

SIDE EFFECTS: STATE ANTI-FRAUD STATUTES, OFF-LABEL MARKETING, AND THE SOLVABLE CHALLENGE OF CAUSATION

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*While the American public remains preoccupied with the lurching implementation of the Affordable Care Act, the regulation of pharmaceutical companies for their off-label marketing and promotion of drugs features a regulatory environment within the health industry that seems to be in wild flux. Following the Second Circuit's decision in *United States v. Caronia*, commentators and providers are unsure about the future of federal regulation in this area, with the FDA seeking to minimize the opinion and pharmaceutical companies celebrating its impact. Much of the understandably spirited reaction to the *Caronia* case has omitted a discussion of the relevant and applicable state-law remedies at the disposal of state attorneys general that seek to punish and prevent the off-label marketing of pharmaceutical drugs. Of particular import, the years-long saga of allegations surrounding Johnson & Johnson (and its subsidiary, Janssen) and its allegedly off-label marketing of the powerful antipsychotic drug, Risperdal, have illustrated the potential of fraud-based state regulation of off-label marketing. Indeed, when an Arkansas jury imposed a \$1.2 billion judgment against the pharmaceutical giant, all took pause, and—even though the jury verdict was ultimately overturned—the case illustrated the potential for wide liability at the state level for pharmaceutical companies following allegedly deceptive marketing practices.*

Besides opening the potential for more state lawsuits in this area, this added attention has also exhibited the still largely unsettled and confusing analysis that occurs when courts review allegations that off-label marketing “caused” a physician to write a prescription and harmed the state Medicaid programs. The courts’ conceptions of causation in these cases seem to rely

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on a view of the physician as impenetrably independent—flying in the face of social science research, the financial success of off-label marketing, and day-to-day pressures on the physicians imposed by the modern administration of health care delivery. Courts cling to these views to the detriment of these states’ Medicaid programs and, indeed, to the benefit of pharmaceutical companies allegedly engaged in off-label marketing. As a result, the causation question has imposed a substantial roadblock to liability at the state level.

Presenting alternative conceptions of causation and evidence to dispute the independence of physicians, this Article advocates for the application of well-worn causation principles to these cases, borrowed primarily from federal courts and the common law of torts to make the argument that states can regulate off-label marketing using these remedial anti-fraud statutes. Ultimately, this Article seeks to unhinge state litigation from the outmoded view of impenetrable physician independence and open up a viable alternative regulatory path in an attempt to prevent the overwhelmingly lucrative practice of deceptive off-label marketing.

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INTRODUCTION

In December 2012, when the Second Circuit overturned the conviction¹ of Alfred Caronia for marketing Orphan Medical’s Xyrem for an off-label use, doctors,² commentators,³ and the academy⁴ called it the “end” of the FDA’s ability to regulate off-label promotion. Some argued the “fundamentally flawed”⁵ decision “destroy[ed]”⁶ drug regulation; accordingly, members of the Pharmaceutical and Research Manufacturers of America (PhRMA) were “pleased,”⁷ and, predictably, defense counsel cheekily noted that 2012 “ended on a high note with the

¹ See *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). Alfred Caronia “was convicted of conspiring to introduce a ‘misbranded’ drug into interstate commerce” in violation of the Food, Drug, and Cosmetic Act. *Id.* at 169 (Livingston, J., dissenting).

² See John Fauber, *Court Ruling May Open Door to More Drug Marketing*, MILWAUKEE J. SENTINEL (Dec. 4, 2012), <http://www.jsonline.com/news/milwaukee/court-ruling-may-open-door-to-more-drug-marketing-3p7tatn-182073791.html> (quoting Cleveland Clinic cardiologist Steven Nissen as saying “[o]ff-label promotion is not about free speech—it is the medical equivalent of yelling fire in a crowded auditorium,” and quoting New York psychiatrist Andrew Kolodny as saying, “[t]his is going to get much worse,” and that “[i]t’s a safe bet that health outcomes will decline from medication side effects, while spending on prescription drugs will continue to rise”).

³ See, e.g., *id.* (noting that Public Citizen doctor Sidney Wolfe “said the decision will further weaken the FDA”); David Lazarus, *Appeals Court Puts 1st Amendment over Public Health*, L.A. TIMES, Dec. 7, 2012, <http://articles.latimes.com/2012/dec/07/business/la-fi-lazarus-20121207> (calling the decision a “serious blow . . . to the . . . [FDA’s] power”).

⁴ See Lazarus, *supra* note 3 (noting University of Minnesota Professor Steven Miles called the decision “a complete disgrace” and commented that “[w]hat this basically does is destroy drug regulation in the United States”). University of Southern California Professor Alexander Capron said that “[t]he danger to consumers is that a drug will be marketed without having the relative balance between efficacy and safety adequately addressed.” *Id.*; see also Aaron S. Kesselheim & Michelle M. Mello, *Prospects for Regulation of Off-Label Drug Promotion in an Era of Expanding Commercial Speech Protection*, 92 N.C. L. REV. 1539, 1573 (2014) (“[T]he Caronia decision marks another setback (following on *Sorrell*) in the government’s effort to limit dangerous public health outcomes from non-evidence-based industry marketing.”); Christopher Robertson, Essay, *When Truth Cannot Be Presumed: The Regulation of Drug Promotion Under an Expanding First Amendment*, 94 B.U. L. REV. 545, 554 (2014) (“Now, if such spoken words are off limits for regulators, the products themselves fall outside the regulation of drugs, and into the no-man’s land of medical quackery, which motivated the enactment of the FDCA in the first place.”).

⁵ See Lazarus, *supra* note 3.

⁶ *Id.*

⁷ John Fauber, *Court: Off-Label Drug Marketing Is ‘Free Speech’*, MEDPAGE TODAY (Dec. 4, 2012), <http://www.medpagetoday.com/PublicHealthPolicy/FDAGeneral/36256>.

much anticipated and potentially game changing decision in *United States v. Caronia*.⁸ In short, there was no shortage of reaction.

Granted, it was not an uncontroversial opinion. Recognizing Mr. Caronia's First Amendment rights to engage in truthful, but off-label, marketing, the court concluded that the sales representative could not be prosecuted for conspiracy to sell a misbranded drug. Of interest in the decision was the court's conclusion that the Food, Drug, and Cosmetic Act (FDCA) did not criminalize truthful off-label marketing of prescription drugs.⁹ Perhaps characterizing its finding as something more straightforward and innocuous than it was, the court ended its decision by stating 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."¹⁰

But it was not the end of off-label regulation¹¹—indeed, as attention focused on *Caronia*, which involved truthful off-label marketing, a parallel regulatory framework was being powerfully employed for other allegations of off-label marketing at the state level. In fact, eight months *before* the Second Circuit "shook the healthcare bar"¹² in *Caronia*, a twelve-member jury in Pulaski County, Arkansas, shook pharmaceutical companies nationwide by finding Janssen Pharmaceuticals, Inc. (Janssen), a wholly-owned subsidiary of Johnson & Johnson (J&J), liable to the state of Arkansas for \$1.2 billion for the misleading off-label marketing of Risperdal,¹³ a powerful antipsychotic

⁸ Anthony H. Choe, Column, *Looking Ahead: Key Takeaways for Manufacturers from the OIG's Work Plan for 2013*, 15 No. 2 J. HEALTH CARE COMPLIANCE 37 (2013).

⁹ *United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012).

¹⁰ *Id.* at 169.

¹¹ Indeed, federal court decisions following the *Caronia* decision did not cite it approvingly. See *McDonald-Lerner v. Neurocare Assocs., P.A.*, No. 373859-V, 2013 WL 7394926, at *8 (Md. Cir. Ct. Aug. 29, 2013) ("As noted by the dissent, the majority's view was ill-considered and effectively would gut the FDA's labeling regulations and premarket approval process for drugs [and medical devices] for specific uses. But even if the two-judge majority is correct, its holding is limited to criminal prosecutions. Similar first amendment concerns do not apply to civil cases." (alteration in original) (citation omitted)). The federal government has maintained that *Caronia* does not apply to FCA allegations. See Statement of Interest of the United States of America, *United States ex rel. Cestra v. Cephalon, Inc.*, No. 10 Civ. 6457 (SHS) (S.D.N.Y. Nov. 7, 2013), ECF No. 83 ("[T]he United States submits this Statement of Interest to advise the Court of its position that the Second Circuit's recent decision in . . . *Caronia*[] does not preclude a cause of action under the False Claims Act based on a manufacturer's off-label marketing of a prescription drug causing the submission of false claims to the federal health care programs. . . . As such, the case before this Court does not implicate the First Amendment concerns raised in *Caronia*.").

¹² See Veronica B. Nannis, *What Effect Will United States v. Caronia Have on Civil Off-Label Cases?*, 9 ABA HEALTH ESOURCE (Apr. 2013), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1304_nannis.html.

¹³ *State v. Ortho-McNeil-Janssen Pharm., Inc.*, No. CV 2007-15345, 2012 WL 1669840 (Ark. Cir. Ct. May 9, 2012); see also *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563, 570 (Ark. 2014). Throughout this analysis, "J&J" will be used to refer to the pharmaceutical company Johnson & Johnson. Janssen has been described as a "unit" of J&J. See Jef Feeley, *J&J Gets \$1.2*

drug.¹⁴ The jury found that the company had violated the Arkansas Medicaid False Claims Act, a twenty-two year old law that prevents the “knowing” submission of false claims to a state or federal entity.¹⁵ The verdict constituted three times the annual shortfall amount of the Arkansas Medicaid program.¹⁶ Nonetheless, less than two years later, the Arkansas Supreme Court would overturn the jury’s finding, absolving J&J and Janssen of any legal liability to the state.¹⁷

The same thing happened, under the same facts, regarding the same Janssen drug, in Louisiana. In early 2014, the Supreme Court of Louisiana overturned a \$330 million finding against Janssen for its misleading marketing of Risperdal.¹⁸ The court found Janssen not liable under the Louisiana Medical Assistance Programs Integrity Law (MAPIL), holding that MAPIL was not violated “because no evidence was presented that any defendant made or attempted to make a fraudulent claim for payment against any Louisiana medical assistance program within the scope of MAPIL.”¹⁹ Only one state supreme court—in South Carolina—has upheld a jury verdict against the companies, but only after substantially reducing the penalty amount.²⁰

Indeed, notwithstanding *Caronia* and the Arkansas and Louisiana Supreme Court cases, the regulation of off-label marketing has continued to be lucrative for both the federal and state governments. By November 2013, J&J had entered into its second nationwide settlement over Risperdal, this one for \$2.2 billion to resolve claims with the DOJ that it violated the federal False Claims Act (FCA), and to resolve various claims—many of them either consumer protection-focused or fraud-based—with forty-five different states.²¹ These swings in liability and the *means* by which off-label marketing is regulated—from the Arkansas, Louisiana, and South Carolina juries; to *Caronia*; to the

Billion Arkansas Risperdal Verdict Tossed, BLOOMBERG (Mar. 20, 2014, 2:23 PM), <http://www.bloomberg.com/news/2014-03-20/j-j-gets-1-2-billion-arkansas-risperdal-verdict-tossed.html>.

¹⁴ See *Risperdal (risperidone)*, NAT’L ALLIANCE ON MENTAL ILLNESS, http://www.nami.org/Template.cfm?Section=About_Medications&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=51&ContentID=20703 (last visited June 1, 2015).

¹⁵ See ARK. CODE ANN. § 20-77-901 (West 2015); *Ortho-McNeil-Janssen Pharm.*, 2012 WL 1669840.

¹⁶ See Chuck Bartels, *Arkansas Judge Fines J&J \$1.1B in Risperdal Case*, YAHOO! NEWS (Apr. 11, 2012, 7:37 PM), <http://news.yahoo.com/arkansas-judge-fines-j-j-1-1b-risperdal-151614143.html> (noting that Arkansas was “facing a projected \$400 million deficit” in its Medicaid program).

¹⁷ See *Ortho-McNeil-Janssen Pharm.*, 432 S.W.3d at 580; see also Feeley, *supra* note 13.

¹⁸ See *Caldwell ex rel. State v. Janssen Pharmaceutica, Inc.*, 144 So. 3d 898 (La. 2014).

¹⁹ *Id.* at 901.

²⁰ See *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 27502, 2015 WL 775094 (S.C. Feb. 25, 2015); Peter Loftus, *States Take Drug Makers to Court Over Marketing*, WALL ST. J. (Apr. 22, 2013, 6:46 PM), <http://www.wsj.com/articles/SB10001424127887323361804578388873516625506>.

²¹ See discussion and accompanying notes *infra* Part II.

Arkansas and Louisiana supreme courts; to the multibillion-dollar settlement—has made for an unpredictable time for the regulation of pharmaceutical off-label marketing. Not only are the rules in flux but, it appears, the primary regulating entity for off-label promotion—whether that be the Food and Drug Administration (FDA), the Department of Justice (DOJ), or state attorneys general—seems to be shifting as well, with unpredictable and inconsistent results playing out at state court.

This Article highlights and explores these shifts, through the usage of the case study of Risperdal. Indeed, regulation at the state level for off-label marketing has become a powerful force in the overall regulatory scheme and, as states face Medicaid shortfalls²²—the battle at the state level will likely become more important. Most simply, this Article seeks to bring additional attention to the state regulation of off-label marketing.

Specifically, in analyzing the state-based regulatory scheme, this Article focuses on the state cases that, due to their conceptions of causation in these off-label marketing cases, found in favor of J&J and Janssen on the Risperdal claims. A formidable hurdle in these claims—called by one judge the “internal causal nexus quandary”²³—this Article documents these causation analyses. The courts’ conceptions of causation in these cases seem to rely on a view of the physician as impenetrably independent—flying in the face of social science research, the financial success of off-label marketing, and testimony from physicians themselves—to the detriment of these states’ Medicaid programs and, indeed, to the benefit of pharmaceutical companies allegedly engaged in off-label marketing. As a result, the causation question has imposed a substantial roadblock to liability in these states, preventing them from imposing liability against pharmaceutical companies for engaging in allegedly deceptive practices.

Finally, this Article builds on previous work in this area by other scholars, primarily seeking to present alternatives to move past these conceptions of physicians as impenetrably independent in an effort to free up the fraud-based regulatory path for state attorneys general. Presenting alternative conceptions of causation and evidence to dispute the independence of physicians, this Article advocates the application of well-worn causation principles, borrowed from federal courts and the common law of torts, to make the argument that states *can* regulate off-label marketing using their remedial anti-fraud statutes.

This Article makes these points in five main parts. Part I summarizes the states’ statutory framework—whether it be consumer

²² See *State Budget Shortfalls, SFY2013*, HENRY J. KAISER FAM. FOUND., <http://kff.org/other/state-indicator/state-budget-shortfalls-sfy13> (last visited June 1, 2015).

²³ *Commonwealth v. Ortho-McNeil-Janssen Pharm. Inc.*, No. 2181, 2010 WL 3548474, at *204 (Pa. Ct. Com. Pl. June 25, 2010).

protection or fraud-based. Part II documents the facts that states alleged against J&J and Janssen concerning the marketing of Risperdal, a drug approved to treat schizophrenia. Part III presents cases where the states elected to take J&J and Janssen to trial, with an emphasis on the states in which causation was a fatal roadblock to the allegations. Part IV consults federal court decisions in this area to present potential alternatives to the causation question. And finally, Part V explores exactly *why* and *how* the courts' conceptions of causation should be changed, with a particular focus on the downfall of the independent physician narrative.

I. DECEPTIVE TRADE PRACTICE OR FALSE CLAIM

Aside from various common law actions, state attorneys general have relied upon two remedial statutory schemes in targeting off-label pharmaceutical marketing at the state level.²⁴ They have pursued pharmaceutical companies under either (1) a consumer protection-based scheme, in which they allege that the pharmaceutical company's marketing efforts deceived consumers (likely either prescribing physicians or authors of state Medicaid drug formularies) in their state; or (2) a fraud-based scheme, in which they generally argue that by engaging in off-label marketing that results in a payment by Medicaid for an off-label usage, the pharmaceutical company committed fraud against the state. Both schemes can prove quite lucrative for the state and, conversely, quite expensive for the pharmaceutical company engaged in the off-label marketing scheme. Depending on the state code, the attorney general may not have to choose; indeed, states can often rely on either—or both—of these schemes in order to impose liability.

States with robust consumer protection statutes—many loosely modeled off of the Federal Trade Commission Act²⁵ (FTCA)—can pursue consumer protection-based actions against pharmaceutical companies for off-label marketing. In these cases, the state argues that, due to its off-label marketing, the company has engaged in a *deceptive* or

²⁴ See Lise T. Spacapan & Jill M. Hutchison, *Prosecutions of Pharmaceutical Companies for Off-Label Marketing: Fueled by Government's Desire to Modify Corporate Conduct or Pursuit of a Lucrative Revenue Stream?*, 22 ANNALS HEALTH L. 407, 432–35 (2013) (summarizing the states' prosecutions relating to Risperdal as either consumer protection based or fraud based). Notably, attorneys general can also bring common law claims of fraud, misrepresentation, or negligence. See *id.* at 432; see also discussion *infra* Part III.D (noting that the Commonwealth of Pennsylvania asserted common law fraud, negligence, and misrepresentation in addition to the statutory fraud-based and consumer protection-based claims).

