TOP 20 FOOD AND DRUG CASES, 2011 & CASES TO WATCH, 2012

Edited by

John B. Reiss, Ph.D., J.D.
Partner, Saul Ewing LLP

Gregory J. Wartman, J.D.
Partner, Saul Ewing LLP

 ISBN 978-1-935065-48-7

To order additional copies of this publication, please visit our website at www.fdli.org.

1155 15th St. NW, Suite 800, Washington, DC 20005
Tel: (202) 371-1420 Fax: (202) 371-0649
email: comments@fdli.org
website: www.fdli.org

CONTENTS

PREFACE

This is the third of FDLI's *Top 20 Cases* series. As in previous years, we summarize the cases, administrative actions and settlements from 2011 that made their mark on the field of food and drug law. The major legislative change in 2011 was the Food Safety Modernization Act (FSMA), signed into law on January 4, 2011, that aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. Many of its provisions were being implemented during this year in review.

The top 20 cases were chosen again using an extensive vetting process by academics and practicing attorneys, including authors and editors of *Food and Drug Law and Regulation*. This year we have changed the presentation format to cluster the cases by topic area rather than presenting them in alphabetical order. If you prefer one approach over the other, please let us know. We fully realize that reasonable legal minds will disagree with our choices for the top 20 cases of 2011. Did you expect more of the Cases to Watch from last year to make it into this year's edition? Let us know about the case we missed—or one that didn't belong on the list.

We hope that the *Top 20 Cases* series will help give our readers a sense of perspective about the evolution of the field of food and drug jurisprudence as laws and regulations change, and court decisions develop the case law. The past few years have been a whirlwind of new legislation and jurisprudence, and it is our hope that these books will help readers understand the changes in the playing field and be prepared for the next challenges to come.

This year some of the Cases to Watch from last year made it into the Top 20, though at least one that we included in the expectation that the United States Supreme Court would have issued a decision by the time we published still awaits the Court's action, so it is likely to appear again in next year's book! As we discussed last year, other cases having to do with criminal indictments of companies and persons demonstrate the time it takes to get to a conclusion on these matters, though we have reported decisions on the majority of such cases.

In our review of agency activities, the Food and Drug Administration (FDA) continues to implement its transparency program, being more open about many aspects of its activities, and increasingly involving industry and the public in discussion of its potential policies. An interesting development is its effort to cooperate with the Centers for Medicare & Medicaid Services by conducting simultaneous review of innovative devices, though the premarket approval process covers a small number of medical devices compared with those subject to FDA clearance. One can hope that success with innovative products will persuade the two agencies to establish a similar program for 510(k) cleared products. FDA has continued to emphasize its enforcement activities, particularly its cooperation with other agencies such as the Federal Trade Commission.

We hope you will use this book as a resource to ensure that you are current on significant litigation in the food and drug area, as well as recent settlement and administrative actions. Looking ahead, the chapter on cases to watch in 2012 discusses selected cases about which there have been generally only preliminary pleadings.

We would like to thank FDLI for its dedication to publishing this valuable book and the authors for their hard work and sharing their expertise in food and drug law and regulation with our readers.

John B. Reiss
Gregory J. Wartman

ABOUT THE EDITORS

John B. Reiss is a partner with Saul Ewing LLP. He helps Life Science companies interrelate clinical trials, FDA clearance or approval, and reimbursement before they initiate development of a new product. This includes identifying appropriate clinical sponsors, as necessary. He assists companies obtain FDA clearance or approval for their products, and obtain payment from third-party payers, including obtaining new payment codes if necessary. He works with companies to establish and implement compliance plans, develop their corporate, partnership and other arrangements, and negotiate contracts, licensing arrangements and other transactions. Dr. Reiss holds a PhD in economics.

Gregory J. Wartman is a partner with Saul Ewing LLP, Philadelphia, Pennsylvania, and a member of the firm's Life Sciences Practice Group. He concentrates his practice in the counseling, prospective risk management, and litigation defense of manufacturers of prescription drugs, medical devices, and piping products. Mr. Wartman handles a wide variety of product liability litigation in state and federal courts nationwide. He has served as coordinating counsel for nationwide product liability litigation involving both pharmaceutical and non-pharmaceutical products. He is also a frequent author on legal issues affecting prescription drug and medical device manufacturers.

ABOUT THE AUTHORS

Anand Agneshwar co-chairs Arnold & Porter LLP's product liability practice group.

Carlos Angulo is a partner at the law firm of Zuckerman Spaeder LLP in Washington DC. Mr. Angulo's practice focuses on food and drug litigation in state and federal courts, administrative practice before FDA and policy counseling on matters before Congress. Mr. Angulo joined Zuckerman Spaeder in 1999 and was a partner from 2003 to 2007. From 2007 to 2010, when he returned to the firm, Mr. Angulo served as Legislative Director for Sen. Sheldon Whitehouse. Before joining Zuckerman Spaeder, Mr. Angulo served as a staff attorney in the U.S. Department of Justice's Civil Division; clerked for the Honorable Phyllis A. Kravitch, U.S. Court of Appeals for the Eleventh Circuit; and served as counsel for Senators Paul Simon and Paul Sarbanes. Mr. Angulo graduated from Haverford College (*magna cum laude*, Phi Beta Kappa) in 1986 and received his law degree from Yale University in 1989.

Edward M. Basile leads the firm's FDA & Life Sciences practice group at King & Spalding and has more than 30 years of experience in interpreting the laws and regulations administered by FDA. His current practice includes representing medical device, pharmaceutical and biotechnology companies. Mr. Basile served as Deputy General Counsel for HIMA, now called AdvaMed, the primary trade association for the medical device industry. Mr. Basile also served in the Chief Counsel's Office of FDA from 1975-1985 as Associate Chief Counsel for Drugs & Biologics and Associate Chief Counsel for Enforcement. Mr. Basile received a BS degree in Mechanical Engineering in 1969 from Lafayette College and a law degree from the National Law Center, George Washington University, where he graduated Order of the Coif.

