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# Physician Conflicts of Interest in Court: Beyond the Independent Physician Litigation Heuristic

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## **PHYSICIAN CONFLICTS OF INTEREST IN COURT: BEYOND THE “INDEPENDENT PHYSICIAN” LITIGATION HEURISTIC**

**Kate Greenwood\***

### ABSTRACT

While physicians’ financial relationships with pharmaceutical and medical device manufacturers are increasingly of concern to legislators and regulators, plaintiffs have had only limited success pursuing private law remedies for the harms that result from conflicts of interest. Courts have long channeled individual patients’ claims against their conflicted doctors into the medical malpractice cause of action, where patients have difficulty establishing that their physicians’ conflicts caused them to suffer concrete and compensable injuries. With recent notable exceptions, courts have also blocked patients’ claims against drug and device manufacturers. Courts apply the learned intermediary doctrine to dispose of failure-to-warn personal injury suits, without regard to whether the plaintiff’s physician had a financial relationship with the defendant manufacturer. Third-party payers, such as employers, insurance companies, and union health and welfare funds, have similarly struggled to overcome a strong presumption of physician independence. Courts routinely find that a physician’s prescribing decision breaks the chain of causation between a manufacturer’s illegal promotional efforts and a payer’s obligation to pay for a prescription, even when those promotional efforts include the payment of kickbacks.

Courts can and should move beyond the “independent physician”

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litigation heuristic. In personal injury cases, courts can do this by engaging in a fact-based analysis of not just whether a financial relationship affected a physician's decision to prescribe a drug or device but also whether the defendant drug or device company intended the relationship to have such an effect. The latter inquiry is more straightforward than the former, which could work to plaintiffs' advantage, and it is equally relevant to the question whether the learned intermediary doctrine should apply. In economic injury cases, courts can move beyond the heuristic by allowing plaintiffs to use standard statistical methods to demonstrate that physicians' prescribing decisions were not independent in the aggregate. If the doctrine were to evolve in these ways, it would bring closer the goal of ensuring that patients and payers are fairly compensated for the harms caused by conflicts of interest. It would also provide an additional incentive to drug and device companies to ensure that the payments they make to physicians are legitimate.

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## INTRODUCTION

Many scholars who have considered the role of private enforcement in the modern regulatory state have concluded that “litigant regulation” is inferior to regulation promulgated and enforced by an administrative agency or other centralized authority.<sup>1</sup> Similarly, scholars who study physicians and their relationships with the pharmaceutical and medical device industries tend to focus on legislative and regulatory fixes to conflict of interest concerns, while discounting or ignoring the private law landscape. Not all of the significant gaps that exist in the regulatory structure governing physician-industry relationships can or will be filled by formal regulation, however. Private lawsuits brought by patients and third-party payers could play a salutary gap-filling role. Whether they do so will depend on how the doctrine—which is in a state of flux—evolves.

While physicians’ financial relationships with pharmaceutical and medical device manufacturers are increasingly of concern to legislators and regulators, plaintiffs have had only limited success pursuing private law remedies for the harms that result from conflicts of interest.<sup>2</sup> Courts have long channeled individual patients’ claims

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1. See David Freeman Engstrom, *Agencies as Litigation Gatekeepers*, 123 YALE L.J. 616, 619 (2013) (explaining that “[c]ritics . . . cast private enforcement as overzealous, uncoordinated, and democratically unaccountable”); Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation-Through-Litigation*, 39 J. HEALTH L. 235, 243 (2006) (opining that “[r]egulation through litigation may be better than no regulation at all, but it is clearly neither the best nor the only choice available with regard to regulation of pharmaceutical marketing practices” (footnote omitted)).

2. See Christopher T. Robertson, *The Money Blind: How to Stop Industry Bias in Biomedical Science, Without Violating the First Amendment*, 37 AM. J.L. & MED. 358, 363–64 (2011) (explaining that “the pharmaceutical and medical device industries may face potential liability [for biasing biomedical science] in the extreme cases that rise to outright fraud, but only on the rare occasion that it can be detected by

against their conflicted doctors into the medical malpractice cause of action, where patients have difficulty establishing that their physicians' conflicts caused them to suffer concrete and compensable injuries.<sup>3</sup> Courts have also blocked patients' claims against drug and device manufacturers.<sup>4</sup> Nearly all courts apply the learned intermediary doctrine, even where the plaintiff's physician has a financial relationship with the defendant manufacturer.<sup>5</sup> Third-party payers, such as employers, insurance companies, and union health and welfare funds, have similarly struggled to overcome a strong presumption of physician independence.<sup>6</sup> Courts regularly find that a physician's prescribing decision breaks the chain of causation between a manufacturer's illegal promotional efforts and a payer's obligation to pay for a prescription, even when those promotional efforts include the payment of kickbacks.<sup>7</sup>

A handful of recent cases have gone the other way, however, including *Murthy v. Abbott Laboratories*, in which a district court in Texas declined to dismiss the plaintiff's failure-to-warn claim on the grounds that a financial relationship between the plaintiff's physician and the defendant manufacturer made the learned intermediary doctrine inapplicable, and *Kaiser Foundation Health Plan v. Pfizer*, in

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plaintiffs, proven in ex post litigation, and where causation of a specific and tangible harm can be demonstrated"); see also Robert Gatter, *Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 375–83 (2003) (characterizing private enforcement of conflicts of interest standards as absent or weak).

3. See, e.g., *D.A.B. v. Brown*, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997) (holding that "the gravamen of the complaint sounds in medical malpractice . . . [because] the kickback scheme involving [a] doctor, drug manufacturer, and drug distributor was dependent on the medical diagnosis, treatment, and care of the patients").

4. See, e.g., *Talley v. Danek Med., Inc.*, 179 F.3d 154, 164 (4th Cir. 1999) (applying the learned intermediary doctrine and dismissing plaintiff's failure-to-warn claim despite plaintiff's physician's consulting relationship with the defendant device manufacturer).

5. See *id.* at 163–64.

6. See Anita Bernstein, *Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation*, 15 J.L. & POL'Y 1051, 1069 (2007). Bernstein explains that "[t]hird-party payors include governments (notably Medicaid at the state level, some federal programs like the Veterans Administration, and more recently Medicare), insurers, and some employers that administer health plans." *Id.* Because they "do most of their drug purchasing in bulk[,] third-party payers, "unlike physicians and patients, are positioned to negotiate terms with the seller." *Id.* Finally, their "principal cost-containment device" is the formulary, which is a database that tells them "which drugs to prefer for the treatment of which conditions." *Id.*

7. Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 196 (2004).

which the First Circuit Court of Appeals approved of the use of a regression analysis to determine what percentage of prescriptions of the anti-epileptic drug Neurontin was caused by the defendants' fraudulent marketing.<sup>8</sup>

The plaintiff in the former case, Gayathri Murthy, participated in a clinical trial of Humira, a rheumatoid arthritis drug manufactured by the defendant, Abbott Laboratories.<sup>9</sup> Murthy's rheumatologist, Dr. Jovan M. Popovich, was one of the clinical trial's investigators and Abbott paid him for his work.<sup>10</sup> After Murthy developed cancer, she sued Abbott for, among other things, negligent failure-to-warn.<sup>11</sup>

Murthy argued that, because Abbott compensated her doctor for his role running the clinical trial, the learned intermediary doctrine did not apply and Abbott had an obligation to warn her of the risks of Humira, instead of, or in addition to, Dr. Popovich.<sup>12</sup> In a decision issued in November of 2011, the *Murthy* court adopted the plaintiff's argument and found, as a matter of law, that "Abbott cannot avail itself of the learned intermediary doctrine."<sup>13</sup> The decision was supported with references to social science research on physician attitudes toward financial relationships with the pharmaceutical industry and to research on the influence on behavior of even token gifts.<sup>14</sup> The court also cited to an article expressing concerns about physician-investigators who are responsible for recruiting and enrolling participants into clinical trials being compensated on a per capita basis.<sup>15</sup> The *Murthy* court concluded that "a doctor who receives gifts or compensation from a drug company may no longer, 'as the prescriber, stand[] between the drug and the ultimate consumer,' as the

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8. *Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.)*, 712 F.3d 21, 30 (1st Cir.), *cert. denied*, 134 S. Ct. 786 (2013); *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 971 (S.D. Tex. 2012).

9. *Murthy*, 847 F. Supp. 2d at 963–64.

10. *Id.* at 964.

11. *Id.* at 965.

12. *See id.* at 964, 977. Murthy alleged that neither the "Consent to Participate" document she signed nor the Humira package insert provided her with an adequate warning of the increased risk of cancer associated with the drug. *Id.* at 964.

13. *Murthy v. Abbott Labs.*, No. 4:11-cv-105, 2011 U.S. Dist. LEXIS 129102, at \*27 (S.D. Tex. Nov. 7, 2011), *superseded by* 847 F. Supp. 2d 958.

14. *Id.* at \*26 n.5.

15. *Id.* at \*26 n.6.

doctor has an incentive to prescribe a particular drug or, in this case, enroll a patient in a clinical trial.”<sup>16</sup>

The court’s decision, and particularly its conclusion that Dr. Popovich’s financial relationship with Abbott compromised his independence, was widely reported and, at least in some quarters, heavily criticized.<sup>17</sup> Defense attorney James M. Beck called *Murthy* “loud wrong,”<sup>18</sup> noting that it “announced what amounts to a per se rule that any doctor receiving compensation for participating in a clinical trial involving an investigational drug can’t qualify as a learned intermediary under Texas law, although, of course, both side’s [sic] experts can be paid much more.”<sup>19</sup>

In March of 2012, in response to a motion seeking permission to appeal, the *Murthy* court withdrew its November decision and issued a new one in its place.<sup>20</sup> The court’s discussion of the learned intermediary doctrine was largely unchanged, except that it was no longer willing to conclude as a matter of law that Dr. Popovich’s independence was compromised.<sup>21</sup> Rather, the court wrote, it “would have to examine the factual circumstances surrounding the compensation of [the plaintiff’s] physician in order to evaluate whether application of the learned intermediary doctrine is appropriate” because, “when a physician receives compensation or gifts from drug companies, his or her role as the neutral decision-maker may be

16. *Id.* at \*26.

17. See, e.g., John T. Aquino, *Learned Intermediary Doctrine Irrelevant When Physician is Paid, Federal Court Holds*, BNA MED. RES. L. & POL’Y REP., Nov. 16, 2011; James M. Beck, *The 10 Worst Drug/Medical Device Decisions of 2011*, LAW360 (Jan. 13, 2012), <http://www.law360.com/articles/299834/the-10-worst-drug-medical-device-decisions-of-2011>.

18. James M. Beck, *Ugly Texas Decision Ignores Erie, Tramples State Law*, DRUG & DEVICE L. (Nov. 11, 2011), <http://druganddevicelaw.blogspot.com/2011/11/ugly-texas-decision-ignores-erie.html>.

19. Beck, *supra* note 17; cf. *Miller v. Pfizer Inc. (Roerig Div.)*, 196 F. Supp. 2d 1095, 1129 & n.108 (D. Kan. 2002). The *Miller v. Pfizer* court held that:

No reasonable jury . . . would find that Dr. Geenens is lying when he says that additional warnings were not necessary and would not have changed his decision to prescribe Zolofl to Matthew. In so holding, the Court does not disregard the possible bias in Dr. Geenens’ testimony arising from his business relationship with Pfizer, i.e. the fact that at or near the time he prescribed Zolofl for Matthew, Dr. Geenens was a paid consultant for Pfizer. Rather, the Court holds that no reasonable jury would discredit his testimony—which is not refuted by any direct or circumstantial evidence—on that ground alone.

*Id.*

20. *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 963 (S.D. Tex. 2012).

21. See *id.* at 967.

diminished.”<sup>22</sup> This was *dicta*, because the court went on to dismiss the plaintiff’s failure-to-warn claim pursuant to a Texas statute providing that warnings approved by the Food and Drug Administration (FDA) for FDA-approved indications are presumed adequate.<sup>23</sup>

The *Murthy* decision was newsworthy because the court did not presume that the plaintiff’s physician was independent of the defendant manufacturer or that the physician’s decision making was unaffected by a conflict of interest. The *Murthy* court declined to deploy the heuristic of the “independent physician” that plays a central role in doctrinal analysis in drug and device litigation.

Litigation heuristics, essentially judicial reasoning and decision making shortcuts, are described in an article by Stephen Bainbridge and Mitu Gulati in which they catalog ten securities law doctrines which, on their account, have two defining features.<sup>24</sup> First, the doctrines that Bainbridge and Gulati deem to be litigation heuristics are founded on a superficial, or at least not self-evidently correct, parsing of subtle questions of fact and inference.<sup>25</sup> Judges invoking the puffery doctrine, for example, did so without citing any “actual evidence that investors or markets were unaffected by vague statements of corporate optimism.”<sup>26</sup> Second, courts deploy litigation heuristics to dismiss cases at an early stage—on a motion to dismiss or for summary judgment—as a matter of law.<sup>27</sup> The independent physician heuristic allows courts to dismiss at an early stage failure-to-warn personal injury suits, in which a manufacturer need only warn the independent physician of the risks of a drug or device, and economic injury suits brought by third-party payers and others, in which the independent physician breaks the causal chain between a manufacturer’s product promotion and the payer’s obligation to pay for prescription drugs and devices.

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22. *Id.* at 973.

23. *Id.* at 976.

24. Stephen M. Bainbridge & G. Mitu Gulati, *How Do Judges Maximize? (The Same Way Everybody Else Does—Boundedly): Rules of Thumb in Securities Fraud Opinions*, 51 EMORY L.J. 83, 118 (2002).

25. *See id.* at 118–38.