²⁵ See 15 U.S.C. §§ 41–58 (2012). But see Henry N. Butler & Joshua D. Wright, *Are State Consumer Protection Acts Really Little-FTC Acts?*, 63 FLA. L. REV. 163 (2011) (concluding that the federal and state acts have different goals and results).

unfair practice that has affected commerce in some way. Just by engaging in off-label marketing, the argument goes, commerce is adversely affected.²⁶ In consumer protection-based claims, it could be either (1) the prescribing provider, or (2) the state Medicaid program, that is misled and “duped.”²⁷ Here, the pharmaceutical company harms the marketplace due to its alleged marketing of a drug for non-FDA-approved uses.

This is different than in fraud-based claims, where the theory of liability implicitly *depends* upon the action of the provider—he has to write a prescription for the drug in order to demonstrate that the pharmaceutical company caused a false claim to be presented to the government for payment. Indeed, states pursue fraud-based claims against pharmaceutical companies for off-label marketing, arguing that the government payer—typically Medicaid—was defrauded when it paid for prescriptions that were written by physicians who were the target of off-label marketing. Thus, in the fraud-based regime, the provider is a *necessary party* in order to maintain the causal chain between the pharmaceutical company and the government payer. In these cases, the argument focuses on the fact that the pharmaceutical company *caused* or *induced* a false or fraudulent claim to be presented to the government—indeed, often the Medicaid program—when they engaged in off-label marketing that targeted the particular health care provider.²⁸

Both strategies can theoretically apply regardless of whether the off-label marketing is actually scientifically accurate.²⁹ Crafted in the shadow of the federal FCA arguments, this strategy features an

²⁶ See, e.g., *Federal Trade Commission Act*, FED. TRADE COMM’N, <http://www.ftc.gov/enforcement/statutes/federal-trade-commission-act> (last visited June 1, 2015) (noting the Federal Trade Commission’s rights under the statute).

²⁷ See, e.g., Jef Feeley & Margaret Cronin Fisk, *J&J Duped Arkansas Doctors over Risperdal, Lawyer Tells Jury*, BLOOMBERG (Mar. 27, 2012, 1:20 PM), <http://www.bloomberg.com/news/2012-03-27/j-j-duped-arkansas-doctors-over-risperdal-lawyer-tells-jury-1-.html>; Jef Feeley, *J&J Duped South Carolina Doctors over Risperdal, Lawyer Says*, BLOOMBERG (Mar. 21, 2011, 5:38 PM), <http://www.bloomberg.com/news/2011-03-21/j-j-duped-south-carolina-doctors-over-antipsychotic-risperdal-lawyer-says.html>.

²⁸ At the federal level, this theory owes its roots to *United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651PBS, 2003 WL 22048255 (D. Mass. Aug. 22, 2003), which led to the first settlement of off-label marketing allegations under the FCA. See Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41, 60-61 (2005) (“The court recognized a viable cause of action because of evidence that the defendant engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid.” (internal quotation marks omitted)).

²⁹ See Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1035 (2012) (noting the criticism the government has received “for targeting pharmaceutical manufacturers that are marketing their drugs by distributing truthful scientific and medical information on unapproved uses of the drugs”); Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 FOOD & DRUG L.J. 653 (2006) (arguing that the False Claims Act should not apply to truthful off-label promotion).

argument that once the provider seeks reimbursement for a drug that has been prescribed for an off-label usage—following its illegal marketing for that off-label usage—analytically, the claim is tainted, no matter the truth or scientific defensibility of the off-label marketing. The fact that the pharmaceutical company engaged in off-label marketing provides the falsity sufficient to allege a fraud claim.

A. *The Importance of Causation in Fraud-Based Regulation*

For fraud-based claims, where the falsity can be easily demonstrated, it is the *causation* question that has proven difficult for state attorneys general. As seen from recent cases in different states, the causation challenge can prove fatal to a state's fraud-based claim. Specifically, under the courts' various conceptions of causation, it is difficult for the state to prove that the provider prescribed the medication for the off-label usage *due to* the off-label and illegal marketing. Indeed, in order to demonstrate the causation required, neither the physician nor the pharmacist involved in prescribing and filling the prescription can be "considered an independent actor sufficient to break the causal chain between the pharmaceutical company's illegal off-label promotion and the submission of a false claim."³⁰

That states have relied on anti-fraud statutes has been unsurprising; the federal government has provided direct additional financial incentives to the states to create their own state "false claims acts." Generally, when a state achieves a settlement or assesses a penalty "relating to false or fraudulent claims" under its Medicaid program, "it must share the recovery with the Federal Government in the same proportion as the Federal medical assistance percentage,"³¹ which is the percentage of "matching funds" that the federal government pays for that state's Medicaid program.³² But as part of the Deficit Reduction Act of 2005 (DRA),³³ the federal government "create[d] a financial incentive

³⁰ Jennifer L. Herbst, *The Short-Sighted Value of Inefficiency: Why We Should Mind the Gap in the Reimbursement of Outpatient Prescription Drugs*, 2 CASE W. RES. J.L. TECH. & INTERNET 1, 22–23 (2011).

³¹ See U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., UPDATED: OIG GUIDELINES FOR EVALUATING STATE FALSE CLAIMS ACTS 2–3 (2013) [hereinafter OIG GUIDELINES], available at <https://oig.hhs.gov/fraud/docs/falseclaimsact/guidelines-sfca.pdf> ("For example, if the State's Medicaid share is 50 percent, the State would be entitled to 60 percent of the amount of the recovery, while the Federal Government would be entitled to 40 percent.").

³² See *Federal Medical Assistance Percentages or Federal Financial Participation in State Assistance Expenditures (FMAP)*, OFF. ASSISTANT SECRETARY FOR PLAN. & EVALUATION, U.S. DEP'T. HEALTH & HUMAN SERVS., <http://aspe.hhs.gov/health/fmap.cfm> (last visited June 1, 2015).

³³ Deficit Reduction Act of 2005, Pub. L. 109-171, 120 Stat. 4 (2006). As part of the implementation, the OIG provided guidelines that it would use in reviewing each state's false

for states to enact legislation that establishes liability to the State for false or fraudulent claims to the State Medicaid program.”³⁴ Specifically, states with eligible “qualifying laws,” that is, states with laws that mirror particular provisions found in the federal FCA,³⁵ receive an increase of ten percentage points “in their share of any amounts recovered under such laws.”³⁶ Once approved by the Health and Human Services’ Office of Inspector General (OIG), states experience increased recovery amounts into their Medicaid programs.

Consequently, the number of state false claims acts has been on the rise. Following Congress’s broadening of the federal civil FCA³⁷ in 1986,³⁸ states have increasingly followed suit in establishing their own similar acts. By 2004, nineteen states had either a criminal or civil false claims act statute, and by 2009, that number had grown to twenty-three states and the District of Columbia.³⁹ By Summer 2014, as many as thirty states had false claims acts,⁴⁰ and as of Spring 2013, twenty-eight states’ laws had been “approved” by the OIG⁴¹ to meet the DRA’s protocol.

claims acts. See Publication of OIG’s Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48552–54 (Aug. 21, 2006).

³⁴ See OIG GUIDELINES, *supra* note 31, at 2.

³⁵ See *State False Claims Act Reviews*, OFF. INSPECTOR GEN., U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp> (last visited June 1, 2015). The state laws must:

establish liability to the State for false or fraudulent claims, as described in the Federal False Claims Act (FCA), with respect to Medicaid spending[;]

contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false or fraudulent claims as those described in the FCA[;]

contain a requirement for filing an action under seal for 60 days with review by the State Attorney General[;] and

contain a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.

Id. More specific requirements are provided as well. See OIG GUIDELINES, *supra* note 31, at 6–11.

³⁶ *State False Claims Act Reviews*, *supra* note 35.

³⁷ 31 U.S.C. § 3729 (2012).

³⁸ The Amendments under the Fraud Enforcement and Recovery Act of 1986 “dramatically expanded the scope of liability under the FCA.” Cynthia Love, Note, *The Fraud Enforcement and Recovery Act of 2009 and the Expansion of Liability Under the False Claims Act*, 2012 UTAH L. REV. 1129 (2012); see also Richard Doan, *The False Claims Act and the Eroding Scierter in Healthcare Fraud Litigation*, 20 ANNALS HEALTH L. 49, 65 (2011) (noting that the amendments strengthened the FCA).

³⁹ See Pamela Bucy et al., *States, Statutes, and Fraud: A Study of Emerging State Efforts to Combat White Collar Crime*, 31 CARDOZO L. REV. 1523, 1535 (2010) (presenting, by Spring 2009, which states had false claims acts, and of those, which had *qui tam* provisions).

⁴⁰ See *States with False Claims Acts*, TAXPAYERS AGAINST FRAUD EDUC. FUND, <http://www.taf.org/states-false-claims-acts> (last visited June 1, 2015).

⁴¹ See *Incentivizing State False Claims Acts*, NAT’L CONF. STATE LEGISLATURES, <http://www.ncsl.org/research/health/clarifying-requirements-for-a-state-false-claims-a.aspx> (last updated Mar. 7, 2013); see also OIG GUIDELINES, *supra* note 31, at 1 (noting that the OIG had reviewed “over 28 different State laws”).

II. CASE STUDY: RISPERDAL

Splashed across newspaper headlines over the past two years, Johnson & Johnson (J&J)—along with its subsidiary Janssen Pharmaceuticals, Inc. (Janssen)⁴²—has settled and litigated claims based on allegations that the company engaged in deceptive marketing for its antipsychotic drug, Risperdal. J&J allegedly pushed its sales representatives to sell the drug—approved by the FDA to treat schizophrenia—for off-label uses. And, in order to do so, according to state and federal governments’ allegations, its sales force misrepresented safety information and downplayed known risks associated with the drug. The government’s allegations—along with the resulting various settlements that resolved those allegations—are summarized below.

A. *The Government’s Allegations Against Janssen*⁴³

According to allegations included in the DOJ’s complaint, J&J and Janssen used a sales force to market Risperdal in an effort to get physicians to prescribe the drug for patients with conditions for which it

⁴² Janssen Pharmaceuticals, Inc., as it is currently known, is “a pharmaceutical company of Johnson & Johnson.” *Our Company*, JANSSEN PHARMACEUTICALS, INC., <http://www.janssenpharmaceuticalsinc.com/our-company> (last visited June 1, 2015). Janssen was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which was brought under the Janssen umbrella name in June 2011. *Our History*, JANSSEN PHARMACEUTICALS, INC., <http://www.janssenpharmaceuticalsinc.com/our-company/our-history> (last visited June 1, 2015).

⁴³ It is important to note that the defendants admitted only a small portion of the federal government’s allegations in the plea agreement and that the occurrences presented here are allegations. Furthermore, neither defendant ever admitted any of the government’s allegations in the settlement agreement. See Civil Settlement Agreement, United States *ex rel.* Starr v. Janssen Pharmaceutica Prods., L.P., No. 04-cv-1529 (E.D. Pa. Nov. 4, 2013), *available at* <http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/civ-settlement-agreement-pa.pdf>.

The settlement agreement between the parties clearly states that it is “not an admission of facts or liability by Defendants, nor a concession by the United States that its claims are not well-founded.” *Id.* at 4. Moreover, “[d]efendants expressly deny the allegations of the United States and Relators . . . and deny that they engaged in any wrongful conduct . . . with the exception of such admissions that are made in connection with the Plea Agreement.” *Id.* In the Plea Agreement, which is between the United States and solely Janssen Pharmaceuticals, Inc., Janssen does acknowledge that Risperdal was illegally misbranded between March 3, 2002 and December 31, 2003. See Guilty Plea Agreement, United States v. Janssen Pharm., Inc., No. 13-cr-605 (E.D. Pa. Oct. 29, 2013), *available at* <http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/janssen-plea-agreement.pdf>. Specifically, Janssen admitted that its ElderCare sales force “promoted Risperdal to health care providers for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly non-schizophrenic dementia patients.” *Id.* at 5. This promotion “caused Risperdal to be misbranded . . . because Risperdal’s labeling did not bear adequate directions for these intended uses.” *Id.*

was not FDA-approved.⁴⁴ Specifically, after having the drug FDA-approved to treat schizophrenia, Janssen's marketing department allegedly tried to get physicians to prescribe Risperdal for patients with dementia.⁴⁵ According to the government, in an effort to push Risperdal for treating dementia, "Janssen directed its ElderCare sales representatives to seek out and market Risperdal to physicians who were medical directors at nursing homes and skilled nursing facilities, directors of nursing at such facilities, and consultant pharmacists who reviewed patient charts at such facilities."⁴⁶ Further, according to the DOJ, Janssen

developed and executed methods to market Risperdal for the treatment of behaviors and psychological symptoms associated with dementia, which were not psychotic symptoms and with no regard for whether or not they were a consequence of psychosis or psychotic symptoms, thereby intending uses for Risperdal that were not FDA-approved during that time period.⁴⁷

The DOJ also alleged that sales representatives were aware of the fact that the vast majority of prescriptions that were written for Risperdal were not to treat schizophrenia, and that Janssen incentivized their marketing team to push Risperdal for off-label uses.⁴⁸ According to the government, Janssen's sales aids and brochures failed to reflect the fact that Risperdal was approved only for schizophrenia, and its marketing materials instead focused on "symptoms or behaviors such as anxiety, agitation, depression, hostility, and confusion, as well as the symptoms hallucinations, paranoia, impulsiveness, and suspiciousness,"⁴⁹ many of which are symptoms of dementia. Therefore, as allegedly marketed, the drug could purportedly be used to treat "symptoms that made treating . . . [dementia] patients a challenge, especially in a nursing home setting."⁵⁰ Indeed, the drug purportedly made dementia patients' "behavioral disturbances" easier to manage.⁵¹ The company also allegedly sought to encourage physicians to use

⁴⁴ Information at 14–15, *United States v. Janssen Pharm., Inc.*, No. 13-cr-605 (E.D. Pa. Nov. 4, 2013) [hereinafter *Janssen Information*], available at <http://www.justice.gov/sites/default/files/opa/legacy/2013/11/04/janssen-info.pdf>.

⁴⁵ *Id.*

⁴⁶ *Id.* at 15.

⁴⁷ *Id.* at 16.

⁴⁸ *Id.* at 17–18.

⁴⁹ *Id.* at 19.

⁵⁰ Katie Thomas, *J&J. to Pay \$2.2 Billion in Risperdal Settlement*, N.Y. TIMES, Nov. 4, 2013, <http://www.nytimes.com/2013/11/05/business/johnson-johnson-to-settle-risperdal-improper-marketing-case.html>.

⁵¹ *Janssen Information*, *supra* note 44, at 19.

Risperdal for the treatment of bipolar disorder and mood and anxiety disorders when the drug was not approved for those uses.⁵²

According to a DOJ press release, “J&J and Janssen were aware that Risperdal posed serious health risks for the elderly, including an increased risk of strokes, but that the companies downplayed these risks.”⁵³ Specifically, the DOJ alleged that “when a J&J study of Risperdal showed a significant risk of strokes and other adverse events in elderly dementia patients, . . . Janssen combined the study data with other studies to make it appear that there was a lower overall risk of adverse events.”⁵⁴ Furthermore, Janssen allegedly mischaracterized studies that showed Risperdal with the same diabetes risk as other similar drugs. In fact, according to the DOJ’s complaint, the company went as far as hiring outside consultants to reevaluate results from a study and publish articles stating that Risperdal was linked to a decreased risk of developing diabetes.⁵⁵

The DOJ further alleged that the company targeted not only dementia patients, but that “one of Janssen’s Key Base Business Goals was to grow and protect the drug’s market share with child/adolescent patients.”⁵⁶ Indeed, according to the government’s complaint, “Janssen told its sales representatives to visit child psychologists and mental health facilities that mainly focused on children, promoting the drug as a safe treatment for disorders like attention deficit hyperactivity disorder and obsessive-compulsive disorder,”⁵⁷ even though the company “knew that children were susceptible to certain health risks from taking Risperdal, including the possibility that boys could develop breasts through elevated production of the hormone prolactin.”⁵⁸

This was all allegedly taking place despite repeated warnings from the FDA to stop misrepresenting the efficacy and potential uses of Risperdal.⁵⁹ Indeed, according to the DOJ, Janssen had attempted to secure FDA approval for dementia because early on, Janssen executives realized the market for schizophrenia was small and that “[a]ggressive expansion of Risperdal use in other indications [was] therefore mandatory,” but the company allegedly lacked clinical data to support

⁵² See Bloomberg News, *J&J to Pay \$2B, Including \$18 Million to N.J., over How It Marketed Antipsychotic Drug*, NJ.COM (Nov. 4, 2013, 1:16 PM), http://www.nj.com/business/index.ssf/2013/11/johnson_johnson_pleads_guilty.html.

⁵³ See Press Release, Dep’t of Justice, *Johnson & Johnson to Pay More than \$2.2 Billion to Resolve Criminal and Civil Investigations* (Nov. 4, 2013), available at <http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html>.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Thomas, *supra* note 50.

⁵⁸ *Id.*

⁵⁹ Press Release, Dep’t of Justice, *supra* note 53.

other uses.⁶⁰ The DOJ noted that the FDA repeatedly “ordered Janssen to stop making false and misleading claims about Risperdal’s superiority”⁶¹ and never approved the drug for treating dementia.