Kenita Barrow is an associate in the FDA & Healthcare practice group in the Washington D.C. office of Arnold & Porter LLP. Her practice is focused on matters related to medical device and pharmaceutical product approvals, cGMPs, adverse event reporting, advertising and promotional matters, FDA inspections, importation issues, and recalls. Additionally, Ms. Barrow's experience includes counseling clients on over-the-counter products, human cell and tissue products, medical foods, dietary supplements and cosmetics. Ms. Barrow received her JD from Vanderbilt University Law School and her BS from the University of Maryland Baltimore County. Ms. Barrow also completed graduate coursework in the Pharmacology and Interdisciplinary Program in Neuroscience at Georgetown University.

Adam Bobel is a student at the University of San Diego (USD) School of Law, graduating class of 2013. During the fall of 2011, Bobel interned at Birch, Stewart, Kolasch & Birch LLP while participating in USD's Technology Entrepreneurship Clinic. Bobel received his Bachelor of Science degree in biology from Georgetown University in 2008 (*cum laude*) and his Master of Science degree in biotechnology from Georgetown University in 2009. Currently, he is pursuing a career in patent prosecution. Outside of academia, some of Bobel's interests include playing the guitar and rooting for his hometown Chicago sports teams.

Mark C. Bolin is an associate in the Research Triangle Park office of the law firm of K&L Gates LLP, where he is a member of the firm's Life Sciences practice group. His practice focuses on serving the corporate legal and FDA regulatory needs of clients in the academic, pharmaceutical and medical device industries. Mr. Bolin graduated with highest distinction from the University of North Carolina at Chapel Hill, where he was also *Phi Beta Kappa*, in 2008. He received his JD and LLM in International and Comparative Law from the Duke University School of Law in 2011.

Kevin A. Cline is an associate in the litigation group at Arnold & Porter LLP where he focuses on drug product liability litigation.

Stacy L. Ehrlich is a partner in the Washington DC law firm of Kleinfeld, Kaplan & Becker LLP, which specializes in food and drug law. Ms. Ehrlich primarily represents pharmaceutical, food, dietary supplement, tobacco, cosmetic and medical device companies on a variety of legal matters. She has authored a number of articles in FDLI's *Update* magazine and chapters in FDLI books, including *Food and Drug Law and Regulation (Second Edition)* and *Top 20 Food and Drug Cases, 2010 & Cases to Watch, 2011*, and currently serves on the FDLI Tobacco Committee. Ms. Ehrlich graduated from Emory University (*magna cum laude*, Phi Beta Kappa) and received her law degree (*cum laude*) from Harvard Law School.

Michael M. Gaba is the federal policy leader of Holland & Knight's national Healthcare & Life Sciences Team. His regulatory and legislative life sciences practice includes counseling and representing medical device and biotech companies before the U.S. Food and Drug Administration, the Centers for Medicare & Medicaid Services and the U.S. Congress. Mr. Gaba serves on the advisory board of Bloomberg BNA's *Medical Devices Law & Industry Report* as well as the editorial advisory board of FDLI's *Food and Drug Law Journal*.

Eric Gotting serves as a partner at Keller and Heckman LLP in the firm's litigation practice group. He specializes in complex civil and appellate matters, with a focus on toxic tort, environmental and corporate litigation. Between 1999-2004, Mr. Gotting took leave from private practice and served as a trial attorney with the U.S. Department of Justice's Civil Division, Environmental Torts Section, where he defended the federal government in multimillion dollar toxic tort cases filed under the Federal Tort Claims Act. He holds a JD from the University of Michigan Law School and a BS from the University of Michigan, School of Natural Resources and Environment.

William F. Gould is a partner in Holland & Knight's National White Collar Defense and Investigations practice. He represents a number of pharmaceutical and medical device companies, as well as other participants in the healthcare field. Prior to joining Holland & Knight, Mr. Gould was a federal prosecutor with the Department of Justice and on the faculty of the University of Virginia School of Law. He also served as a law clerk for Federal District Court Judge Morton A. Brody.

Mark E. Haddad is co-chair of the Global Appellate Practice at Sidley Austin LLP. Resident now in Sidley's Los Angeles office, he practices in federal and state appellate courts throughout the country. His matters involve the impact of federal constitutional, statutory and regulatory provisions on the scope of business liability, often for clients in the life sciences. He joined Sidley's Washington DC office in 1987, following clerkships with Justice William J. Brennan, Jr., of the United States Supreme Court, and The Hon. Louis H. Pollak, United States District Court for the Eastern District of Pennsylvania. He graduated from Yale Law School in 1985, where he was editor-in-chief of the *Yale Law Journal*.

Ralph F. Hall serves as Professor of Practice at the University of Minnesota Law School where he specializes in FDA and health law compliance. He is also Counsel to the law firm of Faegre Baker Daniels where he counsels clients in the area of drug and medical device regulation. He also serves as CEO of MR3 Medical LLC, a start-up medical device company. Professor Hall received his BA (*magna cum laude*) from Indiana University in 1974 and his JD (*cum laude*) from the University of Michigan where he was a Weymouth Kirkland Scholar. Professor Hall's interests include FDA regulation, corporate compliance, negotiations, the interface between corporate practice and the academic world, and the regulation of emerging technologies such as nanotechnology and synthetic biology.