26. *Id.* at 120–21.

27. *Id.* at 118.



Courts that adopt the independent physician heuristic describe doctors and their decision making process as follows. First, doctors make informed decisions.<sup>28</sup> While they may be exposed to a “drug manufacturer’s promotions and literature[,]” they learn about drugs and devices through multiple sources, including medical journals, medical meetings, and their peers.<sup>29</sup> Second, doctors make individualized decisions about the risks and benefits a drug or device poses for a particular patient.<sup>30</sup> While a manufacturer is charged with knowing what there is to know about its drug or device,<sup>31</sup> the decision to prescribe or not rests with the physician, who has “knowledge of both patient and palliative.”<sup>32</sup> Finally, and most importantly, doctors make independent decisions.<sup>33</sup> The Eleventh Circuit has concluded that, “when a [physician] prescribes a drug, he presumably does so only if, in the exercise of his independent medical judgment, he believes the drug will benefit his patient.”<sup>34</sup> The physician’s independence is presumed because, as Paul Rheingold explains, “[m]edical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer’s control, on the part of the doctor.”<sup>35</sup>

This Article poses the question whether and, if so, at what stage of litigation courts should consider the possibility that a physician’s prescribing decision might not have been informed, individualized, or independent. Part I of the Article reviews the empirical evidence linking financial relationships to conscious and (perhaps more often) unconscious bias. Part II addresses plaintiffs’ largely unsuccessful efforts to carve out a conflicts of interest cause of action, while Parts

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28. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (“The [prescription] choice [the physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.”).

29. *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1362–63 (11th Cir. 2011).

30. *See Reyes*, 498 F.2d at 1276.

31. Kate Greenwood, *The Mysteries of Pregnancy: The Role of Law in Solving the Problem of Unknown but Knowable Maternal—Fetal Medication Risk*, 79 U. CIN. L. REV. 267, 300–01 (2010).

32. *Reyes*, 498 F.2d at 1276.

33. *See Ironworkers Local Union 68*, 634 F.3d at 1362.

34. *Id.*

35. Paul D. Rheingold, *Products Liability—The Ethical Drug Manufacturer’s Liability*, 18 RUTGERS L. REV. 947, 987 (1964).

III and IV analyze the role played by the independent physician heuristic in pharmaceutical and medical device cases, in which plaintiffs allege personal and economic injury respectively.

Part V provides an overview of federal and state regulation of physician-industry relationships, paying particular attention to the significant gaps that exist, and then makes the argument that private lawsuits brought by patients and third-party payers could, consistent with at least a strand of current doctrine, fill some of the gaps in the regulation of physician conflicts. In personal injury cases, courts can move beyond the independent physician litigation heuristic by engaging in a fact-based analysis of not just whether a financial relationship affected a physician's decision to prescribe a drug or device but also whether the defendant drug or device company intended the relationship to have such an effect. The latter inquiry is more straightforward than the former, which could work to plaintiffs' advantage, and it is equally relevant to the question whether the learned intermediary doctrine should apply. In economic injury cases, courts can move beyond the heuristic by allowing plaintiffs to use standard statistical methods to demonstrate that physicians' prescribing decisions were not independent in the aggregate. These incremental moves would bring closer the goal of ensuring that patients and payers are fairly compensated for the harms caused by conflicts of interest. They would also provide an additional incentive to drug and device companies to ensure that the payments they make to physicians are legitimate.

#### I. FINANCIAL RELATIONSHIPS, CONFLICTS OF INTEREST, AND CONSCIOUS AND UNCONSCIOUS BIAS

Financial relationships between physicians and the life sciences industry have been the subject of interest and activity because of concern that they subject physicians to a conflict of interest.<sup>36</sup> In its

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36. *See, e.g.*, Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689-96 (2010) (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of Title XI of the Social Security Act by adding section 1128G and requiring pharmaceutical and medical device manufacturers to disclose payments made to physicians and teaching hospitals for, among other things, conducting clinical

2009 report, *Conflict of Interest in Medical Research, Education, and Practice*, the Institute of Medicine defined “conflict of interest” as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.”<sup>37</sup>

The American College of Physicians Ethics Manual provides that the primary interest of a physician in clinical practice is “the patient’s welfare and best interests, whether in preventing or treating illness or helping patients to cope with illness, disability, and death.”<sup>38</sup> Physicians who undertake clinical research have additional primary obligations, including ensuring the integrity of the research and contributing to the advancement of science.<sup>39</sup> Of course, physicians and investigators have a host of secondary interests as well, including earning the respect of their colleagues, advancing their careers, and

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research); CAL. HEALTH & SAFETY CODE § 24173(c)(11) (West, WestlawNext through 2013 Reg. Sess. & 2013–2014 First Ex. Sess.) (requiring disclosure to prospective research participants of “[t]he material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment”); Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 Fed. Reg. 53,256, 53,293 (Aug. 25, 2011) (codified at 42 C.F.R. §§ 50.601-50.607) (adopting “changes that expand and add transparency to Investigators’ disclosure of Significant Financial Interests (SFIs), enhance regulatory compliance and effective institutional oversight and management of Investigators’ financial conflicts of interests, as well as increase the Department of Health and Human Services’ (HHS) compliance oversight”); Press Release, Dep’t of Justice, Minnesota-Based Medtronic Inc. Pays US \$23.5 Million to Settle Claims That Company Paid Kickbacks to Physicians (Dec. 12, 2011), available at <http://www.justice.gov/opa/pr/2011/December/11-civ-1623.html> (announcing settlement to resolve allegations that device maker used post-market studies and device registries as vehicles to pay physician-investigators kickbacks to implant the company’s pacemakers and defibrillators); Press Release, Dep’t of Justice, Minnesota-Based St. Jude Medical Pays U.S. \$16 Million to Settle Claims that Company Paid Kickbacks to Physicians (Jan. 20, 2011), available at <http://www.justice.gov/opa/pr/2011/January/11-civ-078.html> (same).

37. INST. OF MED. OF THE NAT’L ACADS., *CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE* 46 (Bernard Lo & Marilyn J. Field eds., 2009). Interestingly, the *Murthy* court defined the relevant conflict differently, focusing on the “irreconcilabl[e] differen[ce]” between “[t]he responsibilities of pharmaceutical companies and physicians.” *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 972 n.5 (S.D. Tex. 2012).

38. Lois Snyder, *American College of Physicians Ethics Manual: Sixth Edition*, 156 ANNALS INTERNAL MED. 73, 75 (2012). The Ethics Manual goes on to provide that “[t]he interests of the patient should always be promoted regardless of financial arrangements; the health care setting; or patient characteristics, such as decision-making capacity, behavior, or social status.” *Id.* In addition, “[a]lthough the physician should be fairly compensated for services rendered, a sense of duty to the patient should take precedence over concern about compensation.” *Id.*

39. KATHLEEN M. BOOZANG ET AL., CTR. FOR HEALTH & PHARM. LAW & POLICY, SETON HALL UNIV. SCH. OF LAW, *CONFLICTS OF INTEREST IN CLINICAL TRIAL RECRUITMENT & ENROLLMENT: A CALL FOR INCREASED OVERSIGHT* 9 (2009).

financially supporting themselves and their families.<sup>40</sup> These secondary influences are not inherently wrong, but they can create a risk of compromised judgment.<sup>41</sup>

A growing body of empirical evidence suggests that even seemingly trivial “interests”—such as the pens and other reminder items that were once ubiquitous in hospitals and doctors’ offices—can exert undue influence.<sup>42</sup> The most recent iteration of the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals prohibits the distribution of reminder items,<sup>43</sup> but drug samples and free meals are still permitted.<sup>44</sup> Manufacturers spend heavily on these and many practicing physicians accept them.<sup>45</sup> Payments from drug and device companies to doctors for, among other things, conducting research, serving on advisory boards, and giving promotional talks are less common, but not rare.<sup>46</sup>

A study published in 2010 by Eric Campbell and colleagues found that the percentage of primary care and specialist physicians who reported receiving (1) in-kind benefits such as prescription drug samples, food and beverages, and continuing medical education, (2) payments for professional services, and (3) reimbursements fell significantly between 2004 and 2009.<sup>47</sup> That said, physician-industry relationships remained widespread in 2009, with 83.8% of the 1,891

40. *Id.*

41. *Id.*

42. Deborah Korenstein, Salomeh Keyhani & Joseph S. Ross, *Physician Attitudes Toward Industry: A View Across the Specialties*, 145 ARCHIVES SURGERY 570, 573, 577 (2010); see also ASS’N OF AM. MED. COLLS., THE SCIENTIFIC BASIS OF INFLUENCE AND RECIPROCITY: A SYMPOSIUM 1 (2007) (discussing a “growing body of a neurobiological and psychosocial evidence related to the effects of gifts on recipients’ choices and decisions”).

43. PHARM. RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 11 (2008).

44. *Id.* at 4–5, 12.

45. Korenstein, Keyhani & Ross, *supra* note 42, at 570; see also L. Lewis Wall & Douglas Brown, *The High Cost of Free Lunch*, 110 OBSTETRICS & GYNECOLOGY 169, 171 (2007) (noting that “[t]he provision of food is an especially powerful tool in shaping perceptions and increasing the sense of reciprocal obligation in cultures around the world”); Stephanie Saul, *Drug Makers Pay for Lunch as They Pitch*, N.Y. TIMES, July 28, 2006, at A1 (reporting that some physicians’ offices receive breakfast and lunch paid for by pharmaceutical companies every day and that the companies spend hundreds of millions of dollars each year on such meals).

46. Korenstein, Keyhani & Ross, *supra* note 42, at 570.

47. Eric G. Campbell et al., *Physician Professionalism and Changes in Industry Relationships From 2004 to 2009*, 170 ARCHIVES INTERNAL MED. 1820, 1823 (2010).

physicians the authors surveyed reporting a relationship of some type within the previous year. More specifically, 70.8% of the physicians surveyed received gifts (“primarily food and beverages in their offices”) from industry, 63.8% received drug samples, 18.3% received “reimbursements for meetings or free or subsidized admission to CME meetings,” and 14.1% were paid for their professional services.<sup>48</sup> The authors broke the final category down even further, explaining that “payments for speaking engagements were most frequent (8.6% of all respondents), followed by serving as a consultant (6.7%), service on a company advisory board (4.6%), and payments in excess of costs for enrolling patients in clinical trials (1.2%).”<sup>49</sup>

In a study published in 2013, Campbell and colleagues further analyzed the data from their 2009 survey and found that physicians who accepted food and beverages from industry were significantly more likely to acquiesce to a patient’s request for a brand-name medication over an available generic than were physicians who did not accept food and beverages.<sup>50</sup> Physicians who received drug samples were also significantly more likely to comply with their patients’ requests for brand-name medications.<sup>51</sup>

Several widely cited studies from the early 1990s also support the common sense conclusion that drug and device companies would not “spend large sums of money on marketing efforts if they were not felt to be effective.”<sup>52</sup> A 1990 survey study of physicians at seven teaching

48. *Id.*

49. *Id.*

50. Eric G. Campbell et al., *Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey of Physicians*, 173 JAMA INTERNAL MED. 237, 237–38 (2013).

51. *Id.*

52. James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There’s No Such Thing as a Free Lunch*, 102 CHEST 270, 273 (1992). Studies of physicians’ financial relationships unrelated to the pharmaceutical and medical device industries provide further support for the conclusion that secondary interests can influence physician decision making. See, e.g., David Orentlicher, *Cost Containment and the Patient Protection and Affordable Care Act*, 6 FLA. INT’L UNIV. L. REV. 67, 72 (2010) (“[W]hen physicians are paid a salary, [as opposed to being paid on a fee-for-service basis,] they are less likely to order lab tests, request radiologic scans or perform surgeries.”); Christopher Robertson, Susannah Rose & Aaron S. Kesselheim, *Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence*, 40 J.L. MED. & ETHICS 452, 462 (2012) (“Our review has found evidence that financial relationships bias physician decisions to different degrees in all three areas we explored: the payments to referrers, the incentives created by health insurers, and the largesse provided by the drug and device industries.”).

hospitals found a correlation between a report of receipt of a free meal and a report of a change in practice.<sup>53</sup> The same study found a correlation between receipt of honoraria or research support and requests that drugs be added to the hospitals' formularies.<sup>54</sup> A 1994 study compared forty physicians who requested that drugs be added to their hospitals' formularies with eighty physicians who did not and found that accepting money from companies to attend or speak at educational symposia or to perform research was strongly correlated with requesting a formulary addition.<sup>55</sup>

A third study, published in 1992, compared physicians' prescribing of two drugs before and after the physicians and their guests went on all-expenses-paid trips to resorts where they attended symposia on the drugs.<sup>56</sup> The physicians' usage of both drugs increased sharply as soon as the invitations to attend the symposia were extended.<sup>57</sup> The study authors concluded that "[t]he temporal relationship to the expense-paid seminar is difficult to ignore and the two-to three-fold increase in prescribed units is impressive."<sup>58</sup> The authors also noted that there "was no discernible change in the prescribing of the alternative drugs which these new drugs were designed to replace, suggesting that the new drugs were not replacing older alternatives, but instead that the enticements were resulting in additional and perhaps excessive use."<sup>59</sup>

There is also ample anecdotal evidence that financial relationships between doctors and drug and device companies are intended to—and do—influence physician decision making. Michael Oldani, a former pharmaceutical sales representative who is now an anthropologist, describes an episode "during one of [his] last years with Company X" when he was "quite desperate to make 'quota' (i.e., feeling managerial pressure in form of performance reviews to match or exceed the

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53. Nicole Lurie et al., *Pharmaceutical Representatives in Academic Medical Centers: Interaction with Faculty and Housestaff*, 5 J. GEN. INTERNAL MED. 240, 240 (1990).

