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Beyond the Basics: Expanding Theories of Liability and Defenses for Claims Involving Medical Device Sales Representatives

Christiana C. Jacxsens

Sara E. Deskins

Sean P. Jessee

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**BEYOND THE BASICS: EXPANDING THEORIES OF
LIABILITY AND DEFENSES FOR CLAIMS INVOLVING
MEDICAL DEVICE SALES REPRESENTATIVES**

Christiana C. Jacxsens, Sara E. Deskins,
and Sean P. Jessee[†]

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[†] Christiana C. Jacxsens is a shareholder at Greenberg Traurig, LLP, who specializes in the defense of complex pharmaceutical and medical device products liability litigation, as well as advising pharmaceutical and medical device companies on regulatory and compliance matters. Sara E. Deskins and Sean P. Jessee are associates at Greenberg Traurig, LLP who focus their practices on defending products liability matters involving pharmaceutical and medical device companies.

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I. INTRODUCTION

Medical device sales representatives play a unique role in the delivery of treatment to the patient as compared to pharmaceutical sales representatives. Medical device representatives are often in the operating room or present during the patient visit and can provide pretreatment technical information about the device. While this unique role can provide great benefit to the manufacturer, the physician, and the patient, it can also expose a manufacturer and the sales representative to liability. Once limited to basic tort claims, such as negligence for failure to warn or invasion of privacy, the avenues for sales representative liability have blossomed over the last few years. Counsel for a medical device manufacturer (both in-house and outside counsel) must

become familiar with a broader range of claims. This article gives readers an overview of the expanded theories of liability for medical device representative conduct with an emphasis on recent and novel claims, as well as successful defenses to these claims. In order to aid counsel in better understanding the nuances and challenges presented in defending these new claims involving sales representatives, this article uses specific case examples drawn from recent experience.

There are two primary reasons for the increase in claims involving medical device sales representatives. First, as is widely recognized, the U.S. government has increased its enforcement actions against the healthcare industry, including medical device and pharmaceutical manufacturers. More recently, the government has focused on the prosecution of individuals under the responsible corporate officer doctrine. Sales managers and directors have been included as targets in these governmental-enforcement actions. This increase in government actions against medical device and pharmaceutical manufacturers with a focus on responsible corporate officers has given rise to a similar increase in civil products liability actions based on the government actions. This article explores the government's recent use of the responsible corporate officer doctrine as applied in pharmaceutical and medical device prosecutions and explores several recent examples where medical device sales managers or directors were prosecuted by the U.S. government with mixed results.¹ This article also discusses recent products liability cases based on government-enforcement actions involving allegations related to sales representatives.² Finally, this article addresses evidentiary issues in products liability cases where there is a parallel government prosecution.³

The second primary reason for the increase in claims involving medical device sales representatives is the U.S. Supreme Court's recent decision in *Riegel v. Medtronic, Inc.*,⁴ in which the Court held that the Medical Device Amendments precluded state law tort claims challenging the design, manufacture, or labeling of Class III medical devices approved by the Food and Drug Administration (FDA) via the premarket approval process. Since the *Riegel*

1. See *infra* Part II.B.

2. See *infra* Part II.C.

3. See *infra* Part III.D.

4. 552 U.S. 312 (2008).

decision, plaintiffs have attempted to assert novel claims to avoid preemption by focusing on the alleged conduct of sales representatives. This article discusses the application of the *Riegel* decision to allegations involving medical device sales representatives.⁵ This article also examines novel negligence allegations involving sales representative conduct asserted in an attempt to avoid preemption under *Riegel*.⁶ Included in this discussion is a brief overview of the implications of state laws regarding the unauthorized practice of medicine and their relation to negligence claims involving medical device sales representatives.

As a defense strategy, medical device manufacturers often seek to remove cases to federal court based on federal diversity jurisdiction. However, the naming of a typically in-state sales representative as an individual defendant in an attempt to avoid *Riegel* preemption serves the dual purpose of potentially defeating diversity jurisdiction for the out-of-state manufacturer. In those cases, defendants may argue that the sales representative was fraudulently joined. Interestingly, if the sales representative is considered a “seller” or “distributor” under state products liability law, the sales representative could be held strictly liable for device defects, such that the sales representative would not be fraudulently joined and there would be no federal diversity jurisdiction. This article explores the application of various state products liability statutes as applied to sales representatives in the fraudulent joinder context.⁷

Finally, this article tackles recently asserted defenses to allegations involving sales representative conduct as well as ultimate case outcomes.⁸ Case studies provide specific examples of the most prevalently asserted and successful defenses to claims involving sales representative conduct. This article analyzes the new ways that classic defenses are currently being used, including application of the learned intermediary doctrine, absence of duty, captain of the ship doctrine, and lack of causation.⁹ In particular, this article addresses the application of these defenses in recent trials involving sales representative conduct.

5. See, e.g., *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270 (M.D. Fla. 2009); see *infra* Part III.A–B.

6. See *infra* Part III.C.

7. See *infra* Part IV.

8. See *infra* Part V.

9. *Id.*

II. U.S. GOVERNMENTAL ENFORCEMENT ACTIONS AGAINST MEDICAL DEVICE SALES MANAGERS AND DIRECTORS

The increase in government prosecution of individual officers of pharmaceutical and medical device companies, including sales managers and directors, is one factor that is leading to an increase in sales representative products liability cases. The government has based its prosecution of these individuals on the responsible corporate officer doctrine.¹⁰ While the doctrine is generally utilized in the prosecution of corporate executive officers and other high ranking officials, the Department of Justice (DOJ) has expanded its enforcement of the responsible corporate officer doctrine to other corporate officers and employees, including sales managers, directors, and even sales representatives. Courts have generally approved this extension of the responsible corporate officer doctrine, and hefty fines and even prison sentences have been levied on these corporate officers.¹¹ Although the recent landmark Second Circuit decision, *United States v. Caronia*, reversing the conviction of a sales representative for off-label promotion, may mark a shift in prosecutorial policy in the future.¹²

Direct prosecution of medical device sales representatives is still relatively rare; however, the filing of civil products liability claims against medical device sales representatives based, at least in part, on government enforcement actions has continued to grow. Medical device products liability lawsuits involving sales representatives can be based on government action as simple as an FDA warning letter¹³ or as complex as a government prosecution of

10. See, e.g., *Friedman v. Sebelius*, 686 F.3d 813, 816–17 (D.C. Cir. 2012) (involving the prosecution of a pharmaceutical company senior corporate officer convicted under the responsible corporate officer doctrine); *United States v. Huggins*, No. 09-403-3, 2011 WL 6180623, at *1 (E.D. Pa. Dec. 13, 2011) (referencing the guilty plea of medical device corporate officer under the responsible corporate officer doctrine); *United States v. Higgins*, No. 09-403-4, 2011 WL 6088576, at *1 (E.D. Pa. Dec. 7, 2011) (same); *Hermelin v. K-V Pharm. Co.*, 54 A.3d 1093, 1097 (Del. Ch. 2012) (referencing pharmaceutical corporate officer's guilty plea under the responsible corporate officer doctrine).

11. See *infra* Part II.B.

12. 703 F.3d 149, 152 (2d Cir. 2012).

13. An FDA warning letter is a communication sent by the FDA to the product manufacturer notifying the manufacturer that there has been a violation of FDA regulations. The warning letter identifies the violation and provides guidance on how the company must correct the issue. See *Inspections, Compliance, Enforcement, and Criminal Investigations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm278624.htm> (last updated Dec. 8, 2011).

the sales managers or directors. Plaintiffs' attorneys use these government enforcement actions as ammunition against both the medical device company itself, as well as the sales representatives. Products liability actions that involve medical device companies subject to governmental action often raise challenging evidentiary issues at trial. Plaintiffs hope to introduce evidence of corporate wrongdoing through evidence of other bad acts, including previously executed corporate integrity agreements and consent decrees.¹⁴ Defendants have challenged the admission of this evidence with mixed results.

A. *Responsible Corporate Officer Liability Under the Park Doctrine*

The government's health care fraud prevention and enforcement efforts set a new record in fiscal year 2011 with the largest sum ever recovered in a single year.¹⁵ This statistic reflects criminal and civil investigation and enforcement efforts by various governmental entities on both the federal and state levels, including, but not limited to, Offices of the State Attorneys General, U.S. Attorneys' Offices, the U.S. Department of Justice, the Office of the Inspector General for the U.S. Department of Health and Human Services, Congress, the FDA, and the Department of Veterans Affairs.¹⁶ Recently, the focus has shifted

14. Corporate integrity agreements are agreements between the Office of Inspector General for the United States Department of Health and Human Services (OIG) and health care providers and other entities "as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Providers or entities agree to the obligations, and in exchange, OIG agrees not to seek their exclusion from participation in Medicare, Medicaid, or other Federal health care programs." *Corporate Integrity Agreements*, OFF. INSPECTOR GEN., U.S. DEPARTMENT HEALTH & HUM. SERVICES, <http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp> (last visited Feb. 19, 2013). Consent decrees are agreements that all parties agree to, which settle the claims alleged against the individual or company where the individual or company agrees to take specific actions without admitting fault or guilt. Consent decrees have attributes of both contracts and judicial decrees. Some issues are resolved by consent of the parties (as in a contract) and some issues require judicial acts rendered by the judge (as in judicial decrees).

15. Press Release, U.S. Dep't of Justice, Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly \$4.1 Billion (Feb. 14, 2012), *available at* <http://www.justice.gov/opa/pr/2012/February/12-ag-213.html>.

16. In addition, during fiscal year 2011, task forces such as the Health Care Fraud Prevention and Enforcement Action Team, created to prevent fraud, waste, and abuse in the Medicare and Medicaid programs, and various Medicare Fraud Strike Force Teams expanded local partnerships to prevent fraud. *See id.*

from the prosecution of companies to targeting individual executives, including sales executives.¹⁷

Governmental legal authority for criminal and civil investigations of pharmaceutical and medical device companies is derived from several separate statutes and regulations.¹⁸ Prosecutions are generally based on provisions and regulations of the Food, Drug, and Cosmetic Act (FDCA).¹⁹ The concept of the responsible corporate officer (RCO) originated with the U.S. Supreme Court decision in *United States v. Dotterweich*.²⁰ In *Dotterweich*, the president of a pharmaceutical company was convicted of a misdemeanor for shipping adulterated and misbranded drugs in interstate commerce.²¹ The Supreme Court found in *Dotterweich* that a corporate official could be convicted of a misdemeanor under the FDCA if he or she had a “responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs.”²²

The potential for RCO liability further developed in the Supreme Court decision *United States v. Park*.²³ In *Park*, Acme Markets President, John Park, was informed by the FDA of poor conditions in his company’s warehouses in Philadelphia and Baltimore, but the problems persisted.²⁴ The government prosecuted Acme and Park for misdemeanor violations of food adulteration.²⁵ Park was convicted and was fined \$250.²⁶ His conviction was reversed by the appellate court, but the Supreme

17. See Laurence Freedman, *Three Guilty Pleas Under Responsible Corporate Officer Doctrine Signal Heightened Enforcement*, RX COMPLIANCE REP., Aug. 6, 2009, at 10; see, e.g., cases cited *supra* note 10; see also Michael J. Vanselow & Ann M. Bildtsen, *2009—Healthcare Law Enforcement “Perfect Storm,”* HEALTH LAW., Feb. 2010, at 18, 22.

18. See, e.g., Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 331, 333 (2006 & Supp. 2011) (providing authority for government indictments, including the unlawful marketing of medical devices, fraud on the FDA, and the distribution of adulterated products); False Claims Act (FCA), 31 U.S.C. §§ 3729–33 (2006) (providing authority for civil action for false or fraudulent claims for payment and other similar acts). States also have their own False Claims Act statutes and consumer protection laws.

19. 21 U.S.C. §§ 331–350e.

20. 320 U.S. 277 (1943).

21. *Id.* at 278.

22. *Id.* at 284.

23. 421 U.S. 658 (1975).

24. *Id.* at 661–62.

25. *Id.* at 660, 682–83.

26. See *id.* at 666.

Court reversed the appellate court and ordered Park's conviction be reinstated.²⁷ The Supreme Court found in *Park* that the focus of RCO liability lies not in where a corporate defendant's position is within the corporate hierarchy, but rather if the corporate "defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."²⁸

The "*Park* doctrine," as it has evolved and is in use today, provides that a responsible corporate official can be held liable for a first-time misdemeanor and a possible subsequent felony based on a violation of the FDCA, without proof that the corporate official acted with knowledge, intent, negligence, or even participation in the specific offense.²⁹ The prosecution of a responsible corporate official for a misdemeanor violation of the FDCA, a "*Park* Doctrine prosecution," is handled by the DOJ.³⁰ The FDA has found that a *Park* doctrine prosecution has a strong deterrent effect on pharmaceutical and medical device companies and other regulated entities.³¹

In 2011, the FDA released a set of nonbinding criteria to be used to evaluate RCO liability in connection with the *Park* doctrine, referred to as the "*Park* Doctrine Criteria."³² When considering whether to recommend a misdemeanor prosecution against a corporate official, the FDA will consider "the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation."³³ Further, the FDA does not find knowledge of and actual participation in the violation to be prerequisites, but does consider them factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.³⁴ Other factors the FDA will consider in determining whether to recommend a misdemeanor prosecution against a corporate official include but

27. *Id.* at 666, 678.

28. *Id.* at 673-74.

29. U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL § 6-5-3, at 6-49 to -50 (2011), available at <http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf>.

30. *Id.*

31. *Id.*

32. *See id.* (listing "factors that may be relevant when deciding whether to recommend charging a misdemeanor violation").

33. *Id.*

34. *Id.*

are not limited to:

- (1) [w]hether the violation involves actual or potential harm to the public;
- (2) [w]hether the violation is obvious;
- (3) [w]hether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
- (4) [w]hether the violation is widespread;
- (5) [w]hether the violation is serious;
- (6) the quality of the legal and factual support for the proposed prosecution; and
- (7) [w]hether the proposed prosecution is a prudent use of agency resources.³⁵

Today, the current penalties for responsible corporate officers prosecuted under the *Park* doctrine include fines, probation, jail time, and FDA debarment.³⁶ In addition, the Department of Health and Human Services has the authority to exclude individuals from federally funded governmental programs like Medicare and Medicaid as a consequence of felony or misdemeanor convictions for fraud and other misconduct.³⁷

B. Prosecution of Sales Representatives, Managers, and Directors as Responsible Corporate Officers

In a speech given at the 12th Annual Pharmaceutical Regulatory and Compliance Congress on November 2, 2011, Assistant Attorney General Tony West stated that “demanding accountability means we will consider prosecutions against individuals, including misdemeanor prosecutions under the *Park* doctrine.”³⁸ The following examples illustrate that the government

35. *Id.*

36. 21 U.S.C. §§ 333, 335a–335b (2006).

37. 42 U.S.C. § 1320a-7 (2006). *See also* Friedman v. Sebelius, 755 F. Supp. 2d 98, 100–02 (D.D.C. 2010) (excluding three pharmaceutical company executives from participating in Medicare, Medicaid, and other federal healthcare programs for twelve years due to their misdemeanor guilty pleas to charges they served as “responsible corporate officers” who “had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of Oxycontin” during a period in which the company admitted to marketing Oxycontin with the intent to defraud or mislead, in violation of the FDCA).

38. Tony West, Assistant Attorney Gen., Speech at the 12th Annual Pharmaceutical Regulatory and Compliance Congress (Nov. 2, 2011), *available at* www.justice.gov/iso/opa/civil/speeches/2011/civ-speech-111102.html.

is prosecuting not only traditional executives under the responsible corporate officer doctrine, such as chief executive officers, but also less likely targets, including members of pharmaceutical and medical device sales forces.

1. United States v. Stryker Biotech, LLC

In *United States v. Stryker Biotech, LLC*, the president, national sales director, and two regional sales managers of Stryker were indicted for wire fraud, conspiracy, aiding and abetting, and distribution of a misbranded device.³⁹ One executive was also indicted for making false statements.⁴⁰ According to the prosecution, the executives allegedly schemed to promote the combined use of Calstrux, a bone void filler, and OP-1, a protein that promotes bone growth, though the combination of the drugs had not been approved by the FDA, in order to grow sales.⁴¹ Prosecutors further alleged that patients reported adverse events and that, after the executives were aware of these adverse events, they continued to promote off-label and did not warn physicians of the adverse events.⁴² During the trial of three of the executives and the company, the company pled guilty to a misdemeanor and paid a \$15 million fine.⁴³ Prosecutors subsequently dismissed all charges against all four executives after reviewing documents that showed the executives acted in good faith.⁴⁴

2. United States v. Caputo

On February 4, 2003, the government brought a nineteen-count indictment against three officers of AbTox, Inc., a

39. United States v. Stryker Biotech, LLC, No. 09-CR-10330-GAO, 2010 WL 2900684, at *1 (D. Mass. July 21, 2010); Superseding Indictment, *Stryker Biotech*, No. 09-CR-10330-GAO (Oct. 11, 2011), 2011 WL 8612010; Indictment, *Stryker Biotech*, No. 09-CR-10330-GAO (Oct. 28, 2009), 2009 WL 3612189.

40. *Stryker Biotech*, 2010 WL 2900684, at *1.

41. *Id.* at *1-2.

42. *Id.* at *5.

43. Verdict, Agreement and Settlement, *Stryker Biotech*, No. 09-CR-10330-GAO (Jan. 17, 2012), 2012 WL 130887.

44. Assented to Motion to Dismiss, *Stryker Biotech*, No. 09-CR-10330-GAO, (Feb. 2, 2012), ECF No. 309; Assented to Motion to Dismiss, *Stryker Biotech*, No. 09-CR-10330-GAO (Jan. 18, 2012), ECF No. 293; Assented to Motion to Dismiss, *Stryker Biotech*, No. 09-CR-10330-GAO (Jan. 17, 2012), ECF No. 284; David Voreacos, *Stryker Official's Charges Dropped as U.S. Cites New Evidence in Drug Case*, BLOOMBERG (Feb. 2, 2012, 2:34 PM), <http://www.bloomberg.com/news/2012-02-02/stryker-official-s-charges-dropped-as-u-s-cites-new-evidence-in-drug-case.html>.

manufacturer of the Plazlyte sterilizer system, including the director of marketing and vice president of regulatory affairs.⁴⁵ According to the indictment, the defendants agreed, combined, and conspired to defraud the United States by selling an adulterated and misbranded device to various U.S. government agencies and representing that its sterilizer product had been cleared by the FDA.⁴⁶ The director of marketing, who was later employed at AbTox as vice president of sales, pled guilty to introducing into interstate commerce an adulterated and misbranded device.⁴⁷ His plea agreement specifically stated that “[a]s Director of Marketing, defendant . . . played an active role in the overall effort by AbTox to sell the unapproved sterilizer. He played a role in developing and implementing AbTox’s marketing strategy, including its pricing and its promotional literature.”⁴⁸ “[D]efendant . . . also played a role . . . in devising AbTox’s marketing strategy and in training AbTox’s sales and field representatives to implement it.”⁴⁹ The director of marketing was ultimately sentenced to probation for three years and a fine of \$75,000.⁵⁰

3. United States v. Donofrio

In *United States v. Donofrio*, a regional sales director for Exactech, Inc., waived prosecution by indictment for knowingly and willfully conspiring with others to violate the Anti-Kickback Statute.⁵¹ Specifically, the regional sales director was charged with offering payment to orthopedic surgeons for their use of certain

45. Indictment, *United States v. Caputo*, 456 F. Supp. 2d 970 (N.D. Ill. 2006) (No. 03CR0126), 2003 WL 23413059; *see also* *United States v. Caputo*, 288 F. Supp. 2d 912, 914 (N.D. Ill. 2003). *See generally* *Caputo*, 456 F. Supp. 2d at 981 (articulating the court’s reasons regarding the sentencing of defendants), *aff’d in part, vacated in part*, 517 F.3d 935, 944 (7th Cir. 2008) (affirming judgment of district court except with respect to restitution; the award of restitution was vacated and the case remanded for calculation of the amount owed).