At the same time, Janssen was enjoying high sales of the drug. From 2003 to 2010, its worldwide sales totaled \$24.2 billion, making it J&J’s biggest seller.⁶² According to the government’s complaint, Risperdal’s U.S. sales had boomed as well.⁶³ Sales in the United States swelled from \$172 million in 1994, to \$695 million in 1998, to \$1.4 billion in 2002, and, finally, to \$1.7 billion in 2005.⁶⁴ Indeed, the DOJ noted that this may have been due to the fact that “Janssen had the highest market share for the use of atypical antipsychotics in elderly patients with dementia”⁶⁵—by 2001, “Janssen’s market share of the total use of antipsychotic drugs (both conventional and atypical) to treat dementia patients for the prior 12 months was approximately 54.3%.”⁶⁶

According to records obtained by *Bloomberg News*, “[h]undreds of Janssen salespeople sold to doctors, nursing homes, Veteran’s Administration facilities and jails,” and sales representatives “gave doctors materials about studies of unapproved uses for Risperdal.”⁶⁷ Internal business documents allegedly set goals for “increasing the drug’s market share for elderly dementia sales,” even after the FDA had warned the drug maker about its claims about Risperdal.⁶⁸ According to Kurtis J. Barry, a former regional business director for J&J and whistleblower, “[t]he decision to market, promote and sell Risperdal for off-label purposes to the elderly population was made affirmatively and deliberately by defendants’ executive and management personnel, and carried out under their authority and direction.”⁶⁹

⁶⁰ Margaret Cronin Fisk et al., *J&J Pushed Risperdal for Elderly After U.S. Warning, Files Show*, BLOOMBERG (Mar. 10, 2010, 12:01 AM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=ag4Ya8UOIob0>.

⁶¹ *Id.*

⁶² See Sophia Pearson, *Janssen Pleads Guilty to Selling Risperdal Off-Label*, BLOOMBERG (Nov. 7, 2013, 5:47 PM), <http://www.bloomberg.com/news/2013-11-07/janssen-pleads-guilty-to-selling-risperdal-off-label.html>.

⁶³ Janssen Information, *supra* note 44, at 13–14.

⁶⁴ *Id.*

⁶⁵ *Id.* at 14.

⁶⁶ *Id.*

⁶⁷ Fisk, et al., *supra* note 60.

⁶⁸ *Id.*

⁶⁹ David Voreacos & Sophia Pearson, *How Risperdal Whistle-Blowers Made Millions from J&J*, BLOOMBERG (Dec. 9, 2013, 11:29 AM), <http://www.bloomberg.com/news/2013-12-09/how-risperdal-whistle-blowers-made-millions-from-j-j.html>.

B. *Allegations Surrounding the “Dear Doctor Letter”*

Many of the states’ allegations center on action that occurred in Fall 2003 regarding a letter that Janssen sent to providers.⁷⁰ After receiving reports of serious adverse events and completing a “thorough review” of antipsychotics, the FDA “determined to require” additional language to the “Warnings section of the [package insert] for all atypical antipsychotics”—including Risperdal—“regarding the risk of hyperglycemia and diabetes.”⁷¹ The FDA had become increasingly aware of risks associated with diabetes for those who took atypical antipsychotics.⁷²

On September 11, 2003, Janssen was notified of the FDA’s new requirement,⁷³ but allegedly “did not agree with the FDA’s assessment that all second-generation antipsychotics required the same warning.”⁷⁴ After the FDA required that Janssen send a letter that communicated “the important new risk information,”⁷⁵ Janssen sent a letter to providers on November 10, 2003 (Dear Doctor Letter), which contained the following language:

Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.⁷⁶

Because the letter noted that Risperdal did not present the same scope of risks as other antipsychotics, this prompted a “warning letter” from the FDA (Warning Letter).⁷⁷ In it, the FDA and its Division of Drug Marketing, Advertising, and Communications (DDMAC), clearly

⁷⁰ See, e.g., *Kentucky ex rel. Conway v. Janssen Pharm., Inc.*, 978 F. Supp. 2d 788, 790 (W.D. Ky. 2013); *West Virginia ex rel. McGraw v. Johnson & Johnson*, No. 04-C-156, at 2 (W. Va. Cir. Ct. Sept. 9, 2008) [hereinafter *McGraw Order*], available at <http://www.clarkperdue.com/JJOrder.pdf>.

⁷¹ See Warning Letter from Thomas W. Abrams, Dir., Div. of Drug Mktg., Adver. & Comm’ns, Food & Drug Admin., to Ajit Shetty, CEO, Janssen Pharmaceutica, Inc., at 2 (Apr. 19, 2004) [hereinafter *Warning Letter*], available at <http://www.fda.gov/downloads/drugs/guidance/compliance/regulatoryinformation/enforcementactivitiesbyfda/warninglettersandnoticeofviolation/letterstopharmaceuticalcompanies/ucm055315.pdf>.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ See *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563, 566 (Ark. 2014).

⁷⁵ See *Warning Letter*, *supra* note 71, at 2.

⁷⁶ *Id.* at 3.

⁷⁷ *Id.* at 1.

“concluded that the [Dear Doctor Letter was] false or misleading in violation of . . . the Federal Food, Drug, and Cosmetic Act [FDCA].”⁷⁸ In the Warning Letter, the FDA noted that the Dear Doctor Letter,

fails to disclose the addition of information relating to hyperglycemia and diabetes mellitus to the approved product labeling . . . , minimizes the risk of hyperglycemia-related adverse events, . . . fails to recommend regular glucose control monitoring . . . , and misleadingly claims that Risperdal is safer than other atypical antipsychotics.⁷⁹

Calling the “dissemination of this letter at a time critical to educating healthcare providers” a “serious public health issue,” the FDA noted that Janssen failed to “accurately describe” the results of clinical studies that showed an increase risk of diabetes, and also alleged that the letter omitted “material information about Risperdal, minimize[d] potentially fatal risks associated with the drug, and claim[ed] superior safety to other drugs in its class without adequate substantiation.”⁸⁰ Requesting Janssen to both (1) “immediately cease the dissemination of promotional materials” that reflected the allegedly misleading claims; and (2) “provide a plan of action to disseminate accurate and complete information to the audience(s) that received the violative promotional materials,” the FDA reminded Janssen of its “responsibility to ensure that . . . [its] promotional materials for Risperdal comply with each applicable requirement of the . . . [FDCA] and FDA implementing regulations.”⁸¹

Following the Warning Letter, on July 21, 2004, Janssen sent a subsequent letter to 754,000 providers entitled “Important Correction of Drug Information,” in which the company provided new warning information regarding the risk of hyperglycemia and diabetes mellitus, noting that it was providing providers “with complete and accurate information regarding hyperglycemia and Diabetes Mellitus relative to Risperdal.”⁸² On October 14, 2004, DDMAC notified Janssen that, “[i]n light of the . . . actions taken by . . . [Johnson & Johnson Pharmaceutical Research and Development, L.L.C.] regarding Risperdal’s promotional materials, DDMAC considers this matter closed.”⁸³ For its part, the FDA has clearly noted that its Warning Letters are “informal and advisory,” and “do[] not commit [the] FDA to taking enforcement action.”⁸⁴

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.* at 1, 3–4.

⁸¹ *Id.* at 4.

⁸² See *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563, 567–69 (Ark. 2014).

⁸³ *Id.* at 569.

⁸⁴ OFFICE OF REGULATORY AFFAIRS, U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL § 4-1-1 (2014), available at <http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm>.

C. *The Settlements*

J&J has resolved most states' Risperdal allegations through multiple settlements over the last two years. A large patchwork of states and the DOJ have settled separate allegations in two waves during 2012 and 2013, after Texas—the only state at present that has entered into a separate settlement agreement with the company alone—settled its allegations in January 2012. Before turning to the states whose allegations have proceeded to trial—highlighting the difficult causation issues involved—these three settlements are presented briefly below to provide background.

1. The First Nationwide Settlement

In late Summer 2012, following allegations that J&J and its subsidiary, Janssen, deceptively marketed Risperdal and another drug, Invega, the pharmaceutical company entered into a \$181 million settlement with thirty-six states and the District of Columbia.⁸⁵ Called the “largest multistate consumer protection-based pharmaceutical settlement,”⁸⁶ the settlement resolved claims that Janssen “used unfair and deceptive practices in marketing Risperdal.”⁸⁷

Specifically, the claims centered on violations of consumer protection statutes, with the states' allegations focused on the promotion of the drugs “for off-label uses” and for the misuse of “continuing medical education programs” and consulting programs.⁸⁸ The settlement agreement covered “misrepresentations made to doctors of non-Medicaid patients,”⁸⁹ settling allegations that Janssen misrepresented the safety risks to providers and promoted their drug for off-label uses.⁹⁰

⁸⁵ See David Voreacos & Margaret Cronin Fisk, *J&J Will Pay \$181 Million to Settle Risperdal Ad Claims*, BLOOMBERG (Aug. 30, 2012, 3:30 PM), <http://www.bloomberg.com/news/2012-08-30/j-j-will-pay-181-million-to-settle-risperdal-ad-claims.html>. The states in the settlement agreement were Alabama, Arizona, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Vermont, Washington, Wisconsin, and Wyoming. *Id.*

⁸⁶ *Id.*

⁸⁷ Press Release, Or. Dep't of Justice, Oregon Attorney General and 36 Others Reach \$181 Million Risperdal Settlement (Aug. 30, 2012), *available at* <http://www.doj.state.or.us/releases/Pages/2012/rel083012.aspx>; *see also* Loftus, *supra* note 20.

⁸⁸ Voreacos & Fisk, *supra* note 85.

⁸⁹ Andrew Schneider, *Texas, 36 States Reach \$181 Million Settlement with Janssen Pharmaceuticals*, HOUS. PUB. MEDIA (Aug. 30, 2012, 12:09 PM), <http://www.houstonpublicmedia.org/news/1346346584>.

⁹⁰ See Press Release, Or. Dep't of Justice, *supra* note 87.

2. The Second Nationwide Settlement

In late 2013, the DOJ announced a \$2.2 billion settlement with J&J and Janssen, the third largest with a pharmaceutical company ever,⁹¹ and the “largest-ever legal settlement for sales of a single drug.”⁹² The massive settlement included criminal fines and forfeiture totaling \$485 million as well as civil penalties—based on alleged violations of the FCA—of \$1.72 billion.⁹³ The civil penalties also settled claims brought by forty-five states nationwide.⁹⁴ J&J was required to enter into a five-year Corporate Integrity Agreement (CIA).⁹⁵

According to the *New York Times*, the settlement resolved “a decade-long effort by the federal government to hold the health care giant . . . accountable for illegally marketing the drugs as a way to control patients with dementia in nursing homes and children with certain behavioral disabilities, despite the health risks of the drugs.”⁹⁶ Just like the previous settlement agreement in 2012, this settlement resolved allegations surrounding Risperdal and resolved many of the same allegations that were raised by the 2012 settlement, but under different laws. These claims that were resolved were brought under the FCA, with the six former employees serving as *qui tam* relators⁹⁷ and collecting \$167.7 million.⁹⁸ Indeed, in settling these claims, J&J resolved allegations that, due to the deceptive advertising and marketing of Risperdal, states and the federal government “overpaid through Medicare or Medicaid because of J&J’s practices.”⁹⁹

Nevertheless, in the Plea Agreement, Janssen admitted that Risperdal was “illegally misbranded” after its sales force promoted the drug for unapproved uses between March 2002 and December 2003.¹⁰⁰ The federal government contended that the off-label promotion occurred between May 1998 and November 2005,¹⁰¹ but Janssen did

⁹¹ See Laurie Asseo et al., *J&J Will Pay More than \$2.2 Billion to Settle U.S. Cases*, BLOOMBERG (Nov. 4, 2013, 2:21 PM), <http://www.bloomberg.com/news/2013-11-04/j-j-settlement-over-risperdal-said-to-be-announced-today.html>.

⁹² Joe Carlson, *Johnson & Johnson to Pay over \$2 Billion to Settle Risperdal Investigations*, MODERN HEALTHCARE (Nov. 4, 2013, 2:00 PM), <http://www.modernhealthcare.com/article/20131104/NEWS/311049942>.

⁹³ See Press Release, Dep’t of Justice, *supra* note 53.

⁹⁴ Thomas, *supra* note 50.

⁹⁵ See Carlson, *supra* note 92; see also Press Release, Dep’t of Justice, *supra* note 53.

⁹⁶ Thomas, *supra* note 50.

⁹⁷ See Voreacos & Pearson, *supra* note 69. As part of the investigation, the relators wore wires to sales meetings. *Id.*

⁹⁸ See Gregory Wallace, *Johnson & Johnson to Pay \$2 Billion for False Marketing*, CNN MONEY (Nov. 4, 2013, 6:33 PM), <http://money.cnn.com/2013/11/04/news/companies/johnson-and-johnson-settlement>.

⁹⁹ Voreacos & Pearson, *supra* note 69.

¹⁰⁰ See Guilty Plea Agreement, *supra* note 43, at 1, 5.

¹⁰¹ *Id.* at 6.

“not agree that the nature and scope of its conduct or the time period exceeded” the more limited twenty-one-month time frame to which it stipulated.¹⁰²

3. Texas’s Settlement

Aside from the nationwide settlements, the first (and only standalone) settlement regarding the allegations surrounding Risperdal was reached with the state of Texas in January 2012.¹⁰³ J&J settled with the state for \$158 million, resolving allegations that the company “improperly market[ed] its Risperdal antipsychotic drug to state residents” on Medicaid.¹⁰⁴ Based upon the same claims that had been alleged nationwide, Texas argued that J&J marketed the drug for uses that were explicitly mentioned as not being FDA-approved on the label.¹⁰⁵ *Bloomberg News* also reported that “Janssen pushed salespeople in Texas to ‘flood clinics with Risperdal stuff’ in a 2004 campaign to boost prescriptions for children and adolescents.”¹⁰⁶ Tracking the federal allegations, J&J allegedly downplayed the risks of developing diabetes or experiencing severe weight gain.¹⁰⁷

As the first settlement in the allegations surrounding Risperdal, Texas’ settlement marked “the largest in a Texas Medicaid fraud case brought by the state,”¹⁰⁸ and “fully resolve[d] all Risperdal-related claims in Texas,” but did not affect any other Risperdal litigation.¹⁰⁹ Specifically, the settlement resolved “alleged Medicaid overpayments” between 1994 and 2008.¹¹⁰ As a result, Texas was not part of the 2013 nationwide settlement.

¹⁰² *Id.* at 5–6.

¹⁰³ See Corrie MacLaggan, *J&J to Pay \$158 Million to Settle Texas Risperdal Case*, REUTERS, Jan. 19, 2012, available at <http://www.reuters.com/article/2012/01/19/us-johnsonandjohnson-idUSTRE80I1JF20120119>.

¹⁰⁴ *Id.*

¹⁰⁵ See Jef Feeley et al., *J&J to Pay \$158 Million To Settle Texas Risperdal Drug Case*, BLOOMBERG (Jan. 19, 2012, 2:02 PM), <http://www.bloomberg.com/news/2012-01-19/johnson-johnson-to-pay-158-million-to-settle-texas-risperdal-drug-case.html>.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ MacLaggan, *supra* note 103.

¹¹⁰ *Id.*

III. STATES' LITIGATION RESULTS

At least six states—Arkansas, Louisiana, Pennsylvania, South Carolina, West Virginia, and, recently, Kentucky¹¹¹—have litigated, or are set to litigate, cases against J&J for its marketing of Risperdal.¹¹² Discounting Kentucky, where the case remains in the early stages of litigation, five states have taken J&J to trial, alleging a mix of consumer-protection-based and fraud-based claims, as well as common law claims.

Of the five, and with the exception of South Carolina, four states that have litigated the case to conclusion have absolved J&J of liability. Of these four, the courts of first impression in three states—Arkansas, Louisiana, and West Virginia—each found in favor of the state, awarding amounts ranging from \$3.9 million in West Virginia,¹¹³ to \$330 million in Louisiana,¹¹⁴ to \$1.206 *billion* in Arkansas,¹¹⁵ but all three of the courts' verdicts were reversed in sweeping opinions on appeal. In the fourth state, Pennsylvania, the Commonwealth was unsuccessful at each stage of litigation.¹¹⁶

The ultimate decisions in these states may suggest a shift in the availability of state remedies. Indeed, the appellate results indicate that

¹¹¹ See Complaint, Commonwealth *ex rel.* Conway v. Janssen Pharm., Inc., No. 13-CI-002488 (Ky. Cir. Ct. May 14, 2013) [hereinafter Ky. Complaint], available at <http://freepdfhosting.com/f7231f6e46.pdf>; see also *Kentucky Attorney General Sues Johnson & Johnson over Risperdal Marketing*, YAHOO! FINANCE (May 28, 2013, 3:13 PM), <http://finance.yahoo.com/news/kentucky-attorney-general-sues-johnson-191315020.html>. The state is suing under the Kentucky Consumer Protection Act for “[d]efendants’ willful use of unfair, false, misleading, or deceptive acts or practices relative to the promotion and sale of Risperdal through their labeling and sales aids and related promotional materials and messages disseminated and/or communicated to consumers and/or healthcare providers throughout Kentucky.” Ky. Complaint, *supra*, at 1. The state alleges violations in Risperdal’s labeling, a failure to disclose negative results of safety studies and safety profile, misleading promotional materials, and misrepresenting facts regarding diabetes risk. *Id.* at 12–13.