54. *Id.*

55. Mary-Margaret Chren & C. Seth Landefeld, *Physicians' Behavior and Their Interactions with Drug Companies: A Controlled Study of Physicians Who Requested Additions to a Hospital Drug Formulary*, 271 JAMA 684, 684 (1994).

56. Orłowski & Wateska, *supra* note 52, at 270.

57. *Id.* at 271.

58. *Id.* at 273.

59. *Id.*

previous year's sales) for a hospital-based IV antibiotic, Antibiotic S."<sup>60</sup> Oldani created gift cards good for ten free cups of coffee at the hospital coffee cart and gave them out to "anyone who could write a prescription of Antibiotic S."<sup>61</sup> The result was sales of Antibiotic S that "far exceeded" Oldani's expectations, allowing him to achieve his sales quota.<sup>62</sup>

Court documents released by the Department of Justice in July 2012 tell a similar story. In 2000 and 2001, GlaxoSmithKline allegedly promoted its anti-depressant Paxil to psychiatrists during "Paxil Forum" meetings held at "lavish" resorts.<sup>63</sup> In addition to being reimbursed for all of his or her expenses, each psychiatrist who attended was paid a \$750 honorarium; psychiatrists who spoke at the meetings were paid \$2,500.<sup>64</sup> An internal memorandum prepared after the 2000 Paxil Forum meeting reported that "[p]hysicians grew actual market share versus their forecasted share immediately after Forum attendance," and noted that "[t]est physicians grew market share significantly relative to Control physicians."<sup>65</sup> According to the memorandum, the 2000 Paxil Forum meetings "resulted in at least \$900,000 in additional revenue in 2000 alone."<sup>66</sup>

Importantly, individuals are often not conscious of the bias caused by a conflict of interest.<sup>67</sup> Writing in 2003, Jason Dana and George

60. Michael J. Oldani, *Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices*, 18 MED. ANTHROPOLOGY Q. 325, 334 (2004).

61. *Id.* at 335.

62. *Id.*

63. United States' Complaint at 17, *United States ex rel. Thorpe v. GlaxoSmithKline PLC*, No. 11-10398-RWZ (D. Mass. Oct. 26, 2011).

64. *Id.*

65. *Id.* at 18–19.

66. *Id.* at 19.

67. See, e.g., Ann H. Harvey, Ulrich Kirk, George H. Denfield & P. Read Montague, *Monetary Favors and Their Influence on Neural Responses and Revealed Preference*, 30 J. NEUROSCIENCE 9597, 9600–01 (2010) (reporting on research demonstrating that "[a] monetary favor from a company was indeed capable of robustly influencing preference for art paired with the logo of the sponsoring company logo. . . . despite the fact that subjects were unfamiliar with the company logos, subjects had no reciprocal interaction with the company, and the only association between the art and the sponsoring company was visual juxtaposition on a computer screen," and despite the fact that the subjects of the research did not believe "the presence of the logo influenced their ability to judge the paintings"); see also Azgad Gold & Paul S. Appelbaum, *Unconscious Conflict of Interest: A Jewish Perspective*, 37 J. MED. ETHICS 402, 404 (2011) ("It seems that the Talmudic answer to this question is clear. On the psychological level, one cannot escape the deleterious unconscious effects of receiving a gift. As a human being, the recipient is biased, no matter

Loewenstein drew the following conclusions from social science research on conflicts of interest:

First, individuals are unable to remain objective, even when they are motivated to be impartial, demonstrating that self-serving bias is unintentional. Second, individuals deny and succumb to bias even when explicitly instructed about it, which suggests that self-serving bias is unconscious. Third, the studies show that self-interest affects choices indirectly, changing the way individuals seek out and weigh the information on which they later base their choices when they have a stake in the outcomes.<sup>68</sup>

Many doctors concede that even small financial interests may have the potential to influence the judgment of other physicians, but deny that they themselves would be affected. For example, a study published in 2010 found that 52% of the physicians surveyed believed that their colleagues were likely to be biased by free food or gifts, while only 36% thought they themselves would be biased; a number of prior surveys have reached similar conclusions.<sup>69</sup> Other studies have shown that “[r]eceiving a gift and the number of gifts received correlated with the belief that pharmaceutical representatives have no impact on prescribing behavior.”<sup>70</sup> That conflicts of interest work at a subconscious level raises the concern that it may be difficult for

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how wise and otherwise reasonable the person may be.”); Don A. Moore, Philip E. Tetlock, Lloyd Tanlu & Max H. Bazerman, *Conflicts of Interest and the Case of Auditor Independence: Moral Seduction and Strategic Issue Cycling*, 31 ACAD. MGMT. REV. 1, 2 (2006) (arguing that, with specific regard to auditors, “[p]utting the most Machiavellian fringes of professional communities aside, . . . the majority of professionals are unaware of the gradual accumulation of pressures on them to slant their conclusions—a process we characterize as moral seduction”).

68. Jason Dana & George Loewenstein, *A Social Science Perspective on Gifts to Physicians from Industry*, 290 JAMA 252, 253 (2003).

69. Korenstein, Keyhani & Ross, *supra* note 42, at 573; *see also* Kirsten E. Austad, Jerry Avorn & Aaron S. Kesselheim, *Medical Students’ Exposure to and Attitudes About the Pharmaceutical Industry: A Systematic Review*, 8 PLOS MED., May 24, 2011, at 3 (“In most studies, almost two-thirds of students reported that they were immune to bias induced by promotion . . . , gifts . . . , or interactions with sales representatives in general . . . . This perception of immunity to bias was prevalent in both the preclinical and clinical years. It appeared that students were more likely to report that fellow medical students . . . or doctors . . . are influenced by such encounters than they were personally . . .”).

70. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 JAMA 373, 375–76 (2000).



physicians to determine for themselves when the risk that a secondary interest could unduly influence their professional judgment or actions has become a reality.

## II. A CAUSE OF ACTION FOR PHYSICIAN CONFLICTS OF INTEREST?

Patients and research participants have tried with little success to sue physicians and pharmaceutical and medical device companies for conflicts of interest *qua* conflicts of interest.<sup>71</sup> The Minnesota Court of Appeals' 1997 decision in *D.A.B. v. Brown* exemplifies the difficulties.<sup>72</sup> In that case, the plaintiffs, a putative class of minor patients and their parents, sued a physician, Dr. David A. Brown, a drug manufacturer, Genentech, and a drug distributor, Caremark, alleging that the defendants failed to disclose a kickback scheme involving the drug Protoprin, a synthetic form of human growth hormone.<sup>73</sup>

Before the plaintiffs filed their civil suit, Dr. Brown, Caremark, and four individual defendants, who were executives at Caremark and Genentech, had been indicted on multiple counts of mail fraud, wire fraud, and money laundering.<sup>74</sup> They were also charged with violating the federal anti-kickback law, which makes it a felony to offer or pay, or to solicit or receive, "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" for, among other things, "purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program."<sup>75</sup> The

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71. Gatter, *supra* note 2, at 376.

72. *D.A.B. v. Brown*, 570 N.W.2d 168 (Minn. Ct. App. 1997).

73. *Id.* at 169.

74. *Id.*

75. *Id.*; 42 U.S.C. § 1320a-7b(b)(1) & (2) (2006). As David Hyman explains, the anti-kickback law has "statutory exceptions for discounts, payments pursuant to a bona fide employment relationship, group purchasing organizations, waiver of coinsurance obligations, and risk-sharing agreements of managed care organizations," as well as "administrative regulations creating specific safe harbors and advisory opinions covering a number of other arrangements." David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen"*, 30 J. LEGAL STUD. 531, 534-35 (2001).

government alleged that Dr. Brown “solicited and received payments from Caremark, . . . [which] was the exclusive home health distributor of . . . Protropin, in exchange for Brown’s referral of patients for whom he prescribed Protropin and who were participants in the Medicaid program.”<sup>76</sup>

Caremark pled guilty to a single count of mail fraud and entered into a plea agreement in which it “stipulated that it made payments to [Dr. Brown] to induce him to refer patients for Protropin-related services and supplies.”<sup>77</sup> Caremark “agreed to pay a total of \$161 million in fines, penalties, and restitution.”<sup>78</sup> The remaining defendants went to trial. The district court granted the defendant executives’ motions for judgments of acquittal at the close of the government’s case.<sup>79</sup> Dr. Brown was found guilty of two of the nineteen counts submitted against him but was granted a new trial based on juror misconduct and the jury’s exposure to the fact of Caremark’s guilty plea.<sup>80</sup>

Because the anti-kickback law does not have a private right of action, the plaintiffs in *D.A.B.* were in need of a legal theory. They sued for “breach of fiduciary duty, conspiracy to breach that duty, common law fraud, negligent misrepresentation, and violation of the Minnesota Prevention of Consumer Fraud Act.”<sup>81</sup> The court rejected the plaintiffs’ claim under the Consumer Fraud Act for failure to plead a cognizable injury. While the complaint included “a general allegation that the patients and their parents ‘have been harmed’ by the kickback scheme[,]” this was insufficient.<sup>82</sup> The court suggested that the complaint might have survived the motion to dismiss had the plaintiffs been able to allege (1) that they had to pay more for Protropin than they would have for another drug, (2) that they had to pay more in premiums or insurance co-payments as a result of the Protropin they were prescribed, and/or (3) that they “would have stopped Protropin treatment or purchased another drug if the doctor had disclosed the

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76. *United States v. Brown*, 108 F.3d 863, 864 (8th Cir. 1997).

77. *D.A.B.*, 570 N.W.2d at 169.

78. *Brown*, 108 F.3d at 865.

79. *Id.*

80. *Id.* at 866.

81. *D.A.B.*, 570 N.W.2d at 169.

82. *Id.* at 173.

kickback scheme.”<sup>83</sup>

The *D.A.B.* court also rejected the plaintiffs’ common law claims. In the words of the court, the plaintiffs asked the court to “apply[] traditional fiduciary concepts” to put “teeth” into physicians’ duty to provide “medical opinions about treatment plans and referrals unsullied by conflicting motives.”<sup>84</sup> A breach of fiduciary duty claim has “teeth” because, at least in some jurisdictions, a plaintiff need only prove that the defendant breached a fiduciary relationship to make out a *prima facie* case.<sup>85</sup> As the court explained, “‘injury’ would be presumed, due to the nature of the fiduciary relationship, and a fiduciary could be required to disgorge itself of all profits gained as a result of the breach.”<sup>86</sup>

Although the *D.A.B.* court agreed with the plaintiffs “that a physician’s advice about treatment options should be free from self-serving financial considerations,” the court determined that “the gravamen of the complaint sound[ed] in medical malpractice[,]” not breach of fiduciary duty.<sup>87</sup> A breach of fiduciary duty claim, the court suggested, might be available where the underlying facts are independent of medical diagnosis, treatment, and care.<sup>88</sup> That was not the case in *D.A.B.* because Dr. Brown’s treatment of his pediatric patients with Protropin was at the heart of the defendants’ kickback scheme.<sup>89</sup>

The court’s rejection of the breach of fiduciary duty claim posed a problem for the plaintiffs for two reasons. First, as is the case in many or most states, the statute of limitations for medical malpractice actions in Minnesota is very short. The events alleged in the complaint occurred outside of the two-year statute of limitations period for medical malpractice actions but within the six-year statute of limitations for breaches of fiduciary duty.<sup>90</sup> The second, and more

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83. *Id.*

84. *Id.* at 170.

85. Gatter, *supra* note 2, at 379.

86. *D.A.B.*, 570 N.W.2d at 172.

87. *Id.* at 171–72.

88. *Id.* at 171.

89. *Id.*

90. *Id.*

fundamental, problem is that, to adequately plead a medical malpractice claim, a plaintiff must allege that the physician's breach of the standard of care caused the plaintiff to suffer an injury.<sup>91</sup> The plaintiffs in *D.A.B.*, however, did "not allege the Protropin treatment was improper or that the treatment resulted in harm."<sup>92</sup>

As Robert Gatter has explained, even when a patient or research participant is able to allege cognizable harm, to prevail on a medical malpractice or other negligence-based claim, they still bear "the burden of proving causation, which, in a case alleging injury as a result of a financial conflict of interest, means proving a financial motive underlying the defendant's conduct."<sup>93</sup> An injured plaintiff must "establish that, but for the conflict of interest, the [defendant] would have conducted himself or herself in a way that avoided injury to the plaintiff."<sup>94</sup> In Gatter's view, this "burden is almost impossible to satisfy."<sup>95</sup>

In the main, courts have held, as the Minnesota Court of Appeals did in *D.A.B.*, that claims for breach of fiduciary duty do not lie against physicians for their conflicts of interest. Courts have likewise held that such claims do not lie against health plans for the conflicts created by their financial arrangements with physicians. In *Pegram v. Herdrich*, the plaintiff was enrolled in a health maintenance organization (HMO) that paid its physician owners a "year-end distribution" equal to "the profit resulting from their own decisions rationing care."<sup>96</sup> The plaintiff argued that the provision of medical services under those terms "entailed an inherent or anticipatory breach of an [Employee Retirement Income Security Act of 1974 (ERISA)] fiduciary duty, since these terms created an incentive to make decisions in the physicians' self-interest, rather than the exclusive interests of plan

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91. *Id.*

92. *D.A.B.*, 570 N.W.2d at 171.

93. Gatter, *supra* note 2, at 377.

94. *Id.*

95. *Id.* *But see* *Martinez v. Elias*, 922 N.E.2d 457, 465–66 (Ill. App. Ct. 2009) (affirming, in case in which the jury found for the plaintiff, trial court's admission of evidence of a surgeon's financial incentive to perform surgery in support of the plaintiff's claim that the surgery performed was unnecessary).