46. Indictment, *supra* note 45.

47. Plea Agreement at 2, *United States v. Schmitt*, No. 03 CR 126-3 (N.D. Ill. Dec. 23, 2003), 2003 WL 25609246.

48. *Id.* at 4.

49. *Id.* at 6.

50. Sentencing Order at 3, *Caputo*, No. 1:03-cr-00126 (Aug. 22, 2006), ECF No. 432.

51. Information at 1, *United States v. Donofrio*, No. 3:10-cr-00836-GEB (D.N.J. Dec. 7, 2010), ECF No. 1.

hip and knee devices.⁵² The information alleged that from 2002 through 2008, the regional sales director and coconspirators offered and entered into consulting agreements with orthopedic surgeons, which were designed to induce the surgeons to use and purchase Exactech, Inc.'s hip and knee products.⁵³ The regional sales director pled guilty to conspiracy to violate the Anti-Kickback Statute⁵⁴ and was sentenced to five years probation and a \$6000 fine.⁵⁵

4. United States v. Caronia

In *United States v. Caronia*,⁵⁶ a pharmaceutical sales representative for Orphan Medical, Inc. was charged with introduction of a misbranded drug into interstate commerce, healthcare fraud, and conspiracy to commit such violations.⁵⁷ Specifically, the indictment alleged that the defendant sales representative knowingly and intentionally conspired with others to misbrand the drug Xyrem by marketing it for off-label uses.⁵⁸ The sales representative was found guilty of engaging in the interstate commerce of a misbranded drug.⁵⁹ He was ultimately sentenced to one year of probation, 100 hours of community service, and a \$25 special assessment.⁶⁰

The sales representative appealed the conviction, arguing that his right to free speech under the First Amendment was being illegally restricted.⁶¹ On December 3, 2012, the United States Court of Appeals for the Second Circuit reversed the district court's conviction and vacated the criminal conviction of the sales representative.⁶² The Second Circuit reasoned that the FDCA does

52. *Id.* at 2.

53. *Id.*

54. See 42 U.S.C. § 1320a-7b(b) (2006); 18 U.S.C. § 371 (2006).

55. Judgment at 2, *Donofrio*, No. 3:10-cr-00836-GEB (Mar. 5, 2011), ECF No. 10; Plea Agreement at 2, *Donofrio*, No. 3:10-cr-00836-GEB (Dec. 7, 2010), ECF No. 5.

56. 576 F. Supp. 2d 385 (E.D.N.Y. 2008), *vacated*, 703 F.3d 149 (2d Cir. 2012).

57. Superseding Indictment, *United States v. Gleason*, No. 06-229 (ENV) (E.D.N.Y. July 25, 2007), 2007 WL 4185417.

58. *Id.*

59. Judgment at 1, *Gleason*, No. 06-229 (ENV) (Nov. 30, 2009), ECF No. 126.

60. *Id.* at 1, 4-5.

61. See Brief of Defendant-Appellant at 33, *United States v. Caronia*, 703 F.3d 149, 152 (2d Cir. 2012) (No. 09-5006-cr), 2010 WL 6351495.

62. See *Caronia*, 703 F.3d at 152.

not criminalize “simple promotion” of a drug’s off-label use by a sales representative because “such a construction would raise First Amendment concerns.”⁶³ The court ultimately held that “the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.”⁶⁴

5. United States v. Orthofix, Inc.

Orthofix, Inc., a manufacturer of a bone growth stimulator, pled guilty to an information charging it with obstruction of a federal audit for manipulating certificates of medical necessity, a form required by Medicare to be signed by a physician attesting that the bone growth stimulator was medically necessary.⁶⁵ As part of the plea agreement, Orthofix agreed to pay a \$7.65 million criminal fine and \$34.23 million plus interest to resolve civil allegations under the False Claims Act.⁶⁶ In addition to this plea agreement entered into by Orthofix, the investigation resulted in felony charges against executives, employees, and contractors of Orthofix.⁶⁷ Specifically, a former Orthofix vice president of sales pled guilty to paying kickbacks to induce a doctor and a physician’s assistant to prescribe Orthofix products;⁶⁸ a former Orthofix regional sales director pled guilty to making a false declaration to a grand jury about Orthofix conduct;⁶⁹ and two former Orthofix territory managers pled guilty to falsifying patients’ medical records to fraudulently induce Medicare to pay for Orthofix bone growth stimulators.⁷⁰

63. *Id.* at 160.

64. *Id.* at 169.

65. Press Release, U.S. Attorney’s Office, Dist. of Mass., Orthofix, Inc. Agrees to Plead Guilty to Felony (June 7, 2012) [hereinafter USAO Orthofix Press Release], available at www.justice.gov/usao/ma/news/2012/June/OrthofixSettlementPR.html.

66. *See id.* “The civil settlement resolves claims brought against Orthofix in a whistleblower lawsuit filed under the qui tam provisions of the False Claims Act that is pending in the District of Massachusetts: United States ex. rel. Bierman, v. Orthofix International, N.V., et al., Civil Action No. 05-10557-EFH (D. Mass.).” *Id.*

67. *See id.*

68. *Id.*; *see* Plea Agreement, United States v. Guerrieri, No. 1:12-cr-10061-RWZ (D. Mass. Apr. 9, 2012), ECF No. 6.

69. USAO Orthofix Press Release, *supra* note 65; *see also* Plea Agreement, United States v. Salzman, No. 1:11-cr-10385-RWZ (D. Mass. Dec. 14, 2011), ECF No. 7.

70. USAO Orthofix Press Release, *supra* note 65; *see* Plea Agreement, United States v. McKay, No. 1:12-cr-10129-DJC (D. Mass. Apr. 19, 2012), ECF No. 2; Plea

C. *Civil Products Liability Actions Based on Governmental Prosecution of Responsible Corporate Officers*

Just as government enforcement actions have recently focused on corporate officers, including sales directors, so too have civil products liability suits that incorporate or mimic these enforcement actions. For example, in a government prosecution against bone cement manufacturer Norian, Corp., four former executives pled guilty, in 2009, to misdemeanor counts of shipping adulterated and misbranded Norian XR bone cement in interstate commerce.⁷¹ The indictment alleged that the former executives conspired to conduct unauthorized clinical trials of Norian's bone cement in surgeries to treat vertebral compression fractures (VCFs) of the spine without alleged FDA-required clinical testing.⁷² At least three patients died during these allegedly unauthorized clinical trials.⁷³ All four executives received jail sentences of at least five months and a fine of \$100,000 each.⁷⁴ The company pled guilty to felony and misdemeanor criminal charges and paid a \$23.5 million fine.⁷⁵

As a direct result of this prosecution of the company and its corporate officers, civil products liability suits have been filed. For example, Eva Sloan, individually and as executrix of the estate of Lois Eskind, sued Norian and Synthes, Inc. for fraud; conspiracy to

Agreement, United States v. Field, No. 1:12-cr-10057-JLT (D. Mass. Feb. 22, 2012), ECF No. 2; *see also* Electronic Clerk's Notes, *McKay*, No. 1:12-cr-10129-DJC (May 11, 2012) (stating, in part, "Defendant enters plea of guilty"); Electronic Clerk's Notes, *Field*, No. 1:12-cr-10057-JLT (Mar. 22, 2012) (stating, in part, "Defendant enters plea of guilty").

71. Press Release, U.S. Attorney's Office, E. Dist. of Penn., Former Executives of International Medical Device Maker Sentenced to Prison in Unlawful Clinical Trials Case (Nov. 21, 2011), *available at* www.justice.gov/usao/pae/News/2011/Nov/synthesexecs_release.pdf.

72. *Id.* VCFs are a painful condition where the bones of the spine become broken. It is commonly suffered by elderly individuals. *Id.*

73. *Id.*

74. *See* Judgment in a Criminal Case at 2, United States v. Bohner, No. 2:09-cr-00403-LDD (E.D. Pa. Dec. 13, 2011), ECF No. 216; Judgment in a Criminal Case at 2, United States v. Walsh, No. 2:09-cr-00403-LDD (E.D. Pa. Nov. 22, 2011), ECF No. 187; Judgment in a Criminal Case at 2, United States v. Higgins, No. 2:09-cr-00403-LDD (E.D. Pa. Nov. 22, 2011), ECF No. 186; Judgment in a Criminal Case at 2, United States v. Huggins, No. 2:09-cr-00403-LDD (E.D. Pa. Nov. 22, 2011), ECF No. 185.

75. Sophia Pearson, *Synthes Sued over Death Linked to Bone-Cement Trials*, BLOOMBERG (July 30, 2012, 10:57 AM), <http://www.bloomberg.com/news/2012-07-30/synthes-sued-over-death-related-to-unapproved-bone-cement-trial.html>.

commit fraud; willful, wanton, malicious, and reckless misconduct; failure to warn; gross negligence; negligence per se; fraudulent concealment; and wrongful death.⁷⁶ Ms. Sloan's complaint is based on the same conduct at issue in the criminal investigations of the company and its executives—specifically, that the alleged unapproved clinical trial of bone cement caused the death of Lois Eskin after a surgeon injected the bone cement into her spine.⁷⁷ The defendants have denied all allegations.⁷⁸ Similarly, the families of two other patients, who died during surgery that involved the use of the bone cement, filed suit against the company and the four former executives in California Superior Court alleging similar claims.⁷⁹

These “me too” products liability lawsuits are anticipated for the government enforcement actions against sales managers and directors.⁸⁰ For example, the *United States v. Stryker Biotech, LLC*⁸¹ enforcement action prompted the filing of products liability lawsuits, including *Cabana v. Stryker Biotech, LLC*. In *Cabana*, plaintiff April Cabana alleged she was injured by bone void filler products.⁸² The plaintiff specifically referenced the guilty plea of two Stryker Biotech sales representatives regarding the illegal

76. Complaint at 30–46, *Sloan v. Synthes, Inc.*, No. 2:12-cv-04286-LDD (E.D. Pa. July 27, 2012), ECF No. 1.

77. *Id.* at 30–31.

78. See Motion to Dismiss, *Synthes*, No. 2:12-cv-04286-LDD (Oct. 1, 2012), ECF No. 7.

79. Complaint, *Estate of Kikuchi v. Synthes, Inc.*, No. CIVMSC12-00518 (Cal. Super. Ct. Feb. 29, 2012), ECF No. 1; see also Annie Reynolds, *Families Sue Synthes over Bone Cement Surgery Death*, SHERIDAN & MURRAY LLC (Mar. 20, 2012), <http://www.philadelphiainjurylawyerblogs.com/families-sue-synthes-over-bone-cement-surgery-deaths/>.

80. See, e.g., *Abtox Sterilization System May Hurt People's Corneas*, SILVERMAN & FODERA, <http://www.civilrights.com/AbtoxSterilizationSystem.php> (last visited Feb. 21, 2013) (advertising for personal injury suits related to the FDA warning and recall of the AbTox Plazlyte Sterilization System that may cause serious injuries to people's corneas); *Florida Hip Replacement Attorney*, BERKE LAW FIRM, P.A., <http://www.yourinjurylawyer.com/florida-hip-replacement-attorney/> (last visited Feb. 15, 2013) (listing Exactech and Biomet as hip and knee replacement manufacturers); Austin Kirk, *Medtronic Infuse Lawyers Reviewing Lawsuits for Bone Graft Problems*, SAIONTZ & KIRK P.A. (May 7, 2012), <http://www.youhavealawyer.com/blog/2012/05/07/medtronic-infuse-lawyers/> (advertising for potential lawsuits related to “problems following off-label use of the genetically engineered bone growth stimulator”).

81. *United States v. Stryker Biotech, LLC*, No. 09-10330-GAO, 2010 WL 2900684 (D. Mass. July 21, 2010).

82. Complaint, *Cabana v. Stryker Biotech, LLC*, No. BC 465313 (Cal. Super. Ct. July 13, 2011).

promotion of the bone void filler products in violation of the FDCA: “By February 2009, two Stryker Biotech sales representatives had pled guilty to illegally promoting the mixture of OP-1 and Calstrux in violation of the FDCA.”⁸³ She also referenced in her complaint the indictments of Stryker Biotech and its president “arising out of Stryker Biotech’s illegal off-label promotion of OP-1 and Calstrux to surgeons in various states, including California.”⁸⁴ The plaintiff generally alleged that “the Stryker Defendants, through their sales representatives and paid Key Opinion Leaders, directly and indirectly promoted, trained and encouraged Dr. Mesiwala to engage in the off-label procedure of mixing Calstrux with OP-1 Putty.”⁸⁵

The *Cabana* complaint asserted claims of negligence, strict liability, breach of express and implied warranty, fraud, and negligence per se against the Stryker defendants.⁸⁶ Specifically, the plaintiff alleged the Stryker defendants were negligent in (1) “engaging in the illegal off-label promotion of these products”; (2) “failing to disclose that the mixture of these two products had not been approved by the FDA”; (3) “failing to disclose to physicians that the mixture of these two products can result in serious side effects”; (4) “failing to fully disclose the results of the testing and other information in their possession regarding the possible adverse reactions associated with the off-label mixture”; (5) “failing to disclose the lack of clinical or other scientific evidence to support any particular ratio in the mixture”; (6) “representing that the mixture of these two products was safe”; (7) “promoting OP-1 Putty beyond the narrow and limited Humanitarian Device Exception for which it was approved”; (8) “failing to adequately warn the medical community, the general public, plaintiff’s surgeon and plaintiff of the dangers, contra-indications, and side effects from the use, mixed use, and off-label use of these two products”; and (9) “failing to act as a reasonably prudent drug manufacturer.”⁸⁷ The Stryker defendants denied all allegations.⁸⁸

83. *See id.* para. 57.

84. *See id.* para. 58.

85. *See id.* para. 89.

86. *See id.* paras. 101–85.

87. *See id.* para. 105.

88. *See Answer at 1, Cabana*, No. BC 465313 (Nov. 28, 2011).

D. *Evidentiary Issues in Products Liability Actions Where There Is a Parallel Government Prosecution*

Civil products liability cases involving sales representative allegations where there is a parallel government prosecution present unique evidentiary challenges. Plaintiffs may want to introduce the government enforcement action into evidence in the civil case as evidence of wrongdoing or fraud by the defendant company or its sales offices or representatives. This type of evidence is often subject to a pre-trial motion *in limine*, where the defendant will seek to exclude the evidence.⁸⁹ While some courts have admitted evidence regarding prior government enforcement actions or settlements against the defendant company, other courts have excluded the evidence as irrelevant and prejudicial.⁹⁰ A trial court's determination of whether to admit evidence regarding a prior government enforcement action is highly fact dependent and generally will not be disturbed unless there is a clear abuse of discretion.⁹¹

The U.S. District Court for the Southern District of Illinois provides a recent example of a court allowing into evidence at trial documents related to a government enforcement action.⁹² The court found that a defendant's corporate integrity agreement⁹³ regarding, *inter alia*, compliance with the Anti-Kickback statute was

89. See, e.g., *In re Yasmin & Yaz (Drospirenone) Mktg.*, No. 3:09-md-2100-DRH, 2011 WL 6740391, at *3–4 (S.D. Ill. Dec. 22, 2011) (seeking exclusion of a corporate integrity agreement in a motion *in limine*); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *6–7 (M.D. Fla. Jan. 30, 2009) (same); *Block v. Abbott Labs., Inc.*, Nos. 99C7457, 01C1312, 01C1313, 01C1315, 01C1316, 2001 WL 1539159, at *2 (N.D. Ill. Dec. 3, 2001) (seeking exclusion of a consent decree between medical device manufacturer and FDA).

90. See, e.g., *Yasmin*, 2011 WL 6740391, at *4 (admitting evidence of a corporate integrity agreement); *Seroquel*, 2009 WL 223140, at *7 (excluding evidence of a corporate integrity agreement); *Block*, 2001 WL 1539159, at *2 (excluding evidence of a consent decree between medical device manufacturer and FDA).

91. See *U.S. v. Hayden*, 85 F.3d 153, 159 (4th Cir. 1996) (finding admission of other crimes evidence “may be overturned only for an abuse of discretion”); *Kramas v. Sec. Gas & Oil Inc.*, 672 F.2d 766, 772 (9th Cir. 1982) (finding, in action for alleged violations of securities law, it was not reversible error for trial court to refuse to admit evidence of consent decree entered in prior securities enforcement proceedings against defendant and other persons in light of fact that “[t]he consent decree involved no finding of culpability and no judgment of wrongdoing” and the probative value of the evidence was “committed to the trial court’s sound discretion”).

92. See *Yasmin*, 2011 WL 6740391, at *4.

93. See *supra* note 14.

relevant evidence in a civil products liability litigation.⁹⁴ The corporate integrity agreement also specifically referenced a settlement agreement with the United States that was being filed contemporaneously with the corporate integrity agreement.⁹⁵ The motions *in limine* related to one or more cases that were a part of the *In re Yasmin and Yas (Drospirenone) Marketing, Sales Practices and PMF Products Liability Litigation*.⁹⁶ The complaints alleged claims for strict products liability, breach of express and implied warranty, negligence, negligence per se, fraudulent misrepresentation, fraudulent concealment, fraud, and misrepresentation related to the plaintiffs' ingestion of the oral contraceptive Yasmin (also known as YAZ, Ocella, and drospirenone and ethinyl estradiol).⁹⁷ The court provided very little reasoning, other than that the agreements were relevant and a Federal Rule of Evidence 404(b)⁹⁸ character evidence analysis was not required, but even if such an analysis were performed, the evidence was admissible to show intent and lack of mistake.⁹⁹ Although the briefing in this case is sealed, presumably the defendant argued that the corporate integrity agreement should not be admissible at trial because it is evidence of "a crime, wrong, or other act" used to prove Bayer's character and that, here, Bayer acted in accordance with that character.¹⁰⁰ Despite the fact that the corporate integrity agreement makes no mention of the product at issue in the case—

94. *Yasmin*, 2011 WL 6740391, at *4; see also OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND BAYER HEALTHCARE LLC 13 (2008) [hereinafter BAYER CORPORATE INTEGRITY AGREEMENT], available at https://oig.hhs.gov/fraud/cia/agreements/fully_executed_bayer_cia_112508.pdf.

95. BAYER CORPORATE INTEGRITY AGREEMENT, *supra* note 94, at 1.

96. *Sims v. Bayer HealthCare Pharms.*, No. 3:09-cv-10012-DRH-PMF, 2011 WL 6740391 (S.D. Ill. Dec. 22, 2011); *Bradish v. Bayer HealthCare Pharms.*, No. 3:09-cv-20021-DRH-PMF, 2011 WL 6740391 (S.D. Ill. Dec. 22, 2011), *Laforet-Neer v. Bayer HealthCare Pharms.*, No. 3:10-cv-10223, 2011 WL 6740391 (S.D. Ill. Dec. 22, 2011).

97. See, e.g., Complaint at 1–2, *Laforet-Neer*, No. 3:10-cv-10223-DRH-PMF (Feb. 23, 2010), ECF No. 2.

98. FED. R. EVID. 404(b) provides, "Evidence of a crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character;" however, "[t]his evidence may be admissible for another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident."