James R.M. Hemmings is an attorney in the Product Liability and Mass Tort Litigation practice group of Sidley Austin LLP. His practice includes a diverse range of civil litigation matters in both the state and federal courts, and at both the trial court and appellate level. His practice focuses on tort litigation and he has extensive experience defending matters in complex litigation, including the defense of pharmaceutical and medical device makers, food additive purveyors and industrial chemical manufacturers.

Michael H. Hinckle is a partner with the law firm of K&L Gates LLP. Mr. Hinckle's practice focuses on regulatory matters with an emphasis in the area of pharmaceuticals, medical device and tobacco product regulation. Mr. Hinckle has represented clients before FDA, CMS, DEA and various state boards of pharmacy. Prior to entering private practice, Mr. Hinckle worked as a molecular biologist with the American Type Culture Collection and served in the U.S. Navy. He is a former member of the Board of Directors for the Generic Pharmaceutical Association and frequent lecturer on FDA-related matters.

Naomi A. Igra is a litigation associate in the San Francisco office of Sidley Austin LLP. She has assisted life science clients in antitrust, white collar and regulatory enforcement matters. She joined Sidley Austin after graduating from the Georgetown University Law Center in 2009. During law school, she served as an extern for The Hon. Emmet G. Sullivan, United States District Court for the District of Columbia. She was also a Law Fellow in Legal Research and Writing, completed an internship with the legal department at Genentech, Inc. and studied at the Center for Transnational Legal Studies in London.

William M. Janssen is Associate Professor of Law, Charleston School of Law, Charleston, South Carolina. Before joining academia, Professor Janssen was a litigation partner in a mid-Atlantic AmLaw-200 law firm where he chaired the firm's interdisciplinary life sciences practice group; he concentrated his practice in pharmaceutical and medical device litigation. In addition to various writings on pharmaceutical and medical device litigation, he is also the author of *Federal Civil Procedure Logic Maps*, as well as the co-author of three nationally distributed texts on federal civil procedure, the *Federal Civil Rules Handbook*, *A Student's Guide to the Federal Rules of Civil Procedure* and Volume 12B of the nation's leading treatise on federal practice, Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure*.

Daniel Kracov is a partner and Head of the FDA & Healthcare practice group at Arnold & Porter LLP in Washington DC, where he assists clients in negotiating the legal requirements relating to the development, manufacturing, approval and marketing of drugs, biologics and medical devices. He regularly represents clients in complex compliance challenges and product-related crises, as well as FDA-related civil, criminal and congressional investigations. His capabilities in strategic regulatory advice and crisis management have been widely recognized, including by Chambers, *Washingtonian* magazine, Best Lawyers, and the *Legal Times* list of the Top FDA Lawyers.

Marian J. Lee is a partner in the FDA & Life Sciences Practice Group at King & Spalding. Ms. Lee advises medical device, pharmaceutical and biotechnology companies on a broad range of FDA regulatory and compliance issues, including labeling and promotion, complaint handling and adverse event reporting, product recalls, product approvals, quality system regulation (QSR), device reclassifications, regulatory risk assessments, governmental investigations, and due diligence assessments of FDA-regulated entities. Ms. Lee has expertise in the FDA and FTC regulation of promotion and social media, and the regulation of mobile health (mHealth) technologies. Ms. Lee is a member of the *Law 360* Life Sciences Editorial Advisory Board and a 2012 Fellow to the Leadership Council on Legal Diversity. She graduated from Harvard Law School, where she was Articles Editor of the *Harvard Journal of Law and Technology* and Co-Chair of the Harvard Asian Pacific American Law Students Association. She graduated with a Bachelor of Arts, *magna cum laude* and Phi Beta Kappa, from Harvard College.

Benjamin S. Martin is a member of the firm in the Washington DC office of Epstein Becker & Green, P.C. As part of the firm's Health Care and Life Sciences Practice, Mr. Martin provides regulatory counseling and transactional and litigation support on a wide range of issues affecting manufacturers, distributors, pharmacies, providers and other entities along the pharmaceutical and medical device supply chains, including: approval, manufacture, distribution, and promotion of pharmaceuticals and medical devices; coverage of pharmaceuticals and medical devices by governmental and private payers; obligations of pharmaceutical manufacturers under governmental reimbursement, rebate, and procurement programs; prevention of fraud and abuse in the marketing of pharmaceuticals and

medical devices; and all phases of governmental inquiries and investigations. Mr. Martin received his law degree in 1999 from the University of Virginia School of Law, where he was a member of the *Virginia Law Review* and of the *Order of the Coif*.

Madeleine McDonough is Chair of Shook Hardy & Bacon's Pharmaceutical & Medical Device Litigation Division and she co-chairs the Agribusiness & Food Safety Practice and Life Sciences & Biotechnology Practice. She is primarily based in the firm's Washington DC office. Ms. McDonough counsels pharmaceutical manufacturers on FDA regulations and represents clients in litigation, claim resolution, and preventative litigation strategies.

William A. McGrath is a partner in the Food & Drug and Product Safety Practice at Wiley Rein LLP. For the last 15 years, he has counseled a broad spectrum of clients on federal and state regulatory and liability issues raised in the development, safety, approval, advertising and marketing of drugs, medical devices, tobacco products, food and beverages, nutritional supplements, cosmetics, bulk chemicals and consumer products. He represents clients before the U.S. Food and Drug Administration, Consumer Product Safety Commission, Federal Trade Commission, other federal, state and local regulators, and in state and federal courts nationwide.

Rikin S. Mehta is with the U.S. Food and Drug Administration, Center for Drug Evaluation and Research's Office of Compliance. The views presented in this chapter are those of the author only, and do not necessarily reflect those of the Food and Drug Administration.