96. *Pegram v. Herdrich*, 530 U.S. 211, 220 (2000).

participants.”<sup>97</sup>

The Supreme Court rejected the plaintiff’s claim, explaining that an HMO’s defense against a breach of fiduciary duty claim “would be that its physician did not act out of financial interest but for good medical reasons, the plausibility of which would require reference to standards of reasonable and customary medical practices in like circumstances.”<sup>98</sup> This, in turn, would mean that “every claim of fiduciary breach by an HMO physician . . . would boil down to a malpractice claim, and the fiduciary standard would be nothing but the malpractice standard traditionally applied in actions against physicians.”<sup>99</sup> Congress, the Court held, did not enact ERISA in order to “federalize malpractice litigation.”<sup>100</sup> The Court also observed that if claims like the plaintiff’s were permitted to proceed, “[i]t would be so easy to allege, and to find, an economic influence when sparing care did not lead to a well patient, that any such standard in practice would allow a factfinder to convert an HMO into a guarantor of recovery.”<sup>101</sup>

In a small number of cases, plaintiffs have been permitted to pursue claims arising out of a physician’s failure to disclose that he or she had a conflict of interest.<sup>102</sup> In the leading case, *Moore v. The Regents of the University of California*, the plaintiff sued the doctor who treated

97. *Id.* at 216.

98. *Id.* at 235.

99. *Id.*

100. *Id.* at 236.

101. *Id.* at 234–35. While *Pegram* is an ERISA case, its reasoning applies as well to common law breach of fiduciary duty claims. Gatter, *supra* note 2, at 381. In *Neade v. Portes*, for example, the Illinois Supreme Court adopted the United States Supreme Court’s analysis in *Pegram* in dismissing a common law breach of fiduciary duty claim brought against a physician. *Neade v. Portes*, 739 N.E.2d 496, 501–02 (Ill. 2000).

102. *See, e.g.*, *Garcia v. Coffman*, 946 P.2d 216, 219, 221, 226 (N.M. Ct. App. 1997) (upholding jury award of \$2 in nominal damages and \$50,000 in punitive damages against chiropractor who failed to disclose “a scheme to generate income through the provision of unnecessary medical services”); *Minute Order* at 1–2, *McDonald v. UCSD Med. Ctr.*, No. 37-2009-00088181-CU-PO-CTL (Cal. Super. Ct. Oct. 7, 2011), 2011 WL 9517594 (“There is a triable issue of fact whether Dr. Kim should have disclosed his financial relationship with HydroCision and his use of off-label equipment or materials . . . . Dr. Kim admits he had a consulting relationship with HydroCision, used a HydroCision product, a SpineJet Resector, during [the plaintiff’s] surgery and received royalties for certain purchases of the product. . . . Although defendants contend the financial interest was de minimus [sic] and off-label use is permitted, the scope of the physician’s communications to the patient are measured by the materiality to the patient’s decision. Thus, there is a triable issue whether the financial relationship and off-label use should have been disclosed to plaintiff.” (citations omitted)).

him for hairy-cell leukemia, alleging that the doctor withdrew the plaintiff's spleen as well as "blood, bone marrow aspirate, and other bodily substances" without disclosing that the doctor planned to use the plaintiff's cells in potentially lucrative clinical research.<sup>103</sup> In addition to his doctor, the plaintiff sued the Regents of the University of California (the owners of the hospital where the plaintiff was treated) and a researcher employed by the Regents, as well as a pharmaceutical company and another for-profit entity that entered into an agreement with the plaintiff's doctor to commercialize the plaintiff's cells.<sup>104</sup>

The California Supreme Court held that the plaintiff's breach of fiduciary duty claim against his doctor could proceed. Specifically, the court found that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."<sup>105</sup> In deciding on a course of treatment, the court explained, a reasonable patient would want to know whether "an interest extraneous to the patient's health has affected the physician's judgment."<sup>106</sup> The plaintiff did not, however, have a claim against the other four defendants, except "on account of [the doctor]'s acts and on the basis of a recognized theory of secondary

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103. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 480–83 (Cal. 1990).

104. *Id.* at 480–81.

105. *Id.* at 485.

106. *Id.* at 484. The California Supreme Court's holding in *Moore* reflects the fact that California has adopted the "reasonable patient" informed consent standard under which physicians must "provide the information a reasonable patient would deem material." Nadia N. Sawicki, *The Abortion Informed Consent Debate: More Light, Less Heat*, 21 CORNELL J.L. & PUB. POL'Y 1, 19 (2011). Most states instead apply a "reasonable physician" standard under which "the physician would be liable . . . if . . . she failed to disclose the information her colleagues customarily disclose." *Id.*; see also 5 *Med. Malpractice* (Matthew Bender) § 22.05 (2013) (reporting that the reasonable patient standard "remains the minority position"). In states using the reasonable physician standard, a physician would only be required to disclose "an interest extraneous to the patient's health" if other physicians customarily did so. *Moore*, 793 P.2d at 484. Moreover, even in California, in the managed care context, a statute specifically states that health care providers need not supply information about "financial bonuses or any other incentives," unless a person so requests, and that providers may withhold "privileged or confidential" financial information. CAL. HEALTH & SAFETY CODE § 1367.10(b) (West, WestlawNext through 2013 Reg. Sess. & 2013–2014 First Ex. Sess.).

liability, such as respondeat superior.”<sup>107</sup>

The facts of *Moore* are plainly unusual. In a subsequent case involving a more typical physician-industry financial relationship, *Dimmick v. United States*, a Northern District of California court distinguished *Moore* as follows:

Unlike the physician in *Moore*, Dr. Lampiris[, the plaintiff’s doctor,] was not participating in research involving ritonavir[, the drug at issue], nor did he derive any financial benefit by including ritonavir in Dimmick’s[, the plaintiff’s] drug regimen. Rather, Dr. Lampiris received fixed compensation for his consultant work, unlike the physician in *Moore* who received compensation in exchange for administering treatment. Finally, Dr. Lampiris’ testimony that, in prescribing ritonavir as a component of Dimmick’s regimen, his professional judgment was unaffected by his role as a consultant for Abbott[, ritonavir’s manufacturer,] went un rebutted.<sup>108</sup>

The *Dimmick* court went on to find that even if the plaintiff had been able to establish that a reasonable patient would want to know about the defendant physician’s consulting work, the plaintiff would not be able to make the—in Gatter’s estimation “almost impossible”<sup>109</sup>—causation showing.<sup>110</sup> That is, he would not be able to show “that a prudent person would not have taken the ritonavir in light of Dr. Lampiris’ role as a consultant for Abbott.”<sup>111</sup>

In *Wright v. Fred Hutchinson Cancer Center*, the plaintiffs—the estates and surviving relatives of cancer patients who died while participating in a clinical trial—were similarly unsuccessful.<sup>112</sup> The plaintiffs alleged that the defendants—the Fred Hutchinson Cancer

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107. *Moore*, 793 P.2d at 486.

108. *Dimmick v. United States*, No. C 05-0971 PJH, 2006 U.S. Dist. LEXIS 90843, at \*55 (N.D. Cal. Dec. 15, 2006).

109. Gatter, *supra* note 2, at 377.

110. *Dimmick*, 2006 U.S. Dist. LEXIS 90843, at \*56.

111. *Id.* at \*57.

112. *Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1291, 1297 (W.D. Wash. 2002).

Research Center and researchers there—violated the plaintiffs’ rights by failing to disclose that the defendants had a financial conflict of interest.<sup>113</sup> According to an exposé in the *Seattle Times*, the Fred Hutchinson Cancer Research Center had licensed its intellectual property rights in the treatment being studied to a start-up company called Genetic Systems.<sup>114</sup> The Center retained a royalty interest in the treatment and both the Center and the researchers held equity in Genetic Systems.<sup>115</sup>

The District Court for the Western District of Washington allowed the plaintiffs’ state law fraud and informed consent claims to proceed to trial in state court.<sup>116</sup> Before the trial concluded, however, the judge “threw out” the fraud claim, “ruling that the plaintiffs had failed to prove a financial conflict.”<sup>117</sup> The informed consent claim went to the jury, which found for the defendants.<sup>118</sup> Interviews with jurors after the verdict was issued suggested that the plaintiffs were not able to show that if they had known about the defendants’ financial conflicts of interest they would not have consented to participate in the clinical trial.<sup>119</sup>

Finally, in another significant case, *Darke v. Isner*, a Massachusetts Superior Court held that a claim did lie against a conflicted hospital and physician-investigator for gross negligence and deceit.<sup>120</sup> The plaintiff in the case was the widow of a man who died while participating in an experimental gene therapy program.<sup>121</sup> She alleged that her husband would not have elected to participate in the program if he had known that, should the therapy being studied prove effective,

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113. *Id.* at 1297.

114. Duff Wilson & David Heath, *The Blood-Cancer Experiment: Patients Never Knew the Full Danger of Trials They Staked Their Lives On*, SEATTLE TIMES, Mar. 11, 2001, at A1. Note that the Center denied Wilson and Heath’s allegations. See *Q & A on This Series: Questions and Answers About ‘The Hutch’*, SEATTLE TIMES (Mar. 25, 2001), [http://seattletimes.com/uninformed\\_consent/qa.html](http://seattletimes.com/uninformed_consent/qa.html).

115. Wilson & Heath, *supra* note 114, at A15.

116. See David Heath & Luke Timmerman, *Jury Finds Hutch Not Negligent in 4 Deaths*, SEATTLE TIMES, Apr. 9, 2004, at A1, A15.

117. *Id.* at A15.

118. *Id.* at A1.

119. *Id.* at A15.

120. *Darke v. Estate of Isner*, No. 02-2194, 2004 Mass. Super. LEXIS 250, at \*10 (Mass. Super. Ct. June 3, 2004).

121. *Id.* at \*1.



both the hospital and the physician “stood to profit financially in proportion to their ownership stake” in a company called Vascular Genetics that the physician helped to found.<sup>122</sup>

In a May 2005 decision, the superior court denied a defense motion for summary judgment on the plaintiff’s gross negligence claim, holding that enough evidence had been presented to support the allegation that the physician-investigator’s financial stake in the success of the treatment being studied may have compromised how the clinical trial was conducted.<sup>123</sup> The court also held that there was sufficient evidence to go forward with the deceit claim for failure to disclose the financial relationships to the plaintiff and her late husband.<sup>124</sup> The jury, however, rejected the plaintiff’s claims on the merits,<sup>125</sup> providing further support for the conclusion that the burden of causation in such cases is “almost impossible to satisfy.”<sup>126</sup>

### III. PHYSICIAN-INDUSTRY RELATIONSHIPS IN PHARMACEUTICAL AND MEDICAL DEVICE PERSONAL INJURY ACTIONS

Moving on from the largely unsuccessful efforts of patients and research participants to sue physicians and others for conflicts *qua* conflicts, physician-industry financial relationships also play a role—a contested one—in pharmaceutical and medical device personal injury actions. The Restatement (Third) of Torts provides that the manufacturer of a prescription drug or medical device is subject to liability for harm caused by a defect in the drug or device. A drug or device is defective if it “(1) contains a manufacturing defect . . . ; or (2) is not reasonably safe due to defective design . . . ; or (3) is not reasonably safe due to inadequate instructions or warnings . . . .”<sup>127</sup> Most personal injury claims brought by patients and research

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122. *Id.* at \*3–4.

123. *Darke v. Estate of Isner*, No. 02-2194-E, 2005 Mass. Super. LEXIS 663, at \*15–17 (Mass. Super. Ct. Nov. 15, 2005).

124. *Id.* at \*25.

125. Jury Verdict, *Darke v. Estate of Isner*, No. 02-2194-E (Mass. Super. Ct. May 4, 2007), 2007 WL 2219825.

126. Gatter, *supra* note 2, at 377.

127. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(b) (1998).

participants against drug and device manufacturers are failure-to-warn claims that fall into the third category.<sup>128</sup>

The default rule in products liability cases is that a manufacturer has a duty to warn the “ordinary user” of the manufacturer’s product’s risks and provide instruction on the product’s proper use.<sup>129</sup> Under the learned intermediary doctrine,<sup>130</sup> however, drug and device manufacturers can discharge this duty by warning and instructing prescribers.<sup>131</sup> When the doctrine applies, a plaintiff must show two things to make out a failure-to-warn claim: (1) that the warning was inadequate or misleading; and (2) that an adequate warning would have altered the physician’s prescribing decision.<sup>132</sup> Put differently, the inadequate or misleading warning must “be a ‘producing cause’ of the plaintiff’s injuries.”<sup>133</sup> If, for example, a manufacturer failed to warn of a foreseeable risk of harm but the physician independently knew of the risk, the manufacturer would not be liable.

The Restatement provides that the learned intermediary doctrine applies unless a manufacturer “knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”<sup>134</sup> It is here that the significance of physician-industry relationships is debated, as plaintiffs contend that conflicts so undermine physicians’ ability to make unbiased risk-benefit calculations that manufacturers should be required to warn patients directly.

#### *A. The Learned Intermediary Doctrine in Theory and in Practice*

A number of justifications have been offered for the learned

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128. The Restatement defines defective design extremely narrowly to include only those drugs or devices “that reasonable health-care providers, knowing of [the product’s] foreseeable risks and therapeutic benefits, would not prescribe . . . for any class of patients.” *Id.* § 6(c).

129. *Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 263 (Ct. App. 1999).

130. The learned intermediary doctrine was first mentioned by name in 1966. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).

131. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d)(1).

132. *Id.* § 6(d)(1)–(2).