¹¹² Purportedly, the states of Alaska, Montana, New Mexico, and Utah have also sued J&J and Janssen as a result of their marketing and sales strategy of Risperdal. See David Voreacos, *J&J’s Risperdal Wasn’t Factor in Man’s Diabetes, Jury Rules*, BLOOMBERG (Feb. 16, 2012, 1:24 PM), <http://www.bloomberg.com/news/2012-02-16/j-j-s-risperdal-not-substantial-factor-in-diabetes-new-jersey-jury-says.html>. Other states have sued other pharmaceutical companies using the same strategy. See Loftus, *supra* note 20 (noting that Kentucky, Maryland, and Utah have sued GlaxoSmithKline over its marketing of Avandia, while Mississippi and West Virginia have sued Sanofi and Bristol-Myers over the marketing of Plavix).

¹¹³ See McGraw Order, *supra* note 70, at 40.

¹¹⁴ Caldwell *ex rel.* State v. Janssen Pharmaceutica, Inc., No. 04-C-3977-D, 2011 WL 4577780 (La. Dist. Ct. Mar. 9, 2011), *rev’d*, 144 So.3d 898 (La. 2014).

¹¹⁵ State v. Ortho-McNeil-Janssen Pharm., Inc., No. CV 2007-15345, 2012 WL 1669840, (Ark. Cir. Ct. May 9, 2012).

¹¹⁶ See, e.g., Commonwealth v. Ortho-McNeil-Janssen Pharm., Inc., 52 A.3d 498, 503 (Pa. Commw. Ct. 2012); Commonwealth v. Ortho-McNeil-Janssen Pharm. Inc., No. 2181, 2010 WL 3548474, at *204 (Pa. Ct. Com. Pl. June 25, 2010).

the “aggressiveness”¹¹⁷ with which state attorneys general and federal prosecutors have pursued pharmaceutical companies—with the legal theories presented here—may be increasingly minimized. At the least, with state courts’ limitations of the paths available to state attorneys general, the recent pattern may incentivize states to try and avoid litigation in the future by settling claims early with pharmaceutical companies; at the same time, these results may also weaken the states’ abilities to compel settlement in these cases.¹¹⁸ Indeed, the fact that the South Carolina Supreme Court affirmed its jury verdict is an interesting observation,¹¹⁹ given tight Medicaid budgets nationwide.

Five state summaries follow. The first two, West Virginia and South Carolina, feature cases in which the state was suing under a statute that prohibits deceptive trade practices. The final three—Arkansas, Louisiana, and Pennsylvania—feature cases in which the state sued under fraud-based statutes. The lone successful appeal for the state occurred in South Carolina, and in three states—West Virginia, Arkansas, and Louisiana—lower court decisions finding in favor of the state were overturned. Discerning a general pattern from these five states, the state suits primarily featuring a fraud-based claim have been less successful than state suits seeking recompense under a statute that prevents deceptive advertising. The “injury” and “causation” hurdles have been determinative.

A. *West Virginia: Consumer Protection-Based*

The Attorney General of West Virginia sued J&J under the state’s Consumer Credit and Protection Act¹²⁰ (WVCCPA), which prohibits

¹¹⁷ See Press Release, Dep’t of Justice, *supra* note 53 (quoting Stuart F. Delery, Assistant Attorney General for the Justice Department’s Civil Division, as noting that “[a]s patients and consumers, we have a right to rely upon the claims drug companies make about their products. . . . And, as taxpayers, we have a right to ensure that federal health care dollars are spent appropriately. That is why this Administration has continued to pursue aggressively—with all of our available law enforcement tools—those companies that corrupt our health care system.”); see also David Bruser & Jesse McLean, *Dangers of Off-Label Drug Use Kept Secret*, TORONTO STAR (June 26, 2014), http://www.thestar.com/news/canada/2014/06/26/dangers_of_offlabel_drug_use_kept_secret.html (“South of the border, plaintiffs’ lawyers and government investigators have aggressively pursued violators and found evidence of illegal marketing campaigns.”).

¹¹⁸ See Katie Thomas, *Arkansas Court Reverses \$1.2 Billion Judgment Against Johnson & Johnson*, N.Y. TIMES, Mar. 20, 2014, <http://www.nytimes.com/2014/03/21/business/arkansas-court-reverses-1-2-billion-judgment-against-johnson-johnson.html> (quoting one of the attorneys who represented one of the Risperdal whistleblowers in Texas as saying, “[t]here’s a big question about whether off-label marketing cases are on life support If you’re trying to shoehorn off-label claims into a fraud case or a consumer-protection case, that can be really challenging And in Arkansas, it ended up being fatal.”).

¹¹⁹ State *ex rel.* Wilson v. Ortho-McNeil-Janssen Pharm., Inc., No. 27502, 2015 WL 775094 (S.C. Feb. 25, 2015).

¹²⁰ W. VA. CODE ANN. § 46A-1-101 (West 2015).

“[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.”¹²¹ The law allows the attorney general to sue “a creditor or other person to recover a civil penalty” for “willful” violations.¹²² As for penalties, the statute provides for civil damages of “no more than” \$5000 per claim for defendants who engage in “a course of repeated and willful violations” of the law.¹²³ In order to find a violation of the WVCCPA, the state had to prove that the defendant made a false or misleading statement, that they repeatedly violated the law, and that they did so willfully.¹²⁴

In a summary judgment hearing in the Circuit Court of Brooke County, West Virginia, Judge Martin J. Gaughan granted partial summary judgment for the state, concluding that in its communications, J&J’s statements and omissions were false and misleading.¹²⁵ Specifically, the court found that the state had demonstrated the misleading nature of the Risperdal promotional materials, and noted “that it would accept the FDA’s findings that defendants’ statements were false or misleading.”¹²⁶ The court concluded that “when the FDA makes a determination that a prescription drug advertisement is misleading, and a cause of action is brought in state court that coincides with the FDA’s findings, then the FDA does not preempt a state’s consumer protection laws.”¹²⁷

Nearly a month later, after the conclusion of a bench trial that focused primarily on the willfulness and repetitiveness of the violations, as well as the appropriate damages amount, the court awarded the state \$3.9 million¹²⁸ against J&J for its violations of the WVCCPA.¹²⁹ Judge Gaughan concluded that the violations were repeated—noting that the violations “were not isolated events”¹³⁰—and willful—in that J&J “intentionally” sent the Dear Doctor Letter knowing of its falsity.¹³¹ On this point, Judge Gaughan found that J&J’s Dear Doctor Letter “was materially inconsistent with the critical aspects of the diabetes risk warning,” finding that the defendants’ letter “was intentionally

¹²¹ *Id.* § 46A-6-104.

¹²² *Id.* § 46A-7-111(2).

¹²³ *Id.*

¹²⁴ See McGraw Order, *supra* note 70, at 40.

¹²⁵ See State *ex rel.* McGraw v. Johnson & Johnson, 704 S.E.2d 677, 680 (W. Va. 2010).

¹²⁶ *Id.*

¹²⁷ See McGraw Order, *supra* note 70, at 40.

¹²⁸ J&J was penalized \$5000 for each of the 400 allegedly misleading Risperdal sales calls, which the court noted featured personal delivery of “false or misleading message[s] regarding Risperdal in a setting where doctors [we]re more conducive to listening attentively,” and \$500 for each of the Dear Doctor Letters sent to physicians in the state, in which, according to the court, “[t]he defendants directly disobeyed a direct FDA mandate to include diabetes warning language within its Risperdal promotional materials.” *Id.* at 69.

¹²⁹ *Id.* at 68–69.

¹³⁰ *Id.* at 42.

¹³¹ *Id.* at 50–51.

constructed to modify the FDA's warning language and mislead healthcare professionals."¹³²

The circuit court's decision was overturned by the West Virginia Supreme Court of Appeals in Fall 2010, based largely on the fact that FDA's communications—in which it alleged that the information contained in the Dear Doctor Letter was false—were not formal and final opinions.¹³³ Importantly, the appellate court found that “warning letters” are only “informal and advisory,” did “not “constitute a final judgment of the FDA,”¹³⁴ and noted that the FDA does not “employ any due process procedures similar to those accorded defendants in courts of law,” nor does it hold a hearing to adjudicate the issues involved.¹³⁵ In conclusion, the court held that “the circuit court erred in giving preclusive effect to the FDA's determinations that Janssen had violated the FDCA through its statements and omissions in the Risperdal . . . letter.”¹³⁶ Because the FDA's assertion was not a “final adjudication on the merits and Janssen did not have the opportunity to fully and fairly litigate those issues,” the \$3.9 million finding was overturned.¹³⁷

B. *South Carolina: Consumer Protection-Based*

Similar to the applicable law in West Virginia, the Spartanburg County Court of Common Pleas in South Carolina found J&J liable for \$327 million under the South Carolina Unfair Trade Practices Act (SCUTPA).¹³⁸ Under SCUTPA, “[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”¹³⁹ Further, civil penalties are available under SCUTPA:

¹³² *Id.* at 50. The court crafted a damages amount, in which it considered the good or bad faith of J&J, injury to the public, J&J's ability to pay, the desire to eliminate any benefits gained by J&J's violations, and the vindication and protection of the rights of the “citizenry of West Virginia.” *Id.* at 57–68. Consequently, the court crafted a \$3.9 million damages award, based upon the amount of deceptive sales calls and Dear Doctor Letters that were sent to West Virginian providers. *Id.* at 69 (adding the \$2 million penalty for violations as a result of the marketing calls and \$1.95 million as a result of the letters).

¹³³ See *State ex rel. McGraw v. Johnson & Johnson*, 704 S.E.2d 677 (W. Va. 2010).

¹³⁴ *Id.* at 687. The appellate court noted that “[i]n concluding that the statements and omissions at issue [we]re false and misleading as a matter of law, the circuit court relied on the FDA's communications with Janssen,” and proceeded as though the warning letters were “an official determination that certain statements and omissions . . . were false and misleading.” *Id.*

¹³⁵ *Id.* at 688–90.

¹³⁶ *Id.* at 690.

¹³⁷ *Id.* at 690–91.

¹³⁸ See *State ex rel. Wilson v. Ortho-McNeil-Janssen Pharm., Inc.*, No. 07-CP-42-1438, 2011 WL 2185861, at *1, *17 (S.C. Ct. Com. Pl. June 3, 2011) [hereinafter *Wilson Penalty Order*], *aff'd in part, rev'd in part*, No. 27502, 2015 WL 775094 (S.C. Feb. 25, 2015).

¹³⁹ S.C. CODE ANN. § 39-5-20 (West 2015).

If a court finds that any person is willfully using or has willfully used a method, act or practice declared unlawful by [section] 39-5-20, the Attorney General, upon petition to the court, may recover on behalf of the State a civil penalty of not exceeding five thousand dollars per violation.¹⁴⁰

And, like in West Virginia, in determining whether the assessment of civil penalties was appropriate, the court weighed five factors: (1) the good faith or bad faith of the Defendant, (2) the injury to the public, (3) the desire to eliminate the benefits derived by a violation, (4) the necessity of vindicating the authority of the agency involved, and (5) the Defendant's ability to pay.¹⁴¹

Importantly, for this analysis, the court found that J&J "exhibited extreme bad faith," largely because the deceptive contact was "done in such a fashion so as to directly influence the prescribing decisions of doctors."¹⁴² The court bolstered the jury's decision by noting the importance of being truthful when marketing drugs:

The public's interest in requiring that drug manufacturers fully disclose all information available to them concerning the effects of their drugs in a fair and non-deceptive manner is of paramount importance to the health and safety of those using the drugs. Only when full honest and fair disclosure is done, can doctors and patients make fully informed decisions concerning possible side effects that may be suffered as a result of the drug therapy to be used by the patient.¹⁴³

Finally, the court noted that SCUTPA was a consumer protection measure, highlighting the "need for a central authority to challenge those actions and protect the public's interest."¹⁴⁴ The court observed that Risperdal's annual sales between 1994 and 2010 totaled \$29.796 billion, with a 97%-profit margin, before imposing a \$300 fine for each Risperdal sample package insert¹⁴⁵ and a \$4000 fine for each of (1) the Dear Doctor Letters distributed to each South Carolinian physician, and (2) the sales calls made to each South Carolinian physician.¹⁴⁶ The court then imposed a \$327 million penalty.¹⁴⁷

J&J appealed the decision to the South Carolina Supreme Court, which held oral arguments in March 2013¹⁴⁸ and released its decision—

¹⁴⁰ *Id.* § 39-5-110.

¹⁴¹ See Wilson Penalty Order, *supra* note 138, at 3.

¹⁴² *Id.* at 10.

¹⁴³ *Id.* at 12.

¹⁴⁴ *Id.* at 13.

¹⁴⁵ The Court noted there were 509,499 sample boxes distributed in the state up until 2007. *Id.* at 16.

¹⁴⁶ *Id.* at 17.

¹⁴⁷ *Id.* at 13.

¹⁴⁸ See Loftus, *supra* note 20.

reducing but upholding the jury verdict—in late February 2015.¹⁴⁹ In a decision that clearly broke from other states, the South Carolina Supreme Court reduced the overall award to \$136 million but affirmed the jury finding that Janssen violated the SCUTPA.¹⁵⁰ Most importantly, the court rejected Janssen’s argument that the SCUTPA claim had to fail because the state failed to show an “adverse impact” within the state.¹⁵¹ The court strongly rejected Janssen’s argument, calling its actions “seek[ing] to impose an absurd adverse impact element in a claim concerning alleged unfair and deceptive marketing of prescription medicines.”¹⁵² According to the court, Janssen’s argument was “nothing more than an ‘if we lied, nobody fell for it’ defense.”¹⁵³ Relevant to the instant analysis, the court noted that the state “had the burden of proving Janssen’s representations had a tendency to deceive,” but “was not required to show actual deception or that those representations caused any appreciable injury-in-fact or adversely impacted the marketplace.”¹⁵⁴

C. Arkansas: Fraud-Based

In a move that stunned commentators, in April 2012, a jury in the Circuit County of Pulaski County (Little Rock), Arkansas, rendered a \$1.19 billion verdict for the State of Arkansas against J&J. After finding that the pharmaceutical giant violated the Arkansas Medicaid Fraud False Claims Act (Arkansas MFCA) 238,874 times—equaling the number of Risperdal prescriptions presented to Arkansas’s Medicaid program for payment¹⁵⁵ during the relevant time period of December 2002 to June 2006¹⁵⁶—the jury applied the statutory minimum of \$5000 per claim.¹⁵⁷ The jury found that the defendants “caused to be made or induced or sought to induce the making of . . . false statements” on the packaging, labeling, and other materials of Risperdal under the Arkansas MCFA.¹⁵⁸ The court also found J&J in violation of the

¹⁴⁹ State *ex rel.* Wilson v. Ortho-McNeil-Janssen Pharm., Inc., No. 27502, 2015 WL 775094 (S.C. Feb. 25, 2015).

¹⁵⁰ *Id.* at *1.

¹⁵¹ *Id.* at *9.

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Id.* at *10.

¹⁵⁵ State v. Ortho-McNeil-Janssen Pharm., Inc., No. CV 2007-15345, 2012 WL 1669840 (Ark. Cir. Ct. May 9, 2012).

¹⁵⁶ See John Lyon, *Court Overturns \$1.2 Billion Risperdal Judgment*, ARK. NEWS (Mar. 20, 2014, 5:50 PM), <http://arkansasnews.com/news/arkansas/court-overturns-12-billion-risperdal-judgment>.

¹⁵⁷ *Id.*

¹⁵⁸ *Ortho-McNeil-Janssen*, 2012 WL 1669840. Mirroring the federal FCA, a violation of the Arkansas MFCA occurs when an individual “[k]nowingly makes or causes to be made any false

Arkansas Deceptive Trade Practices Act (DTPA), which prevents the making of “deceptive and unconscionable trade practices.”¹⁵⁹ For this violation, the court imposed an \$11.42 million fine.¹⁶⁰ The Arkansas Department of Human Services, which oversees the Medicaid program, was expected to use the “lion’s share” of the penalty to address a nearly \$400 million planned shortfall in 2014.¹⁶¹

But in March 2014, the Arkansas Supreme Court reversed the jury’s determination,¹⁶² concluding that the “state attorney general erred by suing under a law that applied to health care facilities, not drug companies.”¹⁶³ Specifically as to the arguments Janssen put forth to demonstrate it did not violate the Arkansas MFCA, the court focused on the interpretation of the statute.¹⁶⁴ Finding that the subsection of the statute did not apply to pharmaceutical companies—and blaming the

statement or representation of a material fact in any application for any benefit or payment under the Arkansas Medicaid program.” ARK. CODE ANN. § 20-77-902 (2012).

¹⁵⁹ ARK. CODE ANN. § 4-88-107; see also *Ortho-McNeil-Janssen*, 2012 WL 1669840.

¹⁶⁰ See *Ortho-McNeil-Janssen*, 2012 WL 1669840.

¹⁶¹ See Jef Feeley & David Voreacos, *J&J Ordered to Pay \$1.1 Billion Penalty over Risperdal*, BLOOMBERG (Apr. 12, 2012, 3:04 PM), <http://www.bloomberg.com/news/2012-04-11/jnj-told-to-pay-1-1-billion-penalty-in-arkansas-risperdal-trial.html>.

¹⁶² See *Ortho-McNeil-Janssen Pharm., Inc. v. State*, 432 S.W.3d 563 (Ark. 2014).

¹⁶³ Thomas, *supra* note 118.

¹⁶⁴ See *Ortho-McNeil-Janssen*, 432 S.W.3d at 570–74. The relevant portion of the statute reads that a person is liable to the state for civil penalties if he:

(8) Knowingly makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact:

(A) With respect to the conditions or operation of any institution, facility, or entity in order that the institution, facility, or entity may qualify either upon initial certification or upon recertification as a hospital, rural primary care hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity for which certification is required; or

(B) With respect to information required pursuant to applicable federal and state law, rules, regulations, and provider agreements.