Joseph W. Metro is a partner in the Life Sciences and Health Industry Group in the Washington DC office of Reed Smith LLP. Mr. Metro counsels drug and device manufacturers and distributors with respect to healthcare regulatory matters, including fraud and abuse and promotional compliance, the Medicaid rebate statute and similar government pricing programs, and reimbursement under federal healthcare benefit programs. He received his BA from Dickinson College in 1986 and his law degree from George Washington University in 1989.

James W. Mizgala is a partner in the Chicago office of Sidley Austin LLP. His principal areas of practice are products liability and toxic tort litigation. In addition to first-chair trial experience, he has experience in all phases of pretrial litigation on both the national (MDL) and local level. Capitalizing on his training as a neurobiologist, Mizgala has been extensively involved in identifying, interviewing, retaining, deposing and presenting experts for trial and during class certification proceedings, and in drafting and successfully arguing numerous *Daubert/Frye* motions.

Ted Naccarella focuses his practice on a broad range of intellectual property law matters that include domestic and foreign patent preparation, prosecution and counseling, litigation, patent due diligence and opinion work, including patentability, infringement and validity opinions and trademark preparation, prosecution and counseling. His practice is concentrated in the medical device and telecommunications areas. Mr. Naccarella has served as both lead and supporting counsel in patent, copyright and trademark litigation in federal courts and in patent interference and trademark opposition proceedings in the United States Patent and Trademark Office. He also served as a credited consultant for *New York Times* best-selling author, Lisa Scottoline, on intellectual property law for her 2004 legal thriller novel, *Killer Smile*.

Dr. Mark J. Nuell is a registered patent attorney and partner at Birch, Stewart, Kolasch & Birch LLP. Dr. Nuell has been working in the field of intellectual property since 1991 and is a member of the California and Virginia bars. Dr. Nuell assists clients, including start-up and small companies, in the planning of their intellectual property strategy and in the obtaining of patent rights in their inventions. His technical specialties span many fields of genetic engineering, including cloned nucleic acids, vectors, vaccines, gene therapy, cell lines, recombinant proteins, antibodies and various genetic engineering methods. In addition, Dr. Nuell works in the fields of materials science, diagnostic and therapeutic compositions and methods, separation methods, analytic methods and the like. Dr. Nuell's practice also includes a variety of opinion work, including patentability, validity and infringement analyses and freedom to operate opinions. He is a frequent lecturer on intellectual property topics, and has participated as an invited speaker at meetings of the Licensing Executive Society and the Biotechnology Industry Organization as well as providing instruction in U.S. patent practice at client law firms, the Danish Patent Office and at various universities and research institutes. In addition to publishing through the Food and Drug Law Institute, Dr. Nuell is a contributing author to the Practicing Law Institute Practice Center website.

Patrick C. O'Brien is a partner with Holland & Knight where he practices in the healthcare, fraud and abuse, and pharmaceutical, biotechnology and medical device areas. Prior to joining the firm, Mr. O'Brien served as regulatory counsel with the U.S. Food and Drug Administration, as in-house counsel for Johnson & Johnson, and as a litigator. Mr. O'Brien began his career in the healthcare field as a pharmacist. He has over 15 years experience as an attorney and over 20 years experience in the healthcare field.

Andrew R. Oja is an associate in Holland & Knight's National White Collar Defense and Investigations practice. During law school, Mr. Oja worked as an intern in the U.S. Department of Justice Counterterrorism Section and the San Francisco District Attorney's Office. Prior to joining the firm, Mr. Oja worked as a legislative fellow in the office of United States Senator Ron Wyden.

Ginger Heyman Pigott is a shareholder with Greenberg Traurig, LLP's Los Angeles office where she is an integral member of the Pharmaceutical, Medical Device and Health Care Litigation Group. Her 20 years of practice has included significant experience in the defense of product liability claims involving highly sophisticated, life-saving products and technology. Pigott has defended lawsuits involving a wide range of products, including prescription drugs and biologicals, over-the-counter medications, dietary supplements and nutraceuticals, spinal/biological devices, neurological devices, diabetes management devices, cardiovascular devices, implantable devices for various indications, cardiopulmonary bypass equipment, imaging equipment, as well as other external medical devices and related equipment. She also enjoys growing her own vegetables.

Kathleen M. Sanzo is leader of Morgan Lewis & Bockius's FDA and Healthcare Regulation Practice. Her practice focus includes all regulatory matters relating to drugs/biologics from development, testing and manufacture, to promotion and distribution. Following graduation from Duke University in 1979, Ms. Sanzo received her JD from Emory Law School in 1982, and her LLM from The George Washington University National Law Center in 1985, where she was selected as the Food and Drug Law Institute Fellow, and worked at the Office of General Counsel of the Food and Drug Administration. She is author/co-author of many publications and speeches.

Andrew J. Siegel is an associate in the Health Care Practice Group in the Philadelphia office of Saul Ewing LLP. Mr. Siegel concentrates his practice on corporate healthcare law, with a focus on business formation and governance, contractual relationships and business transactions. He also advises healthcare providers and institutions on regulatory and compliance issues, including federal and state privacy and security laws, include HIPAA and the HITECH Act, and federal and state fraud and abuse laws, including the Stark Law, Anti-Kickback Statute and False Claims Act. Mr. Siegel is a graduate of the University of Pittsburgh School of Law and Bowdoin College.

Katherine J. Seikaly is an associate in the Washington DC office of Reed Smith LLP. Ms. Seikaly focuses her practice on government and internal investigations, international and domestic regulatory compliance and enforcement matters, white collar criminal litigation and related civil litigation. She has represented multiple clients in the healthcare industry, including medical device manufacturers, pharmaceutical manufacturers and pharmacies, in all aspects of false claims, fraud, anti-kickback and *qui tam* matters. Ms. Seikaly has also defended clients in cases involving antitrust law, the Foreign Corrupt Practices Act and banking regulations.

