

# Pharmaceuticals and Medical Devices

## Overview

Carlton Fields has extensive experience litigating drug and medical device matters on behalf of industry-leading national and international clients. We defend our clients in individual, mass tort, class action, and other complex litigation matters in state and federal courts, from inception through appeal.

Our pharmaceutical work puts us at the forefront of cutting-edge issues, including preemption of medical device and prescription drug claims, the learned intermediary doctrine, comment k, market share liability, and brand name liability for generic use. We routinely take on *Daubert* and *Frye* expert challenges and summary judgments on medical causation. Our experience encompasses all types of pharmaceutical products and medical devices.

## Experience

### Seminal Representative Matters

Our dedicated pharmaceutical and medical device team has handled the following decisions establishing drug and medical device law:

- *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296 (11th Cir. 2011) (Eleventh Circuit first applies *Riegel* preemption to require specific allegations of parallel claims).
- *Colville v. Pharmacia & Upjohn Co.*, 565 F. Supp. 2d 1314 (N.D. Fla. 2008) (learned intermediary doctrine applies when prescriber independently assesses risk and decides not to warn plaintiff).
- *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360 (S.D. Fla. 2007) (learned intermediary doctrine applies to medical devices and FDUTPA claims, no Florida court recognizes direct-to-consumer or overpromotion exceptions).
- *Alexander v. Danek Med., Inc.*, 37 F. Supp. 2d 1346 (M.D. Fla. 1999), and *Savage v. Danek Med., Inc.*, 31 F. Supp. 2d 980 (M.D. Fla. 1999) (a plaintiff must prove a defect with expert proof).
- *Adams v. G.D. Searle & Co.*, 576 So. 2d 728 (Fla. 2d DCA 1991) (comment k applies as Florida law).

- *Felix v. Hoffmann-La Roche, Inc.*, 540 So. 2d 102 (Fla. 1989) (learned intermediary doctrine adopted as Florida law).

### Additional Published Opinions

- *Grubbs v. DePuy Synthes*, No. 8:15-cv-00443, 2016 WL 360610 (M.D. Fla. Jan. 19, 2016) (granting summary judgment because the plaintiff failed to allege the violation of any federal requirement in the PMA device components that he received).
- *Marshick v. Johnson & Johnson*, No. 5:14-cv-00498, 2015 WL 9266955 (M.D. Fla. Dec. 11, 2015) (granting summary judgment when the plaintiff lacked expert proof of general and specific causation).
- *Teva Pharm. Indus., Ltd. v. Ruiz*, 181 So. 3d 513 (Fla. 2d DCA 2015) (reversing denial of motion to dismiss for lack of personal jurisdiction where general jurisdiction was lacking and the plaintiff failed to establish specific jurisdiction and sufficient minimum contacts to satisfy due process).
- *Marmol v. St. Jude Med.*, 132 F. Supp. 3d 1359 (M.D. Fla. 2015) (dismissing claims against PMA medical device under implied preemption and lack of a remedy to enforce FDA regulations or requirements).
- *Ocasio v. C.R. Bard, Inc.*, No. 8:13-cv-01962, 2015 WL 3496062 (M.D. Fla. June 3, 2015) (granting summary judgment on warnings claim for lack of an expert on inadequacy and rejecting any inference of a manufacturing defect).
- *Homaday v. Smith & Nephew, Inc.*, 994 F. Supp. 2d 1264 (M.D. Fla. 2014) (wrongful death claim in third amended complaint related back to original filing for purposes of the statute of limitations).
- *Brown v. DePuy Orthopaedics, Inc.*, 978 F. Supp. 2d 1266 (M.D. Fla. 2013) (claims against PMA medical device preempted).
- *Kaiser v. DePuy Spine, Inc.*, 944 F. Supp. 2d 1187 (M.D. Fla. 2013) (dismissing claims with prejudice, before discovery, under *Riegel* preemption and *Wolicki-Gables* for failing to specify a parallel claim or allege noncompliance with a formal performance standard established by the FDA).
- *Layton v. SmithKline Beecham Corp.*, No. 05-CA-007440, 2012 WL 4983778 (Fla. Cir. Ct. Oct. 16, 2012) (an evidentiary hearing is not required to determine entitlement to attorneys' fees and costs based upon a proposal for settlement).
- *Chapman v. DePuy Orthopaedics, Inc.*, 760 F. Supp. 2d 1310 (M.D. Fla. 2011) (granting summary judgment for medical device manufacturer based upon choice of law analysis and Virginia's statute of limitations).