99. See *Yasmin*, 2011 WL 6740391, at *4.

100. FED. R. EVID. 404(b)(1).

the drug Yaz—the court still found the agreement relevant and admissible.¹⁰¹

Conversely, the U.S. District Court for the Middle District of Florida found a corporate integrity agreement with the federal government related to the pricing of an anti-cancer medication was not relevant in civil products liability litigation involving the company's anti-psychotic medication.¹⁰² Plaintiffs argued that they would not introduce evidence of the anti-cancer litigation and settlement except to rebut any “good corporate citizen” testimony offered by the defendants at trial.¹⁰³ The court found that “a party's agreement as to a particular standard of care for a completely different medication, used to treat a completely different condition—cancer—is irrelevant to Plaintiffs' claims in this case; its prejudice outweighs any potential probative value, wastes time, and will confuse the jury.”¹⁰⁴

Other courts have evaluated whether consent decrees entered into between the FDA and pharmaceutical or medical device manufacturers are admissible. For example, in *Block v. Abbott Laboratories, Inc.*,¹⁰⁵ the plaintiffs sought discovery regarding a consent decree between Abbott and the FDA regarding failure to comply with FDA regulations.¹⁰⁶ The court evaluated whether such discovery would be relevant, finding that “the Consent Decree is not relevant to Plaintiffs' claims.”¹⁰⁷ The court reasoned that the consent decree did not identify the product at issue in the products liability suit as one of the Abbott products of concern.¹⁰⁸ The court also found that the consent decree was focused on manufacturing deficiencies whereas the plaintiffs' complaint was based upon design defects and a failure to warn.¹⁰⁹ The court concluded, “Plaintiffs have failed to demonstrate how Abbott's

101. See *Yasmin*, 2011 WL 6740391, at *4; see generally BAYER CORPORATE INTEGRITY AGREEMENT, *supra* note 94.

102. See *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *7 (M.D. Fla. Jan. 30, 2009).

103. *Id.*

104. *Id.*

105. Nos. 99C7457, 01C1312, 01C1313, 01C1315, 01C1316, 2001 WL 1539159, at *2 (N.D. Ill. Dec. 3, 2001).

106. *Id.*

107. *Id.* (citing *Rufer v. Abbott Labs., Inc.*, No. 99-2-27090-8 (Wash. Super. Ct. Apr. 19, 2001), which reached the same conclusion and found evidence of the consent decree not admissible at trial).

108. See *id.* at *3.

109. See *id.*

manufacturing practices are relevant to their case.”¹¹⁰

Another court evaluated whether a products liability claim could be filed based entirely on a consent decree. In *Polk v. KV Pharmaceutical Co.*,¹¹¹ the plaintiff filed a putative class action against KV Pharmaceutical Company and Ther-Rx Corporation, in connection with plaintiff’s use of metoprolol succinate ER.¹¹² Prior to the plaintiff’s suit, the FDA formally alleged the defendants were not in compliance with current good manufacturing practices and alleged the medication produced in their facilities was adulterated.¹¹³ The FDA and the defendants entered into a consent decree in which the defendants neither admitted nor denied the allegations levied by the FDA, and the defendants also recalled inventories of metoprolol succinate ER.¹¹⁴ The U.S. District Court for the Eastern District of Missouri granted the defendants’ motion to dismiss, finding that the plaintiff relied heavily on the consent decree, which was “not conclusive proof of wrongdoing” and could not be used to “bootstrap Plaintiff’s claim against Defendants in the absence of any independent factual allegation . . . that the Medication was somehow defective because it is unfit for the ordinary purposes for which it was marketed, thereby injuring the Plaintiff.”¹¹⁵

Various governmental agencies have made it clear that they intend to hold executives, including sales executives, criminally liable for violations of health care laws. Similarly, manufacturers should be aware that aside from exposing themselves and their sales representatives to personal criminal and civil liability for government enforcement actions, any such enforcement actions may also expose the company and its sales representatives to additional civil products liability claims. Moreover, a company should keep in mind that the outcome of any investigation, whether it is no action, a consent decree, a corporate integrity agreement, a fine, or other result, may have implications in its portfolio of civil products liability litigation, even if entirely unrelated to the medical device at issue in the civil products liability lawsuit.

110. *See id.*

111. No. 4:09-CV-00588 SNLJ, 2011 WL 6257466, at *1 (E.D. Mo. Dec. 15, 2011).

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.* at *3, *8.

III. IMPLICATIONS OF *RIEGEL* ON SALES REPRESENTATIVE LIABILITY

The Supreme Court's decision in *Riegel v. Medtronic, Inc.* has changed the landscape of medical device products liability lawsuits.¹¹⁶ This section will briefly discuss the *Riegel* decision and then examine the impact that the decision has had on the type of claims that plaintiffs are bringing to avoid preemption. As this section will demonstrate, *Riegel* has caused plaintiffs to assert novel theories of liability against medical device manufacturers that commonly attack the alleged actions, inactions, and representations of the manufacturers' sales representatives. Finally, this section will examine the small number of judicial decisions that have discussed whether *Riegel* preemption applies even when sales representative liability is asserted and possible areas where a plaintiff may be able to plead a non-preempted claim against a sales representative.

A. *Riegel v. Medtronic, Inc. Overview*

The express preemption clause contained in the Medical Device Amendments ("MDA") to the FDCA specifies that no state is permitted to impose "any requirement" relating to the safety or effectiveness of a medical device or any other matter regulated by the MDA that is "different from, or in addition to, any requirement applicable . . . to the device."¹¹⁷ Because of the extensive requirements imposed upon medical devices through the premarket approval (PMA) process and the express preemption provision in the MDA, the U.S. Supreme Court held in *Riegel* that any state law tort claim seeking to impose requirements "different from, or in addition to" those imposed by the PMA process is expressly preempted.¹¹⁸ Furthermore, the Supreme Court ruled that the MDA's express preemption provision "bars common-law claims challenging the safety and effectiveness of a medical device

116. 552 U.S. 312, 321–22 (2008).

117. 21 U.S.C. § 360k(a) (2006). Specifically, the MDA preemption provision provides that no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement "(1) which is *different from, or in addition to*, any requirement applicable under this [Act] to the device, and (2) which relates to the *safety or effectiveness* of the device or to any other matter included in a requirement applicable to the device under this [Act]." *Id.* (emphasis added); *see also* H.R. REP. NO. 94-853, at 45 (1976).

118. *Riegel*, 552 U.S. at 321–22.

given premarket approval by the [FDA].”¹¹⁹ In concluding the MDA’s preemption clause “‘remove[s] all means of judicial recourse’ for consumers injured by FDA-approved devices,” the Court explained that

the text of the statute . . . suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress’s estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.¹²⁰

In *Riegel*, the plaintiffs alleged that the defendant’s Class III medical device was designed, labeled, and manufactured in a manner that violated state common law and that these defects caused severe injuries.¹²¹ In resolving whether the plaintiffs’ claims were preempted, the Court established a two-step procedure. First, courts must determine whether “the Federal Government has established requirements applicable to” the particular medical device.¹²² The Court found that medical devices approved through the PMA process automatically satisfy the first prong of the *Riegel* preemption analysis.¹²³

As a second step, courts must then determine whether the state law claims at issue “are based upon . . . requirements with respect to the device that are ‘different from, or in addition to’” those imposed by the MDA and if they are, then the claims are preempted.¹²⁴ The *Riegel* Court found that the plaintiffs’ state law defective design, defective manufacturing, defective testing, and failure to warn claims sounding in strict liability, negligence, and breach of implied warranty “constitute[d] ‘requirements’ under the MDA.”¹²⁵ The Court reasoned that “State tort law that requires a manufacturer’s [device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme” and the judgment of a jury should not second-guess the judgment of “the experts at the FDA.”¹²⁶ For purposes of the MDA’s preemption

119. *Id.* at 315.

120. *Id.* at 326.

121. *Id.* at 320.

122. *Id.* at 321.

123. *Id.* at 323; *see also* DeLeon v. Johnson & Johnson, No. C-1-177, 2011 WL 2618957, at *3 (S.D. Tex. July 1, 2011); Yost v. Stryker Corp., No. 2:09-cv-28-FtM-29DNF, 2010 WL 1141586, at *2 (M.D. Fla. Mar. 23, 2010).

124. *Riegel*, 552 U.S. at 322 (quoting 21 U.S.C. § 360k(a) (2006)).

125. *Id.* at 323–24.

126. *Id.* at 325.

clause, state common law duties constitute “requirements,” and “the duties underlying negligence, strict-liability, and implied-warranty claims are . . . maintained with respect to devices.”¹²⁷

Therefore, *Riegel* held unequivocally that the MDA expressly preempts state common-law causes of action that impose “different” or “addition[al]” requirements than any requirement imposed by the PMA of a device.¹²⁸ The Court recognized, however, that the MDA “does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.”¹²⁹ The Court recognized that the issue of whether the plaintiffs had pled a parallel claim was not before them and declined to elaborate on what would constitute a non-preempted parallel claim.¹³⁰ Since *Riegel*, plaintiffs’ primary focus has been trying to plead claims that fit within this “loophole.”¹³¹

B. *Riegel’s Effect on Plaintiffs’ Products Liability Claims*

As other commentators have noted, lower courts’ application of *Riegel* preemption has been somewhat inconsistent.¹³² Nonetheless, post-*Riegel*, the majority of courts addressing state tort law claims involving a Class III medical device have found that the plaintiffs’ claims are preempted.¹³³ In *Riegel*, the Supreme Court

127. *Id.* at 323–26 (internal quotations omitted).

128. *See id.* at 321–22.

129. *Id.* at 330.

130. *See id.*

131. *See generally* Elliot Sheppard Tarloff, Note, *Medical Devices and Preemption: A Defense of Parallel Claims Based on Violations of Non-Device Specific FDA Regulations*, 86 N.Y.U. L. REV. 1196, 1196–97 (2011).

132. *See* Samuel Raymond, Note, *Judicial Politics and Medical Device Preemption After Riegel*, 5 N.Y.U. J.L. & LIBERTY 745, 749–51 (2010).

133. *See, e.g., In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (“In the . . . months following *Riegel*, courts across the country have applied Section 360k(a) broadly, preempting all manner of claims . . .”) (finding breach of express and implied warranty claims, fraud claims, and claims for deceptive trade practices preempted); *see also* James M. Beck, *Federal Preemption in FDA-Regulated Product-Liability Litigation: Where We Are and Where We Might Be Headed*, 32 HAMLINE L. REV. 657, 678–79 (2009) (noting the extensive preemption of premarket approval devices); Malika Kanodia, Comment, *The Fate of the Injured Patient in the Wake of Riegel v. Medtronic: Should Congress Interject?*, 32 HAMLINE L. REV. 791, 794 (2009) (“[*Riegel*] virtually ensures that medical device manufacturers enjoy legal immunity from injury claims involving products that have secured premarket approval from the FDA.”).

suggested that the scope of preemption encompasses traditional products liability claims such as those alleging negligence, strict liability, failure to warn, and breach of warranty.¹³⁴ Lower courts have been fairly consistent in finding that these types of claims are preempted pursuant to *Riegel*. For example, courts have regularly dismissed failure to warn claims involving a Class III medical device's labeling on preemption grounds.¹³⁵ Similarly, courts have found breach of warranty and garden-variety negligence claims asserted against manufacturers to be preempted.¹³⁶

Because a large number of traditional claims against medical device manufacturers have been summarily dismissed, plaintiffs have been forced to seek creative means for pleading a non-preempted claim. One common way that plaintiffs have tried to avoid preemption is by framing their claims as seeking to enforce parallel state obligations to federal law.¹³⁷ However, several courts

134. See *Riegel*, 552 U.S. at 327–29.

135. See, e.g., *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *8–9 (N.D. Ga. Aug. 19, 2011) (dismissing failure to warn claims on express preemption grounds); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1286 (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011) (same); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008) (same). However, even the causes of action specifically addressed in *Riegel* have not been universally found to be preempted. The District Court of Puerto Rico recently found that plaintiffs' claim that they received no warning regarding an EON rechargeable impulse generator was not preempted, noting that the plaintiffs were not "advocating for labeling or warning that is different from or in addition to that which is already approved in the device PMA." *Carrelo v. Advanced Neuromodulation Sys., Inc.*, 777 F. Supp. 2d 303, 312 (D.P.R. 2011); see also *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 832 (S.D. Ind. 2009) (finding no preemption, despite *Riegel's* overt criticism of § 808.1(d)(1)).

136. For examples of breach of warranty claims against manufacturers that courts have found to be preempted, see *Heisner v. Genzyme Corp.*, No. 08-C-593, 2009 WL 1210633, at *3 (N.D. Ill. Apr. 30, 2009) (breach of express warranty claim preempted); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284–87 (E.D.N.Y. 2009) (breach of express warranty, implied warranty of fitness, and implied warranty of merchantability claims, as well as state law claim for deceptive trade practices preempted); *Parker*, 584 F. Supp. 2d at 1301–03 (breach of express warranty, implied warranty of fitness, and implied warranty of merchantability claims preempted). For examples of courts finding that a negligence claim is preempted, see *Walker v. Medtronic, Inc.*, 670 F.3d 569, 577–81 (4th Cir. 2012) (finding claims for strict liability, negligence, and breach of warranty preempted); *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 473 (D. Mass. 2012) (finding negligence claims preempted); *Wheeler v. DePuy Spine, Inc.*, 706 F. Supp. 2d 1264, 1270 (S.D. Fla. 2010) ("Florida law does not authorize the only type of 'negligence' claims that might survive the MDA, i.e., a claim based on violation of federal requirements.").

137. See, e.g., *Steiden v. Genzyme Biosurgery*, No. 3:11 CV-441-S, 2012 WL 2923225, at *3–5 (W.D. Ky. July 18, 2012) (finding that plaintiff pled non-

have rejected plaintiffs' attempts to avoid preemption simply by repeatedly referencing "parallel claims" in their complaints, finding that the claims are nothing more than repackaged claims to impose additional or different obligations on device manufacturers and thus are preempted pursuant to *Riegel*.¹³⁸ The key factor for many courts in deciding whether plaintiffs have adequately pled a parallel claim that avoids preemption is whether they explicitly plead that the defendant violated a specific FDA regulation.¹³⁹ Plaintiffs have also regularly attempted to avoid preemption by alleging that a manufacturer withheld or misrepresented risk information associated with its device during the premarket approval process.¹⁴⁰ However, courts have largely rejected such claims as barred by the Supreme Court's holding in *Buckman v. Plaintiffs' Legal Committee*, where the Court held that fraud-on-the-FDA claims are impliedly preempted by federal law.¹⁴¹

preempted claim of adulteration); *Gelber v. Stryker Corp.*, 788 F. Supp. 2d 145, 161–67 (S.D.N.Y. 2011) (rejecting plaintiff's attempt to plead a parallel claim); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 658–59 (S.D. Tex. 2010) (discussing plaintiff's attempt to plead a state law parallel claim).

138. See, e.g., *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1156–65 (D. Minn. 2009) (rejecting plaintiff's argument that claim was not preempted because parallel to federal law); *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174, 1178–80 (N.D. Ill. 2008) (same); *Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811, at *5–6 (N.D. Ill. July 25, 2008) (same); *Mattingly v. Hubbard*, No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008) (same); see also *Stevens v. Pacesetter, Inc.*, No. 3:07-cv-3812, 2008 WL 2637417, at *1–2 (D.S.C. Apr. 1, 2008) (ruling that wife's loss of consortium claim was not a parallel claim because it relied on the same alleged wrongful conduct as the patient's claims to impose additional or different requirements on the manufacturer).

139. See, e.g., *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440–42 (6th Cir. 2010) (holding claim alleging manufacturer violated good manufacturing practice federal rule not preempted); *Rhynes v. Stryker Corp.*, No. 10-5619 SC, 2011 WL 5117168, at *5 (N.D. Cal. Oct. 27, 2011) (allowing plaintiffs leave to amend to more specifically allege violations of particular FDA requirements); *Phillips v. Stryker Corp.*, No. 3:09-CV-488, 2010 WL 2270683, at *7 (E.D. Tenn. June 3, 2010) (ruling that claims alleging manufacturer's conduct violated 21 C.F.R. §§ 820.20(b)(2) and 820.70(e) were parallel and not preempted); *Horowitz*, 613 F. Supp. 2d at 284 (requiring plaintiff to plead the specific PMA requirement allegedly violated).

140. See, e.g., *Leonard*, 2011 WL 3652311, at *11 (alleging that medical device manufacturer withheld information from the FDA); *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1095 (D. Minn. 2008) (arguing that defendant violated premarket approval authority); *McCutcheon v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008) (same).

141. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (holding that Congress has given the FDA exclusive power to enforce the FDCA and MDA). For examples of cases finding claims to be preempted by *Buckman*, see

C. *Novel Allegations Against Sales Representatives Post-Riegel*

As is the case in most products liability lawsuits, the majority of post-*Riegel* medical device lawsuits have involved claims arising from a manufacturer's design and labeling for a device. However, as one court has stated, it is "a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption."¹⁴² Accordingly, in addition to attempting to repackage and attach different labels to their claims against medical device manufacturers, plaintiffs have also started to attack actions and representations made by a manufacturer's sales representative. An examination of these different types of theories is useful to better understand how the Supreme Court's decision in *Riegel* has resulted in plaintiffs increasingly scrutinizing the actions undertaken by medical device sales representatives.

1. *Duty to Warn, Supervise, or Train*

Perhaps the most common type of claim against medical device sales representatives asserts that the representative breached his or her duty to protect the patient by failing to adequately warn, supervise, or train the operating physician. Although these types of claims existed prior to *Riegel*, they have become more prevalent in the post-*Riegel* legal environment.¹⁴³ A large portion of failure to warn claims involve a sales representative failing to verbally advise a physician about the use or implantation of the product.¹⁴⁴ For

Leonard, 2011 WL 3652311, at *8; *Clark*, 572 F. Supp. 2d at 1095 (holding that plaintiff's efforts to avoid *Riegel* preemption by relying on the manufacturer's alleged withholding risk information from FDA are prohibited by *Buckman* because "Congress has granted the FDA exclusive power to enforce MDA premarket approvals"); *McCutcheon*, 586 F. Supp. 2d at 922. *But see Heisner*, 2008 WL 2940811, at *5 (suggesting that a claim resting on a manufacturer's failure to fully participate in the PMA process is a parallel claim that is not preempted).

142. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)) (internal quotation marks omitted).

143. *See, e.g., Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1279 (M.D. Fla. 2009) (alleging "breach of the duty to use reasonable care in the instruction and education of physicians"); *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 802 (W.D. La. 2008) (alleging that manufacturer failed to adequately train doctor about medical device used during an angiogram); *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1280 (Colo. App. 2010) (regarding plaintiff alleging that the manufacturer and sales representative failed to provide adequate warnings and instructions to surgeons about the dangers and installation of the elbow fixator).

144. *Reuter v. Medtronic, Inc.*, No. L-2592-10, 2012 WL 3635955, at *1 (N.J. Super. Ct. Law Div. June 18, 2012) (regarding plaintiff seeking to amend

example, in *Harrington v. Biomet, Inc.*, the plaintiff alleged that the sales representative was negligent for not advising the surgeon as to what size and type of components to use in a hip replacement surgery and for not suggesting that a different implant might be more appropriate for a younger individual, such as the plaintiff.¹⁴⁵ In addition to alleging that a sales representative failed to verbally warn a physician about a risk associated with a medical device, plaintiffs have also based negligence claims on a representative's failure to provide written package inserts to a physician.¹⁴⁶

While failure to warn and failure to train claims normally focus on what a sales representative *failed* to do, plaintiffs have also attacked the actions that the sales representative actually undertook. In *Adkins v. Cytoc Corp.*, the plaintiff's claim was based on allegations that the defendant's sales representative—who was present during the plaintiff's medical procedure—deviated from FDA-approved materials and provided inaccurate information to the treating physician that resulted in the plaintiff's injuries.¹⁴⁷ In another case challenging a sales representative's actions, rather than inactions, the plaintiff in *William Beaumont Hospital v. Medtronic, Inc.*, alleged that the manufacturer's representative sent a free sample of its pain pump refill kit to the wrong hospital department and represented that the sample could be used in a refill procedure, when in fact it could not, because the sample was a catheter access kit used for a different purpose.¹⁴⁸

2. Off-Label Use and Promotion

Plaintiffs have also commonly brought claims focusing on a device's off-label use in an attempt to avoid preemption, despite the fact that the device at issue in *Riegel*—a balloon catheter—had been used off label.¹⁴⁹ Off-label use of a medical device occurs

complaint to add negligence claim based on sales representative's presence in operating room and failure to advise physician of potential defect with the device).