ARK. CODE ANN. § 20-77-902(8)(A)–(B) (2012). The court concluded that the statutory subsections were inharmonious, focusing on whether the subsections were “to be read together or whether the provisions stand alone to create separate prohibitions.” *Ortho-McNeil-Janssen*, 432 S.W.3d at 572. Based upon legislative history, the court concluded that the Arkansas Code Revision Commission “substantially altered” the statute from what the General Assembly passed, and that the two subsections were not standalone subsections at all, but rather, pieces of one continuous subsection. *Id.* at 572–73. Specifically, the court found that “liability is triggered when either a false statement or a misrepresentation is made regarding the conditions or operations of an institution during certification or recertification or when during the certification or recertification process a false statement or misrepresentation of material fact is made regarding applicable federal and state law, rules, regulations, and provider agreements.” *Id.* at 573 (emphasis in original). During codification, the provisions—which were meant to only apply to health care institutions during the certification or recertification process—seemed to indicate that the law had a much broader applicability, as the two relevant subsections were listed in separate stand-alone provisions. *Id.*

misunderstanding on a drafting error—the court dismissed the state’s MCFA claims.¹⁶⁵

For his part, Attorney General Dustin McDaniel argued that he was “disappointed that the court viewed the law differently” from him.¹⁶⁶ In an email statement he noted that his office “pursued this case based on the belief that the General Assembly intended to give the Attorney General’s Office the authority to pursue penalties against those that would enter our state and blatantly deceive the public.”¹⁶⁷ “Nevertheless,” he commented, “I will keep working to protect consumers against fraud and the kinds of irresponsible and greedy actions shown by Johnson & Johnson and Janssen Pharmaceuticals in their marketing of the drug Risperdal.”¹⁶⁸ The court denied a rehearing request from the state in Spring 2014 after McDaniel argued, to no avail, that “neither the state nor the drug maker had raised the issue of whether [the] Code Revision had wrongly or rightly codified the law, so the Supreme Court should not have considered it.”¹⁶⁹

* * *

Aside from the South Carolina Supreme Court’s clear statement that no evidence of harm was required, the causation-related questions were not central to the courts’ analyses in West Virginia, South Carolina, and Arkansas; however, the question of whether or not the

¹⁶⁵ To correct this error, the court read the subsection as “one sentence”—that the Arkansas MFCA prohibits the making of a “false statement or representation of a material fact with respect to the conditions or operation of any institution, facility or entity” during either initial certification or recertification to the state. *Ortho-McNeil-Janssen*, 432 S.W.3d at 572–73. The court concluded that the law did not apply, noting that “Janssen is indisputably not a healthcare facility and applying for certification or re-certification as described in the statute.” *Id.* at 574. The Supreme Court of Arkansas also reversed the jury’s determination on the Arkansas DTPA claim, holding that the FDA’s Warning Letter was inadmissible hearsay. *Id.* at 579–80. After noting that “circuit courts have broad discretion” in determining the admissibility of evidence, the court observed that “factual findings resulting from an investigation made pursuant to authority of law” were admissible, but the “factual findings resulting from special investigation of a particular complaint, case, or incident” were not admissible. *Id.* at 575; *see also* ARK. R. EVID. 803. Ruling that the Warning Letter was part of a special investigation, and that it was more prejudicial than probative, the court concluded that the Warning Letter was inadmissible hearsay. *Ortho-McNeil-Janssen*, 432 S.W.3d at 579–80. Justice Paul E. Danielson, concurring in part and dissenting in part, argued that the letter was not a result of a “special investigation of a ‘particular complaint, case, or incident,’” arguing instead that the letter “unquestionably” was part of the DDMAC’s “routine duty.” *Id.* at 581.

¹⁶⁶ Feeley, *supra* note 13.

¹⁶⁷ *Id.*

¹⁶⁸ Max Brantley, *Arkansas Supreme Court Reverses Billion-Dollar Risperdal Case*, ARK. TIMES (Mar. 20, 2014, 9:15 AM), <http://www.arktimes.com/ArkansasBlog/archives/2014/03/20/arkansas-supreme-court-reverses-part-of-billion-dollar-risperdal-case>.

¹⁶⁹ John Lyon, *State Supreme Court Won’t Reconsider Risperdal Ruling*, ARK. NEWS (Apr. 24, 2014, 1:59 PM), <http://arkansasnews.com/news/arkansas/state-supreme-court-won-t-reconsider-risperdal-ruling>.

sales marketing team “caused” the filing of fraudulent claims was vital in the two states of Pennsylvania and Louisiana. Breaking from numerous federal courts’ conclusions that causation in these cases can be a manageable hurdle and that alternative theories would demonstrate causation in these cases, the Pennsylvania and Louisiana courts concluded that the off-label marketing of Risperdal did not cause harm to their respective state health care programs and absolved J&J of liability. An analysis of these state cases—with a focus on the important causation issue—follows.

D. *Pennsylvania: Fraud-Based*

Mirroring other allegations, Pennsylvania argued that Janssen “promoted . . . [its] antipsychotic drug[] for non-medically accepted and non-medically necessary uses”¹⁷⁰ and that Janssen “misrepresented the risks associated with [Risperdal].”¹⁷¹ However, in addition to alleging a violation of its Medicaid Fraud Control Act,¹⁷² Pennsylvania also alleged violations of the common law—misrepresentation, fraud, and unjust enrichment, in particular. In 2010, two judges, in two separate hearings in the Pennsylvania Court of Common Pleas, dismissed all of the Commonwealth’s claims against J&J.¹⁷³

In the first hearing in January 2010, the judges dismissed counts alleging false and fraudulent claims under the state health care programs, as well as common law misrepresentation.¹⁷⁴ Then, in August 2010, a second judge granted Janssen’s request for a nonsuit with respect to two additional common law claims—one for fraud and one for unjust enrichment¹⁷⁵—concluding, after the Commonwealth presented evidence for one week and then rested,¹⁷⁶ that Pennsylvania had not carried its burden in order to continue to trial.¹⁷⁷

Like in Arkansas, the Commonwealth’s Medicaid fraud claims were dismissed because of a failure to fit Janssen within the meaning of

¹⁷⁰ See *Commonwealth v. Ortho-McNeil-Janssen Pharm. Inc.*, 2010 WL 3548474, at *188–89 (Pa. Ct. Com. Pl. June 25, 2010).

¹⁷¹ *Id.*

¹⁷² 62 PA. STAT. ANN. §§ 1401, 1407 (West 2015).

¹⁷³ See *Ortho-McNeil-Janssen Pharm.*, 2010 WL 3548474, at *189; Jef Feeley & Margaret Cronin Fisk, *J&J Wins Dismissal of Pennsylvania’s Risperdal Lawsuit*, BLOOMBERG (June 14, 2010, 1:49 PM), <http://www.bloomberg.com/news/2010-06-14/j-j-wins-dismissal-of-pennsylvania-s-risperdal-case.html>.

¹⁷⁴ *Ortho-McNeil-Janssen Pharm.*, 2010 WL 3548474, at *189.

¹⁷⁵ See Tom Moylan, *Pa. Risperdal Off-Label Trial Ends with Nonsuit for Janssen*, LEXISNEXIS LITIG. BLOG (June 14, 2010, 3:47 PM), <http://www.lexisnexis.com/legalnewsroom/litigation/blitigation-blog/archive/2010/06/14/pa-risperdal-off-label-trial-ends-with-nonsuit-for-janssen.aspx>.

¹⁷⁶ *Ortho-McNeil-Janssen Pharm.*, 2010 WL 3548474, at *190.

¹⁷⁷ See Feeley & Fisk, *supra* note 173.

“provider” under the statute.¹⁷⁸ As to the common law fraud and misrepresentation claims, after noting that proof of reliance was not met, and after invoking the Learned Intermediary Doctrine—operating to bar failure-to-warn actions when the pharmaceutical company adequately warns the treating physician—Judge Massiah-Jackson turned to the causation problem, calling it “the internal causal nexus quandary.”¹⁷⁹ The court noted:

The plaintiff-Commonwealth cannot escape the necessity of proof needed to establish a nexus between the allegations of fraudulent misrepresentations or nondisclosure of the drug’s efficacy and safety and the economic injury it claims. Absent proof that if the defendant manufacturer had issued the proper warning or a different warning then the prescribing physicians would change his or her prescription habits, thus causing a different and lower price, this plaintiff cannot meet its burden and the case cannot go forward to a jury.¹⁸⁰

To this point, the court concluded that “[t]he trial record is inadequate to establish causation, that is, had Janssen made different warnings that any physician would prescribed differently.”¹⁸¹ Furthermore, the court noted that the “trial record is inadequate to establish that . . . any Medicaid-related department, clinician or committee within the Commonwealth would have taken any action that would have resulted in fewer prescriptions or purchases of Risperdal.”¹⁸²

Pennsylvania appealed the decision, but the Commonwealth Court of Pennsylvania affirmed the lower court’s decisions. On the Medicaid fraud statute question, the court quickly affirmed that Janssen could not be a “provider” under the Medicaid Fraud Control Act.¹⁸³ The court also dismissed the Commonwealth’s challenge to the lower court’s holdings

¹⁷⁸ See *Commonwealth v. Ortho-McNeil-Janssen Pharm., Inc.*, 52 A.3d 498, 503 (Pa. Commw. Ct. 2012).

¹⁷⁹ *Ortho-McNeil-Janssen Pharm.*, 2010 WL 3548474, at *204.

¹⁸⁰ *Id.*

¹⁸¹ *Id.* at *206.

¹⁸² *Id.*

¹⁸³ See 62 PA. STAT. ANN. § 1407(c)(1) (authorizing civil suit against a provider). Under section (c)(1) of the Act,

If the department determines that a provider has committed any prohibited act or has failed to satisfy any requirement under section 1407(a), it shall have the authority to immediately terminate, upon notice to the provider, the provider agreement and to institute a civil suit against such provider in the court of common pleas for twice the amount of excess benefits or payments plus legal interest from the date the violation or violations occurred.

Id. Noting that the Act only applied to “providers,” the Court also shared the statutory definition of “providers,” which is defined as “any individual or medical facility which signs an agreement with the department to participate in the medical assistance program, including, but not limited to, licensed practitioners, pharmacies, hospitals, nursing homes, clinics, home health agencies and medical purveyors.” See *id.* § 1401. Quite easily, the Court concluded, Janssen was not a provider under the Act. *Ortho-McNeil-Janssen Pharm.*, 52 A.3d at 506–07.

on the common law fraud and unjust enrichment claims.¹⁸⁴ In denying the Commonwealth's reliance argument, the court noted that Pennsylvania's evidence of reliance—that is, that the Commonwealth justifiably relied on the misrepresentation—was insufficient.¹⁸⁵ Still, recognizing that reliance could be presumed, the court examined whether causation could be proven.¹⁸⁶ But the court quickly dispelled this challenge as well, noting that “the Commonwealth did not offer proof that it would have acted differently with knowledge of the ‘true’ facts.”¹⁸⁷

Finally, the court also rejected an appeal to the lower court's unjust enrichment conclusion. The court first focused on the point that “the Commonwealth proved how much it paid to reimburse for various drugs, but its payments were not made to the drug manufacturer. Rather, its reimbursements were made to providers (mostly pharmacies) that sold the drugs to Medicaid and Medicare recipients.”¹⁸⁸ The lack of direct remuneration between the Commonwealth and the drug company—as well as a failure to argue how much of that money the Commonwealth paid that ended up in the hands of J&J or Janssen—proved probative.

Again finding that the causation problem was an insurmountable hurdle to the allegations, the court concluded that “because the Commonwealth did not prove causation, that is, failed to prove any Commonwealth actor would have acted differently with knowledge of the ‘true’ facts about Risperdal, the Commonwealth did not prove any retention was unjust.”¹⁸⁹ Because the Commonwealth could not prove that the off-label marketing actually influenced either physicians—by causing them to write off-label prescriptions—or the state—in determining how to arrange its Medicaid formulary list—the allegations were without merit and had been appropriately dismissed; the causation “quandary” was thus fatal.

E. *Louisiana: Fraud-Based*

In a trial over which District Court Judge Donald W. Hebert of the Parish of St. Landry presided, a unanimous jury found in favor of the Attorney General in the Louisiana and against Janssen for a total of \$330 million, including attorney's fees and other costs; the total penalty

¹⁸⁴ *Ortho-McNeil-Janssen Pharm.*, 52 A.3d at 505–13.

¹⁸⁵ *Id.* at 510.

¹⁸⁶ *Id.* at 510–11.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.* at 512–13.

¹⁸⁹ *Id.* at 513.

amount by itself was \$257 million.¹⁹⁰ Judge Hebert, in examining the causation requirement under Louisiana’s Medical Assistance Programs Integrity Law (MAPIL), noted that “if it is shown that the statements were misleading, fraudulent, whatever the definition stuff is that they’re alleging, that in and of itself provides their causation.”¹⁹¹ Furthermore, the Louisiana appellate court denied Janssen’s appeals in August 2012,¹⁹² noting that “if the Attorney General was able to prove ‘false, misleading, misrepresentative, deceitful, intent to defraud type statements . . . Janssen would be liable for civil penalties under MAPIL.”¹⁹³

In January 2014, the Louisiana Supreme Court reversed the jury’s unanimous decision that J&J violated MAPIL.¹⁹⁴ The court’s decision constrained the application of the 1997 law, which led commentators to note that “[b]ecause the Louisiana statute bears similarities with false claims act statutes in other jurisdictions, this is a significant ruling for manufacturers defending false marketing claims elsewhere.”¹⁹⁵ And, like in Pennsylvania, underpinning the court’s conclusions was a lack of confidence that the off-label marketing *caused* the filing of false claims with the state’s Medicaid program.

On its face, Louisiana’s MAPIL is quite similar to the FCA.¹⁹⁶ Its three provisions read:

- A. No person shall knowingly present or cause to be presented a false or fraudulent claim.
- B. No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.
- C. No person shall knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to

¹⁹⁰ Caldwell *ex rel.* State v. Janssen Pharmaceutica, Inc., No. 04-C-3977-D, 2011 WL 4577780 (La. Dist. Ct. Mar. 9, 2011), *rev’d*, 144 So.3d 898 (La. 2014).

¹⁹¹ Caldwell *ex rel.* State v. Janssen Pharm., Inc., 100 So.3d 865, 875–76 (La. Ct. App. 2012) (quoting the trial court), *rev’d*, 144 So.3d 898 (La. 2014).

¹⁹² See Bloomberg News, *Johnson & Johnson Loses Bid to Throw out \$258 Million Risperdal Jury Award*, NJ.COM (Aug. 31, 2012, 2:48 PM), http://www.nj.com/business/index.ssf/2012/08/johnson_johnson_loses_bid_to_t.html.

¹⁹³ Caldwell, 100 So.3d at 876.

¹⁹⁴ See Caldwell, 144 So.3d 898.

¹⁹⁵ See Jonathan Cohn & Josh Fougere, *Supreme Court of Louisiana Overturns \$330 Million Judgment in Off-Label Marketing Case*, ORIGINAL SOURCE—THE SIDLEY AUSTIN FALSE CLAIMS ACT BLOG (Feb. 4, 2014, 3:32 PM), <http://fcablog.sidley.com/blog.aspx?entry=395>.

¹⁹⁶ See Letter from Daniel R. Levinson, Inspector Gen., Office of Inspector Gen., Dep’t of Health & Human Servs., to Nicholas J. Diez, Assistant Att’y Gen., State of La. Dep’t of Justice (Nov. 15, 2011), *available at* <https://oig.hhs.gov/fraud/docs/falseclaimsact/Louisiana.pdf>.

knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs.¹⁹⁷

Given the wide similarity between MAPIL and the FCA, one would assume that the causation question—if not a hurdle in the federal courts that have examined the FCA’s application in off-label marketing cases¹⁹⁸—would not be a roadblock to liability in Louisiana. Nevertheless, by a four to three decision, the Louisiana Supreme Court overturned the jury verdict, based on its interpretation of the statute.

First, in response to the challenge under subpart A, the court noted that MAPIL was not violated “because no evidence was presented that any defendant made or attempted to make a fraudulent claim for payment against any Louisiana medical assistance program within the scope of MAPIL.”¹⁹⁹ Furthermore, due to the structure of MAPIL, the court found that because no “health care provider or his billing agent . . . knowingly present[ed] a claim for payment that [was] false, fictitious, untrue, or misleading,” no liability could attach.²⁰⁰

This conclusion was compelled, according to the court, because of the narrow construction of MAPIL. Tracking the standard state and federal FCA provision, the Louisiana MAPIL provides that “[n]o person shall knowingly present or cause to be presented a false or fraudulent claim.”²⁰¹ However, MAPIL then defines a “false or fraudulent claim” as “a claim which the health care provider or his billing agent submits knowing the claim to be false, fictitious, untrue, or misleading in regard to any material information.”²⁰² Finally, “knowing” is defined as “means that the person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.”²⁰³

The narrow wording of MAPIL constrains its reach significantly. According to the court, liability under the law for the pharmaceutical company’s deceptive marketing of its drugs is determined by the knowledge of the prescribing health care *provider*. The court noted in its opinion the possibility that the “doctor or health care provider could have still medically determined that Risperdal is the more appropriate drug for a particular patient, . . . in which case there could be no legitimate basis for alleging the doctor knowingly presented a false claim for payment.”²⁰⁴ Indeed, to be liable under MAPIL, the “doctor or health

¹⁹⁷ See LA. REV. STAT. ANN. § 46:438.3 (2011).