Jennifer Stonecipher Hill is an Associate in Shook Hardy & Bacon's Pharmaceutical & Medical Device Litigation Division and bases her practice from the firm's Kansas City, Missouri, offices.

Farah Tabibkhoei is an associate in the Los Angeles office of Reed Smith LLP where she is a member of the Western Commercial Litigation Group. Her practice focuses on defense of product liability claims against leading medical device manufacturers and pharmaceutical companies stemming from recalls of prescription medical devices and prescription drugs. Tabibkhoei's practice also includes representation of large corporations in legal malpractice suits as well as breach of contract suits involving equipment finance. She has experience in all phases of pre-trial litigation including discovery and motion practice. Tabibkhoei graduated *magna cum laude* from UC Irvine with a BA in political science and received her JD from USC Law School where she was a senior editor of the *Interdisciplinary Law Journal*.

James William Woodlee practices law as an associate with Kleinfeld, Kaplan and Becker, LLP, in Washington DC. He primarily counsels and advocates on behalf of clients regulated by FDA, DEA, USDA, FTC and related state and federal agencies. Before entering private practice, he served as an Attorney Advisor in the United States Department of Labor's Office of Administrative Law Judges. He earned a JD from Wake Forest University School of Law, where he served as an Executive Editor for the *Wake Forest Law Review*, and a BA from Wake Forest University. He has contributed to several FDLI publications, most recently as the editor of *The Food Safety Modernization Act: A Comprehensive, Practical Guide to the Landmark Legislation*.

CHAPTER 3

WALTON v. BAYER CORP.

MADELEINE MCDONOUGH, RIKIN MEHTA* AND JENNIFER STONECIPHER HILL

I. Why It Made the List

In deciding *Walton v. Bayer Corp.*, the Seventh Circuit took a rare opportunity to address a growing body of case law on the propriety of removal based on the fraudulent joinder doctrine. Courts increasingly have addressed whether a pharmaceutical manufacturer may remove a product liability case based on diversity of citizenship, despite a plaintiff's attempt to defeat the removal by joining a nondiverse pharmacy as a defendant. Because federal courts of appeals are prohibited by statute from reviewing most decisions remanding cases to state court for lack of subject matter jurisdiction, the vast majority of cases evaluating these complex questions arise from the federal district courts. The decision in *Walton* clarifies how district courts can evaluate claims of fraudulent joinder when allegations against pharmacies and pharmaceutical manufacturers are joined in suit.

II. Facts of Case

The plaintiff, Cathy Walton, sued Bayer Corporation and related Bayer entities in Illinois state court for personal injuries allegedly caused by her use of Yasmin, an FDA-approved prescription oral contraceptive.[1] The Bayer defendants ("Bayer") were distributors of Yasmin; the Bayer affiliate that manufactured the product was not named in the lawsuit.[2] The plaintiff also named as a defendant Niemann Foods, Inc. ("Niemann"), the pharmacy that allegedly

---

* The views expressed in this chapter are the author's, and do not necessarily reflect those of the U.S. FDA.

1 Walton v. Bayer Corp., 643 F.3d 994, 997 (7th Cir. 2011).

2 *Id.* at 1001.

filled her Yasmin prescription.[3] She asserted claims for strict products liability, negligence, failure to warn, breach of implied warranty and statutory fraudulent misrepresentation.[4]

The Bayer defendants, all citizens of states other than Illinois, removed the case to federal court based on diversity of citizenship, even though complete diversity did not apparently exist because Niemann, like the plaintiff, was an Illinois citizen.[5] Once in federal court, the case was consolidated with the multidistrict litigation, pending in the Southern District of Illinois. The plaintiff moved to remand the case to state court on three bases. First, the plaintiff claimed that the threshold amount-in-controversy requirement for federal court jurisdiction had not been satisfied. The plaintiff's complaint asserted that she:

> Incurred substantial damages, including, but not limited to, injury to her gall bladder sufficient to require its surgical removal, as well as other severe and personal injuries, including future thromboembolic events, which are permanent and lasting in nature, physical pain and mental anguish, diminished enjoyment of life, medical, health, incidental and related expenses, the need for lifelong medical treatment, monitoring and/or medications, and the fear of developing any of the above named health consequences.[6]

The plaintiff sought damages "in excess of $50,000."[7]

Second, the plaintiff argued that Bayer's removal notice was defective under 28 U.S.C. § 1446(a), which requires a defendant to file its notice of removal along with "a copy of all process, pleadings, and orders served upon such defendant or defendants in such action." When Bayer filed its notice of removal during the 30-day removal period, it failed to attach a copy of the state court summons.[8] However, shortly after the 30-day removal period expired, Bayer supplemented its original notice to include the summons.[9]

Arguing for remand, the plaintiff claimed that the district court lacked diversity jurisdiction based on the presence of Niemann, an Illinois corporation. Bayer responded by asserting that Niemann had been fraudulently joined to destroy diversity jurisdiction. Although Niemann, the pharmacy that sold Yasmin to the plaintiff, did not manufacture the medication, the plaintiff nonetheless alleged that Niemann failed to warn her of Yasmin's side ef-

---

3 *Id.* at 997.

4 *In re* Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Products Liab. Litig., 692 F. Supp. 2d 1025, 1028 (S.D. Ill. 2010), *aff'd sub nom.*, Walton v. Bayer Corp., 643 F.3d 994 (7th Cir. 2011).

5 *Walton*, 643 F.3d at 997.

6 *In re Yasmin*, 692 F. Supp. 2d at 1039.

7 *Id.*

8 *Id.* at 1029.

9 *Id.*

fects.[10] According to Bayer, because there was no legal basis for the claims against Niemann, the district court should disregard the citizenship of the nondiverse defendant and retain subject matter jurisdiction.