145. No. CIV-07-25-R, 2008 WL 2329132, at *7 (W.D. Okla. June 3, 2008).

146. See *Wehner v. Linvatech Corp.*, No. 06-CV-1709 JMR/FLN, 2008 WL 495525, at *4 (D. Minn. Feb. 20, 2008) (alleging that the manufacturer violated its duty to warn because sales representatives did not provide package inserts to physicians).

147. No. 4:07CV00053, 2008 WL 2680474, at *2–3 (W.D. Va. July 3, 2008).

148. No. 09-CV-11941, 2009 WL 2849546, at *7 (E.D. Mich. Aug. 31, 2009).

149. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008) (concerning a catheter that was used in a diffusely diseased and heavily calcified artery, despite warnings that such use was contraindicated and was inflated beyond its rated burst pressure).

when a device is used in a manner different from the use approved by the FDA.¹⁵⁰ Although FDA has the power to regulate off-label promotion of devices, it does not have any power “to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.”¹⁵¹

In light of *Riegel*, plaintiffs are asserting that a device manufacturer’s off-label promotion of its products allows otherwise preempted failure-to-warn or negligence claims to survive preemption.¹⁵² The implication of a sales representative’s conduct in a plaintiff’s claim relating to off-label promotion is evident in the recent case *Hall v. Horn Medical, L.L.C.*¹⁵³ In *Hall*, the plaintiff brought negligence claims against a distributor of a spinal-fusion device and a negligent-misrepresentation claim against an independent contractor working as a sales representative for the distributor.¹⁵⁴ The implanting surgeon ignored explicit instructions in the device’s package insert and testified that he performed the procedure because the sales representative told him that the device was appropriate for this particular “off-label use.”¹⁵⁵ In other cases, plaintiffs have alleged that a sales representative’s mere presence at a procedure involving an off-label use of a device constitutes unlawful off-label marketing and promotion and allows otherwise preempted claims to survive.¹⁵⁶

3. *Unauthorized Practice of Medicine*

Sales representatives who engage in extensive conduct in the operating room or in pretreatment analysis of medical records or radiology films often run the risk of running afoul of a state statute

150. See *Wolicki-Gables v. Arrow Int’l, Inc.*, 641 F. Supp. 2d 1270, 1283 (M.D. Fla. 2009).

151. 21 U.S.C. § 396 (2006).

152. *Coleman v. Medtronic Corp.*, No. SC112290, 2012 WL 2335532, at *1 (Cal. Super. Ct. June 13, 2012) (addressing claims of off-label promotion); *O’Shea v. Cordis Corp.*, No. 50 2006 CA 013019 AA, 2008 WL 3139428, at *1 (Fla. Cir. Ct. May 19, 2008) (same); *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1057 (N.J. 2012) (same).

153. No. 11-1032, 2012 WL 1752546, at *1 (E.D. La. May 16, 2012).

154. *Id.* at *1, *3.

155. *Id.*

156. See, e.g., *Wolicki-Gables v. Arrow Int’l, Inc.*, 641 F. Supp. 2d 1270, 1283 (M.D. Fla. 2009); see also *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 778 (D. Minn. 2009) (rejecting argument that off-label use makes *Riegel* inapplicable).

regulating the unauthorized practice of medicine.¹⁵⁷ Although some states have made the unauthorized practice of medicine a crime,¹⁵⁸ plaintiffs may also bring civil claims against medical device sales representatives based on these statutes. In *Disbrow v. Smith & Nephew Richards Inc.*, the plaintiffs sued the device manufacturer and its sales representative for “practicing medicine without a license” when a handle on a tool being used in plaintiff’s hip replacement surgery broke.¹⁵⁹ According to the plaintiffs, the sales representative was present during the surgery and was responsible for locating a new handle for the tool.¹⁶⁰ Likewise, in *Wilkerson v. Christian*, a patient underwent a procedure to remove tumors from her liver by burning them with an electrode.¹⁶¹ After the procedure was unsuccessful and the patient died, the plaintiff brought a wrongful death action against the manufacturer of the electrode and its sales representative alleging that the sales representative “personally performed the ablation procedure when she operated medical equipment that was directly, by way of a continuous circuit, inserted into [Plaintiff’s] body.”¹⁶² Although the case was dismissed on statute of limitations grounds, the court noted: “Plaintiff alleged facts, in good faith, that raise serious questions regarding the propriety of sales representatives in the operating room. The gravity of Plaintiff’s allegation that a sales representative performed, or participated in, [Plaintiff’s] tumor ablation procedure is not lost on this court.”¹⁶³

4. *Invasion of Privacy/Informed Consent and Assault/Battery*

Another theory that plaintiffs traditionally have advanced and possibly will assert more frequently against sales representatives post-*Riegel* is that a sales representative’s undisclosed presence

157. For examples of state statutes prohibiting the unauthorized practice of medicine by non-physicians, see MASS. GEN. LAWS ANN. ch. 112, § 6 (West, Westlaw through 2012 2d Annual Sess. General Court) and TEX. OCC. CODE ANN. § 155.001 (West, Westlaw through end of 2011 Reg. Sess. and 1st Called Sess. of 82d Legislature) (requiring a medical license to practice medicine).

158. For examples of state statutes making the unauthorized practice of medicine a crime, see MINN. STAT. § 147.081 (2012); TEX. OCC. CODE ANN. § 165.153(a) (Westlaw).

159. No. 14-95-00759-CV, 1996 WL 593780, at *1 (Tex. Ct. App. Oct. 17, 1996).

160. *Id.* at *2.

161. No. 1:06CV00871, 2008 WL 483445, at *1 (M.D.N.C. Feb. 19, 2008).

162. *Id.* (internal quotations omitted).

163. *Id.* at *13.

during a surgery constituted an invasion of the patient's privacy. A claim for intentional invasion of privacy occurs when someone "intentionally intrudes . . . upon the solitude or seclusion of another or his private affairs . . . if the intrusion would be highly offensive to a reasonable person."¹⁶⁴ Thus, plaintiffs have argued that a sales representative's presence during a medical procedure—without the consent of the patient—constitutes an invasion of privacy.¹⁶⁵ For instance, in *McDaniel v. Synthes, Inc.*, a patient and her husband sued a medical device manufacturer, sales consultant, and the hospital for, *inter alia*, invasion of privacy as a result of the sales consultant's attendance during a surgical procedure where an allegedly defective orthopedic implant was removed and taken by the sales representative for analysis.¹⁶⁶ Similarly, in *Wolicki-Gables v. Arrow International, Inc.*, the plaintiff alleged that the sales representative violated his informed consent by attending a surgical procedure and disposing of a catheter connector removed during the procedure.¹⁶⁷

Under some states' laws, similar allegations can also give rise to a claim for battery if the sales representative directly or indirectly touched the patient without his or her express consent. For example, in *Clifford v. Tacogue*, the plaintiff brought a claim for medical battery against the manufacturer of a vascular closure device used during a cardiac catheterization.¹⁶⁸ In this case, the plaintiff asserted that the manufacturer was vicariously liable for the sales representative entering the operation room and providing the doctor with a closure device, which the doctor then allegedly implanted without the patient's consent.¹⁶⁹

164. RESTATEMENT (SECOND) OF TORTS § 652B (1977).

165. See, e.g., *McDaniel v. Synthes, Inc.*, No. 2:07-CV-245RM, 2007 WL 3232186, at *1 (N.D. Ind. Oct. 29, 2007). In a slightly different context, the plaintiff in *Sanchez-Scott v. Alza Pharmaceuticals* alleged that a pharmaceutical sales representative observed her follow-up breast cancer appointment without informing her that the individual observing the appointment was a drug representative. 103 Cal. Rptr. 2d 410 (Ct. App. 2001). After the trial court dismissed the patient's complaint, the California Court of Appeal reversed, holding that breast cancer patients have an objectively reasonable expectation that they will not be observed by anyone other than medical personnel. *Id.* at 418.

166. *McDaniel*, 2007 WL 3232186, at *1.

167. 641 F. Supp. 2d 1270, 1291–92 (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011).

168. No. M2009-01703-COA-R3-CV, 2010 WL 2712534, at *1 (Tenn. Ct. App. July 8, 2010).

169. *Id.* at *1–2.

D. Preemption of Claims Involving Allegations of Sales Representative Misconduct

Despite the variety of claims being brought against sales representatives in the post-*Riegel* landscape, only a handful of courts have explicitly analyzed whether claims seeking to impose liability based on the action or inaction of a medical device sales representative survive preemption. This part will analyze the reasoning used by the courts that have applied the *Riegel* analysis in the context of sales representative liability and also discuss some cases outside the context of sales representative liability, but that nonetheless could be useful to a party seeking to evoke the preemption defense set forth in *Riegel*.

Although plaintiffs have increasingly pled claims based on the conduct of sales representatives, their attempts to avoid *Riegel* preemption in this manner have been met with mixed results. At least one court has found that claims against sales representatives are preempted in their entirety. In *Wolicki-Gables*, the plaintiff attempted to avoid preemption of his traditional products liability claims against the manufacturer of a pain pump by focusing on the alleged actions of the manufacturer's representative, who was present during a surgical procedure.¹⁷⁰ In this case, the plaintiff asserted that the sales representative was negligent because he: (1) breached a duty to instruct and educate the implanting doctor about the pump; (2) breached a duty to ensure the pump worked properly before it was implanted; (3) breached a duty to verify informed consent to his presence; and (4) breached a duty to verify that plaintiff consented to disposal of a removed part of the device.¹⁷¹ Without much discussion of its preemption analysis, the court ruled that all of the claims against the manufacturer for strict liability, negligence, and vicarious liability, as well as the negligence claims against the representative, were expressly preempted under *Riegel*.¹⁷²

On the other hand, one of the most plaintiff-friendly decisions analyzing preemption in the context of sales representative liability

170. 641 F. Supp. 2d at 1282–91.

171. *Id.* at 1291.

172. *Id.* at 1282–87, 1291. The court in *Wolicki-Gables* also provided alternative grounds for dismissing the plaintiff's claims based on the sales representative's conduct, most notably the lack of any duty to undertake the actions asserted by the plaintiff. *Id.* at 1291.

is the decision in *Adkins v. Cytoc Corp.*¹⁷³ In *Adkins*, the plaintiff alleged that the manufacturer was negligent based on its sales representative's directions for surgery and preoperative procedures.¹⁷⁴ In reasoning that such a claim was not preempted, the court noted that "[t]he FDA does not regulate interactions between corporate representatives and physicians on-site at a particular surgery," and "[t]hese localized situations are traditional matters for the common law."¹⁷⁵ Therefore, the court ruled that, because such a claim did not challenge the design, manufacture, or labeling of the device, it was not preempted by *Riegel*.¹⁷⁶ As two legal commentators have noted, pursuant to the reasoning in *Adkins*, almost any claim based upon a representative's actions at a surgery would survive preemption.¹⁷⁷

Similar reasoning is found in the decision in *William Beaumont Hospital v. Medtronic, Inc.*¹⁷⁸ In this case, the court acknowledged—as it must—that any claim based on the device's FDA-approved label was preempted by *Riegel*.¹⁷⁹ However, the court found that the plaintiffs' claim alleging liability based on the actions of a sales representative in sending samples to the wrong hospital department did not call into question the adequacy of the label and, thus, the claim survived preemption.¹⁸⁰

Several courts have found that claims alleging off-label promotion—claims that almost necessarily implicate the actions of a sales representative in charge of such promotion—are not preempted under *Riegel*.¹⁸¹ In one of these cases, the New Jersey Supreme Court recently held that, to the extent the defendant manufacturer and its employees marketed or promoted off-label uses of a device outside of the FDCA safe harbor for certain

173. No. 4:07CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008).

174. *Id.* at *2.

175. *Id.* at *3.

176. *Id.*

177. See Edward W. Gerecke & David J. Walz, *Sales Reps in the OR: The Hunt for Non-Preempted Claims*, FOR DEF., Oct. 2010, at 27.

178. No. 09-CV-11941, 2009 WL 2849546, at *7–8 (E.D. Mich. Aug. 31, 2009).

179. *Id.* at *7.

180. *Id.*

181. See, e.g., *James v. Stryker Corp.*, No. 1:10-CV-2082, 2011 WL 292240, at *3 (M.D. Pa. Jan. 27, 2011) (plaintiff's allegations against manufacturer relating to off-label promotion not preempted); *O'Shea v. Cordis*, No. 50 2006 CA 013019 AA, 2008 WL 3139428 (Fla. Cir. Ct. May 19, 2008) ("Claims asserting that the Defendants were negligent in marketing and promoting off label uses are not preempted."); *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1057 (N.J. 2012) (same).

promotional activities, the plaintiffs' failure to warn claim survived preemption.¹⁸² Similarly, the federal court in *James v. Stryker Corp.* reasoned that claims attacking a manufacturer's off-label promotion of a device are different from a failure to warn claim and survive preemption.¹⁸³ However, it should also be noted that some courts have found that claims involving unlawful off-label promotion of a device may be impliedly preempted under the Supreme Court's *Buckman* decision because "enforcing the FDCA is exclusively the province of the federal government."¹⁸⁴

Although not explicitly discussing sales representatives, several judicial decisions have found that claims alleging that a manufacturer failed to adequately train a physician about its product are expressly preempted.¹⁸⁵ Because sales representatives are often the individuals who communicate directly with a physician about how to use a device, their conduct will often play a central role in such claims.¹⁸⁶ An example of a court's preemption analysis in the failure to train context is evident in *Rollins v. St. Jude Medical*, in which the plaintiff alleged that the manufacturer failed to train her surgeon on the proper use of the Angio-Seal device implanted during an angiogram.¹⁸⁷ The court ruled that the failure to train claim pled by the plaintiff was preempted, but noted that a claim that the defendant manufacturer failed to abide by the training requirements imposed by the FDA would survive preemption as a parallel claim.¹⁸⁸

Preemption decisions analyzing fraud and express warranty claims also provide some insight into whether a claim challenging representations made by a sales representative would be found preempted. Although the majority of courts have found express

182. *Cornett*, 48 A.3d at 1057.

183. *James*, 2011 WL 292240, at *3.

184. *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 776 (D. Minn. 2009).

185. *See, e.g.*, *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919, 931–33 (5th Cir. 2006) (holding that that a plaintiff's failure-to-train claims were preempted because the manufacturer's training requirements and informational materials had been previously approved by the FDA as part of the premarket approval process); *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 801–02 (W.D. La. 2008) (rejecting claim of failure to train physician); *Mattingly v. Hubbard*, No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 30, 2008) (holding that claim made against manufacturer for failure to train physicians is preempted).

186. *See generally* Gerecke & Walz, *supra* note 177 (noting that often "the case against a manufacturer's representative really boils down to a claim for 'failure to train my physician'").

187. 583 F. Supp. 2d at 801–02.

188. *Id.* at 802.

warranty claims based on a device's label or representations about the safety and effectiveness of the device to be preempted,¹⁸⁹ a few courts have held that breach of express warranty claims are not necessarily preempted if they involve statements not approved or mandated by the FDA, as these claims are more akin to a contractual bargain between parties and are outside the purview of the FDA.¹⁹⁰ For example, in *Cornett v. Johnson & Johnson*, the court held that the plaintiffs' breach of warranty claims were preempted, "except to the extent plaintiffs allege defendants have made voluntary statements to third parties beyond and different from the information on the approved label or packaging."¹⁹¹ However, at least one court has expressed doubt as to whether a mere statement about a product by a sales representative to a doctor would constitute an express warranty under state law.¹⁹²

A handful of courts have applied the same preemption reasoning to fraud and misrepresentation claims, finding that these claims based on unregulated statements to doctors may survive preemption.¹⁹³ These courts have reasoned that this type of fraud

189. See, e.g., *Cooley v. Medtronic, Inc.*, No. 09-30-ART, 2012 WL 1380265, at *4 (E.D. Ky. Apr. 20, 2012) (finding that the MDA preempts express warranty claims relating to the safety and efficacy of a device because a finding that the device was not safe and effective would be contrary to the FDA's approval of the device); *Riley*, 625 F. Supp. at 787 (D. Minn. 2009) (finding that plaintiff's breach-of-warranty claim was preempted by 21 U.S.C. § 360k(a) to the extent it was based on the contents of the device's label).

190. See *Ali v. Allergan USA, Inc.*, No. 1:12-CV-115 (GBL/TRJ), 2012 WL 3692396, at *16 (E.D. Va. Aug. 23, 2012) (holding that a claim for breach of express warranty would not be preempted to the extent that it is based on representations made by the manufacturer about the device that were not approved by the FDA); *O'Shea v. Cordis Corp.*, No. 50 2006 CA 013019 AA, 2008 WL 3139428 (Fla. Cir. Ct. May 19, 2008) ("Nevertheless, it is clear that express warranty claims focus on the contractual bargain between the parties and the express representations made by one party to another. Therefore, the Court concludes that Plaintiff's claim for breach of express warranty is not preempted."); *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1058 (N.J. 2012) ("[T]o the extent the breach of express warranty claim is based on voluntary statements, i.e., statements not approved by the FDA or mandated by the FDA about the use or effectiveness of the product for on-label or off-label uses, a breach of express warranty claim may proceed because federal law requires any warranty statement to be truthful and accurate.").

191. *Cornett*, 48 A.3d at 1059.

192. See *Cline v. Advanced Neuromodulation Sys., Inc.*, No. 1:11-CV-4064-AT, 2012 WL 3631320, at *4 n.4 (N.D. Ga. June 15, 2012) (noting that any argument that a sales representative's statements to a doctor constituted an express warranty stood on much weaker ground than an argument asserting that a written limited warranty constituted an express warranty).

193. See, e.g., *James v. Stryker Corp.*, No. 1:10-CV-2082, 2011 WL 292240, at *3

and misrepresentation claim withstands the implied preemption doctrine set forth in *Buckman* because the alleged fraud is being committed on the physicians and patients, not the FDA.¹⁹⁴

While courts at times have struggled to consistently apply the preemption doctrine expounded upon in *Riegel*, the number of claims against medical device manufacturers found to be preempted will likely result in a continued focus on the actions and representations of sales representatives. In the limited number of judicial decisions analyzing whether allegations against sales representatives are preempted, two important themes emerge for guiding medical device manufacturers related to their sales representatives' interactions with physicians. First, a court is more likely to find that a claim against a sales representative survives preemption if it is based on an affirmative action by the sales representative, such as physically assisting or providing direction during a surgery. Second, some courts may allow plaintiffs to plead claims that survive preemption if they are based on statements or promotional activities of a sales representative to a doctor regarding an off-label use of a device or another matter outside of the FDA-approved labeling.

It seems likely that plaintiffs will continue to pursue novel theories against medical device sales representatives in an attempt to navigate through the post-*Riegel* legal landscape. As the next section will demonstrate, however, plaintiffs' allegations against medical device sales representatives can be motivated by other purposes in addition to trying to avoid preemption.

IV. FRAUDULENT JOINDER AS A DEFENSE STRATEGY

Following *Riegel*, there has been an increase in cases where a sales representative is named as an individual defendant in order to defeat preemption. However, both prior and subsequent to the *Riegel* decision, plaintiffs also have named sales representatives

(M.D. Pa. Jan. 27, 2011) (holding plaintiff's allegations that manufacturer committed fraud through off-label promotion not preempted); *O'Shea*, 2008 WL 3139428 (finding that fraud and misrepresentation claims regarding off-label promotion survived preemption, but to the extent the plaintiff sought to rely on general representations made concerning the devices contained in approved labeling or brochures, such claims are preempted).