¹⁹⁸ See discussion and accompanying notes *infra* Part IV.A.

¹⁹⁹ *Caldwell*, 144 So.3d at 901.

²⁰⁰ *Id.* at 909.

²⁰¹ LA. REV. STAT. ANN. § 46:438.3(A) (West 2015).

²⁰² *Id.* § 46:437.3(7).

²⁰³ *Id.* § 46:437.3(11).

²⁰⁴ *Caldwell*, 144 So.3d at 909.

care provider would have had to have knowingly committed malpractice, prescribing or dispensing Risperdal despite knowing there were better, cheaper, or safer, more efficacious drugs available.”²⁰⁵ Because no evidence existed demonstrating that any prescribing health care provider had the requisite knowledge, no claim could be maintained.²⁰⁶ Put simply, the Louisiana Supreme Court found J&J not liable under subpart A because the prescribing physicians did not know of the deceptive nature of the off-label marketing.

Under subpart B, MAPIL provides that “[n]o person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.”²⁰⁷ Furthermore, “payment” means “the payment to a health care provider from medical assistance programs funds pursuant to a claim, or the attempt to seek payment for a claim.”²⁰⁸ “Misrepresentation” is defined as “the knowing failure to truthfully or fully disclose any and all information required, or the concealment of any and all information required on a claim or a provider agreement or the making of a false or misleading statement to the department relative to the medical assistance programs.”²⁰⁹

Again, the court denied the Attorney General’s argument that J&J violated the MAPIL, noting that “there was no showing that the defendants attempted to obtain payment to a health care provider directly from medical assistance program funds pursuant to a claim.”²¹⁰ According to the court, MAPIL compelled the conclusion that the “obligation of truthful and full disclosure [is placed] on the health care provider or any person seeking to obtain payment through a claim made against medical assistance program funds or entering into a provider agreement.”²¹¹ The court seemed to conclude that the law did not stretch to reach the pharmaceutical companies in this scenario.

Finally, and most importantly for this analysis, under subpart D,²¹² the court rejected the Attorney General’s argument, again noting that the fact that J&J did not fail “to truthfully or fully disclose or conceal[] any information required on a claim for payment made against the medical assistance programs, or that these statements were made to the

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 913.

²⁰⁷ LA. REV. STAT. ANN. § 46:438.3(B).

²⁰⁸ *Id.* § 46:437.3(19).

²⁰⁹ *Id.* § 46:437.3(15).

²¹⁰ *Caldwell*, 144 So.3d at 908.

²¹¹ *Id.* at 912.

²¹² Subpart D provides that “[n]o person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining or attempting to obtain, payment for a false or fraudulent claim.” LA. REV. STAT. ANN. § 46.438.3(D).

department relative to the medical assistance programs.”²¹³

The court continued, explicitly noting a failure of causation:

Further[,] even if the defendants’ conduct was intended to influence the prescribing decisions of doctors treating schizophrenia patients, there *has been no causal connection between this conduct and any false or fraudulent claim for payment* to a health care provider or other person. The purpose of MAPIL is to prevent false or fraudulent claims from being presented to and paid by the medical assistance programs. Thus, *there must be a causal link between the misleading marketing statement and a false or fraudulent claim for payment* to a health care provider or other person to establish liability under MAPIL.²¹⁴

This concept—that the deception must be more intimately related to a claim for payment—shows how constricted liability is under MAPIL. Indeed, it seems that the only time the law may be violated by a pharmaceutical company is when the prescribing provider knows that the prescribed drug is not as effective as a different candidate drug would be. Of course, if the provider knew of the deception, he would have been complicit in the fraud and, perhaps, even liable for medical malpractice—knowingly prescribing a drug for a malady for which it is not approved, and for which its pharmaceutical company engaged in marketing that was deceptive. Outside of this scenario, it is hard to imagine how MAPIL would apply to prevent allegedly deceptive marketing.

Mirroring the causation conception in Pennsylvania and, assuming the marketing was in fact deceptive, the Louisiana Supreme Court decision hinged on whether the off-label marketing *caused* the filing of a false claim. After a jury verdict found the other way, the court noted that no “causal link” existed. Interestingly, both state court decisions seemingly fail to draw on developed causation theories—both from federal courts that have heard off-label claims like this before, and, most basically, from the common law of torts.

IV. CAUSATION FOR FRAUD-BASED OFF-LABEL CLAIMS

The Risperdal state cases highlight the thorny importance of the causation requirement in a state law fraud-based off-label case. Indeed, in a consumer protection-based statute like the one in South Carolina, such a showing was unnecessary.²¹⁵ Nevertheless, for fraud-based enforcement, such a causation challenge in litigation for off-label

²¹³ *Caldwell*, 144 So.3d at 913.

²¹⁴ *Id.* (emphases added).

²¹⁵ *See supra* Part III.B.

marketing is nothing new; scholars have noted the difficulty in proving causation in a variety of contexts involving alleged conflicts of interest, RICO and consumer protection contexts, and malpractice actions.²¹⁶ Still, federal courts have analyzed the causation requirements under the federal FCA in off-label cases without too much difficulty. Exactly why the Pennsylvania and Louisiana Supreme Court decisions do not engage in a discussion of the well-worn legal causation analysis that typically accompanies causation questions in fraud-based off-label marketing cases leaves open a noteworthy issue.

Even within the fraud-based context, federal courts have seemingly not evinced the same despair over the causation inquiry—albeit at the motion to dismiss and summary judgment stages—that the state courts have over the “internal causal nexus quandary,” as Judge Messiah-Jackson in Pennsylvania called it.²¹⁷ As one federal court that has analyzed the causation question in an FCA case put it, “[c]ausation is not a stringently enforced FCA element.”²¹⁸

A. *Causation at the Federal Level for Off-Label Marketing*

First, it is worth noting that federal courts have settled the point that, for application of the FCA to be appropriate, the pharmaceutical company does not have to be the party that submits the claim to the government for reimbursement. As Professor Vicki Girard has commented:

That a company lacks any direct involvement in the actual preparation or submission of the request for reimbursement under Medicaid or Medicare is irrelevant under the DOJ’s theory if there is sufficient circumstantial evidence to suggest that the company acted in a way that induced the false claim(s) to be submitted.²¹⁹

Thus, the analysis focuses on whether the pharmaceutical marketing strategy set a causal chain in motion, resulting in the foreseeable act of

²¹⁶ See, e.g., Robert Gatter, *Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 377 (2003); Kate Greenwood, *Physician Conflicts of Interest in Court: Beyond the “Independent Physician” Litigation Heuristic*, 30 GA. ST. U. L. REV. 759, 799 (2014) (noting the “causal chain of injury” hurdle in malpractice, RICO, and consumer protection actions).

²¹⁷ *Commonwealth v. Ortho-McNeil-Janssen Pharm. Inc.*, No. 2181, 2010 WL 3548474, at *204 (Pa. Ct. Com. Pl. June 25, 2010).

²¹⁸ *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 405 (D. Mass. 2010) (at the pleading stage, “a rigid showing of causation is not a ticket to discovery”).

²¹⁹ Vicki W. Girard, *Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act Is the Wrong Rx*, 12 J. HEALTH CARE L. & POL’Y 119, 140–41 (2009).

the physician filing a claim for reimbursement with the state Medicaid program.

The first federal case to recognize that the FCA could apply to off-label pharmaceutical marketing allegations shares a number of factual similarities with the Risperdal allegations.²²⁰ Specifically, in that case, the allegations centered on whether or not the Neurontin sales representatives of Parke-Davis, a division of Warner-Lambert, undertook “a marketing campaign that caused physicians to write off-label prescriptions of its product.”²²¹ As part of this marketing campaign, sales representatives allegedly disseminated false information that induced providers to prescribe the drug for uses that had not been FDA approved.²²² The campaign was financially successful, and Neurontin quickly became a blockbuster drug, with its sales for unapproved uses making up the majority of its sales.²²³ A past medical liaison for Warner-Lambert, David Franklin, was the relator in the FCA case.²²⁴ Parke-Davis moved for summary judgment against Franklin, raising a number of arguments; none, for the purposes here, were more important than the court’s causation analysis.

The District of Massachusetts, in two opinions, rejected Parke-Davis’s motions for summary judgment. In the first, as to causation, Judge Patty Saris denied Parke-Davis’s argument that the relator failed to demonstrate that the marketing *caused* the false claims “because the actions of the[] . . . [physicians] were an intervening force that br[oke] the chain of legal causation.”²²⁵ According to commentators, the court seemed to be saying that “the participation of doctors and pharmacists in the submission of false claims to Medicaid had not only been foreseeable,”²²⁶ but rather, “was an intended consequence of the alleged scheme of fraud.”²²⁷

²²⁰ The litigation resulted in a \$430 million settlement. Press Release, Dep’t of Justice, *Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion* (May 13, 2004), available at http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm.

²²¹ Greene, *supra* note 28, at 59.

²²² *Id.*

²²³ *Id.* at 60 (noting that “[w]hen the defendant initiated its off-label marketing campaigns in late 1995, off-label uses for Neurontin were less than 15 percent of its sales”).

²²⁴ Press Release, Dep’t of Justice, *supra* note 220.

²²⁵ United States *ex rel.* Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 52 (D. Mass. 2001).

²²⁶ Richard C. Ausness, “*There’s Danger Here, Cherie!*”: *Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 BROOK. L. REV. 1253, 1283 (2008) (“Parke-Davis maintained that the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who filled them had been an intervening force that broke the chain of legal causation from the pharmaceutical manufacturer. However, the court pointed out that such an intervening force would break the causal connection only if it were unforeseeable. In this case, the participation of doctors and pharmacists in the submission of false claims to Medicaid had not only been foreseeable but was the intended result of the defendant’s fraudulent scheme. Thus, this argument by the defendant was also unavailing.”); *see also* Greene, *supra* note

In the second summary judgment opinion, after addressing whether the claims were false for purposes of FCA application, Judge Saris applied common law tort principles for a robust causation analysis.²²⁸ Judge Saris focused on the requirements that, in an FCA case—like under the common law of torts—the relator must prove factual causation, which is defined as “whether the defendant’s conduct was a ‘substantial factor’ in producing the harm.”²²⁹ Secondly, the relator must prove proximate causation, which focuses on whether the harm was foreseeable.²³⁰

The court quickly concluded that the relator had shown enough evidence to create “at least a genuine issue of material fact” as to whether the conduct of the pharmaceutical company was a substantial factor in bringing about the harm.²³¹ As to proximate causation, in addition to reminding the parties of the previous conclusion regarding proximate causation, Judge Saris likewise concluded that the relator had “presented evidence showing that it was foreseeable that Parke-Davis’s conduct . . . would ineluctably result in false Medicaid claims.”²³² Notably, in the first federal court to grapple with causation issues in a FCA-based off-label marketing case, the court had obtained records that

showed the differences in off-label prescription rates before and after contact between the physicians and Parke-Davis representatives, as well as market research reports that recorded the doctors’ state of mind after meetings with sales representatives The court did not require proof that individual doctors relied on false statements by sales representatives.²³³

By the late spring of 2004, Parke-Davis, and its parent company, Warner-Lambert, had entered into a settlement agreement for \$430 million to resolve the FCA allegations.²³⁴ In the decade that has followed, multiple federal courts that have examined the issue have

28, at 63 (noting that, in Parke-Davis, “the court found that the plaintiff had introduced enough circumstantial evidence to raise a question of fact regarding causation in fact”).

²²⁷ Greene, *supra* note 28, at 63.

²²⁸ United States *ex rel.* Franklin v. Parke-Davis, No. Civ.A. 96-11651PBS, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003).

²²⁹ *Id.* (citing W. PAGE KEETON ET AL., PROSSER & KEETON ON TORTS §§ 41-42 (5th ed. 1984)).

²³⁰ *Id.*

²³¹ *Id.* at *5. The relator had provided evidence off-label prescription rates before and after Parke-Davis-hosted conferences and “reports recording doctors’ state of mind after marketing meetings.” *Id.*

²³² *Id.*

²³³ Greene, *supra* note 28, at 63 (“The court recognized the oft-cited principle that an intervening force breaks the causal connection only when such intervention is unforeseeable. The court noted that in this case, the participation of physicians in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.” (internal citations and quotation marks omitted)).

²³⁴ Press Release, Dep’t of Justice, *supra* note 220.

applied a similar analysis as the *Franklin* court, sometimes with varying results.²³⁵

In 2009, the U.S. District Court for the Northern District of California declined to dismiss FCA allegations against a pharmaceutical manufacturer for inducing physicians to file false claims.²³⁶ There, the court found that the manufacturer “created the market for off-label use” of the drug at issue, and noted that “all such uses can be traced back to [the] [d]efendants’ actions.”²³⁷ One year later, the U.S. District Court for the District of Massachusetts similarly denied a motion to dismiss allegations that Abbott Laboratories’ off-label marketing induced providers to file false claims with the federal government in violation of the FCA.²³⁸ The court noted that

[a]ccepting the proposition that a misleading promotion of the uses of a drug might foreseeably lead doctors to prescribe the drug for such uses, the relevant issue is whether Abbott’s conduct (as alleged) could have played a substantial role in causing the presentment of reimbursement claims to the government.²³⁹

The court was satisfied enough with the “very thin” allegations of misrepresentations related to marketing the drug for off-label usage²⁴⁰ to deny dismissal.

²³⁵ Finally ruling in favor of a pharmaceutical company on the causation question in 2011, the U.S. District Court for the Eastern District of Virginia granted Takeda Pharmaceuticals’ motion to dismiss, finding that the relator’s complaint failed “to plead facts sufficient to make plausible Relator’s claim that Takeda ‘caused’ any off-label prescriptions to be issued.” *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, No. 1:09-cv-1086 (AJT), 2011 WL 3911095, at *5 (E.D. Va. Sept. 6, 2011). Notably, the court stated that “[c]ourts recognize that physicians are not unsophisticated lay persons and it is reasonable to assume that they are familiar with relevant medical literature.” *Id.* Noting that “off-label FCA cases generally involve allegations that the judgment of a physician was altered or affected by the defendant’s fraudulent activities, which also typically involve improper payments, benefits or inducements, or misrepresentations,” and that the relator made no allegation “regarding kickbacks or other improper incentives or attempts to distort otherwise objective medical literature,” the court found that he had not pled adequate facts to demonstrate the marketing caused false claims to be filed in violation of the FCA. *Id.* The Court of Appeals for the Fourth Circuit affirmed the dismissal, finding that the relator did not adequately demonstrate that the claim was presented to the government, and never reached the causation question. *United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 455 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1759 (2014). The court found that the relator failed to adequately allege that the rheumatologists targeted with the off-label marketing “wrote any off-label prescriptions that were submitted to the government for payment,” what the court calls “a critical omission in a case brought under the Act.” *Id.* at 457–58 (holding that “when a defendant’s actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment”).

²³⁶ *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884 (N.D. Cal. 2009).

²³⁷ *Id.* at 895.

²³⁸ *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395 (D. Mass. 2010).

²³⁹ *Id.* at 406.

²⁴⁰ *Id.* at 407.

In 2013, in a case involving off-label marketing allegations, the U.S. District Court for the Eastern District of Pennsylvania denied Novartis's motion to dismiss a FCA claim while specifically applying the "substantial factor" test, concluding that "the first amended complaint plausibly suggests that doctors wrote off-label Elidel prescriptions because of Novartis's marketing, and that Novartis's actions thus played a substantial and foreseeable role in the submission of false claims."²⁴¹ In reviewing the allegations, the court rejected Novartis's argument that the physicians' "independent medical decisions" severed the causal chain.²⁴²

Finally, in Summer 2014, the U.S. District Court for the Central District of California denied a motion to dismiss after analyzing factual and proximate causation issues for similar allegations.²⁴³ Calling the causal chain "straightforward," the court mirrored Judge Saris's language in *Franklin*, noting that the off-label prescriptions that resulted "were not only foreseeable, they were an intended consequence of Celgene's alleged fraudulent scheme."²⁴⁴ The court concluded that Celgene "could . . . reasonably foresee that these off-label prescriptions would result in false claims for reimbursement," and that the "alleged misleading marketing was a substantial factor in at least some physicians' decisions to prescribe" the drugs at issue for off-label use.²⁴⁵ The court rejected Celgene's argument to "presume that physicians based their prescription decisions on their own independent medical judgment," provocatively finding that the "physicians[] exercise[] [of] their independent judgment does not defeat the causal connection here."²⁴⁶ The court concluded sharply:

To suggest that Celgene's alleged expansive, multi-faceted efforts to create an off-label market for Thalomid and Revlimid did not cause physicians to prescribe Thalomid or Revlimid for non-reimbursable

²⁴¹ United States *ex rel.* Galmines v. Novartis Pharm. Corp., No. 06-3213, 2013 WL 2649704, at *11 (E.D. Pa. June 13, 2013).