Niemann moved the district court to dismiss the claims against it under Federal Rule of Civil Procedure 12(b)(6).[11] The district court denied the plaintiff's motion to remand and dismissed Niemann with prejudice.[12] Following the denial of her motion to remand, the plaintiff seemingly abandoned the litigation and failed to respond to discovery requests by Bayer. Subsequently, the district court dismissed the plaintiff's case with prejudice as a discovery sanction, and the plaintiff appealed from the final order.[13]

III. Court Ruling

In a decision by Judge Posner, the Seventh Circuit affirmed the district court's decision and agreed that subject matter jurisdiction existed and that the case had been properly dismissed. As a preliminary matter, the court rejected Bayer's challenge to the court's jurisdiction over the appeal. According to Bayer, the plaintiff should not have been permitted to challenge the interlocutory order, which denied remand, by dismissing the case altogether.[14] The court concluded that it could properly review the remand order, because the plaintiff had "wagered her entire claim on being proved right about jurisdiction."[15] The court quickly disposed of the plaintiff's challenge that the jurisdictional amount-in-controversy threshold had been satisfied.[16] The court also rejected the plaintiff's argument that Bayer's failure to attach the state court summons required remand.[17]

As for the plaintiff's primary challenge to diversity jurisdiction, the court ruled that Niemann had been fraudulently joined and was properly dismissed, leaving only diverse defendants.[18] A significant aspect of the ruling is that, under the learned intermediary doctrine, pharmacies are not required to warn their customers of the risks associated with the drugs they sell, and therefore the plaintiff's claims against Niemann were groundless.[19] Further, the plaintiff could not rely on the "common defense" exception to avoid a finding

---

10 *Walton*, 643 F.3d at 997.
11 *In re Yasmin*, 692 F. Supp. 2d at 1029.
12 *Walton*, 643 F.3d at 997.
13 *Id.*
14 *Id.*
15 *Id.* at 998.
16 *Id.*
17 *Id.*
18 *Id.* at 1001.
19 *Id.* at 1000-01.

of fraudulent joinder by showing that Niemann's learned intermediary doctrine defense was common to all defendants. The court found the allegation that the manufacturer concealed information about Yasmin's side effects was incompatible with the learned intermediary doctrine.[20] Thus, the pharmacy and manufacturer did not share a "common defense." The court affirmed the dismissal.

IV. Rationale for Decision

Ultimately, the Seventh Circuit's decision thoughtfully analyzed how the learned intermediary doctrine applies to claims against pharmacies and distributors such as Niemann—a pharmacy that merely supplied the prescription drug here at issue.

A. The Fraudulent Joinder Doctrine

Ordinarily, the presence of a nondiverse defendant will destroy a federal court's diversity jurisdiction under 28 U.S.C. § 1332(a). Thus, to prevent the removal of a state court case to federal court, creative plaintiffs will often join a nondiverse defendant whose citizenship would prevent a federal court from exercising jurisdiction over the case.[21] However, when the claims against the nondiverse defendant have no legal basis, and the nondiverse defendant was joined simply to preclude removal, a federal court may retain jurisdiction over the case under the doctrine of fraudulent joinder.[22]

The fraudulent joinder doctrine has been applied by federal courts across the country.[23] The doctrine has a long history, stemming from United States Supreme Court decisions in the early 1900s.[24] In *Wecker v. National Enameling & Stamping Co.*, the Supreme Court affirmed the denial of remand when there was no basis for allegations against a nondiverse defendant, who was joined merely to prevent removal.[25] The Court reasoned that, "[w]hile the plaintiff, in good faith, may proceed in the state courts upon a cause of action which he alleges to be joint, . . . the Federal courts should not sanction devices intended to prevent a removal to a Federal court where one has that right."[26] In *Chesapeake & Ohio Railway Co. v. Cockrell*, the Court further solidified the doctrine by explaining that a defendant's "right of removal cannot be defeated by a fraudulent joinder

---

20 *Id.* at 1001.

21 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 3641.1 (3d ed. 2009).

22 *See Walton*, 643 F.3d at 999.

23 *See* Wright & Miller § 3641.1 (citing cases).

24 *See generally* Matthew J. Richardson, *Clarifying and Limiting Fraudulent Joinder*, 58 Fla. L. Rev. 119, 126-27 (2006).

25 Wecker v. Nat'l Enameling & Stamping Co., 204 U.S. 176, 185-86 (1907).

26 *Id.*

of a resident defendant having no real connection with the controversy."[27] Under *Cockrell*, the removing party must show that there was no "reasonable basis" to join the nondiverse party.[28]

Federal courts have described the standard for finding fraudulent joinder, with slight variations.[29] The Seventh Circuit declared that a defendant must establish, after resolving all issues of fact and law in favor of the plaintiff, that there is no "reasonable possibility" that the plaintiff could prevail against a nondiverse defendant.[30] Despite the terminology, actual proof of fraud is not necessary for a finding of fraudulent joinder.[31] Instead, there must be "proof that the claim against the nondiverse defendant is utterly groundless."[32] Thus, the fraudulent joinder doctrine "permits a district court considering removal to disregard, for jurisdictional purposes, the citizenship of certain nondiverse defendants, assume jurisdiction over a case, dismiss the nondiverse defendants, and thereby retain jurisdiction."[33]

B. Pharmacy Liability under the Learned Intermediary Doctrine

In evaluating whether Niemann had been fraudulently joined, in that there was no reasonable possibility that the plaintiff could succeed in her claims, the *Walton* court considered the precise allegations against Niemann.[34] The court began by analyzing how the learned intermediary doctrine applied to pharmacies.[35]

As noted by the *Walton* court, the learned intermediary doctrine has been applied by most jurisdictions, including Illinois.[36] The learned intermediary doctrine recognizes that the prescribing physician acts as the "learned intermediary"—"the medical professional who, equipped with the knowledge imparted to him by the drug's manufacturer, determines, weighing benefit against risk, the drug's suitability for a particular patient."[37] Under the learned intermediary doctrine, the manufacturer is not required to directly warn consumers of the risks associated with a drug, as long as the manufacturer adequately warns physicians

---

27 Chesapeake & Ohio Ry. Co. v. Cockrell, 232 U.S. 146, 152 (1914).

28 *Id.* at 153.