133. *Patteson v. AstraZeneca, LP*, 876 F. Supp. 2d 27, 34 (D.D.C. 2012).

134. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d)(2); *see also* Ruling on Plaintiff’s Motion for Directed Verdict on Defendant’s Learned Intermediary Doctrine Defense, *In re Vioxx Cases*, No. JCCP 4247 (Cal. Super. Ct. Dec. 19, 2006), 2006 WL 6305292.

intermediary doctrine.<sup>135</sup> In an early case decided in 1973, *Gravis v. Parke-Davis*, a Texas appellate court explained that it was applying the doctrine because physicians and other prescribers are in “the best position to evaluate the warnings put out by the drug industry.”<sup>136</sup> The *Gravis* court also relied on its belief that, “[g]enerally speaking, only a physician would understand the propensities and dangers involved.”<sup>137</sup> Finally, the court emphasized, “[t]he entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people.”<sup>138</sup> In *Taurino v. Ellen*, decided in 1990, a Pennsylvania appellate court elaborated on the third point, finding that warning patients directly was not necessary because each prescribing physician has a duty “to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking” as well as “to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.”<sup>139</sup> Finally, in 1999 in *Perez v. Wyeth Laboratories*, the New Jersey Supreme Court listed several other justifications for the doctrine (all of which, it concluded, no longer obtained).<sup>140</sup> These included “(1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of ‘doctor knows best’ of need for the patient’s informed consent; [and the] (3) inability of drug manufacturer to communicate with patients . . . .”<sup>141</sup>

The learned intermediary doctrine has also been justified as an

135. See generally RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt. b.

136. *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. 1973); see also RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d)(1) (providing that the doctrine applies where the prescriber is “in a position to reduce the risks of harm in accordance with the instructions or warnings”).

137. *Gravis*, 502 S.W.2d at 870.

138. *Id.*

139. *Taurino v. Ellen*, 579 A.2d 925, 927 (Pa. Super. Ct. 1990) (quoting *Makripodis v. Merrell-Dow Pharms., Inc.*, 523 A.2d 374, 378 (Pa. Super. Ct. 1987)).

140. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1255 (N.J. 1999). With regard to the third justification, Lars Noah has explained that “[u]nlike [over-the-counter] products, pharmacists usually dispense prescription drugs from bulk containers rather than as unit-of-use packages in which the manufacturer may have enclosed labeling.” Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 158 (1997). The *Perez* court concluded that manufacturers could nonetheless communicate directly with patients, citing in support the rise of direct-to-consumer advertising. *Perez*, 734 A.2d at 1255–56.

141. *Perez*, 734 A.2d at 1255.

instantiation of the proximate cause requirement. In a 2012 Eastern District of Pennsylvania case, the court accepted the defendant's argument that the learned intermediary doctrine required that the plaintiff's claim under Pennsylvania's Unfair Trade Practices and Consumer Protection Law (UTCPL) be dismissed because, the court explained, "the UTCPL requires proof of causation and reliance."<sup>142</sup> A physician or other prescriber "breaks the chain in terms of reliance," because even if a drug or device manufacturer failed to warn a patient adequately, "the patient cannot obtain prescription drugs without the physician no matter what [the patient] believe[s] about them."<sup>143</sup>

While the learned intermediary doctrine does not self-evidently favor plaintiffs or defendants, it is manufacturers that seek its protection and patients and research participants who argue that exceptions should be made to it. This no doubt results from the fact that, if the doctrine applies, the deep-pocketed drug or device company is likely to escape liability. As Lars Noah has explained:

The 'learned intermediary' rule has important consequences for litigation. . . . Typically, physicians will concede that they understood the relevant risk information as contrasted with the likely testimony of the plaintiff that any warning communicated directly to them seemed less than fully adequate. Moreover, plaintiffs would have to introduce expert testimony to support any inadequacy claim, vis-a-vis physician labeling, as contrasted with a consumer-directed warning to which juries could apply their common sense.<sup>144</sup>

When the doctrine applies, a plaintiff will often be unable make out a failure-to-warn claim. The plaintiff's physician will testify that he or she was aware that the side effects experienced by the plaintiff could occur and that the physician prescribed the drug at issue anyway,

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142. *Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012).

143. *Id.* (citations omitted) (alteration in original).

144. Lars Noah, *The Learned Intermediary Doctrine: A Sensible Duty Limitation or an Anachronism?*, 10 KAN. J.L. & PUB. POL'Y 98, 99 (2000).

because it was the right choice for the plaintiff. Unless it is contradicted, the physician's testimony makes it impossible for the plaintiff to show that the cause of his or her injuries was the manufacturer's failure-to-warn the physician. In the words of Judge Jack B. Weinstein, the learned intermediary doctrine "cannot be viewed as an all-or-nothing regulation that absolves the manufacturer, shifting the onus entirely to the treating physician, but its force in ameliorating liability for damages of the manufacturers cannot be ignored."<sup>145</sup>

### *B. Exceptions to the Learned Intermediary Doctrine*

The "clearest and most widely accepted exception to the learned intermediary [doctrine]"<sup>146</sup> was made for vaccines, because they were often administered "outside the context of a doctor-patient relationship"<sup>147</sup> and "without the sort of individualized medical balancing of the risks to the vaccinee" that the doctrine contemplates.<sup>148</sup> While relatively uncontroversial, the exception to the learned intermediary doctrine for vaccines is no longer operative because the National Vaccine Injury Compensation Act provides that

[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.<sup>149</sup>

Less widely adopted than the exception for vaccines is the exception for prescriptions for birth control. The Supreme Court of

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145. *Souther v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 489 F. Supp. 2d 230, 244 (E.D.N.Y. 2007).

146. Hall, *supra* note 7, at 207.

147. *Id.* at 207–08.

148. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1277 (5th Cir. 1974).

149. 42 U.S.C. § 300aa-22(c) (2006).

Massachusetts adopted the exception in 1985 in *MacDonald v. Ortho Pharmaceutical*.<sup>150</sup> The court based its decision on, among other things, the belief that “the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use ‘the pill,’ as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.”<sup>151</sup> The *MacDonald* decision broke new ground—the dissenting justice wrote that “no other court has embraced the rule laid down today by the court”<sup>152</sup>—and few courts have followed it.<sup>153</sup>

Also less than uniformly accepted is an exception made to the learned intermediary doctrine when the FDA requires that a warning be delivered directly to patients.<sup>154</sup> This exception overlaps with the exception for birth control because “the FDA’s extensive regulation of contraceptive drugs and devices” includes “requirements for patient and physician warnings with regard to intrauterine devices and birth control pills.”<sup>155</sup> The Restatement explains that while “[s]ome case law supports the position that warnings should be given directly to patients when government regulations so require . . . an equal number of decisions reject this development.”<sup>156</sup>

An exception has also been made to the learned intermediary doctrine where a drug has been promoted directly to consumers.<sup>157</sup> This direct-to-consumer advertising exception overlaps with the government-mandated direct warnings exception, because, in the words of the Restatement, FDA “regulations require that, when drugs are so advertised, they must be accompanied by appropriate information concerning risk so as to provide balanced advertising.”<sup>158</sup>

The direct-to-consumer advertising exception has only been adopted by a handful of courts, including the Supreme Court of New

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150. *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985).

151. *Id.* at 69.

152. *Id.* at 73 (O’Connor, J., dissenting).

153. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 766 (Ky. 2004) (“Virtually every other jurisdiction that has addressed the issue has rejected an exception for oral contraceptives.”).

154. *Edwards v. Basel Pharm.*, 933 P.2d 298, 301 (Okla. 1997).

155. *Id.* (citing 21 C.F.R. §§ 310.501, 310.502 (1997)).

156. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6 cmt.e (1998).

157. *See id.*

158. *Id.*

Jersey in *Perez v. Wyeth Laboratories*.<sup>159</sup> As noted above, the *Perez* court concluded that the premises underlying the learned intermediary doctrine, which include

(1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of ‘doctor knows best’ of need for the patient’s informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject; *are all (with the possible exception of the last) absent in the direct-to-consumer advertising of prescription drugs*.<sup>160</sup>

The court held

that when mass marketing of prescription drugs seeks to influence a patient’s choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.<sup>161</sup>

Finally, some courts have made an exception to the learned intermediary doctrine where the manufacturer engaged in “overpromotion” of the product that harmed the plaintiff.<sup>162</sup> In an

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159. *Accord* Hill v. Searle Labs., 884 F.2d 1064, 1070 (8th Cir. 1989); *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991), *rev’d on other grounds*, 976 F.2d 77 (1st Cir. 1992); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985); *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1247 (N.J. 1999); *cf.* *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (“While the *Perez* court found that the law should be changing in response to changes in marketing strategies by drug manufacturers, New Jersey is the only state to have done so. It is now eight years since *Perez* was decided, and no other state has followed suit.”).

160. *Perez*, 734 A.2d at 1255 (emphasis added).

161. *Id.* at 1247. The recognition of an exception for direct-to-consumer advertising has not been as beneficial to plaintiffs proceeding in New Jersey or under New Jersey law as might have been expected. *See* Hall, *supra* note 7, at 233 (“Even in New Jersey, however, recognition of this exception has not resulted in subsequent litigation seeking to hold drug manufacturers liable for failure to warn.”). This is in part because the *Perez* court also announced a rebuttable presumption that the duty to warn is satisfied “in the area of direct-to-consumer advertising of pharmaceuticals . . . when a manufacturer complies with FDA advertising, labeling and warning requirements.” *Perez*, 734 A.2d at 1259; *see also* William A. Dreier, *Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806, 810–11 (2000).

162. *See, e.g.*, *Dean v. Eli Lilly & Co.*, 387 F. App’x 28, 30 (2d Cir. 2010) (quoting *Beale*, 492 F. Supp. 2d at 1377); *Love v. Wolf*, 58 Cal. Rptr. 42, 49 (Ct. App. 1967); *cf.* *Salmon v. Parke, Davis & Co.*, 520

Eastern District of New York case, *In re Zyprexa Products Liability Litigation*, Judge Weinstein explained that “[i]n unusual cases, courts have found that a drug manufacturer’s excessive promotion of its product may negate or call into question operation of the learned intermediary doctrine.”<sup>163</sup> Judge Weinstein went on to caution that “[a] plaintiff arguing in favor of application of the overpromotion exception with respect to a prescription drug must establish with *individualized* proof that such overpromotion caused the physician to initiate or maintain the prescription at issue.”<sup>164</sup> It is not enough, Judge Weinstein explained, to make general claims of overpromotion unconnected to the decision making process of the plaintiff’s particular physician.<sup>165</sup> Overall, apart from the—now statutorily overridden—exception for vaccines, defendants have been very successful at fending off attacks on the learned intermediary doctrine.<sup>166</sup>

### C. *An Exception for Physician-Industry Relationships?*

Plaintiffs have repeatedly sought an exception to the learned intermediary doctrine where the physician has a financial relationship with the manufacturer.<sup>167</sup> If the physician is not independent of the manufacturer, the argument goes, he or she is not well-positioned to evaluate the risk-benefit information the manufacturer provides, and it does not make sense to conceive of him or her as the consumer. With the notable exception of *Murthy v. Abbott*, discussed above, courts typically reject plaintiffs’ claims that an exception to the learned

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F.2d 1359, 1363–64 (4th Cir. 1975) (holding that the question whether an otherwise valid warning could be rendered ineffective by overpromotion was a question of fact for the jury to decide); *Incollingo v. Ewing*, 282 A.2d 206, 219–20 (Pa. 1971) (same), *abrogated on other grounds by Kaczkowski v. Bolubasz*, 421 A.2d 1027 (Pa. 1980).

163. *Head v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, 649 F. Supp. 2d 18, 33 (E.D.N.Y. 2009), *aff’d*, 394 F. App’x 819 (2d Cir. 2010).

164. *Id.*

165. *See id.*; *see also Dean*, 387 F. App’x at 30 (“Although the record reflects a vigorous sales campaign for Zyprexa aimed at Dr. Rousseau, Dean points to no evidence that Lilly’s salespeople either misled Dr. Rousseau about the link between Zyprexa and diabetes or caused Dr. Rousseau to prescribe Zyprexa to Dean.”).

166. *See Hall*, *supra* note 7, at 217.

167. *See generally Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999); *Trimble v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-3457, 2010 U.S. Dist. LEXIS 109843 (E.D.N.Y. Jan. 28, 2010).



intermediary doctrine is appropriate where a physician has a financial relationship with a manufacturer.<sup>168</sup> One court went so far as to pronounce that if a physician has “allowed himself to become a mere conduit” for a manufacturer, that is the fault of the doctor, not the drug or device company.<sup>169</sup> A drug company, the court opined, “cannot remove a physician from the decision making process, only the physician can do that by avoiding his responsibility to make an individualized balancing of the risks and benefits associated with a drug and to advise the patient of possible adverse reactions.”<sup>170</sup>

In *Talley v. Danek Medical*, a 1999 Fourth Circuit decision reviewing a trial court’s grant of summary judgment, the court set forth the following rule for evaluating the significance of a physician’s conflict of interest.<sup>171</sup> If a doctor is “an employee of [the manufacturer,]” the *Talley* court held, “or so closely related to [the manufacturer] that he could not exercise independent professional judgment, a question could legitimately be raised as to whether he was an intermediary.”<sup>172</sup> To resolve that “complex question,” the court said, it would have to evaluate “the nature of the relationship between the manufacturer and the physician and the extent to which the physician was in fact afforded independence in making medical judgments.”<sup>173</sup>

The ties between the physician in *Talley*, Hallett Mathews, and the defendant manufacturer were different in kind and degree than those in *Murthy*. As the court explained, Dr. Mathews:

served as a consultant to [the defendant] Danek, designing endoscopes and assisting in efforts to secure FDA approval for the use of the endoscopes in the spine . . . . As part of this consulting arrangement, Dr. Mathews’ office served as a ‘receptorship site’

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168. See *Talley*, 179 F.3d at 163–64.

