).
- [FDA Shows the Fizz in FSMA Suspending the Registration of a Food Manufacturer](#), Food and Drug Law Blog (3 Dec. 2012).
- [The FDA and the First Amendment: Off-Label Promotion, Due Process, and the Commercial Speech Doctrine](#), Food and Drug Law Blog (29 Nov. 2012).

Food and Drug Law Blogs and Alerts

- [Pharmacy Compounding the Mess the Excuse and the Proposal](#), Food and Drug Law Blog (15 Nov. 2012).
- [WARNING: FDA seeks Greater Surveillance, Increased enforcement and Authority for Civil Penalties for Dietary Supplement Manufacturers](#), Food and Drug Law Blog, 3 Oct. 2012.
- [According to the DC Circuit "FDA Cannot Get Around the First Amendment by Pleading Incompetence."](#) Food and Drug Law Blog (31 Aug. 2012).
- [Direct-to-Customer Advertising and the Learned Intermediary Doctrine](#), Food and Drug Law Blog (22 Aug. 2012).
- [FDA and Social Media - The Safety and Innovation Act Gives FDA Two More Years to Explain the Rules on How Industry May Use the Internet and Social Media](#), Food and Drug Law Blog (9 Jul. 2012)
- [FCC v Fox: The Supreme Court finds fleeting indecency standards unconstitutionally vague but avoids First Amendment issue](#), Trial and Error: The Appellate Blog (25 Jun. 2012).
- [Just How Wonderful is the FTC Ruling?](#) Food and Drug Law Blog (4 Jun. 2012).
- [FDA Compliance and Social Media – Data Smog, Digital Strangers and FDA’s Road Not Taken](#), Food and Drug Law Blog (10 April 2012).
- [Fifth Circuit Delivers Knockout Punch to Drug Claims](#), Food and Drug Law Blog (3 April 2012).
- [Par Vs. USA - Off-Label Promotion and the First Amendment](#), Food and Drug Law Blog (13 Feb. 2012).
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- [You Cannot Sue For What They Cannot Do](#), Law 360 (October 26, 2011)

Representative Litigation

- National coordinating counsel and MDL counsel in MDL proceedings in the Southern District of New York.
- Served as Texas coordinating counsel, liaison counsel in consolidated proceedings, state MDL counsel for manufacturers, distributors and retailers in mass tort, toxic exposure, consumer fraud, nuisance, and property damage actions.
- Lead counsel in Federal Circuit Court of Appeals on issues concerning federal preemption for prescription drug products.
- Lead Texas counsel for the Customs and Tax Administration of the Kingdom of Denmark in a world-wide tax fraud scheme.
- Counseled foreign drug and biologics manufacturer on licensing and breach of contract dispute with large multinational manufacturer.
- Defense of a manufacturer in injury claims related to a medical device in clinical trial under an investigational device exemption (IDE).

Representative Compliance Counseling

- Counseled national frozen dairy manufacturer on FSMA compliance and supply agreements.
- Counseled large foreign international food packaging (i.e. food contact substances) on FSMA compliance and regulatory issues.
- Counseled national retailer, international ingredient manufacturer and other food, drug and cosmetics entities on CBD manufacturing, labeling, marketing, distribution, importation and sale.
- Counseled cosmetic and dietary supplement manufacturer on regulatory compliance for sale of company assets.
- Counseled foreign drug and biologics manufacturer on contract terms, licensing and indemnification.
- Counseled foreign medical device manufacturer on regulatory compliance and negotiated with domestic customers regarding compliance.
- Counseled large national natural food distributor on FSMA compliance including drafting Foreign Supplier Verification Program (FSVP) documents and vendor verification program, Intentional Adulteration (IA) rule compliance, and Sanitary Transportation rule compliance.
- Counseled food manufacturers, including regional meat and poultry processor, on FSMA's food safety compliance requirements including updating compliance documentation.
- Counseled dairy manufacturer on product recall, including public relations issues.
- Counseled national dairy cooperative on GMO/non-GMO labeling issues.
- Counseled equipment manufacturer on product recall
- Counseled restaurant franchisor on federal menu labeling requirements.
- Resolved disputes between manufacturers and large national retailer over misbranding and labeling compliance issues
- Negotiated multiple copacking agreements for distributors and major retailer.
- Responded on behalf of manufacturer to FDA warning letter for medical device
- Review product launch and social media materials for OTC and Class II medical device.
- Advised cosmetic manufacturer on labeling compliance and product classification issues.

Representative Compliance Counseling

- Created Social Media policies and procedures for online content.
- Counseled device manufacturers on Sunshine Act compliance and CMS Open Payments program.
- Counsel manufacturers on labeling content for OTC, cosmetic and dietary supplement products.
- Analysis of supply chain agreements and policies and negotiation of terms.
- Negotiated manufacturing agreements for food, dietary supplement, OTC and cosmetic manufacturers and marketers.
- Counseled on master vendor supply agreement for Contract Research Organization.
- Established Compliance programs, including SOPs for OTC, compounding and dietary supplement manufacturers.
Address compliance regarding FDA 483 issues in connection with laboratory facility.
- Resolved federal enforcement and investigation concerning use of unapproved foreign manufactured drugs for medical facilities.
- Advise physicians and product developers on development and marketing of combination products, compounded products and dietary supplements.
- Advise on acquisition of clinical trials company and establishment of risk factors for Private Placement.
- Advise on sale of biologics company and negotiation of representations.
- Food Safety Modernization Act (FSMA) advised client on contract revisions and updates for large national food distributor.
- Advised large national distributor on new FSMA requirements and compliance issue
- Coordinated national recall of misbranded food products and negotiated enforcement with FDA.
- Coordinated national recall of misbranded meat products and negotiated terms of recall and enforcement with USDA.
- Advised regional restaurant chain on licensing issues and State regulatory enforcement related to Texas Home Rule provisions.
- Advised large regional convenience store chain on federal menu labeling requirements
- Product launch and labeling review and FDA compliance for cosmetic brand and compliance review regarding 510k issues.
- Product launch labeling review and FDA compliance for OTC products, and review of manufacturing and supply agreements.
- Negotiated with state regulators concerning product adulteration, detention and corrective action for food manufacturer (dairy).
- Food and dietary supplement label auditing.
- Labeling counsel on new dietary ingredients.
- Resolved non-compliance with Prior Notice of Imported food regarding importation of food products.
- Negotiation California Prop 65 claims regarding alleged elevated levels of contaminants in food product and other products.
- Advise food packaging manufacturer and importer on food contact substance requirements and regulations.