- *Gomez v. Pfizer, Inc.*, No. 1:09-cv-22700, 2010 WL 4102922 (S.D. Fla. Oct. 18, 2010) (plaintiff alleging failure to warn claims regarding over-the-counter product must respond to discovery and provide specific warning language that allegedly should have accompanied product).
- *Howe v. Wyeth Inc.*, No. 8:09-cv-00610, 2010 WL 1708857 (M.D. Fla. Apr. 26, 2010) (granting summary judgment for brand-name manufacturers when plaintiff used only generic product).
- *Levine v. Wyeth Inc.*, 684 F. Supp. 2d 1338 (M.D. Fla. 2010) (granting summary judgment for brand-name manufacturers when plaintiff used only generic product).
- *Doriand v. Centocor Inc.*, No. 1:09-cv-00078, 2010 WL 325742 (N.D. Fla. Jan. 26, 2010) (rejecting plaintiff's attempt to add a "sharing" provision to a protective order).
- *Gomez v. Pfizer, Inc.*, 675 F. Supp. 2d 1159 (S.D. Fla. 2009) (granting motion to dismiss claims of negligence and strict liability under *Iqbal* and *Twombly*).
- *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009) (granting summary judgment for brand-name manufacturers when plaintiff used only generic product).
- *Devore v. Howmedica Osteonics Corp.*, 658 F. Supp. 2d 1372 (M.D. Fla. 2009) (defendant properly removed based upon plaintiff's discovery responses and fraudulent joinder of alleged product distributor).
- *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009) (granting summary judgment of claims against alleged manufacturer, distributor, and manufacturer's representative under *Riegel* preemption, learned intermediary doctrine, and failure to present expert proof).
- *Wolicki-Gables v. Arrow Int'l, Inc.*, No. 8:08-cv-00151, 2008 WL 2773721 (M.D. Fla. June 17, 2008) (granting motion to dismiss claims of strict liability and negligence under *Twombly*).
- *Chase v. Novartis Pharm. Corp.*, 740 F. Supp. 2d 1295 (M.D. Fla. 2006) (granting summary judgment under learned intermediary doctrine).
- *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006) (granting summary judgment for brand-name manufacturers when plaintiff used only generic product), *aff'd per curiam*, 952 So. 2d 555 (Fla. 1st DCA 2007).

## Insights

05.20.2019

Admissibility Hurdles for 510(k) Evidence in Medical Device Litigation

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03.18.2019  
Trial Checklist

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10.04.2016  
A Look At Manufacturer Liability For The Internet Of Things

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09.01.2016  
Preemption and Other Defenses to Claims by Study Subjects

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08.01.2016  
Companies That Collect Sensitive Consumer Data Should Note the FTC's LabMD Ruling

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02.15.2016  
Food for Thought: 2015 Litigation Annual Review

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12.23.2015  
Could Your Medical Device Be a Hacker's Gateway into a Hospital Network?

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08.05.2015  
Kane v. Healthfirst and the 60-day Repayment Rule

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03.19.2015  
Food for Thought: Florida District Court Denies Class Certification Based on Failure to Show Ascertainability

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10.01.2014  
The Corporate Representative's Deposition Bill Of Rights (And Wrongs)

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12.26.2013  
CMS and OIG Release Final Rules Extending Stark Law Exception and Anti-Kickback Statute Safe Harbor for Donations of Electronic Health Records Technology

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10.02.2013  
Data Collection Under the Sunshine Act

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09.03.2013

Florida's Third DCA Limits Scope of Discovery in Premises Liability Cases

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08.30.2013

A Double Play for Prescription Drug Manufacturers in the Eleventh Circuit

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08.29.2013

OMG! I Have to Produce What? 4 Steps to Tipping the Field With Social Media

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07.02.2013

Florida Medicaid Liens after Wos

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07.02.2013

Does Florida Recognize a Duty to Warn in Spanish or Additional Languages Other Than English?

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06.27.2013

Florida's Supreme Court Limits the Economic Loss Rule

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06.17.2013

Personal Injury: Defendants May Conduct Multiple Independent Medical Examinations with Good Cause

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04.12.2013

Q&A With Carlton Fields' Gregory Cesarano

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12.18.2012

Personal Injury Defendant Entitled to Discovery Regarding Extent of Relationship Between Plaintiff's Lawyer and Plaintiff's Doctor

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12.17.2012

Proposals for Settlement: How to draft ones that will stick and how to deal with them when they land on your desk

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07.12.2012

Premises Liability – No Duty to Preserve Surveillance Videos Without a Specific Written Request

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07.02.2012

Heaters: No Duty to Supply Bilingual Warnings for Heater Not Targeted at Hispanic Market

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03.30.2012

Taking and Defending Rule 30(b)(6) Depositions for Young Lawyers

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03.08.2012

Florida Offers of Judgment: A New Trend To Uphold

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02.12.2012

FDA Denies Petition to Ban BPA in Food and Beverage Packaging

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01.06.2012

Changes to Removal and Remand Procedures for Civil Actions

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12.20.2011

Pharmaceutical and Medical Device Industry Links

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10.04.2010

Sales Reps in the OR: The Hunt for Non-Preempted Claims

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09.30.2009

A Shot in the Arm: “Procedural Preemption” of Vaccine Claims

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07.01.2009

The Learned Intermediary Landscape: A View From the Patient’s Perspective

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06.03.2009

New Case on Class Action Settlement

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10.31.2008

Finding, Building, and Marketing a Niche: It's Never Too Early to Start

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10.07.2007

Removal after Lowery v. Alabama Power Co. A Whole New Bag of Tricks?

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02.05.2007

Mass Tort or Mass Fraud?

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07.01.2006

AIDS: Implications for Pregnancy

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06.01.2006

Cross-Appeals in Civil Cases

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04.01.2006

Removal

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09.01.2005

Litigation 101: Preparing a Bill of Costs

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09.01.2005

A 50-State Review of State Warnings Law

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04.21.2003

The Implications of Expert Testimony in the Wake of Daubert v. Merrell Dow Pharmaceuticals

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01.01.2000

Consumer and Customer Disputes with Goods or Services Providers

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08.01.1999

State-by-State Summary of the Law on Liability for Off Label Use of Drugs and Medical Devices  
(Florida Section)

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# Our Team

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## Related Capabilities

### Practices

- Health Care
- Appellate & Trial Support
- Business Transactions
- Corporate Law and Governance
- Government Law & Consulting
- Intellectual Property
- Life, Annuity, and Retirement Litigation
- Litigation and Trials

### Industries

- Health Care

- Mass Tort and Product Liability
- Private Equity and Venture Capital
- International: Latin America
- International Litigation & Arbitration
- Antitrust and Trade Regulation
- International
- Class Actions