169. *Burton v. Am. Home Prods. Corp.* (*In re Norplant Contraceptive Prods. Liab. Litig.*), 955 F. Supp. 700, 706 (E.D. Tex. 1997), *aff’d sub nom. Harrison v. Am. Home. Prods. Corp.* (*In re Norplant Contraceptive Prods. Liab. Litig.*), 165 F.3d 374 (5th Cir. 1999).

170. *Id.*

171. *Talley*, 179 F.3d at 163–64.

172. *Id.*

173. *Id.* at 164.

[sic] to teach surgeons surgical techniques involving both Danek products and other products. For these consulting services, Dr. Mathews received an annual consulting fee of \$250,000, a travel budget, research funds, and 25,000 shares of stock in Danek Group, Inc., the parent of Danek Medical, Inc.<sup>174</sup>

Despite Dr. Mathews' close and extensive ties to Danek, the Fourth Circuit affirmed the district court's grant of summary judgment, finding as a matter of law that Dr. Mathews' financial ties to Danek did not interfere with his independent medical judgment and that it was therefore appropriate to apply the learned intermediary doctrine to bar the plaintiff's claims.<sup>175</sup>

The *Talley* court reasoned that (1) Dr. Mathews' consulting relationship with Danek involved endoscopes whereas the case at hand involved an internal fixation device, (2) Dr. Mathews offered testimony explaining how he selects which device to use and supporting his choice of the Dyna-Lok internal fixation device in the plaintiff's case, (3) Dr. Mathews continued to use the Dyna-Lok device, and (4) Dr. Mathews did not use the Dyna-Lok device exclusively—he did not always use an internal fixation device and, when he did, he used more than one type.<sup>176</sup> The significance of these four facts is not self-evident. None would seem to preclude a conflict.

The FDA's regulations require that research sponsors inform the agency when annual payments to investigators exceed \$25,000 a year.<sup>177</sup> Sponsors are encouraged to take steps to manage the risk to research integrity posed by payments that exceed the \$25,000 threshold.<sup>178</sup> Dr. Mathews received ten times that amount from Danek.<sup>179</sup> The Public Health Service's (PHS) regulations, which apply

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174. *Id.* at 157.

175. *Id.* at 164.

176. *Id.*

177. 21 C.F.R. §§ 54.2(f) & 54.4 (1999).

178. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR CLINICAL INVESTIGATORS, INDUSTRY, AND FDA STAFF: FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS pt. IV.A.2 (2013), available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>.

179. *Talley*, 179 F.3d at 157.

to, among other things, institutions that receive funding from the National Institutes of Health, are triggered at \$5,000 a year; Dr. Mathews received fifty times that.<sup>180</sup> The FDA's regulations also require reporting of equity stakes in public companies worth more than \$50,000 and any equity stake in private companies, while the PHS' regulations apply to equity stakes in public companies worth more than \$5,000 and any equity stake in private companies.<sup>181</sup> The *Talley* court, by contrast, made its decision without regard to the value of Dr. Mathew's 25,000 shares of Danek.<sup>182</sup>

Other courts have been similarly dismissive of the possibility of an exception to the learned intermediary doctrine where the physician has a financial relationship with the manufacturer.<sup>183</sup> For example, in a 2006 directed verdict ruling in the *In re Vioxx Cases*, the California Superior Court rejected the plaintiffs' argument that an exception to the doctrine was warranted because the physician in question was paid "hundreds of thousands of dollars over the years to conduct research and give lectures."<sup>184</sup> The court credited the physician's own testimony that he was unbiased by his relationship with the defendant, testimony that the plaintiffs did not counter with "evidence of actual bias."<sup>185</sup>

In explaining its decision, the *In re Vioxx Cases* court took note of the fact that while "payment for research is a widespread practice . . . the court was unable to find a case where a physician who was paid for research was considered to have abrogated his or her role of learned intermediary."<sup>186</sup> The court went on to suggest that if it were

180. *Id.*; 42 C.F.R. § 50.603 (2011).

181. 42 C.F.R. § 50.603; 21 C.F.R. § 54.2(b).

182. *Talley*, 179 F.3d at 157.

183. *See, e.g.*, *Trimble v. Eli Lilly & Co. (In re Zyprexa Prods. Liab. Litig.)*, Nos. 04-MD-1596, 06-CV-3457, 2010 U.S. Dist. LEXIS 109843, at \*27-29 (E.D.N.Y. Jan. 28, 2010) (applying the learned intermediary doctrine where physician "conducted paid research" and "served as a paid speaker" for the defendant); *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 876, 879 (Ohio 1991) (applying the learned intermediary doctrine because while the defendant, Merrell Dow, paid the plaintiff's physician, Dr. Donald Epstein, \$15 for each participant the physician enrolled in a clinical trial of the anti-smoking drug Nicorette, there was no evidence that the doctor was "an employee of Merrell Dow or . . . was acting under the control of Merrell Dow").

184. Ruling on Plaintiff's Motion for Directed Verdict on Defendant's Learned Intermediary Doctrine Defense, *supra* note 134, at 4.

185. *Id.*

186. *Id.*

to hold that such payments alone did constitute “special circumstances[,]” it would create practical problems for the manufacturer, which “would have to obtain the patient list of every physician it pays for research in order to somehow provide direct warnings.”<sup>187</sup>

In a 2011 summary judgment decision that is part of the Trasyolol multi-district litigation, the court similarly declined to adopt the plaintiff’s argument that the learned intermediary doctrine should not apply because her doctor, Stanley K. Lochridge, was “biased and failed to exercise independent medical judgment.”<sup>188</sup> Dr. Lochridge, the court explained, “signed an agreement with Bayer [Trasyolol’s manufacturer] to act as a temporary consultant at a cardiac meeting held on December 10-12, 2004 where Trasyolol and other drugs were discussed.”<sup>189</sup> Pursuant to the agreement, Dr. Lochridge was reimbursed for his travel-related expenses and was paid a maximum of \$500 for his consulting services.<sup>190</sup>

The court agreed with prior decisions holding that plaintiffs have to do more than present evidence of the fact of a financial relationship to create an issue of material fact with regard to the applicability of the learned intermediary doctrine.<sup>191</sup> To successfully defend against the manufacturer’s motion for summary judgment, the court held, the plaintiff would have had to “offer evidence that Dr. Lochridge’s choice to prescribe Trasyolol . . . was not an informed one, or that he did not exercise individualized medical judgment in making that decision.”<sup>192</sup>

The court’s decision also tracked prior decisions in that in addition to crediting factors like Dr. Lochridge’s “undisputed experience as a cardiothoracic surgeon and with prescribing Trasyolol[,]” it afforded significant weight to the doctor’s own testimony on the effect of his or her financial relationships on his or her decision making.<sup>193</sup> The court

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187. *Id.*

188. *In re Trasyolol Prods. Liab. Litig.-MDL-1928*, Nos. 08-cv-80386, 08-MD-01928, 2011 U.S. Dist. LEXIS 57057, at \*15 (S.D. Fla. May 23, 2011).

189. *Id.* at \*4.

190. *Id.*

191. *Id.* at \*15–16.

192. *Id.* at \*15.

193. *Id.* at \*16.

noted that “Dr. Lochridge’s testimony and the agreement itself indicate that its purpose was for Dr. Lochridge to attend one cardiac meeting[.]” at which, according to Dr. Lochridge’s testimony, “Trasylol and other drugs were discussed.”<sup>194</sup> In addition, again per Dr. Lochridge’s own testimony, his “decision to prescribe Trasylol was [not] automatic; on the contrary, he testified that [he] considered the particular circumstances of [the plaintiff’s] case, including that she was going to undergo a surgery with a significant risk of blood loss.”<sup>195</sup>

#### IV. PHYSICIAN-INDUSTRY RELATIONSHIPS IN PHARMACEUTICAL AND MEDICAL DEVICE ECONOMIC INJURY ACTIONS

In the personal injury cases discussed in the previous section, courts held that physicians could serve as learned intermediaries despite financial relationships with the defendant manufacturers.<sup>196</sup> In drug and device cases in which the plaintiffs seek compensation for economic injuries, courts have similarly found or presumed that physicians’ prescribing decisions were informed, individualized, and independent.<sup>197</sup> The plaintiffs in these cases typically allege that they bought or paid for drugs or devices that would not have been prescribed but for the fact that the manufacturer’s promotional tactics violated one of the numerous state and federal laws to which prescription drug and device promotion must conform,<sup>198</sup> including the Federal Food Drug & Cosmetic Act (FDCA)<sup>199</sup> and the Anti-Kickback Act (AKA).<sup>200</sup>

Drug and device cases in which economic injury is alleged have proliferated in recent years, typically following closely on the heels of an announcement by the Department of Justice or other government

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194. *In re Trasylol Prods. Liab. Litig.*, 2011 U.S. Dist. LEXIS 57057, at \*16.

195. *Id.*

196. *See* discussion *supra* Part III.A.

197. *See* discussion *infra* Part IV.

198. *See generally In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009); *Roberson v. Medtronic, Inc.*, 494 F. Supp. 2d 864 (W.D. Tenn. 2007).

199. 21 U.S.C. §§ 301–399f (2012).

200. 42 U.S.C. § 1320a-7b(b).

entity that it has entered into a settlement with a manufacturer.<sup>201</sup> These cases can be brought by patients—usually a putative class of patients—or by third-party payers such as employers, union health and welfare funds, insurance companies, and others.<sup>202</sup> The defense lawyer James Beck writes, colorfully, that so-called third-party payer suits arise out of an “unholy alliance” between payers and plaintiffs’ lawyers.<sup>203</sup> He argues that third-party payers should and do lose these suits because, “having already set their premiums and recovered for their expenses . . . they can[not] prove that anybody was actually hurt.”<sup>204</sup> The independent physician heuristic also stands in the way. Third-party payer and other economic injury suits are frequently dismissed at an early stage as a matter of law, on the grounds that the independent decision making of physicians breaks the chain of causation between a defendant manufacturer’s illegal promotion and the obligation to pay for a prescription drug or device.<sup>205</sup>

Neither the FDCA nor the AKA has a private right of action, so those harmed when a drug is promoted fraudulently or illegally cannot simply allege that one of those statutes was violated.<sup>206</sup> An insurance company or other third-party payer who covered and paid out claims for such a drug or device will instead bring suit alleging, among other things, common law fraud, violations of state consumer protection statutes, and civil Racketeering Influenced and Corrupt Organizations Act (RICO) offenses.<sup>207</sup>

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201. *See, e.g.*, *Health Care Serv. Corp. v. Olivares*, No. 2:10-CV-221-TJW-CE, 2011 U.S. Dist. LEXIS 117750, at \*6–7 (E.D. Tex. Sept. 2, 2011) (magistrate judge’s report and recommendation) (“HCSC alleges that when Pfizer settled its claims with the United States in September 2009, [third-party payers] like HCSC began to understand the fraudulent behavior of some of Pfizer’s agents related to the marketing of various drugs.”).

202. James M. Beck, *TPPs Hoisted by Their Own Petard?*, *DRUG & DEVICE L.* (July 5, 2012), <http://druganddevicelaw.blogspot.com/2012/07/tpps-hoisted-by-their-own-petard.html>.

203. *Id.*

204. *Id.*

205. *See* discussion *infra* Part IV.A.

206. 21 U.S.C. § 337(a) (2012) (“Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.”); *Allstate Ins. Co. v. Linea Latina De Accidentes, Inc.*, 781 F. Supp. 2d 837, 850 (D. Minn. 2011) (“At least one circuit court of appeals and many district courts have held that there is no private right of action to enforce § 1320a-7b(b).”).

207. *See, e.g.*, *District 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 518, 530, 531 (D.N.J. 2011).

The common law fraud cause of action poses a number of difficulties for plaintiffs, including heightened pleading standards and barriers to certification as a class action.<sup>208</sup> With regard to the latter, courts typically decline to certify consumer fraud class actions because there are questions of fact that are unique to each class member.<sup>209</sup> In particular, individuals typically vary as to whether and to what extent they relied on the alleged fraud when they made the decision to purchase the product at issue.<sup>210</sup> Where the alleged fraud crossed state lines, as is often true in drug and device cases brought by patients and payers, plaintiffs also confront the absence of a common question of law.<sup>211</sup>

Plaintiffs have had somewhat better luck pursuing class action certification based on violations of state consumer protection statutes.<sup>212</sup> As defense attorney Joseph Leghorn and his colleagues have explained, these statutes “generally proscribe ‘unfair or deceptive acts or practices’ in connection with trade or commerce,”<sup>213</sup> and, in almost every state, they have a private right of action.<sup>214</sup> Many states’ consumer protection statutes allow for actual damages but also provide for “minimum statutory damages as well as multiple damages, punitive damages, and attorneys’ fees.”<sup>215</sup> As compared to common law fraud,

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208. See FED. R. CIV. P. 9(b) (“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.”); Shawn S. Ledingham, Jr., Note, *Aggregate Reliance and Overcharges: Removing Hurdles to Class Certification for Victims of Mass Fraud*, 85 N.Y.U. L. REV. 289, 290–91 (2010).

209. Ledingham, *supra* note 208, at 290–91.

210. *Id.* at 291.