²⁴² *Id.* Similarly, in 2013, the Seventh Circuit relied on section 443 of the *Second Restatement of Torts* to reverse a summary judgment finding against the relator at the trial court level on different facts, but on similar allegations. See United States v. King-Vassel, 728 F.3d 707, 714 (7th Cir. 2013). In reinstating allegations brought against the relator's *psychiatrist*—not a pharmaceutical company—and alleging that the psychiatrist's off-label prescriptions damaged the Medicaid program—thus a different (and perhaps, easier to resolve) causation issue—the court discussed the causal chain of filing a claim with Medicaid for reimbursement as "an automobile." *Id.* at 715. The court stated that, "while most people could not explain every step between key-turn and ignition, the cause-effect relationship is commonly appreciated"—in describing the causal chain that starts with a writing of a prescription and ends with the Medicaid program paying a claim. *Id.*

²⁴³ United States *ex rel.* Brown v. Celgene Corp., No. CV 10-3165-GHK (SSx), 2014 WL 3605896, at *8 (C.D. Cal. July, 10, 2014).

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ *Id.*

uses strains credulity. It is implausible that a fraudulent scheme on the scope of that alleged by Brown would be entirely feckless.²⁴⁷

B. Causation in Related Fraud Contexts

Outside of the off-label pharmaceutical context, federal courts have modeled causation analyses off of *Franklin* in other FCA cases. One year after *Franklin*, in *United States ex rel. Schmidt v. Zimmer, Inc.*, the Third Circuit reversed a lower court's dismissal and found that the relator's complaint stated an FCA claim against a medical device company for its incentivized marketing scheme.²⁴⁸ Mirroring the *Franklin* analysis, the court noted that "[w]hile it is true that Mercy [Hospital and Health System] allegedly made its own decision to file a false certification, this is not inconsistent with a conclusion that Zimmer caused that filing."²⁴⁹ On the causation question, the court concluded:

[A]ssuming that a jury were to conclude that Zimmer's marketing scheme was a substantial factor in bringing about Mercy's filing and that Mercy's filing was a normal consequence of the situation created by that scheme, Zimmer could be found to have caused, and thus be held responsible for, that filing.²⁵⁰

The court relied on section 443 of the Second Restatement of Torts to provide guidance on the causation question.²⁵¹

Finally, the First Circuit, in *United States ex rel. Hutcheson v. Blackstone Medical, Inc.*,²⁵² highlighted the potential breadth of fraud-based statutes when regulating pharmaceutical and medical device companies. In *Blackstone*, the First Circuit reversed a lower court's grant of dismissal of an FCA claim against a medical device manufacturer.²⁵³ Defense counsel and other commentators criticized the opinion—written by Chief Judge Sandra Lynch—noting that the court had “rewritten” the FCA and significantly expanded potential liability.²⁵⁴

²⁴⁷ *Id.*

²⁴⁸ *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004).

²⁴⁹ *Id.* at 244.

²⁵⁰ *Id.* at 244–45.

²⁵¹ *Id.* Section 443 of the Second Restatement reads, “[t]he intervention of a force which is a normal consequence of a situation created by the actor's negligent conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about.” RESTATEMENT (SECOND) OF TORTS § 443 (1965). “Normal,” according to comment b, is defined as “the court or jury, looking at the matter after the event, and therefore knowing the situation which existed when the new force intervened, does not regard its intervention as so extraordinary as to fall outside of the class of normal events.” *Id.* cmt. b.

²⁵² 647 F.3d 377 (1st Cir. 2011).

²⁵³ *Id.*

²⁵⁴ See *First Circuit Rewrites False Claims Act Requirements and Significantly Expands Potential Liability*, SIDLEY AUSTIN LLP (Aug. 1, 2011), <http://www.sidley.com/First-Circuit-Rewrites-False->

Notably relevant to this analysis, the court rejected Blackstone's argument that there could be no FCA violation if the entity submitting the claim for reimbursement did not know of a potential FCA violation caused by some other third party.²⁵⁵ The court continued:

When the defendant in an FCA action is a non-submitting entity, the question is whether that entity knowingly caused the submission of either a false or fraudulent claim or false records or statements to get such a claim paid. The statute makes no distinction between how non-submitting and submitting entities may render the underlying claim or statements false or fraudulent.²⁵⁶

Indeed, in the First Circuit, for purposes of FCA liability, "unlawful acts by non-submitting entities may give rise to a false or fraudulent claim even if the claim is submitted by an innocent party."²⁵⁷ The court's analysis concluded by noting that "the Supreme Court has held [that], in enacting the FCA, 'Congress wrote expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the Government.'"²⁵⁸ Holdings like the First Circuit's in *Hutcheson* highlight the importance, and potential breadth, of the causation question, and the court seemed to recognize it. After noting that "the policy concerns" raised by Blackstone were "overblown," it observed that "[t]he term 'causes' is hardly boundless," and "has been richly developed as a constraint in various areas of the law," including tort law.²⁵⁹

V. TO THE STATES: CAUSATION FOR FRAUD-BASED OFF-LABEL MARKETING

In order to serve as a viable tool to penalize off-label marketing and promotion, states' fraud-based litigation must present a coherent theory of causation. As federal courts regularly refer to the common law of torts when analyzing causation in this area, it is worthwhile to break down the instant analysis similarly. First, as evinced by the Pennsylvania and Louisiana cases, state attorneys general must have a winning argument on factual, or "but-for" causation; second, of course, states must be able to demonstrate proximate causation. Both analyses follow below.

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²⁵⁵ See *Blackstone Med.*, 647 F.3d at 389.

²⁵⁶ *Id.*

²⁵⁷ *Id.* at 390.

²⁵⁸ *Id.* at 392 (quoting *Cook Cnty., Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003)) (internal quotation marks omitted).

²⁵⁹ *Id.* at 391.

A. *Factual Causation*

First, in its simplest terms, the causation inquiry in the cases highlighted above typically hinges on the “but-for,” or factual causation, requirement. For a potential cause to be deemed *the* cause of a legally compensable harm within the common law of torts, it must be the case that, but for the existence of that potential cause, the harm would have not occurred. Before one begins grappling with Justices Cardozo and Andrews as part of the proximate cause analysis, the alleged cause must satisfy the factual causation test.²⁶⁰

In off-label marketing—as illustrated by the recent state cases—it is the “but-for” causation requirement that presents the challenge for the plaintiff—whether it be the state in a state law fraud-based action²⁶¹ or a plaintiff in a malpractice case.²⁶² States bringing fraud-based claims have been unable to prove or even adequately allege those claims to the supreme courts’ satisfaction²⁶³ that off-labeling or deceptive marketing *caused* harm to the state. That is, states are unable to prove that, but for the off-label marketing of Risperdal, the state would have not been harmed. The courts’ assumption here is that the provider still would have written the prescription for the off-label usage; this is likely an assumption derived from the fact that, while pharmaceutical companies cannot promote or market a drug for an off-label usage, providers are free to prescribe them for any off-label usage. Thus, the argument goes, the provider would have prescribed the drug irrespective of the off-label marketing.

The most apt guidepost could be the federal courts’ analyses of the causation issue when examining the federal FCA in the context of off-label marketing. Indeed, when wielding the federal FCA, prosecutors rely on the argument that off-label marketing “induces physicians to file false claims.”²⁶⁴ In fact, unlike the Pennsylvania and Louisiana Supreme Courts, when analyzing the federal FCA, courts have broken down the causation inquiry, often borrowing “general tort law principles to

²⁶⁰ See *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99 (N.Y. 1928).

²⁶¹ See Katherine A. Blair, Note, *In Search of the Right Rx: Use of the Federal False Claims Act in Off-Label Drug Promotion Litigation*, 23 HEALTH LAW. 44 (2011) (“[T]he causation theory assumes that giving providers information on off-label drug indications ‘causes’ or ‘induces’ them to write an off-label prescription. . . . [T]he theory overlooks the possibility of the physician’s decision being an intervening act that would break the causal chain.”); Girard, *supra* note 219, at 140 (“In the most general sense, the use of the False Claims Act against unlawful drug promotion by a pharmaceutical company is premised on the DOJ’s assumption that the drug company’s unlawful marketing is the but for cause of the physician’s decision to prescribe the drug and request federal health care program reimbursement.”).

²⁶² See Greenwood, *supra* note 216, at 799 (presenting the “causal chain of injury” hurdle in economic injury actions brought by plaintiffs).

²⁶³ See *supra* Part III and accompanying notes.

²⁶⁴ Girard, *supra* note 219, at 153 (internal quotation marks omitted).

analyze the FCA's causation element.”²⁶⁵ In order for the relator to satisfy the factual causation requirement, courts have asked whether the alleged wrongdoing by the defendant was a “substantial factor” in bringing about the harm.

In addition to traditional notions, courts could also rely on an alternative causation test. Alternative liability theory was conceived in the classic California Supreme Court case of *Summers v. Tice*.²⁶⁶ In the case, the plaintiff sued two defendants after being shot in the eye on a hunting trip.²⁶⁷ The plaintiff did not know which one of the two defendants was responsible for striking him in the eye; he knew that one of them caused the injury but could not demonstrate which one.²⁶⁸ The defendants argued that there was “not sufficient evidence to show which defendant was guilty of the negligence which caused the injuries.”²⁶⁹ Still, the court noted that in order to address unfairness involved in requiring the plaintiff to name which shooter it was that struck him, it would shift the burden to the defendants to prove their own innocence.²⁷⁰ The court agreed with the plaintiff's argument that

[t]here should be a relaxation of the proof required of the plaintiff . . . where the injury occurs as the result of one where more than one independent force is operating, and it is impossible to determine that the force set in operation by defendant did not in fact constitute a cause of the damage, and where it may have caused the damage, but the plaintiff is unable to establish that it was a cause.²⁷¹

For states' fraud-based off-label marketing claims, both the alternative causation theories of market share/enterprise liability and quantity effect theory could be viable.

First, in another landmark decision, the California Supreme Court decided *Sindell v. Abbott Laboratories* in 1980.²⁷² In this products liability case, Judith Sindell was suing for injuries that she allegedly suffered as a result of diethylstilbestrol (DES) while in utero.²⁷³ Because a number of different companies manufactured and sold DES, Sindell did not know—and was unable to prove—which defendant actually

²⁶⁵ United States *ex rel.* Brown v. Celgene Corp., No. CV 10-3165-GHK (SSx), 2014 WL 3605896 (C.D. Cal. July 10, 2014).

²⁶⁶ 199 P.2d 1 (Cal. 1948).

²⁶⁷ *Id.* at 1-2.

²⁶⁸ *Id.* at 2.

²⁶⁹ *Id.*

²⁷⁰ *Id.* at 4.

²⁷¹ *Id.* (alteration in original). Alternate liability theory has spawned other causation theories, including market share liability and enterprise liability. Neither seems applicable in the Risperdal context, most specifically because the defendant that engaged in the conduct at issue is knowable and ascertainable. For an example of a case where the defendant who actually manufactured the drug could not be determined, see *Sindell v. Abbott Laboratories*, 607 P.2d 924, 928 (Cal. 1980).

²⁷² 607 P.2d 924.

²⁷³ *Id.* at 925.

manufactured the drug that her mother took during pregnancy and caused her injury.²⁷⁴ While relying on *Summers*, the California Supreme Court recognized enterprise liability for the first time.

Noting that the “plaintiff is not at fault in failing to provide evidence of causation, and although the absence of such evidence is not attributable to the defendants,” the court imposed a new test.²⁷⁵ According to the court, defendants are “better able to bear the cost of injury” of the drug, and “the consumer is virtually helpless to protect himself from serious, sometimes permanent, sometimes fatal, injuries caused by deleterious drugs.”²⁷⁶ Finding that there was chance that none of the five defendants sued in Sindell’s lawsuit actually “produced the offending substance,” the court extended the *Summers* rule.²⁷⁷ The court finally noted that it was “reasonable . . . to measure the likelihood that any of the defendants supplied the product which allegedly injured plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose.”²⁷⁸ For the new theory to apply, the court required that each of the manufacturers had some role in manufacturing and selling the defective identical drug and that each of them combined to have a “substantial share of the DES” manufacturing in the industry. This made the “injustice of shifting the burden of proof to defendants to demonstrate that they could not have made the substance which injured plaintiff . . . significantly diminished.”²⁷⁹

Second, although not yet successful in RICO cases, courts could rely on what is known as the quantity effect theory, a viable alternative to the “substantial factor” or “but-for” tests that are commonly applied in analyses of factual causation.²⁸⁰ This theory stands for the idea “that

²⁷⁴ *Id.* at 928.

²⁷⁵ *Id.* at 936.

²⁷⁶ *Id.*

²⁷⁷ *Id.* at 936–37.

²⁷⁸ *Id.* at 937.

²⁷⁹ *Id.*

²⁸⁰ See Greenwood, *supra* note 216, at 801–03. In a claim against a pharmaceutical company alleging RICO claims, consumer protection claims, and common law claims, the Second Circuit doubted the applicability of the quantity effect theory, but reserved judgment on it at the summary judgment stage. *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 136 (2d Cir. 2010). The court seemed skeptical, noting that “[t]he nature of prescriptions, however, means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof. . . . Lilly was not, however, the *only* source of information on which doctors based prescribing decisions.” *Id.* at 135; see also Greenwood, *supra* note 216, at 801–04. Like the *Eli Lilly* case, a subsequent federal court denied the application of the “quantity effect” theory in a RICO claim. In that case, the court described the theory and stated that the “[d]efendants admitted that some prescriptions (amounting to approximately sixty-five percent of all off-label Bextra sales) were the result of fraud, and Plaintiffs paid for ‘millions’ of dollars worth of Bextra prescriptions, so some of the prescriptions it paid for must have been the result of fraud.” *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05–CV–01699 CRB, MDL No. 1699, 2012 WL 3154957, at *7

improper promotion of off-label use for . . . [a drug] result[s] in more off-label prescriptions for . . . [the drug] than would otherwise have been written.”²⁸¹ As Professor Kate Greenwood has noted, the quantity effect theory allows the plaintiff to show a causal connection between the off-label marketing and the filing of a false claim.²⁸² While none of the state fraud-based claims have relied on the quantum effect theory in order to link off-label marketing to harm experienced by the government,²⁸³ it could presumably be used to do so.

Nonetheless, both of these alternative conceptions of causation could have been employed in the Louisiana and Pennsylvania Risperdal cases, but not without challenges. Indeed, neither of the state cases focused on the arguments that typically accompany a robust factual causation analysis; both seemed to short-handedly evince an assumption that once the physician’s prescription-writing authority is presented, the causal chain that started with the sales representative is quickly severed.

Plaintiff’s allegations demonstrate that the drug companies are marketing the off-label uses but, because they cannot demonstrate with any accuracy *which* of the claims are actually directly influenced by the marketing and which ones are not—or, more simply, whether they actually influenced the provider to write the off-label prescription or if they simply did so without any marketing or promotion—arguing that the marketing *caused* a particular false claim can be challenging. Should a court resort to the alternative liability theory espoused in *Sindell*, following the plaintiff’s prima facie showing, the burden would shift to the pharmaceutical company to prove that it did not cause the filing of a false claim with a state Medicaid agency.²⁸⁴

To courts that accept it, quantity effect—the alternative causation theory which focuses itself on the difference between the number of prescriptions written before the allegedly deceptive marketing and the number of prescriptions written after the allegedly deceptive marketing—may also establish causation. This theory would allow the state to allege factual causation by showing an increase in prescriptions of Risperdal for off-label uses after the allegedly misleading marketing. Indeed, given Risperdal’s sales numbers, this demonstration would seemingly be a simple exercise. However, this theory is not typically employed for fraud-based claims; instead, it has been attempted—nonetheless, without success—in RICO claims.²⁸⁵

(N.D. Cal. Aug. 2, 2012); *see also* Greenwood, *supra* note 216, at 807–08. Furthermore, the court noted that the theory was “unpersuasive because it require[d] too much speculation.” *Bextra*, 2012 WL 3154957, at *7.

²⁸¹ *UFCW Local 1776*, 620 F.3d at 129.

²⁸² *See* Greenwood, *supra* note 216.

²⁸³ *See* discussion and accompanying notes *supra* Part III.

²⁸⁴ *See supra* text accompanying notes 267–75.

²⁸⁵ *See* Greenwood, *supra* note 216, at 799–803.

B. *Proximate Causation*

Second, in a traditional proximate cause analysis, the court examines whether or not the harm was a foreseeable, or “natural,” consequence of the defendant’s action.²⁸⁶ Of particular import—and often the crux of the defendant’s argument—is whether or not the “independent” action of the physician—i.e., legally writing a prescription for the off-label use—constitutes a superseding cause that breaks the causal chain. Under the common law of torts, if the provider’s action was a superseding cause, the party whose action initiated the causal chain—in these cases, the pharmaceutical company’s off-label marketing—would be absolved from liability.²⁸⁷ If that is the case, it cannot be said that the pharmaceutical company’s actions *caused* the injury. But when the intervening act of the third party—here, the provider’s writing of the prescription—is foreseeable and not “extraordinary,” the causal chain is not severed.²⁸⁸

In these cases, the off-label marketing, the action of the pharmaceutical company that starts the causal chain, is undertaken with the *intent* that the third party actor, the provider, prescribes the drug for the off-label use. Within tort law, this action would not only be foreseeable and not “extraordinary,” but it is actually the sought-after result. An innocent, foreseeable act by a third party provider does not sever the causal chain; therefore, it cannot be said that the initial tortfeasor did not proximately cause the ultimate harm experienced. As a result, proximate causation appears to be a lower hurdle for the states than does factual causation in these cases.