194. See *James*, 2011 WL 292240, at *3 n.2 ("Plaintiff's allegations that Defendants made fraudulent misrepresentations to Plaintiff and her physicians are also distinct from a claim that Defendants made fraudulent misrepresentations to the FDA.").

individually in order to prevent removal to federal court on the basis of diversity jurisdiction. Federal court is generally seen as more favorable to defendant manufacturers and, in contrast to the manufacturer, sales representatives are often located in the same state as the plaintiff. In order to establish jurisdiction in federal court, out-of-state defendant manufacturers often argue that the in-state sales representative was fraudulently joined. This section will explore recent case examples where defendants have asserted fraudulent joinder related to a defendant sales representative. This section also includes a discussion of whether sales representatives are considered “sellers” under state products liability law in the context of alleged fraudulent joinder of the sales representative. Where examples of medical device sales representative cases do not exist, analogies are drawn to the available case law in those jurisdictions, including cases involving pharmaceutical sales representatives.

A. *Fraudulent Joinder Overview*

A fraudulently joined party cannot defeat a court’s subject matter jurisdiction.¹⁹⁵ The burden of demonstrating that a plaintiff fraudulently joined a resident defendant rests on the defendant.¹⁹⁶ This has been described as a “heavy burden” because the defendant must show:

1. there is no possibility the plaintiff can establish a cause of action against the resident defendant;¹⁹⁷ or
2. the plaintiff has fraudulently pled jurisdictional facts to bring the resident defendant into state court;¹⁹⁸ or
3. there is no real connection between the claims against a diverse defendant and those against a non-diverse defendant.¹⁹⁹

195. *Wilson v. Republic Iron & Steel Co.*, 257 U.S. 92, 97 (1921).

196. *Id.*

197. *Patterson v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20521, 2011 WL 3047794, at *2 (N.D. Ohio July 25, 2011) (discussing Eleventh Circuit fraudulent joinder standard); *see also Wilson*, 257 U.S. at 97.

198. *Patterson*, 2011 WL 3047794, at *2; *see also In re Diet Drugs Prods. Liab. Litig.*, 294 F. Supp. 2d 667, 672 (E.D. Pa. 2003) (discussing Third Circuit fraudulent joinder standard).

199. The argument that a resident defendant has been fraudulently joined because there is no real connection between the claims against the diverse defendant and the non-diverse defendant is sometimes referred to as fraudulent misjoinder or procedural misjoinder. The practical implications of a court finding

In evaluating a defendant's allegation that a non-diverse party has been fraudulently joined, the court must find joinder proper and remand the case back to state court if there is even a possibility that a state court would find that the complaint states a cause of action against the non-diverse defendant.²⁰⁰ The plaintiff is merely required to show that he has asserted a "colorable claim" or an arguably "reasonable basis" that state law could hold the non-diverse defendant liable based on the alleged facts.²⁰¹ The possibility that the resident defendant could be liable must be reasonable and not theoretical.²⁰² Whether the claims against the joined defendants are viable is a matter of state law.²⁰³

Courts finding pharmaceutical and medical device sales representatives fraudulently joined cite three primary reasons why there is no possibility that plaintiff can state a claim against the sales representative. First, courts examine whether the claim against the non-diverse sales representative was properly pled under Federal Rule of Civil Procedure 8(a) and the cases interpreting pleading standards for complaints.²⁰⁴ If the complaint

a non-diverse defendant misjoined as opposed to fraudulently joined are the same—denial of the motion to remand and severance of the claims against the non-diverse defendant. *See, e.g.,* *Crockett v. R.J. Reynolds Tobacco Co.*, 436 F.3d 529, 533 (5th Cir. 2006) (holding that if the claims asserted against the non-diverse defendants differ enough from the claims against the diverse defendants such that they do not meet the joinder requirements of Federal Rule of Civil Procedure 20(a) or its state counterpart, the parties have been misjoined and removal is proper); *Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353, 1360 (11th Cir. 1996) (adopting the doctrine of fraudulent misjoinder); *Rutherford v. Merck & Co.*, 428 F. Supp. 2d 842, 850 (S.D. Ill. 2006) (finding fraudulent misjoinder is an additional form of fraudulent joinder, "namely, 'egregious' misjoinder of claims that is tantamount to fraudulent joinder"); *Greene v. Wyeth*, 344 F. Supp. 2d 674, 683–85 (D. Nev. 2004) (applying the doctrine of fraudulent misjoinder); *In re Diet Drugs*, 294 F. Supp. 2d at 673 (describing procedural misjoinder as an "attempt to defeat removal by joining together claims against two or more defendants where the presence of one would defeat removal and where in reality there is no sufficient factual nexus among the claims to satisfy the permissive joinder standard"); *Lee v. Mann*, 51 Va. Cir. 465 (Cir. Ct. 2000) (same); 14B CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 3723 (3d ed. 1998).

200. *See Pacheco de Perez v. AT&T Co.*, 139 F.3d 1368, 1380 (11th Cir. 1998); *In re Diet Drugs*, 294 F. Supp. 2d at 672.

201. *In re Diet Drugs*, 294 F. Supp. 2d at 675.

202. *See Legg v. Wyeth*, 428 F.3d 1317, 1325 n.5 (11th Cir. 2005) (citing *Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 312 (5th Cir. 2002)).

203. *See In re Diet Drugs*, 294 F. Supp. 2d at 672.

204. *See* FED. R. CIV. P. 8(a); *see also, e.g.,* *Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007).

is short on factual detail related to the claims against the sales representative, this may be a successful way to challenge the joinder of the sales representative.²⁰⁵ Second, some jurisdictions have found uncontroverted affidavits or declarations from the sales representative sufficient to establish fraudulent joinder.²⁰⁶ Finally, federal district courts analyze whether under state law the sales representative owed a legal duty that could form the basis of plaintiff's claim.²⁰⁷ Many states have adopted the learned intermediary doctrine, and this can act as a bar to plaintiff's failure to warn claims.²⁰⁸

1. *Insufficient Pleading Under Federal Rule of Civil Procedure 8(a)*

Recently, defendants have paired the doctrine of fraudulent joinder with motions to dismiss, asserting that plaintiffs failed to meet the pleading requirements of Federal Rule of Civil Procedure 8(a).²⁰⁹ Although this tactic has not been employed in any reported medical device sales representative cases, it has been successfully applied in cases involving medical device companies as well as pharmaceutical sales representatives. These cases provide ammunition for similar arguments in cases where a medical device sales representative may be fraudulently joined. For example, in *Beavers v. DePuy Orthopaedics, Inc.*,²¹⁰ the defendants successfully argued fraudulent joinder by asserting that plaintiffs failed to meet the pleading standard articulated in *Twombly* and *Iqbal*.²¹¹ In *Beavers*, plaintiffs filed a complaint in Kentucky state court naming medical device companies DePuy Orthopaedics, Inc.; DePuy, Inc.; Johnson & Johnson, Inc.; Johnson & Johnson Services, Inc.

205. See, e.g., *Beavers v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20275, 2012 WL 1945603, at *5 (N.D. Ohio May 30, 2012) (“[T]he lack of factual allegations regarding Orthopaedic Partners, LLC, provides no more than labels and conclusions insufficient to sustain viability of the legal claims.”).

206. See, e.g., *Southern v. Pfizer, Inc.*, 471 F. Supp. 2d 1207, 1214 (N.D. Ala. 2006); *In re Diet Drugs Prods. Liab. Litig.*, No. 03-20611, 2004 U.S. Dist. LEXIS 19848, at *5–6 (E.D. Pa. Sept. 28, 2004).

207. See *Catlett v. Wyeth, Inc.*, 379 F. Supp. 2d 1374, 1381 (M.D. Ga. 2004) (holding that pursuant to the learned intermediary doctrine, the sales representative does not owe a legal duty to warn the patient of the risks associated with the device); *Lizana v. Guidant Corp.*, No. Civ.A 1:03CV254GRO, 2004 WL 3316405, at *3 (S.D. Miss. Jan. 21, 2004).

208. See *Catlett*, 379 F. Supp. 2d at 1381.

209. See *Iqbal*, 556 U.S. at 670; *Twombly*, 550 U.S. at 555.

210. *Beavers*, 2012 WL 1945603, at *1.

211. *Id.* at *2.

(collectively referred to as the DePuy Defendants); and Orthopaedic Partners, LLC. The DePuy Defendants removed the case to the U.S. District Court for the Western District of Kentucky on the basis of diversity jurisdiction and fraudulent joinder of Orthopaedic Partners, LLC.²¹² The DePuy Defendants moved to stay all state court proceedings pending transfer of the action to MDL 2197 (*In re DePuy Orthopaedics Inc. ASR Hip Implant Products Liability Litigation*) and the plaintiffs subsequently filed their motion to remand to state court.²¹³ The Judicial Panel on Multidistrict Litigation transferred the case from the Western District of Kentucky to the multidistrict litigation in the Northern District of Ohio.²¹⁴

The issue before the U.S. District Court for the Northern District of Ohio was whether the case should be remanded back to Kentucky state court.²¹⁵ Plaintiffs argued that defendant Orthopaedic Partners, LLC was a Kentucky resident (like plaintiffs) and destroyed diversity jurisdiction because plaintiffs asserted a colorable claim against that defendant.²¹⁶ The defendants argued that removal was appropriate because there was no viable claim against defendant Orthopaedic Partners (in other words, Orthopaedic Partners had been fraudulently joined).²¹⁷ Specifically, the defendants argued that plaintiffs failed to meet the pleading standard articulated in *Twombly*²¹⁸ and adopted by the Sixth Circuit in *Association of Cleveland Fire Fighters v. City of Cleveland, Ohio*.²¹⁹

The U.S. District Court for the Northern District of Ohio looked to the characterization of and factual allegations against Defendant Orthopaedic Partners, LLC that plaintiffs' asserted in their complaint.²²⁰ The court noted that the complaint referred to all defendants collectively and defendant Orthopaedic Partners, LLC was only mentioned twice throughout the eighty-nine-paragraph complaint.²²¹ The court found that "the allegations

212. *See id.* at *1.

213. *Id.*

214. *Id.*

215. *See id.*

216. *Id.* at *2.

217. *See id.*

218. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

219. 502 F.3d 545, 548 (6th Cir. 2007).

220. *See Beavers*, 2012 WL 1945603, at *4.

221. *See id.*

against Orthopaedic Partners, LLC . . . fall well below the threshold required to meet the plausibility standard required under *Twombly* Plaintiffs' allegations fail to distinguish between the DePuy Defendants' allegedly wrongful acts and those of Orthopaedic Partners, LLC."²²² The court went on to find, "Assuming the facts as alleged against Orthopaedic Partners, LLC to be true, without a modicum of additional facts, Plaintiff has failed to establish a colorable basis for liability."²²³ The court explained that "the lack of factual allegations regarding Orthopaedic Partners, LLC, provides no more than labels and conclusions insufficient to sustain viability of the legal claims."²²⁴ Thus, the court found "Orthopaedic Partners, LLC to be fraudulently joined."²²⁵

Similarly, claims involving pharmaceutical or medical device sales representatives may be subject to fraudulent joinder arguments where the factual allegations asserted against the sales representative are deficient.²²⁶ In *In re Diet Drugs Products Liability Litigation*,²²⁷ defendant Wyeth removed six lawsuits from Georgia state court to the U.S. District Court for the Northern District of Georgia on the basis of diversity jurisdiction.²²⁸ Each of the complaints named three Georgia sales representatives of Wyeth as defendants.²²⁹ Wyeth argued that the Georgia sales representative defendants were fraudulently joined to defeat diversity jurisdiction and should be disregarded for purposes of determining diversity of citizenship of the parties.²³⁰ The plaintiffs asserted claims against the sales representatives along with Wyeth for negligence and negligent/reckless misrepresentation by marketing the drugs as safe.²³¹ However, the complaints did not allege that any of the

222. *Id.* at *5.

223. *Id.*

224. *Id.*

225. *Id.*

226. *But see* *Stibor v. Ethicon, Inc.*, No. 04 C 1255, 2005 WL 1793589, at *4 (E.D. Wis. July 27, 2005) ("[P]laintiffs' complaint plainly states a cause of action . . .").

227. 294 F. Supp. 2d 667 (E.D. Pa. 2003).

228. *See id.* at 670.

229. *Id.* at 671. These cases also include allegations against two non-diverse Wyeth government-relations employees as well as a non-diverse phentermine manufacturer. Wyeth also argued that these parties were fraudulently joined. Ultimately, the court found that these additional non-diverse defendants were also fraudulently joined. *Id.* at 679.

230. *Id.* at 672.

231. *Id.* at 677.

representatives actually had contact with the patients or physicians or that they made specific misrepresentations.²³² Further, the duties of the named sales representatives consisted solely of making visits to physicians in Georgia to discuss an entirely different drug than the drug plaintiffs allegedly had taken.²³³ The court concluded that “[t]he pleadings simply do not allege colorable claims” against the sales representatives and that the representatives were, therefore, fraudulently joined.²³⁴

Beavers and *In re Diet Drugs* are examples of the successful use of the doctrine of fraudulent joinder through the lens of a Rule 8 pleading challenge. While the standard for fraudulent joinder is stringent, it may prove to be more successful if it is able to be paired with a challenge to the sufficiency of the pleading itself. This strategy may be most useful for complaints that assert vague claims against non-diverse defendants or complaints that lump all the defendants together and merely assert collective claims without specifying the involvement of the non-diverse defendant.

2. Sales Representative’s Affidavit Provides Facts Showing Claims Impossible Under Applicable State Law

In cases alleging claims against sales representatives individually, a common strategy is to submit a declaration or affidavit²³⁵ from the sales representative to provide facts showing the claims are impossible under applicable state law and the sales representative is, thus, fraudulently joined. In fact, some jurisdictions have found uncontroverted affidavits sufficient to establish fraudulent joinder.²³⁶ While defendants are generally

232. *Id.*

233. *Id.* Only one out of six of the plaintiffs ingested a drug that the sales representatives marketed. *See id.*

234. *Id.*; *see also In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 282 (S.D.N.Y. 2001) (finding “plaintiffs do not allege that the defendant sales representatives failed to warn the particular physicians who prescribed the drug for them” and “plaintiffs’ conclusory allegations” were not sufficient to support their claims for failure to warn).

235. The terms “declaration” and “affidavit” are used interchangeably in this article.

236. *See, e.g., Spataro v. DePuy Orthopaedics, Inc.*, No. CIV 08-0274 JCH/LAM, 2009 WL 382617, at *10 (D.N.M. Jan. 9, 2009); *Southern v. Pfizer, Inc.*, 471 F. Supp. 2d 1207, 1214 (N.D. Ala. 2006); *Faison v. Wyeth, Inc.*, 353 F. Supp. 2d 1273, 1278 (S.D. Ga. 2004); *In re Diet Drugs Prods. Liab. Litig.*, No. 03-20611, 2004 U.S. Dist. LEXIS 19848, at *5–6 (E.D. Pa. Sept. 28, 2004); *In re Rezulin*, 133 F. Supp. 2d at 281.

prohibited from going outside the pleadings when moving for dismissal under Federal Rule of Civil Procedure 12(b), defendants are permitted to include information outside the complaint when responding to a motion to remand.²³⁷ The proceeding for resolving a claim of fraudulent joinder is more closely related to the procedure used for ruling on a motion for summary judgment under Federal Rule of Civil Procedure 56(b): “[T]he determination of whether a resident defendant has been fraudulently joined must be based upon the plaintiff’s pleadings at the time of removal, supplemented by any affidavits and deposition transcripts submitted by the parties.”²³⁸

In *Patterson v. DePuy Orthopaedics, Inc.*,²³⁹ the plaintiff, an Alabama resident, filed his complaint in Alabama state court against out-of-state hip manufacturers, DePuy and its parent company, Johnson & Johnson. The plaintiff also named a DePuy medical device sales representative, who was an Alabama resident.²⁴⁰ The plaintiff alleged his hip implant caused him damage because of DePuy’s conduct in connection with the development, testing, manufacture, distribution, and sale of the hip implant.²⁴¹ The defendants removed the case to the U.S. District Court for the Middle District of Alabama on the basis of diversity jurisdiction.²⁴² The defendants then filed a motion to stay proceedings pending transfer to multidistrict litigation.²⁴³ The Judicial Panel on Multidistrict Litigation transferred this case to the Northern District of Ohio for consolidated proceedings.²⁴⁴ The plaintiff filed a motion to remand arguing that the U.S. District Court for the Northern District of Ohio lacked subject matter

237. See, e.g., *Legg v. Wyeth*, 428 F.3d 1317, 1322–23 (11th Cir. 2005); see also *Baeza v. Tibbetts*, No. 06-0407 MV/WPL, 2006 WL 2863486, at *3 (D.N.M. July 7, 2006) (“Although the court’s inquiry bears some resemblance to that of a motion to dismiss pursuant to Rule 12(b)(6), the scope of the inquiry is different, and the court may look beyond the pleadings to determine whether the joinder is fraudulent.”).

238. *Legg*, 428 F.3d at 1322–23; see also *Dacosta v. Novartis AG*, No. CV 01-800-BR, 2002 U.S. Dist. LEXIS 21313, at *34 (D. Or. Mar. 1, 2002) (finding the sales representative was a “sham defendant” who had been fraudulently joined after reviewing the sales representative’s affidavit and facts developed during jurisdictional discovery).

239. No. 1:11 dp 20521, 2011 WL 3047794, at *1 (N.D. Ohio July 25, 2011).

240. See *id.*

241. See *id.*

242. See *id.*

243. See *id.*

244. See *id.*

jurisdiction because the defendants failed to prove fraudulent joinder of the sales representative.²⁴⁵ The defendants opposed the motion to remand and submitted the resident sales representative's declaration in support.²⁴⁶

The court held that the sales representative was fraudulently joined to defeat diversity jurisdiction and denied the plaintiff's motion to remand.²⁴⁷ As to plaintiff's claims for negligent or defective design, the court found that a claim against the sales representative was not possible because the sales representative submitted a declaration stating that he was without knowledge of and has never been personally involved with the design of the device.²⁴⁸ Specifically, the court found:

Plaintiff has not shown that the resident defendant had a duty to warn the Plaintiff, nor has he produced evidence to overcome the resident defendant's testimony that he has no knowledge of or involvement in the design of the product. As a result, there is no possibility that Plaintiff could establish a cause of action for negligence against the resident defendant in an Alabama state court.²⁴⁹

Similarly, the court found there was no possibility that plaintiff could establish causes of action for products liability under the Alabama Extended Manufacturer's Liability Doctrine,²⁵⁰ breach of express and implied warranties, or misrepresentation and fraudulent concealment against the sales representative.²⁵¹

The strategy of providing an affidavit or declaration from the sales representative in order to prove the sales representative has been fraudulently joined essentially shifts the burden onto the plaintiff to provide factual evidence in support of the claims. As the *Patterson* court found, it is the plaintiff's burden to produce evidence "to overcome the resident defendant's testimony."²⁵²

245. *See id.*

246. *See id.*

247. *See id.* at *2.

248. *Id.* at *3–4.

249. *Id.* at *4.

250. ALA. CODE § 6-5-500 (West, Westlaw through 2012 Reg. Sess. and 1st Special Sess.); *see also* *Atkins v. Am. Motors Corp.*, 335 So. 2d 134 (Ala. 1976) (articulating the Alabama Extended Manufacturer's Liability Doctrine); *Casrell v. Altec Indus., Inc.*, 335 So. 2d 128 (Ala. 1976).

251. *Patterson*, 2011 WL 3047794, at *6–9.

252. *Id.* at *4. *Patterson* is one of many related actions contained in the multidistrict litigation entitled *In re DePuy Orthopaedics, Inc. ASR Hip Implant Prods. Liab. Litig.*, 1:10 md 2197, MDL 2197. *See Patterson*, 2011 WL 3047794, at *1 n.1.