211. *Id.*

212. See, e.g., *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 751 F. Supp. 2d 277, 287–88 (D. Mass. 2010) (applying California’s False Advertising Law, under which a “presumption, or at least an inference, of reliance arises whenever there is a showing that a misrepresentation was material,” and holding that “[b]ased on the facts alleged . . . a reasonable juror could find that knowledge of the Lundbeck study would be material to a physician’s decision to prescribe Celexa and that such materiality was proof that [the plaintiff’s son’s] physician (and the physicians of the other class members) relied on Forest’s alleged misrepresentations in deciding to prescribe Celexa”); see also Joseph J. Leghorn, Christopher Allen, Jr. & Tavares Brewington, *Defending an Emerging Threat: Consumer Fraud Class Action Suits in Pharmaceutical and Medical Device Products-Based Litigation*, 61 FOOD & DRUG L.J. 519, 519 (2006) (“Consumer fraud class action suits describe a relatively new species of products-based litigation that have found fertile ground in the pharmaceutical and medical device landscape and are grounded primarily, if not exclusively, upon violations of state consumer protection acts (CPAs).”).

213. Leghorn, Allen, Jr. & Brewington, *supra* note 212, at 519.

214. *Id.*

215. *Id.*

these statutes facilitate suit by, depending on the state in question, 1) declining to impose a heightened pleading standard, 2) eliminating one or more of the common law elements, for example the requirement that plaintiffs prove “specific medical causation,” and/or 3) lowering the burden of proof.<sup>216</sup>

The civil RICO vehicle also has advantages for plaintiffs, including the possibility of treble damages and a broad choice of venues.<sup>217</sup> Even more important, in the opinion of defense attorney Gordon Cooney and his colleagues, by bringing suit pursuant to RICO, plaintiffs can “sidestep the predominating choice-of-law issues that typically prevent nationwide class actions based on fraud or deceptive practice law.”<sup>218</sup>

To state a civil RICO claim, a plaintiff must plead (1) the existence of an enterprise affecting interstate commerce, (2) a pattern of racketeering activity, which is defined to include, among other enumerated predicate offenses, bribery, mail fraud, and wire fraud, that persists for a substantial time period or threatens to continue into the future, and (3) direct injury to the plaintiff’s business or property.<sup>219</sup> The civil RICO statute requires that the asserted injury to the plaintiff’s business or property occur “by reason of” the alleged predicate offense or offenses.<sup>220</sup> To meet the “by reason of” requirement, a civil RICO plaintiff must show that the defendant’s offense was not just the “but for” cause of his or her injury but also that it was the proximate cause.<sup>221</sup> This “requires some direct relation between the injury

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216. *See id.* at 519–20.

217. J. Gordon Cooney, Jr., John P. Lavelle, Jr. & Bahar Shariati, *Back to the Future: Civil RICO in Off-Label Promotion Litigation*, 77 DEF. COUNS. J. 168, 169 (2010); *see also* Pamela Bucy Pierson, *RICO Trends: From Gangsters to Class Actions*, 65 S.C. L. REV. 213, 258 (2013) (noting that “[u]sing RICO to bring pharmaceutical fraud class actions is a recent phenomenon” and predicting that the “trend of using RICO to bring class actions aimed at pharmaceutical fraud is likely to accelerate”).

218. Cooney, Lavelle & Shariati, *supra* note 217, at 169.

219. 18 U.S.C. § 1962(c) (2012) (“It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity . . . .”); *Id.* § 1964(c) (“Any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney’s fee . . . .”).

220. *Id.* § 1964(c).

221. *Hemi Group, LLC v. City of New York, N.Y.*, 559 U.S. 1, 8–9 (2010) (citing *Holmes v. Sec.*



asserted and the injurious conduct alleged. A link that is too remote, purely contingent, or indirect is insufficient.”<sup>222</sup>

Notably, the Supreme Court has held that a civil RICO plaintiff does not need to allege “first-party reliance,” that is, that he or she personally relied on the defendant’s misrepresentations, in order to show that he or she was injured “by reason of” a pattern of mail or wire fraud.<sup>223</sup> An allegation “that *someone* relied on the defendant’s misrepresentations” can suffice.<sup>224</sup> The RICO statute’s proximate cause requirement has nonetheless proven to be a formidable hurdle for third-party payers and other plaintiffs alleging economic injury caused by illegal promotion of drugs or devices to physicians.<sup>225</sup> Most courts confronted with these cases have held that the physicians’ presumably independent and individualized prescribing decisions break the chain between the manufacturer’s illegal promotion and a third-party payer or other plaintiff’s obligation to pay for a drug or device.

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Investor Prot. Corp., 503 U.S. 258, 268, 271, 274 (1992)).

222. *Id.* at 9 (internal quotation marks omitted). Borrowing from antitrust law, the Supreme Court has explained that the directness requirement serves a number of purposes:

First, the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff’s damages attributable to the violation, as distinct from other, independent, factors. Second, quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries. And, finally, the need to grapple with these problems is simply unjustified by the general interest in deterring injurious conduct, since directly injured victims can generally be counted on to vindicate the law as private attorneys general, without any of the problems attendant upon suits by plaintiffs injured more remotely.

*Holmes*, 503 U.S. at 269–70 (citations omitted); *see also* District 1199P Health & Welfare Plan v. Janssen, L.P., 784 F. Supp. 2d 508, 523 (D.N.J. 2011) (“In other words, the proximate cause requirement ensures that 1) there are no independent variables that could account for a plaintiff’s injuries, 2) there is no risk of duplicative recoveries by plaintiffs, and 3) there are no more immediate victims better situated to sue for the injuries alleged.” (citing *Bridge v. Phx. Bond & Indem. Co.*, 553 U.S. 639, 658 (2008))).

223. *Bridge*, 553 U.S. at 649.

224. *Id.* at 658 (emphasis in original).

225. Other elements have also posed hurdles. *See, e.g.*, *McCullough v. Zimmer, Inc.*, 382 F. App’x 225, 232 (3d Cir. 2010) (holding that plaintiffs failed to plead the existence of a RICO enterprise because physicians who accepted kickbacks from defendant device companies did not “combine[] as a unit with any semblance of an organizational framework or common purpose”); *District 1199P Health & Welfare Plan*, 784 F. Supp. 2d at 529 (holding that plaintiffs failed to plead the RICO predicate act of bribery because “the Complaint does not assert any instances where Defendants provided remuneration to a physician and thereby caused the physician to prescribe Risperdal when it was not in the patient’s best interests” and because the plaintiffs did not “allege that any ‘bribes’ to physicians resulted in prescriptions for which Plaintiffs should not have paid”).

A. *The “Causal Chain of Injury” Hurdle*

A 2009 decision in the *In re Actimmune Marketing Litigation* exemplifies the difficulties plaintiffs in drug and device cases face establishing causation under both RICO and state consumer protection statutes.<sup>226</sup> *Actimmune* was a proposed nationwide class action brought by patients and payers who alleged that the defendant manufacturers “engaged in a fraudulent and deceptive scheme to market and sell the drug Actimmune®” to treat idiopathic pulmonary fibrosis (IPF), an off-label use.<sup>227</sup> The plaintiffs alleged that the defendants’ marketing campaign was multi-faceted, including

. . . disseminating a number of press releases, . . . sending letters to patients taking Actimmune®, setting up booths at medical conferences, setting up a registry known as the Actimmune® Safe and Appropriate Use Program . . . for doctors to join and obtain information, creating a nonprofit patient advocacy group called the Coalition for Pulmonary Fibrosis, and sponsoring meetings and medical programs for pulmonologists.<sup>228</sup>

The defendants also “sen[t] sales representatives to visit physicians,” and “instructed and encouraged [them] to misrepresent the state of scientific evidence relating to Actimmune® in treating IPF.”<sup>229</sup> The plaintiffs, the court wrote, “generally conclude that [the defendants’ marketing] campaign caused physicians to prescribe Actimmune®, and caused consumers and [third-party payers] to pay for Actimmune®, despite an absence of scientific proof to support its effectiveness.”<sup>230</sup>

The court dismissed the plaintiffs’ RICO claim, finding that the “allegations relating to the *causal chain of injury* as a result of [the defendants’] marketing efforts . . . [were] scanty.”<sup>231</sup> The court held

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226. *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037 (N.D. Cal. 2009).

227. *Id.* at 1040.

228. *Id.* at 1044.

229. *Id.*

230. *Id.* at 1045.

231. *Id.* at 1051 (emphasis added).

that the “[p]laintiffs need[ed] to allege what specific information the individual plaintiffs or their physicians had about the drug, the extent to which they relied upon that information, and that the information relied upon was false, misleading or otherwise fraudulent.”<sup>232</sup> In particular, the plaintiffs needed “to allege that it was defendants’ allegedly fraudulent misrepresentations about Actimmune®, rather than the scientific literature or any other factor, that led directly to the plaintiffs [sic] injuries.”<sup>233</sup>

The *Actimmune* court also dismissed the plaintiffs’ fraud-based state consumer protection law claims, on the grounds that the plaintiffs sought to use the fraud on the market theory to “handwave” the lack of connection between the defendants’ product promotion and the plaintiffs’ injury.<sup>234</sup> As the Supreme Court has explained, “[t]he fraud on the market theory is based on the hypothesis that, in an open and developed securities market, the price of a company’s stock is determined by the available material information regarding the company and its business.”<sup>235</sup> As a result, “[m]isleading statements will . . . defraud purchasers of stock even if the purchasers do not directly rely on the misstatements . . . .”<sup>236</sup> Stephen Bainbridge and Mitu Gulati characterize the fraud on the market theory as a pro-plaintiff litigation heuristic which creates a rebuttable presumption of reliance where fraudulent statements are disseminated to an open securities market.<sup>237</sup>

The *Actimmune* court declined to apply the pro-plaintiff fraud on the market theory, because “the presumption of reliance does not work in non-efficient markets like prescription drug ‘markets’ (if individual

232. *In re Actimmune*, 614 F. Supp. 2d at 1052.

233. *Id.* at 1053.

234. *Id.* at 1054. In a subsequent decision, the court dismissed the plaintiffs’ non-fraud-based claims as well, holding that “[t]he shortcoming in the consumer plaintiffs’ pleadings is simple: all of the consumer plaintiffs fail to allege that their doctors believed that Actimmune was an effective treatment for IPF ‘as a result of’ defendants’ off-label promotion of Actimmune.” *In re Actimmune Mktg. Litig.*, No. C 08-02376 MHP, 2010 U.S. Dist. LEXIS 90480, at \*30–31 (N.D. Cal. Sept. 1, 2010).

235. *Basic Inc. v. Levinson*, 485 U.S. 224, 241 (1988).

236. *Id.* at 241–42.

237. Bainbridge & Gulati, *supra* note 24, at 118–19 (“Take the fraud on the market doctrine, which we do not discuss as one of our ten heuristics. This is a pro-plaintiff doctrine which provides the plaintiff with a strong presumption regarding the issue of reliance. It can still be seen as a shortcut though, because it enables the judge to avoid deciding the often messy issue of reliance.” (footnote omitted)).

patients purchasing drugs prescribed by individual doctors for personalized conditions can even constitute a ‘market’) . . . .”<sup>238</sup> The court chose to rely instead on the pro-defendant independent physician heuristic, keying in on, for example, the plaintiffs’ failure to address the possibility that physicians relied on studies in the scientific literature and not the defendants’ marketing campaign in making prescribing decisions.<sup>239</sup>

The connection between the defendants’ product promotion and the plaintiffs’ injury was also at issue in *UFCW Local 1776 v. Eli Lilly*, a Second Circuit case decided in 2010.<sup>240</sup> The plaintiffs in that case, unions and insurers, alleged that the defendant, Eli Lilly, engaged in a multi-faceted marketing campaign that misrepresented the safety and efficacy of its second-generation anti-psychotic medication Zyprexa to physicians.<sup>241</sup> The district court certified a class of third-party payers that alleged that Lilly’s actions constituted RICO violations.<sup>242</sup> With regard to the “causal chain of injury,” the plaintiffs put forth two theories: the “excess price” or “loss-of-value” theory and the “quantity effect” theory.<sup>243</sup> Under the first, the plaintiffs claimed that their “harm was the monetary difference between what the plaintiff class was allegedly led to believe Zyprexa was worth and the actual economic value of Zyprexa, taking into account the lesser efficacy and greater harmful side effects allegedly hidden or misrepresented by Lilly.”<sup>244</sup> Under the second, the plaintiffs argued that “they paid for . . . prescriptions that would not have been written absent the fraud.”<sup>245</sup>

The Second Circuit reversed the district court’s class action

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238. *In re Actimmune*, 614 F. Supp. 2d at 1054. At least one other court has held similarly, expressing a surprising degree of skepticism that there is a “market” for prescription drugs and devices. *See, e.g., Heindel v. Pfizer Inc.*, 381 F. Supp. 2d 364, 380 (D.N.J. 2004) (holding that “there is no prescription drug ‘market,’ at least as that term is understood in the securities context. . . . The suggestion that consumers might be inclined to take a drug with certain side affects [sic] if they could pay less for it, or that drugs with certain side effects should cost less, defies both reality and common sense”).

239. *In re Actimmune*, 614 F. Supp. 2d at 1055.

240. *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 123 (2d Cir. 2010).

241. *Id.*

242. *Id.* at 130.

243. *Id.* at 129.