29 Compare Wiles v. Capitol Indem. Corp., 280 F.3d 868, 871 (8th Cir. 2002) ("Joinder is fraudulent and removal is proper when there exists no reasonable basis in fact and law supporting a claim against the resident defendants."), with Henerson v. Wash. Nat. Ins. Co., 454 F.3d 1278, 1283 (11th Cir. 2006) (A court should deny remand based on fraudulent joinder only where the defendant has proven "by clear and convincing evidence" that there is "no possibility that the plaintiff can establish a cause of action against the non-diverse defendant.").

30 Schur v. L.A. Weight Loss Centers, Inc., 577 F.3d 752, 764 (7th Cir. 2009).

31 *Walton*, 643 F.3d at 999.

32 *Id.*

33 *Schur*, 577 F.3d at 763.

34 *Walton*, 643 F.3d at 999.

35 *Id.*

36 *Id.*; *see also* Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 392 (Ill. 1987).

37 *Walton*, 643 F.3d at 1000.

of the risks, who then can make informed decisions about prescribing drugs to particular patients.[38] As traditionally applied, the doctrine protects manufacturers against claims for failing to warn patients directly.[39]

Recognizing that a prescribing physician acts as a learned intermediary who is responsible for weighing a drug's risks and benefits for a given patient, the *Walton* court noted that only narrow situations give rise to a pharmacy's duty to warn its customers. A pharmacy must warn customers of the risks of prescription drugs only when it knows that a "particular customer" is susceptible to the side effects of a drug.[40] The court explained, "[A] manufacturer or a pharmacy must warn a customer of dangers known to it of which physicians have not been warned, but not of dangers of which physicians have been warned."[41] As applied in *Walton*, the plaintiff's allegations against Niemann were insufficient. "[I]f Niemann knew that the plaintiff was abnormally susceptible to a particular side effect of [Yasmin], it had a duty to warn her or her physician. But she doesn't allege that the pharmacy knew anything about her susceptibility, and so it had the full protection of the learned-intermediary doctrine."[42] Because the plaintiff had no viable claims against Niemann, the Seventh Circuit affirmed the district court's finding of fraudulent joinder.[43]

C. The "Common Defense" Exception to Fraudulent Joinder

The Seventh Circuit went on to analyze whether the defendants shared a common defense, such that no single defendant could be considered fraudulently joined. Some jurisdictions have expressly limited the district court's ability to disregard the citizenship of nondiverse defendants by applying an exception to the fraudulent joinder doctrine when the defendants share a common defense.[44] Under this exception, a plaintiff can rebut a finding of fraudulent joinder by proving that his claim against the nondiverse defendant "is no weaker than his claim against the diverse defendants."[45] The common defense exception is based on the idea that, when the claims and defenses are identical among diverse and nondiverse defendants, a fraudulent joinder argument is an attack on the merits of the suit; an issue properly addressed in the state court where the lawsuit was filed.[46]

---

38 *Id.* at 999-1000.

39 *See id.*

40 *Id.* at 1000.

41 *Id.*

42 *Id.* at 1000-01.

43 *Id.* at 1001.

44 See Smallwood v. Ill. Cent. R.R., 385 F.3d 568, 574-75 (5th Cir. 2004) ("When the only proffered justification for [fraudulent joinder] is that there is no reasonable basis for predicting recovery against the in-state defendant, and that showing is equally dispositive of all defendants rather than to the in-state defendants alone, the requisite showing has not been made."); Boyer v. Snap-On Tools Corp., 913 F.2d 108, 112-13 (3d Cir. 1990) ("[W]here there are colorable claims or defenses asserted against or by diverse and non-diverse defendants alike, the court may not find that the non-diverse parties were fraudulently joined based on its view of the merits of those claims or defenses."); see also Hunter v. Philip Morris USA, 582 F.3d 1039, 1044-45 (9th Cir. 2009) (preemption defense, which would "effectively decide the entire case," could not be the basis for a finding of fraudulent joinder).

45 *Walton*, 643 F.3d at 1001.

46 *Id.*

The plaintiff argued that Niemann was identically situated to the Bayer entities, who were the marketers and distributors of Yasmin.[47] However, the *Walton* court determined that the common defense exception did not apply to the plaintiff's claims against Bayer and Niemann. The court explained that the plaintiff's theories asserted against the diverse and nondiverse defendants were inconsistent and did not give rise to a common defense.[48] While the learned intermediary doctrine does not permit distributors to conceal a drug's side effects, the plaintiff alleged that Bayer—not Niemann—concealed the side effects of Yasmin.[49] Therefore, the court reasoned that "[t]he learned-intermediary doctrine that shields Niemann does not shield [the Bayer defendants], and thus is not a defense common both to the diverse defendants and to the nondiverse one."[50]

Furthermore, the court pointed out the irreconcilable position that the plaintiff had advanced on appeal. Had the plaintiff successfully argued that the learned intermediary doctrine operated as a defense common to all defendants, removal would be barred and the case should be remanded. However, the case would be subject to dismissal in state court because the learned intermediary doctrine would be a complete defense.[51] The plaintiff's only option at that point would be "to turn around and argue in the state court that her claim against the diverse defendants was not subject to the learned-intermediary doctrine after all and so her claim against them should survive Neimann's dismissal."[52] Based on principles of judicial estoppel, however, the plaintiff would not be permitted to do so.[53]