Indeed, ignoring a defendant's affidavit has been found to be legal error and, therefore, an abuse of discretion.²⁵³

In addition to affidavits provided by the sales representative, an affidavit or testimony from the treating physician may be useful to prove there is no colorable claim against the sales representative. For example, in a case alleging failure to warn, the physician's affidavit might state that even if the warning had been given to the physician by the sales representative just as the plaintiff claims it should have been, the warning would not have been material to the physician, and the physician would not have changed the manner in which the physician provided advice, care, and treatment to the patient.²⁵⁴ A physician's affidavit could also state that the physician independently decided to use the device and did not rely on any information provided by the sales representative.²⁵⁵ In this context, the physician's affidavit is submitted on behalf of the sales representative in order to break the chain of proximate cause and show that under applicable state law, there is no possibility that the plaintiff has a cognizable claim against the non-diverse sales representative.

3. *Sales Representative Has No Legal Duty to Warn Pursuant to the Learned Intermediary Doctrine*

Another commonly cited argument to support fraudulent joinder of a sales representative is the learned intermediary doctrine. The learned intermediary doctrine holds that any duty to warn exists only between the manufacturer of the device and the

Indeed, the same result—finding a non-diverse sales representative defendant has been fraudulently joined based, in part, on the uncontroverted affidavit of the sales representative—has been reached in several other cases in that litigation. *See, e.g., Harper v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20522, 2011 WL 3049082 (N.D. Ohio July 25, 2011) (applying Alabama law and finding non-diverse sales representative defendant fraudulently joined); *Taylor v. DePuy Orthopaedics, Inc.*, No. 1:22 dp 20523, 2011 WL 3055295 (N.D. Ohio July 25, 2011) (same); *Slay v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20524, 2011 WL 3052531 (N.D. Ohio July 25, 2011) (same); *Milner v. DePuy Orthopaedics, Inc.*, No. 3:11 dp 20529, 2011 WL 3102320 (N.D. Ohio July 25, 2011) (same).

253. *See Legg v. Wyeth*, 428 F.3d 1317, 1323 (11th Cir. 2005) (“In the case at bar, the Defendants submitted sworn affidavits that were undisputed and, in such a case, a court cannot resolve the question of fraudulent joinder by refusing to consider the defendants’ submissions.”).

254. *See, e.g., Bloodsworth v. Smith & Nephew*, 417 F. Supp. 2d 1249, 1252 (M.D. Ala. 2006).

255. *See Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004).

plaintiff's prescribing physician or surgeon.²⁵⁶ Under this doctrine, no duty exists between the plaintiff and the sales representative.²⁵⁷

*Lizana v. Guidant Corp.*²⁵⁸ is an example of a court applying the learned intermediary doctrine to find a medical device sales representative owed no legal duty to plaintiff. In *Lizana*, the plaintiffs moved the U.S. District Court for the Southern District of Mississippi to remand their case to the Circuit Court of Harrison County, Mississippi.²⁵⁹ The plaintiffs alleged that plaintiff Howard Lizana collapsed at work due to a malfunctioning pacemaker manufactured by Guidant Corporation.²⁶⁰ Plaintiffs sued both Guidant Corporation as well as the Guidant representative who performed routine checks on Mr. Lizana's pacemaker.²⁶¹ The plaintiffs specifically asserted that the medical device representative (1) did not inform them that the pacemaker was subject to a recall, (2) participated in the initial implant surgery, and (3) assured plaintiffs that the pacemaker was functioning "perfectly."²⁶² The defendants argued that removal was proper because the sales representative's citizenship should be disregarded because he was fraudulently joined.²⁶³ The court concluded that the sales representative could not be liable for any alleged failure to warn nor was there any basis for the strict liability claims asserted against him.²⁶⁴ The court reasoned, in part, that under Mississippi law, the learned intermediary doctrine applies to all medical devices, and sales representatives are under no obligation to warn patients about the device.²⁶⁵ Thus, the medical device sales representative in the case could not be liable for any alleged failure to warn.²⁶⁶

256. See, e.g., *Patterson*, 2011 WL 3047794, at *4; *Catlett v. Wyeth, Inc.*, 379 F. Supp. 2d 1374, 1381 (M.D. Ga. 2004) (arguing that pursuant to the learned intermediary doctrine, the sales representative does not owe a legal duty to warn the patient of the risks associated with the device). But see, e.g., *Salazar v. Merck & Co.*, No. 05-445, 2005 U.S. Dist LEXIS 27776 (S.D. Tex. Nov. 2, 2005).

257. See *Patterson*, 2011 WL 3047794, at *4.

258. No. Civ.A 1:03CV254GRO, 2004 WL 3316405, at *1 (S.D. Miss. Jan. 21, 2004).

259. *Id.*

260. *Id.*

261. *Id.*

262. *Id.*

263. *Id.* at *2.

264. *Id.*

265. See *id.*

266. See *id.*; see also *Patterson v. DePuy Orthopaedics, Inc.*, No. 1:11 dp 20521, 2011 WL 3047794, at *4 (N.D. Ohio July 25, 2011) (applying the learned intermediary doctrine in the fraudulent joinder context and finding that, under

B. Medical Device Sales Representatives as “Sellers” Under State Products Liability Law

The question of whether a sales representative qualifies as a “seller” under state products liability law has recently arisen in medical device cases in the context of fraudulent joinder. If the sales representative is considered a seller under the state products liability statute, the sales representative could be held strictly liable for device defects, such that a colorable claim against the sales representative exists and the sales representative would not be fraudulently joined. Because the determination of whether a sales representative qualifies as a “seller” under state products liability law necessarily turns on the statutory interpretation of state law, there has been a wide range of outcomes, with some states finding sales representatives are unequivocally not sellers and other states finding sales representatives could possibly be sellers such that joinder was not fraudulent.²⁶⁷

Alabama law, the sales representative did not owe a duty to the patient and could not possibly be liable for negligent failure to warn). *But see* *Gibbs v. I-Flow, Inc.*, No. 1:08-cv-708-WTL-TAB, 2009 WL 482285, at *4 (S.D. Ind. Feb. 24, 2009) (“[A]pplication of the [learned intermediary] doctrine is fact-sensitive, and there are too many uncertainties to be able to reasonably conclude that [defendant] will prevail on such a defense.”).

267. *See, e.g., Patterson*, 2011 WL 3047794, at *3 (citing *Bloodsworth v. Smith & Nephew*, No. Civ.A. 2:05CV622-D, 2005 WL 3470337, at *21 (M.D. Ala. Dec. 19, 2005)) (applying Alabama law and finding sales representatives are not sellers); *Rundle v. DePuy Orthopaedics, Inc.*, No. 2:11-cv-00634-PMP-GWF, 2011 WL 3022569 (D. Nev. July 6, 2011) (applying Nevada law and finding it possible that a sales representative could be strictly liable); *Askew v. DC Medical, LLC*, No. 1:11-cv-1245-WSD, 2011 WL 1811433 (N.D. Ga. May 12, 2011) (applying Georgia law and finding sales representatives are not sellers); *Lizana*, 2004 WL 3316405 (same applying Mississippi law); *Memphis Bank & Trust Co. v. Water Serv. Inc.*, 758 S.W.2d 525 (Tenn. 1998) (holding that a sales representative is not subject to strict products liability under Tennessee law); *see also* *McCarty v. Johnson & Johnson*, No. 1:10-CV-00350 OWW-DLB, 2010 WL 2629913 (E.D. Cal. June 29, 2010) (applying California law and finding sales representatives may be sellers); *Gibbs*, 2009 WL 482285 (same applying Indiana law); *Spataro v. DePuy Orthopaedics, Inc.*, No. CIV 08-0274 JCH/LAM, 2009 WL 382617 (D.N.M. Jan. 9, 2009) (same applying New Mexico law); *Rape v. Medtronic, Inc.*, No. 9:04-CV-225, 2005 WL 1189826 (E.D. Tex. May 19, 2005) (same applying Texas law); *Bittler v. White & Co., Inc.*, 560 N.E.2d 979, 982 (Ill. App. 1990) (applying Illinois law and limiting sales representative strict liability to cases where there is a “‘participatory connection’ with the allegedly defective product”); *Brumbaugh v. CEJJ, Inc.*, 152 A.D.2d 69, 71 (N.Y. App. Div. 1989) (applying New York law and limiting sales agent strict products liability to cases where the sales agent is a “mandatory link in [the] distributive chain”).

1. *States Finding Sales Representatives Are Not “Sellers”*

Courts applying Alabama, Mississippi, Georgia, and Tennessee law have found that under the respective state products liability statutes, sales representatives do not qualify as “sellers.”²⁶⁸ Thus, if a plaintiff asserts a strict liability claim against a salesperson on the grounds that the salesperson is a “seller” in the chain of distribution of the product in one of these states, no colorable claim against the sales representative exists, such that a fraudulent joinder argument would be successful.

In a case involving a medical device sales representative, the U.S. District Court for the Middle District of Alabama, applying Alabama law, found that the Alabama Extended Manufacturer’s Liability Doctrine (AEMLD) does not include a sales representative within the definition of “seller” or “manufacturer.”²⁶⁹ The court cited the reasoning from the U.S. District Courts for the Southern District of New York and the District of Minnesota in *In re Rezulin Products Liability Litigation*²⁷⁰ and *In re Baycol Products Liability Litigation*,²⁷¹ respectively, applying Alabama law, as persuasive.²⁷² In *Rezulin*, the court found that “holding a sales representative liable under the AEMLD would contravene the doctrine’s scope and purpose,” and the “sales representative was merely an agent of the manufacturer/seller, and, as a ‘corporate employee,’ he was not ‘the one best able to prevent sales of defective drugs.’”²⁷³ Similarly, the court in *Baycol* reached the same conclusion, finding “the purpose of the AEMLD did not support a claim against a sales agent who ‘had no authority to compel or prevent the distribution

268. See, e.g., *Patterson*, 2011 WL 3047794, at *3 (holding that a sales representative is not subject to strict products liability under Alabama law) (citing *Bloodsworth*, 2005 WL 3470337, at *21); *Askew*, 2011 WL 1811433 (same applying Georgia law); *Lizana*, 2004 WL 3316405 (same applying Mississippi law); *Memphis Bank & Trust*, 758 S.W.2d 525 (same applying Tennessee law).

269. See *Bloodsworth*, 2005 WL 3470337, at *5 (“A defendant is liable under the AEMLD if the plaintiff shows the following: ‘(1) [that] he suffered injury or damages to himself . . . by one who sold a product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to, and did, reach the user or consumer without substantial change in the condition in which it was sold.’” (quoting *Atkins v. Am. Motors Corp.*, 335 So. 2d 134, 141 (Ala. 1976))).

270. 133 F. Supp. 2d 272, 287–88 (S.D.N.Y. 2001).

271. M.D.L. No. 1431 (MJD), at *4–7 (D. Minn. Mar. 26, 2004) (order denying motion to remand).

272. See *Bloodsworth*, 2005 WL 3470337, at *6.

273. See *id.* (quoting *In re Rezulin Prods.*, 272 F. Supp. 2d at 287–88).

of particular products.”²⁷⁴ The U.S. District Court for the Middle District of Alabama also cited the Supreme Court of Alabama, finding that the court had “rejected the theory that a retailer who lacks knowledge of a product’s dangerous defect can be liable under the AEMLD simply for ‘the mere selling of a defective product.’”²⁷⁵ Synthesizing these cases, the U.S. District Court for the Middle District of Alabama found there was no reasonable possibility that an Alabama court would find the medical device sales representative liable under the AEMLD.²⁷⁶

In some states, a straightforward interpretation of the state products liability statutes provides clear guidance on whether a salesperson can be held strictly liable under state law.²⁷⁷ Courts applying Mississippi law have held that medical device sales representatives are not considered sellers and therefore are not subject to strict liability for product defects.²⁷⁸ Similarly, courts applying Georgia law have found that medical device sales representatives do not meet the definition of “sellers” under Georgia law and cannot be found strictly liable for product defects.²⁷⁹ Both Mississippi and Georgia have explicit statutory provisions regarding who is and who is not considered a seller under state law.²⁸⁰ For example, Mississippi law provides that a seller other than the manufacturer will not be liable unless certain requirements are met:

[T]he seller of a product other than the manufacturer shall not be liable unless the seller exercised substantial control over that aspect of the design, testing, manufacture, packaging or labeling of the product that

274. See *id.* at *6 (quoting *In re Baycol Prods.*, M.D.L. No. 1431 (MJD), at *4).

275. See *id.* at *7 (quoting *Atkins v. Am. Motors Corp.*, 335 So. 2d 134, 139 (Ala. 1976)).

276. See *id.*

277. See, e.g., GA. CODE ANN. § 51-1-11.1 (West, Westlaw through 2012 Reg. Sess.); MISS. CODE ANN. § 11-1-63 (West, Westlaw through 2012 Reg. Sess.).

278. See, e.g., *Lizana v. Guidant Corp.*, No. Civ.A 1:03CV254GRO, 2004 WL 3316405, at *2 (S.D. Miss. Jan. 21, 2004) (applying Mississippi law).

279. See, e.g., *Askew v. DC Medical, LLC*, No. 1:11-cv-1245-WSD, 2011 WL 1811433 (N.D. Ga. May 12, 2011) (holding that Depuy’s sole distributor of the ASR hip device in Georgia was fraudulently joined because Georgia’s strict products liability statute imposes liability only on the manufacturer of a product and a seller or distributor is not strictly liable); see also *Davenport v. Cummins Ala., Inc.*, 644 S.E.2d 503, 507–08 (Ga. Ct. App. 2007) (citing several Georgia decisions and discussing the definition of a “seller” under Georgia law).

280. See GA. CODE ANN. § 51-1-11.1(a) (Westlaw); MISS. CODE ANN. § 11-1-63(h) (Westlaw).

caused the harm for which recovery of damages is sought; or the seller altered or modified the product, and the alteration or modification was a substantial factor in causing the harm for which recovery of damages is sought; or the seller had actual or constructive knowledge of the defective condition of the product at the time he supplied the product. It is the intent of this section to immunize innocent sellers who are not actively negligent, but instead are mere conduits of a product.²⁸¹

The legal definition of a “seller” under Georgia law encompasses sales representatives:

[A] person who, in the course of a business conducted for the purpose leases or sells and distributes; installs; prepares; blends; packages; labels; markets; or assembles pursuant to a manufacturer’s plan, intention, design, specifications, or formulation; or repairs; maintains; or otherwise is involved in placing a product in the stream of commerce.²⁸²

However, Georgia’s Products Liability Act also explicitly provides that “[f]or purposes of a product liability action based in whole or in part on the doctrine of strict liability in tort, a product seller is not a manufacturer as provided in Code Section 51-1-11 and is not liable as such.”²⁸³

Although Tennessee courts have not specifically addressed whether a medical device sales representative would be defined as a “seller” under the Tennessee Products Liability Act (TPLA), the Tennessee Supreme Court evaluated whether a general product sales representative could be subject to strict products liability in *Memphis Bank & Trust Co. v. Water Services, Inc.*²⁸⁴ By analogy, this case could be persuasive in Tennessee courts evaluating whether a medical device sales representative qualifies as a seller under TPLA and is, thus, instructive. In *Memphis Bank*, the owner of a large commercial bank building brought a products liability action against a corporation operating a commercial and industrial water treatment business as well as the corporation’s sales representative.²⁸⁵ Plaintiff alleged breach of warranty, negligence, and strict liability in tort for damage to the building’s windows and

281. MISS. CODE ANN. § 11-1-63(h) (Westlaw).

282. GA. CODE ANN. § 51-1-11.1(a) (Westlaw).

283. *Id.* § 51-1-11.1(b); *see also id.* § 51-1-11.

284. 758 S.W.2d 525 (Tenn. 1988).

285. *Id.* at 525.

aluminum siding, which had become discolored by water containing chemicals from the building's air conditioning system.²⁸⁶ After a bench trial, the trial court dismissed all of the claims.²⁸⁷ The Tennessee Court of Appeals subsequently reversed the judgment of the trial court and rendered judgment for the plaintiff against both the corporation and the individual sales representative on the theory of strict liability, assessing the sales representative with a personal judgment of \$78,808.²⁸⁸ The Tennessee Supreme Court, however, found that the sales representative was not a "seller" or "manufacturer" of a product as defined by TPLA.²⁸⁹ The court pointed to evidence in the record that the sales representative was paid a commission on all sales, was not a stockholder, a director, or an officer of the corporation, and the products he sold did not belong to him.²⁹⁰ Thus, defendants arguing a sales representative has been fraudulently joined in Alabama, Mississippi, Georgia, or Tennessee, will likely be successful in asserting that the plaintiff cannot state a claim for strict products liability as to the salesperson.

2. States Finding Sales Representatives May Be "Sellers"

While a few states have clear guidance on whether a salesperson may be subject to strict products liability claims, the vast majority of states have not definitively answered this question.²⁹¹ Illinois and New York have answered the question in the affirmative, but have placed specific limitations on claims

286. *Id.*

287. *Id.*

288. *Id.* at 525–26.

289. *Id.* at 526; *see also* TENN. CODE ANN. §§ 29-28-102(4), (7) (West, Westlaw through 2012 2d Reg. Sess.) (defining "manufacturer" as "the designer, fabricator, producer, compounder, processor or assembler of any product or its component parts" and "seller" as "a retailer, wholesaler, or distributor, and . . . any individual or entity engaged in the business of selling a product, whether such sale is for resale, or for use or consumption").

290. *Memphis Bank & Trust*, 758 S.W.2d at 526.

291. *See, e.g., Rundle v. DePuy Orthopaedics, Inc.*, No. 2:11-cv-00634-PMP-GWF, 2011 WL 3022569, at *7–13 (D. Nev. July 6, 2011) (applying Nevada law); *McCarty v. Johnson & Johnson*, No. 1:10-CV-00350 OWW-DLB, 2010 WL 2629913, at *3–5 (E.D. Cal. June 29, 2010) (applying California law); *Gibbs v. I-Flow, Inc.*, No. 1:08-cv-708-WTL-TAB, 2009 WL 482285, at *3–4 (S.D. Ind. Feb. 24, 2009) (applying Indiana law); *Spataro v. DePuy Orthopaedics, Inc.*, No. CIV 08-0274 JCH/LAM, 2009 WL 382617, at *5–8 (D.N.M. Jan. 9, 2009) (applying New Mexico law); *Rape v. Medtronic, Inc.*, No. 9:04-CV-225, 2005 WL 1189826, at *2–3 (E.D. Tex. May 19, 2005) (applying Texas law).

against sales representatives.²⁹² In these jurisdictions, defendants will likely be less successful arguing that the sales representative has been fraudulently joined where the plaintiff claims strict liability against the sales representative as a seller of the product because these states have found that there is a “possibility” that a claim could be sustained under applicable state law.

The majority of courts that have evaluated the issue under the applicable state law, including Nevada, California, Indiana, New Mexico, and Texas law, have found that while the issue has not been definitively decided by the state’s highest court, in a fraudulent joinder analysis it is possible that plaintiff could state a claim for strict products liability against a pharmaceutical or medical device sales representative.²⁹³ For example, the U.S. District Court for the District of Nevada found that a medical device sales representative may be strictly liable for design defects:

Because it is possible that the Nevada Supreme Court will hold that a manufacturer’s exclusive sales representative is strictly liable for design defects based on the type of conduct alleged in this case, Precision Instruments has not been fraudulently joined so long as there is a causal nexus between its alleged conduct and Plaintiffs’ injuries.²⁹⁴

The U.S. District Court for the Eastern District of California, applying California law, found that it is possible a plaintiff could recover against a medical device sales representative under the stream of commerce theory.²⁹⁵ The court, in *McCarty v. Johnson & Johnson*,²⁹⁶ found that the medical device sales representative “worked for a separate sales company and attended Plaintiff’s surgery to assure presence of the product” and the fact that neither the sales representative nor his employer held title to the product

292. See, e.g., *Bitter v. White & Co.*, 560 N.E.2d 979, 981–82 (Ill. App. Ct. 1990) (applying Illinois law and limiting sales representative strict liability to cases where there is a “‘participatory connection’ with the . . . defective product”); *Brumbaugh v. CEJJ, Inc.*, 547 N.Y.S.2d 699, 700–02 (N.Y. App. Div. 1989) (applying New York law and limiting sales agent strict products liability to cases where the sales agent is a “mandatory link in [the] distribution chain”).