C. *The Resulting Demise of the Independent Physician Narrative*

Indeed, a more robust causation analysis by these state courts would further the demise of the independent physician narrative. Instead, the court decisions in Louisiana and Pennsylvania treat the physician as above any influence of persuasion. Accompanying the courts’ analysis is a presumption that the pharmaceutical company must prove a linkage between its act and the prescription—a highly difficult

²⁸⁶ See W. PAGE KEETON ET AL., PROSSER & KEETON ON TORTS § 41 (5th ed. 1984); Jessie Allen, *The Persistence of Proximate Cause: How Legal Doctrine Thrives on Skepticism*, 90 DENV. U. L. REV. 77, 85–86 (2012); Tracy A. Thomas, *The Prophylactic Remedy: Normative Principles and Definitional Parameters of Broad Injunctive Relief*, 52 BUFF. L. REV. 301, 344 n.181 (2004).

²⁸⁷ Debra Burke et al., *Women and Guns: Legal and Ethical Implications for Marketing Strategy*, 12 ST. LOUIS U. PUB. L. REV. 393, 405 (1993) (noting that a superseding cause “breaks the proximate cause link” in the context of products liability).

²⁸⁸ See, e.g., *Derdiarian v. Felix Contracting Corp.*, 51 N.Y.2d 308, 315 (1980) (referencing the general rule).

task. According to these courts, without affirmative proof of persuasion, when the physician writes a prescription, he is severing the causal chain. But the primary way to prove persuasion *is the actual writing of the prescription*. Oddly, the act that severs the chain is also the necessary act in proving the false claim.

This concept fits the historic court-created fiction that, in health care fraud cases, individual providers are treated as highly autonomous and independent actors who are solely responsible for their clinical decisions.²⁸⁹ As employed by the courts in Louisiana and Pennsylvania, this legal view can be referred to—as Professor Greenwood has adroitly referred to it—the “independent physician heuristic.”²⁹⁰ This narrative maintains the view that providers are not easily swayed by influence. A holdover from the deified view of the independent physician that dominated the early twentieth century, health laws often inculcate the value of the independent provider into their provisions, and courts weave it—presumably unknowingly—into their decisions.²⁹¹ Indeed, judges, prosecutors, and lawmakers—someday likely to become the hospitals’ patients—do not want to believe that their doctors are so easily persuadable.

But a quick analysis of clinical practice casts doubt on the accuracy of this presumption. Applying a statutory framework and litigation viewpoint that assumes that they are above influence may perpetuate a legal fiction. This prevailing view specifically fails to take account of three particular pressures that should unravel the “independent provider heuristic,” or at least lessen its grip on jurists. The three pressures include (1) the providers’ lack of awareness regarding their *own* reasons for selecting a particular treatment regimen; (2) the influence and pressure of the institution on the physician’s treatment decisions; and (3) the powerful peer pressure and “bunkering” that occurs within the medical profession. Surfacing and addressing these pressures could align the regulatory regime so it more accurately reflects clinical realities. This would involve disentangling a physician’s independent decision-making ability, which is not challenged here, from the fact that physicians are not above persuasion. These powerful pressures are documented below.

²⁸⁹ See generally Greenwood, *supra* note 216, at 759; Jessica Mantel, *The Myth of the Independent Physician: Implications for Health Law, Policy, and Ethics*, 64 CASE W. RES. L. REV. 455 (2013).

²⁹⁰ Greenwood, *supra* note 216, at 765–66.

²⁹¹ *Id.*

1. From Within

The administration of health care is a complex endeavor, and clearly identifying what causes providers to administer the type of care that they do is a similarly difficult task. When investigating health fraud allegations, however, federal prosecutors review provider behavior on the lookout for fraudulent intent—a difficult and often incomplete exercise. As this Article has noted above,²⁹² proving provider intent is complicated, and it is nearly impossible when providers *themselves* do not consciously recognize the reasons for their actions. This is particularly challenging because providers often administer care without meaningful deliberation. Interestingly, they are often incentivized to mechanize and standardize the care they administer to, quite clearly, act *without* deliberate, fraudulent intent.

As a result, instead of always considering a full menu of options for every patient who presents before them, providers draw upon their experiences and biases to use decision-making “short cuts,” often unaware of these pervasive influences on their clinical judgments. In order to act quickly in the face of time constraints, resource limitations, and clinical uncertainty, physicians use these preorganized schemas²⁹³ or heuristics²⁹⁴ to quickly classify and treat patients.²⁹⁵ This is what makes drug marketing so potentially profitable; once a sales representative has developed a rapport with a particular physician,²⁹⁶ due to the physician’s mechanized clinical manner, the pharmaceutical company may have a dependable stream of business.

Fascinatingly, even providers *themselves* largely do not recognize the effect of pharmaceutical marketing on their prescribing patterns.²⁹⁷

²⁹² See Isaac D. Buck, *Enforcement Overdose: Health Care Fraud in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259 (2015).

²⁹³ See Mantel, *supra* note 289, at 477–82.

²⁹⁴ See Charity Scott, *Ethics Consultations and Conflict Engagement in Health Care*, 15 CARDOZO J. CONFLICT RESOL. 363, 401–02 (2014).

²⁹⁵ Heuristics are defined as “short cuts or rules-of-thumb used in decision making.” See *id.* “[P]eople unconsciously use [heuristics] when they have limited amounts of time and information to make a decision.” Elizabeth J. Reese, *Techniques for Mitigating Cognitive Biases in Fingerprint Identification*, 59 UCLA L. REV. 1252, 1259 (2012). They are sometimes helpful, but when combined with biases, heuristics can lead to “irrational decisions.” *Id.* Similarly, schemas are cognitive beliefs and judgments “rarely result[ing] from conscious, deductive reasoning.” Mantel, *supra* note 289, at 477. Like heuristics, schemas serve as sorting and mapping mechanisms, allowing physicians to subconsciously organize large amounts of information to assist the physician in accessing and implementing diagnostic and treatment plans. *Id.* at 477–82. Both heuristics and schemas have been shown to affect physician decision-making. Reese, *supra*, at 1259.

²⁹⁶ See Katherine T. Vukadin, *Failure-to-Warn: Facing up to the Real Impact of Pharmaceutical Marketing on the Physician’s Decision to Prescribe*, 50 TULSA L. REV. 75 (2014).

²⁹⁷ See *id.* at 111 (noting that “physicians are affected by marketing, even though they are often confident that they are not so affected”).

But even when providers lack awareness of its effect, “research indicates that advertising does influence prescribing behavior” and that “no one is entirely immune.”²⁹⁸ This allows “[a] small number of drug firms . . . [to] have inordinate influence over how medical knowledge is produced, circulated, and consumed, and thereby influence the decisions made by physicians.”²⁹⁹ As a result, this independent provider narrative may end up shielding pharmaceutical companies from liability—perhaps an unintended consequence of the narrative—under federal and state fraud-based marketing statutes, like those in Louisiana and Pennsylvania.

2. Other Pressures: From the Top and the Side

Physicians and other providers are also influenced by powerful organizational dynamics at their institutions.³⁰⁰ As more providers join hospitals,³⁰¹ these powerful entities are exerting more power over the clinical decision-making of their provider-employees. Indeed, studies have shown that providers “conform to the norms of the organization where they practice.”³⁰² In addition to influencing providers’ behavior through the traditional levers of power and money, institutions can also bestow social rewards on actors who inculcate their values and norms, whatever they may be.³⁰³

Most basically, institutions can shape physicians’ behavior by shifting or changing incentives to administer treatment in a particular manner. These institutions are often able to do so without the provider consciously *choosing* to shift his own practice patterns. Instead, powerful organizational factors can invisibly be applied to providers by their institutions, causing the providers to view supporting evidence differently. This change in behavior is immediately defensible based upon the clinical evidence, but the *way* the evidence is weighed by the provider has undoubtedly been changed.³⁰⁴

For example, if a[] . . . [health care organization] rewards its physicians for lowering costs, physicians financially benefit when

²⁹⁸ Lars Noah, *Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 ARIZ. L. REV. 373, 431–32 (2002).

²⁹⁹ Marc A. Rodwin, *Institutional Corruption and the Pharmaceutical Policy*, 41 J.L. MED. & ETHICS 544, 547 (2013).

³⁰⁰ See Mantel, *supra* note 289, at 458.

³⁰¹ *Id.*; see also BARRY R. FURROW, ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 422 (7th ed. 2013) (“Many physicians are moving from practicing in small groups to some form of employee in a changing delivery system.”).

³⁰² Mantel, *supra* note 289, at 486.

³⁰³ *Id.* at 500.

³⁰⁴ *Id.*

they prescribe less expensive therapies over their more costly alternatives. To justify doing so, physicians may give more weight to studies finding little or no difference between the less and more costly therapies, or may be dismissive of clinical studies finding that the costly therapy is more effective. . . . [W]hen a[] . . . [health care organization] rewards a physician based on productivity, the physician benefits from adopting an aggressive approach to patient management. Cognitively motivated to treat patients' conditions aggressively, the physician may invoke heuristics that support doing so Likewise, the physician may find compelling those scientific assumptions favoring aggressive treatment.³⁰⁵

Indeed, as Professor Jessica Mantel has noted, "ignoring the influence of the organization thus leads to a factually inaccurate account of patient care upon which to base health care policy."³⁰⁶

Finally, providers rely on one another as an important resource, often modeling their clinical practice off each other—for comfort, social status, financial reasons, and efficiency.³⁰⁷ Indeed, peer influence is powerful within medical practice; when faced with uncertainty, "physicians are more likely to turn to physician colleagues for advice rather than referring to journal articles or other decision supports."³⁰⁸ The importance of extraclinical guidance—whether it be from the industry or the law—pales in comparison.

This fact is unsurprising. Historically, physicians, when in need of guidance, have solicited "trusted colleagues" and "local opinion leaders,"³⁰⁹ rather than writing to trade organizations, consulting guidelines, or even approaching legal advisors.³¹⁰ Indeed, in high-stress, time-limited, and factually ambiguous clinical settings, "[c]onforming to one's peers . . . permits individuals to delude themselves into believing that an ambiguous situation is not in fact ambiguous, further providing a false sense of security."³¹¹

This reliance on peers mirrors the generally accepted practice of dissemination within the profession—many providers rely "heavily on personal experience and anecdotal information."³¹² In short, physicians learn by doing, and a peer's war story is invaluable to a young doctor. When providers consult each other frequently, this practice has the effect of standardizing medical practice and socially binds providers

³⁰⁵ *Id.* at 503–04.

³⁰⁶ *Id.* at 458.

³⁰⁷ *Id.* at 488–91.

³⁰⁸ Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 994 (2009).

³⁰⁹ Noah, *supra* note 298, at 488.

³¹⁰ Johnson, *supra* note 308, at 1014.

³¹¹ Mantel, *supra* note 289, at 488.

³¹² Noah, *supra* note 298, at 382.

with their colleagues.³¹³ Similarly, providers are hesitant to disagree with and criticize colleagues; if one has been persuaded by a sales representative to prescribe Risperdal for an off-label use, it should not be surprising to learn that peers of the provider are doing so as well.³¹⁴

D. *The Success of Off-Label Marketing as Proof*

Others have noted that off-label marketing continues because, from the pharmaceutical companies' perspectives, the "practice is simply too lucrative to pass up."³¹⁵ And as settlements for deceptive marketing with drug companies mount, and HHS' Office of Inspector General (OIG) continues to elect corporate integrity agreements as its chosen method of resolution,³¹⁶ the pattern shows no signs of slowing. Indeed, "off-label prescriptions account for 20 percent of all

³¹³ Because of the strength of the social support among peers, an atmosphere of what can be called "bunkering" results. In addition to relying on each other in times of uncertainty, colleagues protect their peers—even for relatively egregious clinical practice patterns and harmful medical errors. See Thomas H. Gallagher et al., *Talking with Patients About Other Clinicians' Errors*, 369 NEW ENG. J. MED. 1752 (2013); Kim Carollo, *Many Doctors Reluctant to Report Inept or Impaired Colleagues*, ABC NEWS (July 14, 2010), <http://abcnews.go.com/Health/doctors-reluctant-report-inept-impaired-colleagues/story?id=11154982> (noting that "31 percent [of surveyed physicians who responded] objected to the idea that they should have a responsibility to report physicians who are incompetent or impaired"); see also Susan Donaldson James et al., *Nurse Whistle-Blower Not Guilty for Reporting Doctor*, ABC NEWS (Feb. 11, 2010), <http://abcnews.go.com/WN/texas-nurse-whistleblower-anne-mitchell-acquitted-harassing-doctor/story?id=9781119> (noting the case of a Texas nurse who was prosecuted for, but later acquitted of, harassment after she reported a physician to the Texas Medical Board); Rita Rubin, *Study: Doctors Don't Always Report Colleagues' Errors*, USA TODAY (Dec. 3, 2007, 10:19 PM), http://usatoday30.usatoday.com/news/health/2007-12-03-doctor-standards_N.htm (noting that "[a]lthough virtually all doctors think they should report impaired or incompetent colleagues or serious medical errors to the relevant authorities, nearly half don't"). In the study, "only 55% of those with direct personal knowledge of such doctors in the past three years said they did so." *Id.* As Professor Johnson has noted, "[t]hreats against the bad apples in the profession are internalized by the audience of good doctors who identify with colleagues in trouble and see a fine line between themselves and these other doctors." Johnson, *supra* note 308, at 1012. This phenomenon is on particular display following the occurrence of a medical error; "providers are [reluctant] to disclose their own medical errors—much less those made by their colleagues." *NEJM: Doctors Should Report a Colleague's Mistakes. Here's How.*, ADVISORY BOARD DAILY BRIEFING (Nov. 1, 2013), <http://www.advisory.com/daily-briefing/2013/11/01/nejm-doctors-should-report-colleagues-mistakes-heres-how>.

³¹⁴ See *NEJM: Doctors Should Report a Colleague's Mistakes*, *supra* note 313.

³¹⁵ Michael Bobelian, *J&J's \$2.2 Billion Settlement Won't Stop Big Pharma's Addiction to Off-Label Sales*, FORBES (Nov. 12, 2013, 1:59 PM), <http://www.forbes.com/sites/michaelbobelian/2013/11/12/jjs-2-2-billion-settlement-wont-stop-big-pharmas-addiction-to-off-label-sales>; see also George S. Craft, Jr., *Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model*, 8 HOUS. J. HEALTH L. & POL'Y 103, 120 (2007) ("[O]ff-label promotion is a profitable, albeit illegal, business plan."); Robertson, *supra* note 4, at 548; Elissa Philip, Comment, *United States v. Caronia: How True Does "Truthful" Have to Be?*, 67 VAND. L. REV. EN BANC 157, 158 (2014) ("Pharmaceutical companies . . . have every incentive to market their drugs for off-label uses, even off-label uses that have not been proven to be safe or effective.").

³¹⁶ See generally Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033 (2012).

prescriptions, totaling more than \$40 billion in sales annually.”³¹⁷ As a result, commentators have noted that pharmaceutical companies view the fines and penalties imposed for off-label promotion simply as “just another cost of doing business.”³¹⁸ Indeed, when a company’s sales of blockbuster drugs combine to make nearly \$28 billion in sales over the course of multiple years, a \$3 billion settlement—exactly the amount of GlaxoSmithKline’s settlement for the illegal marketing of Avandia, Paxil, and Wellbutrin—is dwarfed.³¹⁹

As Lewis Morris, former Chief Counsel for the OIG, has said:

We are concerned that the providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business. As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue. For example, some major pharmaceutical corporations that have been convicted of crimes and paid hundreds of millions of dollars in False Claims Act settlements continue to participate in the Federal health care programs, in part because of the potential patient harm that could result from an exclusion.

One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.³²⁰

A clear way to “alter the cost-benefit calculus” is for states to litigate these claims in front of juries. The calculus may shift with an increasing number of eye-popping verdicts, but only with appellate decisions that apply causation analyses that track the federal courts’ treatment.

CONCLUSION

With the federal regulation of off-label marketing in flux and with the full effect of the Second Circuit’s *Caronia* decision still unknown,

³¹⁷ See Bobelian, *supra* note 315.

³¹⁸ David Evans, *Pfizer Broke the Law by Promoting Drugs for Unapproved Uses*, BLOOMBERG (Nov. 9, 2009, 12:01 AM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a4yV1nYxCGoA>.

³¹⁹ See Katie Thomas & Michael S. Schmidt, *Glaxo Agrees to Pay \$3 Billion in Fraud Settlement*, N.Y. TIMES, July 2, 2012, <http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html>.

³²⁰ *Improving Efforts to Combat Health Care Fraud: Hearing Before the Subcomm. on Oversight of the H. Comm. on Ways & Means*, 112th Cong. (2011) (statement of Lewis Morris, Chief Counsel, Office of Inspector Gen., U.S. Department of Health and Human Services), available at <http://www.hhs.gov/asl/testify/2011/03/t20110302h.html>.

regulators are searching for alternative mechanisms to prevent pharmaceutical companies from engaging in off-label marketing, and pharmaceutical companies are looking for the new rules that govern a practice that is as lucrative as it is illegal. The next regulatory platform for targeting off-label promotion and marketing may be at the state level, with state attorneys general bringing claims on behalf of their states' Medicaid trust funds and doctors. Using state statutes can inflict substantial pain on those companies for off-label promotion, but only if the state supreme courts that interpret the applicable state statutes apply principles of causation that jettison the increasingly outdated independent physician narrative. If not, the state regulatory framework may wane in importance and potentially collapse, leaving the pharmaceutical industry with fewer limitations—and much smaller speed bumps—for its off-label marketing efforts.