V. Impact of Decision

The *Walton* decision clarifies the propriety of joining in-state pharmacies in failure-to-warn pharmaceutical cases. Before *Walton*, the Southern District of Illinois had expressed skepticism as to whether the learned intermediary doctrine could serve as a basis for a fraudulent joinder determination. For example, in *McNichols v. Johnson & Johnson*, the Southern District of Illinois granted a plaintiff's motion to remand in a product liability lawsuit involving a prescription contraceptive device.[54] The plaintiff sued the manufacturer, as well as the nondiverse pharmacy that dispensed the product.[55] The manufacturer removed the case to federal court, arguing that the pharmacy had been fraudulently joined because the claim

47 *Id.*
48 *Id.*
49 *Id.*
50 *Id.*
51 *Id.* at 1002.
52 *Id.*
53 *Id.* at 1002-03.
54 McNichols v. Johnson & Johnson, 461 F. Supp. 2d 736 (S.D. Ill. 2006).
55 *Id.* at 738.

against it was barred by the learned intermediary doctrine.[56] The court questioned whether the learned intermediary doctrine was a proper basis for a claim of fraudulent joinder, because "it implicates issues about foreseeability and causation germane to the liability of both [the manufacturer and the pharmacy]."[57] The Southern District of Illinois ultimately concluded that the applicability of the learned intermediary doctrine was a question of fact that must be resolved by the state court.[58]

The same court later explained that its previous skepticism had "ripened into a firm conviction" that the learned intermediary doctrine could not serve as a basis for a manufacturer's argument that a pharmacy was fraudulently joined.[59] In *Brooks v. Merck & Co., Inc.*, the Southern District of Illinois rejected Merck's claim that a pharmacy defendant had been fraudulently joined.[60] In ordering remand, the court reasoned, "Merck's invocation of the learned intermediary doctrine is merely an attack on the merits of Plaintiff's claims."[61] According to the *Brooks* court, such an attack was insufficient because "fraudulent joinder is not shown merely by removing a case to federal court on the basis of a defense that is equally applicable to a plaintiff's claims against both [a] diverse and non-diverse defendant."[62]

The *McNichols* and *Brooks* remand decisions were not reviewed on appeal, and the Southern District of Illinois continued to reach the same result in remanding similar cases.[63] The Seventh Circuit's lack of appellate review until *Walton* is perhaps not surprising, as appellate courts are prohibited from reviewing remand orders in many situations, and this issue in particular has largely evaded review. 28 U.S.C. § 1447(d) provides that, excepting certain civil rights cases, "[a]n order remanding a case to the State court from which it was removed is not reviewable on appeal or otherwise . . . ."[64] Unlike *McNichols* and *Brooks*, review of the district court's decision on fraudulent joinder in *Walton* was not prohibited by section 1447(d) because the statute does not prevent a court from reviewing an order *denying* remand.[65] The plaintiff's challenge of the district court's subject matter jurisdiction in *Walton* allowed the Seventh Circuit to analyze a developing body of case law that frequently arises in product liability cases involving prescription medications.

---

56 *Id.* at 739.

57 *Id.*

58 *Id.* at 741.

59 Brooks v. Merck & Co., Inc., 443 F. Supp. 2d 994, 998-99 (S.D. Ill. 2006).

60 *Id.* at 1005.

61 *Id.* at 1004.

62 *Id.* at 1005.

63 *See* Smith v. Merck & Co., Inc., 472 F. Supp. 2d 1096, 1099 (S.D. Ill. 2007) (rejecting Merck's fraudulent joinder argument because "Merck asserts no flaw specific to the joinder of Walgreens and instead merely raises a defense equally dispositive of [the plaintiff's] claims for relief against both Merck and Walgreens"); Robinson v. Ortho-McNeil Pharm., Inc., 533 F. Supp. 2d 838, 841-42 (S.D. Ill. 2008) (rejecting a claim of fraudulent joinder because the learned intermediary defense was equally dispositive to the manufacturer and pharmacy).

64 28 U.S.C. § 1453(c), however, authorizes review of orders granting or denying motions to remand in class actions removed pursuant to the Class Action Fairness Act.

65 *See* Caterpillar, Inc. v. Lewis, 519 U.S. 61, 76 (1996). As the *Walton* court noted, any appeal would nevertheless need to comply with the final-decision rule set forth in 28 U.S.C. § 1291 or an exception thereto.

While *Walton* did not expressly overturn the Southern District of Illinois precedent, the court's reasoning suggests that the decision will have a significant impact on future cases removed from the Seventh Circuit. The court explicitly discussed a pharmacy's limited duty to warn, noting that "[i]t would be senseless, especially given drug regulation by the Food and Drug Administration and the extensive tort liability of drug manufacturers, to make pharmacies liable in tort for the consequences of failing to investigate the safety of thousands of drugs."[66] Although factual distinctions may exist in the specific allegations advanced against pharmacies and manufacturers, the *Walton* decision casts significant doubt on the continued viability of district court precedent within the Seventh Circuit that has refused to find fraudulent joinder by concluding that the manufacturer and pharmacy shared a common defense.

VI. Conclusion

Walton signals a potential shift in Seventh Circuit precedent on fraudulent joinder in pharmaceutical product liability cases. The decision illustrates the critical analysis required for evaluating failure-to-warn claims against pharmacies and allegations of fraudulent joinder. Future litigants should carefully consider the precise legal bases for the theories asserted against each defendant at every stage of the litigation.

---

66 *Walton*, 643 F.3d at 1000.