293. See, e.g., *Rundle*, 2011 WL 3022569 (applying Nevada law); *McCarty*, 2010 WL 2629913 (E.D. Cal. June 29, 2010) (applying California law); *Gibbs*, 2009 WL 482285 (applying Indiana law); *Spataro*, 2009 WL 382617 (applying New Mexico law); *Rape*, 2005 WL 1189826 (applying Texas law).

294. *Rundle*, 2011 WL 3022569, at *13.

295. See *McCarty*, 2010 WL 2629913, at *5.

296. *Id.*

was “of no moment.” Similarly, other federal district courts in California have granted motions to remand products liability actions brought against resident independent sales representatives of medical device manufacturers or suppliers on the grounds that the sales representatives may potentially be liable under California strict products liability law for defectively designed products whose sales they facilitate.²⁹⁷

Federal district courts interpreting state products liability laws in Indiana, New Mexico, and Texas have found that even though the highest court of the particular state has not determined that a strict products liability claim against a medical device sales representative is cognizable, an argument can be made that there is a possibility the products liability statute applies. The U.S. District Court for the Southern District of Indiana stated: “Even in the absence of any Indiana cases on point, the Court concludes that Plaintiffs can manage to make a reasonable argument in support of their product liability claim by applying Indiana’s rules for statutory construction.”²⁹⁸ Likewise, the U.S. District Court for the District of New Mexico explained that “[w]hile it is not entirely clear whether [plaintiff] could establish a strict liability cause of action against [the sales representative] in state court, this Court cannot conclude that there is no possibility of this.”²⁹⁹ And the U.S. District Court for the Eastern District of Texas found “[the defendant] has not shown that it is clear under Texas law that a sales representative of a manufacturer, who might be some type of independent contractor or retailer, and not an employee, can never be considered a seller as defined in § 82.001.”³⁰⁰

Although neither Illinois nor New York courts have specifically

297. See, e.g., *Hinds v. Zimmer, Inc.*, No. 1:09cv0442 AWI DLB, 2009 WL 1517893 (E.D. Cal. June 1, 2009); *Becraft v. Ethicon, Inc.*, Nos. C00-1474CRB, C00-1493CRB, C00-1495CRB, C00-1496CRB, 2000 WL 1721056 (N.D. Cal. Nov. 2, 2000).

298. *Gibbs*, 2009 WL 482285, at *3; see also IND. CODE ANN. § 34-6-2-77(a)(1) (West, Westlaw through 2012 2d Reg. Sess.); *McDaniel v. Synthes, Inc.*, No. 2:07-CV-245RM, 2007 WL 3232186 (N.D. Ind. Oct. 29, 2007).

299. *Spataro v. DePuy Orthopaedics, Inc.*, No. CIV 08-0274 JCH/LAM, 2009 WL 382617, at *8 (D.N.M. Jan. 9, 2009); see also *Baeza v. Tibbetts*, No. 06-0407 MV/WPL, 2006 WL 2863486, at *4-5 (D.N.M. July 7, 2006) (reaching the same conclusion).

300. *Rape v. Medtronic, Inc.*, No. 9:04-CV-225, 2005 WL 1189826, at *3 (E.D. Tex. May 19, 2005); see also TEX. CIV. PRAC. & REM. CODE ANN. §§ 82.001, 82.003 (West, Westlaw through the end of 2011 Reg. Sess. and 1st Called Sess. of 82d Leg.).

analyzed whether a medical device sales representative could be held liable for strict products liability, decisions in other products liability contexts in these states demonstrate that the courts will likely broadly interpret application of the respective products liability laws to include medical device sales representatives. This loose interpretation could include all individuals with a “participatory connection” or a “mandatory link” to the injury-causing product. The Illinois Appellate Court, in *Bittler v. White & Co., Inc.*,³⁰¹ analyzed the issue of whether an exclusive sales representative company could be strictly liable under Illinois law for personal injuries the plaintiff claimed to have sustained during the course of his employment when he was struck on the head by the tailgate of a truck-mounted vacuum loader and cleaner.³⁰² The court found that the determining factor was “whether the party in question has any ‘participatory connection, for personal profit or other benefit, with the injury-causing product and with the enterprise that created consumer demand for and reliance upon the product.’”³⁰³ Ultimately the court found that the sales company had a participatory connection with the allegedly defective product such that it could be strictly liable.³⁰⁴

The Supreme Court of New York’s Appellate Division also found that an exclusive sales agent may be subject to strict products liability where the agent is a “mandatory link” in the distribution chain.³⁰⁵ In *Brumbaugh v. CEJJ, Inc.*,³⁰⁶ the plaintiff’s decedent was killed when a dumpster swung loose from a trash compactor and pinned him against his truck.³⁰⁷ Plaintiff sued the trash compactor manufacturer’s exclusive marketing agent claiming that the safety latch on the compactor was defective.³⁰⁸ The court analyzed whether the exclusive marketing agent of the trash compactor could be held strictly liable under New York products liability law.³⁰⁹ The court found that “[l]iability is not to be imposed, however, upon a party whose role in placing the defective product in the

301. 560 N.E.2d 979 (Ill. App. Ct. 1990).

302. *Id.* at 980–81.

303. *Id.* at 981 (quoting *Kasel v. Remington Arms, Inc.*, 24 Cal. App. 3d 711, 725 (Ct. App. 1972)).

304. *See id.* at 982.

305. *See Brumbaugh v. CEJJ, Inc.*, 152 A.D.2d 69 (N.Y. App. Div. 1989).

306. *Id.* at 70.

307. *See id.*

308. *See id.*

309. *See id.*

stream of commerce is so peripheral to the manufacture and marketing of the product that it would not further these policy considerations.”³¹⁰ The policy considerations identified included whether injured consumers would be afforded a greater opportunity to bring an action against the responsible party, whether the entity is in a position to exert pressure on the manufacturer to improve safety of the product, and whether liability would ensure that the burden of injury from the product would be treated as a cost of production by placing liability on marketers.³¹¹ The court also noted that whether these potential litigants in the distributive chain have an opportunity to seek contribution or indemnification from the manufacturer is a factor.³¹² Based on these factors, the court held that the exclusive sales agent could be subject to strict products liability under New York law.³¹³ The court reasoned that “[i]ts activities involve it so substantially, if not pervasively, in introducing these compactors into the stream of commerce that it is fair to say that it is a mandatory link in this distributive chain; hence, it may properly be held liable in strict products liability.”³¹⁴

V. RECENTLY ASSERTED DEFENSES AND ULTIMATE CASE OUTCOMES
IN CASES INVOLVING ALLEGATIONS OF SALES
REPRESENTATIVE MISCONDUCT

Products liability cases involving medical device sales representative conduct ultimately turn on the role of the representative in patient treatment or the use of the medical device during the surgery. The American Medical Association’s Code of Medical Ethics provides that “[m]anufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians.”³¹⁵ To date, products liability actions involving allegations that a medical device

310. *Id.* at 71.

311. *See id.*

312. *See id.*

313. *See id.* at 71–72.

314. *Id.* at 72.

315. AM. MED. ASS’N, CODE OF MEDICAL ETHICS, OPINION 8.047 (2007), *available at* <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion8047.page>.

sales representative acted inappropriately attempt to impose a duty on the sales representative, the medical device manufacturer, or both based simply on the representative's presence in the operating or treatment room. The question then becomes what the appropriate role of the medical device sales manufacturer in the operating or treatment room is. While medical device sales representatives can be an asset to physicians and surgical teams, there is also potential liability for both the individual representative as well as the device manufacturer.

This section explores the practical implications of an increase in claims involving medical device sales representatives, including the ultimate outcome of suits involving medical device sales representatives. Each of the most commonly asserted defense theories in cases asserting a medical device sales representative owed a heightened duty of care to plaintiff are examined, including the learned intermediary doctrine, absence of duty, captain of the ship doctrine, and lack of causation. The available case law makes clear that the potential liability of the medical device sales representative is largely fact-sensitive and still under development.

A. *Learned Intermediary Doctrine*

As commentators and courts have noted, the “learned intermediary” doctrine is a defense that applies in the overwhelming majority of jurisdictions in cases against drug and medical device manufacturers.³¹⁶ Courts applying the learned intermediary doctrine to medical device cases have reasoned that when a device is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but rather to the prescribing doctor.³¹⁷ Therefore,

316. *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1280 (11th Cir. 2002) (noting that the learned intermediary doctrine has repeatedly been applied to medical devices); *McPheron v. Searle Labs., Inc.*, 888 F.2d 31, 33 (5th Cir. 1989) (“The great weight of the authority in other jurisdictions is to the contrary [to Plaintiff’s assertion]; most courts have found that a medical device which must be prescribed and inserted by a physician falls under the learned intermediary doctrine.”); Philips Combs & Andrew Cooke, *Modern Products Liability Law in West Virginia*, 113 W. VA. L. REV. 417, 438 (2011). In fact, West Virginia is the only state that has completely rejected the learned intermediary doctrine. *See State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 906, 914 (W. Va. 2007).

317. *See Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Baker v. Danek Medical*, 35 F. Supp. 2d 875, 881 (N.D. Fla. 1998).

under the learned intermediary doctrine, the question before the court is whether the plaintiff established that his or her surgeon would not have used the device if he or she had received an adequate warning.³¹⁸

The rationale for the learned intermediary doctrine is set forth in the Restatement (Third) of Torts as follows:

[O]nly health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.³¹⁹

The reasoning behind the learned intermediary doctrine is perhaps even more persuasive when medical devices—rather than prescription drugs—are involved because it is not reasonably conceivable that an individual could implant a device that requires a trained surgeon and “it is highly likely a patient and doctor spend considerably more time discussing the risks and benefits of a surgically implanted device than they would discussing the risks and benefits of routinely prescribed prescription drugs.”³²⁰

Although the learned intermediary doctrine has traditionally been applied to the warnings a manufacturer has provided in product labeling and package inserts, it also is equally applicable to the warnings that sales representatives provide.³²¹ As one court in a jurisdiction that has adopted the learned intermediary doctrine has stated “any duty to warn exists only between the manufacturer and the plaintiff’s surgeon, not between the plaintiff and the sales representative.”³²² Thus, claims alleging that a sales representative failed to adequately warn a plaintiff about a device’s risks have

318. Smith v. Johnson & Johnson, Inc., 483 F. App’x 909, 912 (5th Cir. 2012).

319. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) & cmt. b (1998).

320. See Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007).

321. For examples of cases applying the learned intermediary doctrine to allegations involving the conduct of a medical device manufacturer’s sales representatives, see *Wolicki-Gables v. Arrow International, Inc.*, 641 F. Supp. 2d 1270, 1286–87 (M.D. Fla. 2009); *Beale*, 492 F. Supp. 2d at 1366–78; *O’Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281–82 (Colo. App. 2010); *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 784–86 (Ill. App. Ct. 2006).

322. *Patterson v. DePuy Orthopaedics, Inc.*, No. 1:11-dp-20521, 2011 WL 3047794, at *4 (N.D. Ohio July 25, 2011).

generally failed.³²³

Some courts have recognized that a dispositive motion based on the learned intermediary defense may be defeated if there is an issue of fact related to a sales representative's actions or representations. However, the learned intermediary defense may still be successful subsequently at trial. For example, in *Hurley v. Heart Physicians, P.C.*, the plaintiff admitted that the warning provided by a pacemaker manufacturer in its technical manual was adequate, but asserted that advice given by a sales representative to the physician contradicted the manual and nullified the warnings contained in the technical manual.³²⁴ Specifically, a pacemaker sales representative was asked by the plaintiff's cardiologist to attend an examination of the plaintiff "to test the battery in her pacemaker" and "to make adjustments" as needed.³²⁵ At the examination of the plaintiff, the sales representative found that the battery was low and needed to be replaced as soon as possible.³²⁶ The plaintiff's mother refused to consent to the replacement and insisted that the plaintiff no longer required the pacemaker.³²⁷ The physician asked the sales representative for options to determine whether the plaintiff required the pacemaker.³²⁸ The sales representative stated that one option was downward adjustment to the rate of the pacemaker, which would also conserve battery life.³²⁹ The physician decided to adjust the rate downwards.³³⁰ The plaintiff subsequently suffered a cardiac event and resulting brain damage.³³¹

The trial court granted the defendant manufacturer's motion for summary judgment based on the learned intermediary doctrine.³³² However, the Connecticut Supreme Court reversed the trial court, finding that a material question of fact existed as to whether "the warnings given by the . . . representative were consistent with the manual and, therefore, the trial court improperly determined that the defendant was entitled to prevail

323. See, e.g., *id.*; *Wolicki-Gables*, 641 F. Supp. 2d at 1286–87; *O'Connell*, 250 P.3d at 1281–82.

324. 898 A.2d 777 (Conn. 2006).

325. *Id.* at 780.

326. *Id.*

327. *Id.*

328. *Id.*

329. *Id.* at 781.

330. *Id.*

331. *Id.*

332. *Id.* at 782.

under the learned intermediary doctrine as a matter of law.”³³³ The Connecticut Supreme Court focused on the presence and involvement of the representative with the adjustment to plaintiff’s pacemaker:

What is at issue . . . is whether, notwithstanding the FDA approved written pacemaker replacement warnings, [the representative], by his *oral* communications to [the cardiologist] that turning down the pacemaker was an option, accompanied by his *physical* adjustment of the pacemaker . . . actually contradicted the manual, thereby vitiating and nullifying the manual’s warnings³³⁴

Because the Connecticut Supreme Court found that this was a question of fact, the case was remanded to the trial court for further proceedings.³³⁵ The trial was limited to the issue of whether the representative’s oral statements and adjustment of the pacemaker were for “diagnostic” purposes or whether they “actually contradicted” the technical manual and therefore nullified the accompanying warnings.³³⁶ The case was tried before a jury and, after a twenty-six day trial, a defense verdict was returned.³³⁷ The jury specifically found that the sales representative’s actions did not nullify the written warnings.³³⁸ The plaintiff appealed to the Connecticut Supreme Court, but the verdict was upheld on appeal.³³⁹ Thus, although the trial court opened the door to sales representative liability even where a learned intermediary defense was proffered, the defense ultimately prevailed at trial.

Moreover, a few courts have recognized an “overpromotion” exception to the learned intermediary doctrine that is largely dependent on the conduct of a manufacturer’s sales representatives. Under this exception, which has typically been applied in the prescription drug context, a few courts have called into question the application of the learned intermediary doctrine where drug salesmen encouraged physicians to prescribe a drug by providing information that contradicted the warnings, thus allegedly influencing a physician to prescribe a drug more freely

333. *Id.* at 779.

334. *Id.* at 786–87.

335. *Id.* at 789.

336. *See Hurley v. Heart Physicians, P.C.*, 3 A.3d 892, 899–900 (Conn. 2010).

337. *See id.* at 898–99.

338. *See id.*

339. *Id.* at 896, 912.

than the physician otherwise would.³⁴⁰ However, in *Beale v. Biomet, Inc.*, the court rejected the plaintiff's argument that a device manufacturer's overpromotion of a knee implant created an exception to the learned intermediary doctrine.³⁴¹ There, the court ruled that the plaintiff failed to produce evidence showing that the manufacturer's sales representatives influenced the implanting doctor to inappropriately select patients for the device; thus, the learned intermediary doctrine shielded the manufacturer from liability.³⁴²

B. *Absence of Duty*

Several courts have been unwilling to find that a sales representative's presence in an operating room during the implantation of a medical device creates an additional duty to provide certain advice or warnings to a physician.³⁴³ For example, in *Wolicki-Gables v. Arrow International, Inc.*, the court rejected the plaintiff's attempt to impose an affirmative duty on a sales representative present during the implantation of a pain pump.³⁴⁴ The plaintiff's negligence action against the sales representative "alleged breach of the duty to use reasonable care in the instruction and education of physicians."³⁴⁵ The court found that even if the sales representative did have some interaction with the surgeon during the surgery, he did not have a duty to affirmatively tell the doctor while he was performing the surgery how to use the device.³⁴⁶ The court, therefore, granted the sales representative's motion for summary judgment, reasoning:

The undisputed facts show that [the sales representative] did not participate in the decision-making during [the] procedure. [His] role was limited to carrying "back up" products in their sterile packages to have available for the

340. See, e.g., *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973); *Love v. Wolf*, 38 Cal. Rptr. 183 (Ct. App. 1964); *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971); *Baldino v. Castagna*, 454 A.2d 1012 (Pa. Super. Ct. 1982), *rev'd*, 478 A.2d 807 (Pa. 1984).

341. 492 F. Supp. 2d 1360, 1377–78 (S.D. Fla. 2007).

342. *Id.*

343. See, e.g., *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1291–92 (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011); *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 786–87 (Ill. App. Ct. 2006).

344. *Wolicki-Gables*, 641 F. Supp. 2d at 1291–92.

345. *Id.* at 1279.

346. *Id.* at 1291.

surgeon's use, if necessary, and to observe preparation of the products. [He] did not "scrub in" for the procedure . . . and did not enter the sterile field. . . . [The surgeon] testified that the decisions made while he performed surgery were his own decisions.³⁴⁷

Another example of a plaintiff's unsuccessful attempt to impose an affirmative duty on a sales representative is evident in *Kennedy v. Medtronic*.³⁴⁸ In this case, the plaintiff claimed that the manufacturer of a pacemaker and its leads owed the patient "a duty to refrain from providing a pacemaker . . . and participating in the [surgery] once [the representative] discovered the procedure was being performed in a setting that was not part of a hospital."³⁴⁹ The plaintiff alternatively pled that the manufacturer had voluntarily assumed a duty of care for the decedent by sending a representative to the surgery.³⁵⁰ The pacemaker manufacturer's clinical specialist was present at the surgery "to provide technical support and ensure that the [pacemaker's] lead parameters were correctly calibrated and the lead was functioning properly."³⁵¹

In affirming the trial court's granting of summary judgment for the manufacturer, the court rejected the plaintiff's argument that the sales representative voluntarily undertook a duty outside of the limited role he had agreed to perform, which was to ensure the leads were properly calibrated.³⁵² The court also held that no duty of care existed for the manufacturer because the plaintiff's injuries were not reasonably foreseeable and the burden and consequences of imposing a duty on the manufacturer would be "substantial," as it "would be a significant burden to require [the manufacturer] to monitor the conditions under which a doctor performs surgery."³⁵³

The court opined:

It would be unreasonable, and potentially harmful, to require a clinical specialist . . . to delay or prevent a medical procedure simply because she believes the setting is not appropriate or the doctor is unqualified. To hold otherwise would place a medical device manufacturer . . .

347. *Id.*

348. *Kennedy*, 851 N.E.2d at 778.

349. *Id.* at 785.

350. *Id.* at 786.

351. *Id.* at 787.

352. *Id.*

353. *Id.* at 786.

in the middle of the doctor-patient relationship.³⁵⁴

Similarly, in rejecting a plaintiff's attempt to impose an affirmative duty to prevent a doctor's misuse of the company's products, another court recognized "[i]t is both impractical and unrealistic to expect . . . manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams."³⁵⁵

A small handful of courts, however, have imposed a duty on a sales representative when the representative is present during a surgical procedure and assisting with some aspect of the surgery. For example, in *Zappola v. Leibinger* the court held that the written instructions for a device to close a cranial bone flap did not satisfy the manufacturer's duty under the learned intermediary doctrine where the medical device sales representative recommended the product to the physician without conveying certain recommendations contained in the device's instructions.³⁵⁶ In *Zappola*, the defendant sales representative was present at the plaintiff's surgery to remove a brain tumor.³⁵⁷ Based on the size and location of the tumor, the plaintiff's surgeon decided he could not use the representative's medical device to reattach the plaintiff's bone flap as planned.³⁵⁸ The surgeon specifically asked the sales representative "to observe the size of the cranial defect in [the plaintiff's] skull."³⁵⁹ The surgeon and the sales representative then discussed possible methods of closing the skull, and, during this conversation, the representative suggested another of the manufacturer's products.³⁶⁰ When the surgeon expressed concern about using the device based on his past experience, the sales representative told the surgeon that the device "had been improved."³⁶¹ The surgeon used the product, which ultimately fragmented, causing the plaintiff a cerebrospinal fluid leak and four additional surgeries.³⁶²

354. *Id.*

355. *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 471 (5th Cir. 1987) (pharmaceutical case).

356. Nos. 86038, 86102, 2006 WL 1174448, at *6 (Ohio Ct. App. May 4, 2006).

357. *Id.* at *2.

358. *Id.*

359. *Id.*

360. *Id.*

361. *Id.*

362. *Id.* at *3.

The defendant manufacturer argued that it satisfied its duty to warn the surgeon because the written warnings that accompanied the product provided instructions and guidance regarding closing a cranial defect like the plaintiff's defect.³⁶³ The court disagreed and found that the key factor was that the sales representative was present in the operating room and observed the plaintiff's condition:

Although the written instructions [provided recommendations for use], [the sales representative] did not make these recommendations to the doctor. Despite the fact that he was professionally obligated to inform [the surgeon] about the use of the product and personally observed the size of [the plaintiff's] cranial defect, [the sales representative] did not uphold his duty of ensuring that the product was used properly.³⁶⁴

In essence, the court in *Zappola* imposed a duty on the defendant sales representative to inform the surgeon about the uses of the product, in part because the representative affirmatively recommended the product after observing the plaintiff's cranial defect.³⁶⁵ The case was tried and a jury found the plaintiff's surgeon, the medical device manufacturer, and the sales representative liable for negligence.³⁶⁶

Under similar circumstances, the court in *Chamian v. Sharplan Lasers, Inc.* found that the manufacturer "provided a technician to assist in the surgery, and, by doing so, assumed a duty to [the plaintiff] to ensure that the technician . . . was knowledgeable about the equipment and competent to provide technical assistance to physicians using the equipment."³⁶⁷ The defendant manufacturer's technician was present during plaintiff's plastic surgery to test the device, make sure that it was working properly, and assist the physician by entering and adjusting settings as directed by the surgeon.³⁶⁸ During the surgery, the physician asked the representative to recommend appropriate settings for the device, which the representative provided.³⁶⁹

363. *Id.* at *6.

364. *Id.* at *6.

365. *See id.* at *6.

366. *See id.* at *1.

367. No. 200000171, 2004 WL 2341569, at *8 (Mass. Super. Ct. Sept. 24, 2004).

368. *See id.* at *3.

369. *See id.* at *5.

In both *Zappola* and *Chamian*, the courts appeared to place great significance on the fact that the physician consulted with the sales representative during surgery regarding medical decisions relating to the device at issue. The presence of the sales representative in the operating room was also a major factor. However, as the next section will show, other courts have taken a different view, finding that physicians are the “captain of their ship” and thus responsible for all medical decisions that they make.

C. *Captain of the Ship Doctrine*

The captain of the ship doctrine relies on many of the same justifications as the learned intermediary doctrine and provides that a “licensed physician is the principal or master while performing medical services within a hospital.”³⁷⁰ On the other hand, hospital personnel assisting under the surgeon’s control are borrowed servants, and thus, the surgeon is liable for their negligence once he or she assumes control in the operating room.³⁷¹ An example of application of the captain of the ship doctrine to medical device sales representatives is evident in *O’Connell v. Biomet, Inc.*, where the Colorado Court of Appeals upheld the trial court’s decision that a sales representative present during a surgical procedure was an agent of a doctor, who was the “captain of the ship” and in control of the surgery.³⁷² The court described the roles of the surgeon and the sales representative:

The sole purpose of [the sales representative] being in the operating room was to provide [the surgeon] with information about the [device], which information [the surgeon] then used to make his medical judgments. That is, [the surgeon] remained in control of the surgery vis-à-vis [the sales representative] and all other non-physicians in the operating room. Because [the surgeon] remained in control of the surgery, anything [the sales representative] might have done during that surgery, including any advice he allegedly gave or should have given to [the surgeon], was done as a crew member, so to speak, of the surgical ship.³⁷³

Because the sales representative in this case was the doctor’s agent

370. *O’Connell v. Biomet, Inc.*, 250 P.3d 1278, 1283 (Colo. App. 2010).

371. *Id.*

372. *Id.* at 1283–84.

373. *Id.*

during the surgery and the plaintiff settled his claims against the doctor, the appellate court affirmed the trial court's dismissal of the claims against the sales representative.³⁷⁴

Courts have applied the reasoning behind the captain of the ship doctrine to defeat claims attacking a sales representative's statements for failure to warn.³⁷⁵ In *Hall v. Horn Medical, L.L.C.*, the plaintiff alleged that a sales representative negligently represented to a doctor that an intradiscal cage device could be used without performing a bone graft, despite the fact that the written warnings accompanying the device explicitly stated that the device was intended to be used with a bone graft.³⁷⁶ Plaintiff sued the surgeon for medical malpractice and the sales representative for negligent misrepresentation.³⁷⁷ The implanting doctor testified that he would not have implanted the device without a bone graft if the sales representative had not told him that this was an acceptable off-label use.³⁷⁸ Not surprisingly, the sales representative denied ever recommending the device for a use that was not only off-label, but affirmatively contraindicated by the written warnings.³⁷⁹ However, the court found that—even if the sales representative told the implanting doctor that he could use the device without a bone graft—any reliance by the doctor on that statement was unreasonable as a matter of law.³⁸⁰ In reaching this conclusion, the court reasoned “[a]s a seasoned neurosurgeon, it is patently unreasonable for [the implanting surgeon] to rely on a sales representative's opinion about the type of procedure that should be employed in operating on a patient's spine.”³⁸¹

Accordingly, because a physician is the “captain of the ship” when it comes to making medical decisions regarding a patient's surgery, defendant manufacturers will want to argue that any reliance on representations made by a sales representative—who has neither the medical experience nor education of a physician—about issues dealing with medical care is per se unreasonable.

374. *Id.* at 1284.

375. *See, e.g., Hall v. Horn Med., L.L.C.*, No. 11-1032, 2012 WL 1752546 (E.D. La. May 16, 2012).

376. *Id.* at *1–3.

377. *Id.* at *1.

378. *Id.* at *3.

379. *Id.* Promotion of off-label use is strictly prohibited by federal regulations and sales representatives have been prosecuted for violation. *See supra* Part II.

380. *Hall*, 2012 WL 1752546, at *3.

381. *Id.*

D. Lack of Causation

Challenging causation has also been an effective defense for medical device manufacturers facing claims based on the conduct of their sales representatives. It is a basic principle of tort law that a plaintiff must show that a defendant's actions proximately and actually caused the plaintiff's injury.³⁸² Accordingly, courts have been disinclined to allow claims to proceed past summary judgment where the plaintiff cannot show that a sales representative's mere presence in an operating room was causally related to the injury the plaintiff suffered.³⁸³ This is especially true if the sales representative did not participate in the decision making during the procedure and if his role was primarily to provide technical support.³⁸⁴ For claims attacking instructions or representations that a sales representative made, the plaintiff must allege and show that the sales representative's alleged negligence caused the plaintiff's injuries, rather than some other cause such as medical malpractice or a defect in the device—the latter of which is often found to be preempted.³⁸⁵ Causation arguments have also been successfully asserted by defendants against allegations that they failed to adequately report adverse events, even if a sales representative is present at a surgery.³⁸⁶

A defense based on causation is also available to defend against a failure to warn claim where the “failure of the manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is not the proximate cause of a patient's injury [because] the prescribing

382. See generally RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM §§ 26–28 (2010).

383. See, e.g., *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1291–92 (M.D. Fla. 2009), *aff'd*, 634 F.3d 1296 (11th Cir. 2011).

384. See *id.* at 1291 (“The undisputed facts show that [the sales rep] did not participate in the decision-making during [the] procedure. [His] role was limited to carrying ‘back up’ products in their sterile packages to have available for the surgeon's use, if necessary, and to observe preparation of the products. [He] did not ‘scrub in’ for the procedure . . . and did not enter the sterile field.”).

385. See *Adkins v. Cytoc Corp.*, No. 4:07CV00053, 2008 WL 2680474, at *3 (W.D. Va. July 3, 2008) (dismissing plaintiff's complaint because it was equally possible that faults in the medical device caused plaintiff's damages rather than negligent instruction by the physician); see also *supra* Part III (discussing preemption in the context of medical device cases).

386. Cf. *Rollins v. St. Jude Med.*, 583 F. Supp. 2d 790, 803–04 (W.D. La. 2008) (dismissing plaintiff's claims that defendant manufacturer failed to properly report adverse events unrelated to plaintiff's surgery because plaintiff failed to allege how this alleged failure caused her injuries).

physician had independent knowledge of the risk that the adequate warning should have communicated.”³⁸⁷ In other words, “the causal link between a patient’s injury and the alleged failure to warn is broken when the prescribing physician had ‘substantially the same’ knowledge as an adequate warning from the manufacturer should have communicated to him.”³⁸⁸ Therefore, to succeed with a failure to warn claim, the plaintiff must demonstrate that the alleged warning that the sales representative should have provided concerned a matter outside of the physician’s knowledge. Furthermore, some courts have taken an even more expansive view and found that “a medical device manufacturer has no duty to warn physicians of a device’s dangers which the medical community generally appreciates.”³⁸⁹

Courts have also generally recognized that plaintiffs cannot show causation where the physician testifies that he or she would have still prescribed the drug or device even with a stronger warning, such as when the physician never read the warning that accompanied a device.³⁹⁰ However, courts are sometimes hesitant to let a device manufacturer off the hook just because a physician did not read materials accompanying the device. In the recent decision in *Bonander v. Breg*, the court refused to grant summary judgment on the plaintiff’s strict liability and failure to warn claims despite the fact that the doctor who inserted the pain pump in the plaintiff’s shoulder testified that he did not read the pain pump’s package insert.³⁹¹ The court in *Bonander* ruled that there remained a genuine issue of fact whether warnings from, *inter alia*, the defendant’s sales representatives to the physician would have

387. *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995); *see also* *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1365 (S.D. Fla. 2007) (quoting *Christopher*, 53 F.3d at 1192).

388. *Christopher*, 53 F.3d at 1192; *see also* *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (“[T]he manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk.”).

389. *Hansen v. Baxter Healthcare Corp.*, 723 N.E.2d 302, 312 (Ill. App. Ct. 1999).

390. *See* *Johnson v. Zimmer, Inc.*, No. 02-1328 JTNFLN, 2004 WL 742038, at *10 (D. Minn. Mar. 31, 2004) (finding that where the physician testified that he never saw the warnings that accompanied the device, causation for plaintiff’s failure to warn claim does not exist as a matter of law); *cf.* *Motus v. Pfizer Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (“[A] product defect claim based on insufficient warnings cannot survive summary judgment if stronger warnings would not have altered the conduct of the prescribing physician.”).

391. *Bonander v. Breg, Inc.*, No. 09-2795 (JRT/JJK), 2012 WL 4128386, at *4 (D. Minn. Sept. 18, 2012).

prevented the plaintiff's injuries.³⁹² One particularly problematic aspect of this opinion is that the physician testified that he did not rely on medical device companies to provide information regarding the risks and benefits of a medical device.³⁹³ In essence, this opinion states that if there is any chance that the implanting physician possibly could have heeded a different warning, then a plaintiff's claims may be able to survive a motion for summary judgment. Thus, while causation arguments generally may provide a safe-haven for medical device manufacturers faced with claims involving sales representative conduct, the manufacturer should be aware of exceptions that may exist in the applicable jurisdiction.

In a recent medical device case involving claims against both the medical device manufacturer of an intrathecal neurostimulator and the sales representative, the defendants argued that the learned intermediary doctrine precluded plaintiffs' claims, the defendants did not owe a duty to plaintiffs, and plaintiffs did not present evidence that any representations made by the sales representative in the operating room caused plaintiffs' injuries.³⁹⁴ Plaintiffs' original petition alleged that "[a]s a result of the fraudulent and negligent acts of Defendants Medtronic, Inc. and [Medtronic's representative], the Plaintiffs suffered permanent and irreversible injuries."³⁹⁵ Specifically, the defendants "intentionally misrepresented the efficacy and necessity of their Medtronic medical device," causing the plaintiff to undergo an unnecessary surgical procedure.³⁹⁶ The plaintiffs alleged that Medtronic's representative told the plaintiffs "that he was there to make everything safe" and he and another representative "portrayed themselves as medical consultants and made recommendations" to the plaintiffs.³⁹⁷ Plaintiffs also sued the implanting physician, Peter Lotze.³⁹⁸ Medtronic and its sales representative moved for summary judgment, arguing that the plaintiffs' physician, Dr. Lotze, was responsible for all patient, clinical, medical, and surgical decisions

392. *See id.*

393. *See id.*

394. *See* Defendants Medtronic, Inc. & Stuart Ison's Traditional & "No Evidence" Motion for Summary Judgment & Supporting Memorandum of Law at 2-3, *Howton v. Medtronic, Inc.*, No. 2009-47341 (Tex. Dist. Ct. Mar. 31, 2011) [hereinafter Defendants' Traditional & "No Evidence" Motion].

395. Plaintiffs' Original Petition at 3, *Howton*, No. 2009-47341 (July 27, 2009).

396. *Id.*

397. *Id.* at 10.

398. *See id.* at 26-27.

and, thus, the learned intermediary doctrine barred plaintiffs' claims.³⁹⁹ Defendants also attacked the plaintiffs' negligence claims, arguing that Medtronic and the sales representative owed no duty to the plaintiffs and there was no evidence establishing the element of causation.⁴⁰⁰

Plaintiffs countered that the learned intermediary doctrine did not apply to this case because there was a direct misrepresentation regarding the medical device's alleged dangerous propensities to the consumer.⁴⁰¹ Plaintiffs also argued that their claims were not negligence claims, but were instead fraud claims.⁴⁰² The case ultimately went to trial on the question of whether Medtronic and its sales representative committed fraud against the plaintiff.⁴⁰³ After an approximately one-month long trial, the jury found Medtronic and its sales representative not liable to the plaintiffs for fraud.⁴⁰⁴ While the plaintiffs were able to avoid application of the learned intermediary doctrine, absence of duty, and causation defenses to their claims by couching them as fraud claims instead of negligence claims, this strategy ultimately proved unsuccessful at trial.

VI. CONCLUSION

Medical devices are becoming increasingly complex in technology and often require specific training or special knowledge or experience to be used effectively in patient treatment. Further, physicians are faced with several competing options in terms of medical devices available for a particular patient condition. It is not surprising then that medical device representatives are increasingly requested to attend surgeries or to offer technical information, support, or assistance regarding the device. The

399. See Defendants' Traditional & "No Evidence" Motion, *supra* note 394, at 9, 27–28 (referring to the district court's order granting Plaintiffs' Notice of Partial Nonsuit of Defendant Peter Lotze, M.D., *Howton*, No. 2009-47341 (Mar. 18, 2011), which dismissed Lotze).

400. See *id.* at 30, 32–35.

401. See Plaintiffs' Response to Defendants Medtronic, Inc. & Stuart Ison's Traditional & "No Evidence" Motion for Summary Judgment at 12–14, *Howton*, No. 2009-47341 (Apr. 18, 2011); see also Plaintiffs' Sur-Reply to Defendants Medtronic, Inc. & Stuart Ison's Reply in Support of their Traditional & "No Evidence" Motion for Summary Judgment at 5–6, *Howton*, No. 2009-47341 (Apr. 26, 2011) [hereinafter Plaintiffs' Sur-Reply].

402. See Plaintiffs' Sur-Reply, *supra* note 401, at 1.

403. See Jury Charge at 3, *Howton*, No. 2009-47341 (June 3, 2011).

404. See *id.*

increasing technical need for medical device sales representatives coupled with an increase in government enforcement actions and post-*Riegel* civil products liability actions involving sales representative conduct is rapidly changing liability issues faced by medical device sales representatives.

Not only must medical device manufacturers be aware of new claims related to their sales representatives, but the manufacturers and their outside counsel must develop new defenses and defense strategies. An analysis of recent relevant case law reveals several practical steps that a manufacturer and its counsel can take to assist in the defenses of these claims. For example, coordination between counsel handling government enforcement actions and civil products liability actions is key to consistent positions and defenses for the manufacturer. In addition, it is possible that individual sales officers or directors may have counsel or may need counsel separate from that of the manufacturer, with whom coordination will also be necessary, particularly as it relates to any testimony by the sales officer or director. Depending on the procedural posture, products liability counsel may want to approach the court regarding coordination in terms of timing of discovery and trial with the government enforcement action. Further, outside products liability counsel must be prepared to move to exclude or limit evidence of irrelevant government enforcement actions in civil actions.

At the outset of a case, counsel should examine the complaint to determine if removal to federal court is possible based on a fraudulent joinder argument as to the diversity-defeating sales representative. A fraudulent joinder argument is most likely to succeed in cases where: (1) the complaint lacks detailed allegations as to the sales representative; (2) the learned intermediary argument is particularly strong in the applicable jurisdiction; (3) an affidavit from the sales representative or the prescribing physician establishes that there is no colorable claim against the sales representative; and (4) the sales representative is not considered a seller and could not otherwise be held liable under the applicable state products liability statute.

Further, as a first line of defense in products liability actions involving sales representative conduct, when a PMA-approved device is involved, counsel should consider an early dispositive motion based on *Riegel* preemption. Counsel should be aware of the most recent decisions both within the jurisdiction and outside

the jurisdiction and be ready to distinguish those cases finding an issue of fact. Cases involving detailed allegations of actual actions taken or representations made by the sales representative, particularly in the off-label promotion context, may be more difficult to resolve on a preemption dispositive motion.

Should a *Riegel*-preemption argument not be feasible or successful, manufacturers and their counsel should be prepared to proceed to discovery with an eye towards establishing support for key defenses to claims involving sales representatives: the learned intermediary doctrine, captain of the ship, lack of duty, and lack of causation. There is no general consensus among the courts regarding application of the learned intermediary doctrine or the captain of the ship doctrine, and arguments regarding duty and causation fall on both sides of the liability spectrum. Ultimately, each case must be examined closely based on the facts to determine if there is a real danger of liability based on the representative's involvement in the patient's care. In recent years, there have been few sales representative cases that proceeded to trial, but those that have met with overall success for manufacturers. Keys to success for either a dispositive motion—based on the learned intermediary doctrine, captain of the ship, lack of duty, and lack of causation—or at trial, not surprisingly, include strong testimony at deposition by the sales representative as well as the prescribing physician. Understanding the nuances of the applicable jurisdiction's case law related to these defenses in advance of these key depositions is necessary in order to obtain the helpful testimony needed. Even if a dispositive motion or trial is not successful, manufacturers and their counsel have been successful challenging the verdicts or negative decisions of the trial courts on appeals.

Consequently, while the increase in government enforcement actions involving sales personnel and the post-*Riegel* environment have given rise to novel claims and liability concerns involving sales representatives, manufacturers and their counsel can defend and resolve these claims successfully through preparation and novel defense strategy approaches.