244. *Id.*

245. *Id.* at 131.

certification, holding that neither the excess price theory nor the quantity effect theory was susceptible to generalized proof. With regard to the excess price theory, the court held as follows:

[T]he [plaintiff third-party payers] do not allege that *they* relied on Lilly's misrepresentations—the misrepresentations at issue were “directed through mailings and otherwise at doctors.” Because only the TPPs were in a position to negotiate the price paid for Zyprexa, however, the only reliance that might show proximate causation with respect to price is reliance by the TPPs, not reliance by the doctors.<sup>246</sup>

The Second Circuit also rejected the quantity effect theory. Under this theory, the alleged chain of causation was as follows: “TPPs place Zyprexa on their formularies as approved drugs, Lilly distributes misinformation about Zyprexa, physicians rely upon the misinformation and prescribe Zyprexa, and TPPs pay for too many Zyprexa prescriptions.”<sup>247</sup> While this causal chain had the advantage of relative simplicity, it was “interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof.”<sup>248</sup> The Second Circuit explained the problem as follows:

Lilly was not . . . the *only* source of information on which doctors based prescribing decisions. An individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa are all considerations that would have been taken into account in

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246. *UFCW Local 1776*, 620 F.3d at 134 (citation omitted).

247. *Id.* at 135.

248. *Id.*; see also *United Food & Commercial Workers Cent. Pa. & Reg'l Health & Welfare Fund v. Amgen, Inc.*, 400 F. App'x 255, 257 (9th Cir. 2010) (“Moreover, the complaint failed to plead a cognizable theory of proximate causation that links Amgen's alleged misconduct to Appellants' alleged injury. Instead, the complaint proffered an attenuated causal chain that involved at least four independent links, . . . [one of which was] doctors' decisions to prescribe Aranesp and Epogen for [the uses at issue].” (citation omitted)).

addition to the alleged misrepresentations distributed by Lilly.

Furthermore, . . . evidence showed that at least some doctors were not misled by Lilly's alleged misrepresentations, and thus would not have written "excess" prescriptions as identified by the plaintiffs. This makes general proof of but-for causation impossible.<sup>249</sup>

Thus, the physicians' independent prescribing decisions stood between the putative plaintiff class and recovery. The court did, however, remand the case for further proceedings, holding that while the quantity effect theory could not "support class certification, it is not clear that the theory is not viable with respect to individual claims by some [third-party payers] or other purchasers."<sup>250</sup> The Second Circuit's requirement that plaintiffs produce individualized proof of causation would be challenging for even individual third-party payers to meet, however, because each pays for prescriptions written by multiple physicians.

In *Ironworkers Local Union 68 v. AstraZeneca*, which was decided in 2011, the Eleventh Circuit affirmed the dismissal of the plaintiffs' complaint, finding that "[i]n light of physicians' exercise of professional judgment, a patient suffers no economic injury merely by being prescribed and paying for a more expensive drug."<sup>251</sup> The plaintiffs were patients and health care plans who alleged that the defendants inflated the price of the atypical antipsychotic Seroquel by making false representations about its safety and efficacy.<sup>252</sup> The court held that to state a claim the patients would have had to allege that the prescriptions for which they paid were either "unnecessary or inappropriate according to sound medical practice—i.e., the drug was either ineffective or unsafe for the prescribed use."<sup>253</sup> Even if "the

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249. *UFCW Local 1776*, 620 F.3d at 135.

250. *Id.* at 136.

251. *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP.*, 634 F.3d 1352, 1363 (11th Cir. 2011).

252. *Id.* at 1356.

253. *Id.* at 1363. The court explained that "[t]o make this showing, the payer-plaintiff must allege a counterfactual: that her physician—had he known all the true information about the medication—would not have prescribed the drug under the standards of sound medical practice because the drug actually was unsafe or ineffective in treating the plaintiff's condition." *Id.*

physician's decision to prescribe the more expensive drug in lieu of a cheaper alternative is the product of fraud[,]" the court held, liability does not attach.<sup>254</sup> The court's rationale appeared to be that because physicians have no duty to consider price in making prescription decisions, patients prescribed safe, effective, and medically necessary drugs suffer no compensable harm no matter what the price of those drugs may be.<sup>255</sup>

The Eleventh Circuit also held that the plaintiff third-party payers had no recompense, because they should have factored into the premiums they charge the possibility of paying for "medically unnecessary or inappropriate prescriptions—even those caused by fraudulent marketing."<sup>256</sup> Fraudulent marketing by drug manufacturers, the court concluded "is just another cost to be factored into premiums."<sup>257</sup>

The third-party payer cases discussed above turned on allegations of false or misleading advertising and promotion, not—at least not primarily—the payment of kickbacks. But courts' "causal chain of injury" analyses do not typically vary based on the presence or absence of kickback allegations.<sup>258</sup> For example, in *Health Care Service*

254. *Id.*

255. *Id.*

256. *Id.* at 1364.

257. *Ironworkers Local Union 68*, 634 F.3d at 1368.

258. See *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, Master Case No. 05-CV-01699 CRB, Individual Case No. 11-CV-00310 CRB, 2012 U.S. Dist. LEXIS 111446, at \*208, \*224, \*226 (N.D. Cal. Aug. 2, 2012) (dismissing case in which the plaintiff accused the defendant of, among other things, "paying physicians to attend presentations to induce them to promote and prescribe Bextra" and in which the defendant admitted that "approximately sixty-five percent of all off-label Bextra sales . . . were the result of fraud" because the plaintiff did not "make specific allegations that individual physicians actually relied on these misrepresentations in writing the challenged prescriptions"); District 1199P Health & Welfare Plan v. Janssen, L.P., 784 F. Supp. 2d 508, 517, 524 (D.N.J. 2011) (dismissing case in which the plaintiff accused the defendant of providing physicians with "expensive dinners and lavish vacations in return for prescribing Risperdal, and excessive payments to physicians for conducting clinical trials of Risperdal" because "Plaintiffs may not aver 'causation by way of generalized allegations and aggregate proof,' because there are numerous factors that could influence a physician when deciding to prescribe a certain drug" (citation omitted)); Phila. Firefighters Union Local No. 22 Health & Welfare Fund v. Bayer Healthcare Pharm. Inc. (*In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*), Nos. 3:09-md-02100-DRH-PMF, 3:09-cv-20071-DRH-PMF, 2010 WL 3119499, at \*3, \*7 (S.D. Ill. Aug. 5, 2010) (dismissing case in which the plaintiff accused the defendant of, among other things, "providing financial incentives to physicians as 'rewards for past high-prescribing and inducements to write future prescriptions for off-label uses of YAZ,'" because "[t]o assess damages, the Court would have to delve into the specifics of each physician patient relationship to determine what

*Corporation v. Olivares*, a 2011 Eastern District of Texas decision, the plaintiff Health Care Service Corporation (HCSC), a third-party payer, alleged that the defendant Pfizer, among other things, (1) “bribed or promised kickbacks to doctors who prescribed Geodon for uses other than those that were approved by the FDA,” (2) “made offers and payments of illegal bribes and kickbacks to physicians during the marketing of Lyrica,” and (3) “made or promised bribes or kickbacks to doctors in exchange for the doctors’ promotion of [Zyvox] to their patients.”<sup>259</sup>

The *Olivares* court adopted the Eleventh Circuit’s analysis in *Ironworkers Local Union 68*, calling it “a nearly identical case[,]” despite the fact that the *Ironworkers Local Union 68* decision makes no reference to kickbacks.<sup>260</sup> Following the Eleventh Circuit, the *Olivares* court held that the plaintiff failed to adequately plead an economic injury because the plaintiff did “not allege that any physician, had he or she known all the true information about Geodon, Lyrica, or Zyvox, would not have prescribed the drugs under the standards of sound medical practice because the drugs actually were unsafe or ineffective in treating their patients’ conditions.”<sup>261</sup> The *Olivares* court also followed the Eleventh Circuit in holding that “HCSC assumed the risk that some of its reimbursements would be for off-label uses—even those uses that may have been a product of the alleged marketing fraud.”<sup>262</sup>

The *Olivares* court went on to hold that HCSC’s complaint was subject to dismissal for failure to allege a “viable theory of causation.”<sup>263</sup> The court agreed with the defendants that “HCSC’s complaint fail[ed] to sufficiently connect Defendants’ allegedly deceptive conduct to HCSC’s payment for prescription medications”

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damages were caused by Bayer’s alleged fraudulent conduct, as opposed to what damages were caused by the physician’s independent medical judgment”).

259. *Health Care Serv. Corp. v. Olivares*, No. 2:10-CV-221-TJW-CE, 2011 U.S. Dist. LEXIS 117750, at \*4–5 (E.D. Tex. Sept. 2, 2011) (magistrate judge’s report and recommendation). The district court adopted this report and recommendation. *Health Care Serv. Corp. v. Olivares*, No. 2:10-CV-221-DF-CE, 2011 U.S. Dist. LEXIS 112544, at \*3–4 (E.D. Tex. Sept. 30, 2011).

260. *Olivares*, 2011 U.S. Dist. LEXIS 117750, at \*12.

261. *Id.* at \*17.

262. *Id.* at \*18.

263. *Id.*



because HCSC did not allege that “it directly relied upon misrepresentations by Pfizer or actually reimbursed patients for prescriptions written by doctors who relied on Pfizer’s misrepresentations . . . .”<sup>264</sup> Kickbacks notwithstanding, the plaintiff bore the burden of alleging and proving that “any doctors or other health care professional relied on any Pfizer misrepresentation promoting an off-label use, as opposed to relying on the professional’s own judgment and expertise, when prescribing the drugs.”<sup>265</sup>

*B. Unbreaking the Causal Chain: Establishing the Proximate Cause of a Prescription*

There are very few economic injury cases in which plaintiffs have overcome the independent physician heuristic and successfully pled or proved that they paid for prescriptions that were proximately caused by the defendants’ illegal promotional efforts.<sup>266</sup> An early example was *Desiano v. Warner-Lambert*, a 2003 Second Circuit case in which the plaintiffs were insurance companies seeking “to recover the moneys they spent purchasing Rezulin[,]” a diabetes medication that was unacceptably unsafe and had been withdrawn from the market.<sup>267</sup> What distinguishes *Desiano* from the cases described above is that the plaintiff insurers alleged (1) that they were a target of the defendant’s fraudulent marketing scheme and (2) “that, had they not been deceived by the Defendants’ misrepresentations about the safety of Rezulin, they would have taken steps so as not to purchase Rezulin at the prices set by Warner-Lambert.”<sup>268</sup> Because the chain of causation bypassed

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264. *Id.* at \*20.

265. *Id.* at \*25.

266. Interestingly, in a case brought by an auto insurance company against a physician group alleged to have engaged in fraud—that is, a case in which the doctors in question were alleged to have joined the RICO enterprise—the court declined to find as a matter of law that the doctors’ prescribing decisions were independent. *See* *State Farm Mut. Auto. Ins. Co. v. CPT Med. Servs., P.C.*, No. 04 CV 5045 (ILG), 2008 U.S. Dist. LEXIS 71156, at \*17–18 n.6 (E.D.N.Y. Sept. 5, 2008) (“Defendants argue that the Amended Complaint should be dismissed because the doctors who referred and ordered the CPT tests made a medical determination that the tests were necessary, and because the New York No-Fault laws have not issued any statements regarding the reliability of CPT tests. This is not a proper objection at the pleading stage. The district court must accept all allegations as true, including State Farm’s claim that the tests were not medically necessary.”).

267. *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 345 (2d Cir. 2003).

268. *Id.* at 349 n.9 (“Among the steps Plaintiffs might have taken were to exclude [Rezulin] altogether

physicians, the *Desiano* plaintiffs did not have the same difficulty establishing the “causal chain of injury” that other third-party payers have encountered.<sup>269</sup>

In 2007, in the *Bextra* and *Celebrex* multi-district litigation, a District Court in the Northern District of California approved a theory of causation that did not bypass physicians.<sup>270</sup> The plaintiffs alleged that the “defendants convinced physicians to prescribe *Celebrex* and third-party payors to pay for it—at 10-times the cost of traditional NSAIDs—by falsely claiming that it is superior to traditional NSAIDs.”<sup>271</sup> The court found that the “unmistakable inference” was that physicians must have been exposed to, and persuaded by, the defendants’ deceptive advertising because “*there [was] no reason for physicians to prescribe and for consumers and third-party payors to pay for Celebrex other than defendants’ false claims . . .*”<sup>272</sup> It is notable that in a subsequent decision, the court retreated from this very plaintiff-friendly causation analysis, finding that it need not follow it where less than 100% of the prescriptions at issue were caused by the defendants’ deceptive advertising.<sup>273</sup>

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from their approved schedules, set a low scheduled value, set a high copay obligation, and otherwise dissuade doctors from prescribing it.”)

269. See *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 257 F.R.D. 315, 333 (D. Mass. 2009) (explaining that third-party payers “have fewer difficulties regarding causation” than individual consumers do, because they do “not have to prove that the misrepresentations caused a specific doctor to prescribe Neurontin to an individual patient[,]” but rather that the third-party payers themselves were “fraudulently induced to approve Neurontin for a specific indication”), *vacated*, 712 F.3d 60 (1st Cir. 2013). Notably, even third-party payers that were the targets of a fraudulent marketing scheme have been barred from proceeding as a class. As the Supreme Court of New Jersey held in *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck and Co.*, “the commonality of defendant’s behavior” was outweighed by “evidence about [the proposed class members’] separately created formularies, different types of tier systems, and individualized requirements for approval or reimbursement imposed on various plans’ members and, to some extent, their prescribing physicians.” *Int’l Union of Operating Eng’rs Local No. 68 Welfare Fund v. Merck & Co.*, 929 A.2d 1076, 1087 (N.J. 2007).

270. *In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.*, No. MDL 05-01699 CRBe1, 2007 U.S. Dist. LEXIS 102340, at \*196–99 (N.D. Cal. July 10, 2007).

271. *Id.* at \*196.

272. *Id.* at \*198.

273. *Health Care Serv. Corp. v. Pharmacia & Upjohn, Inc. (In re Bextra & Celebrex Mktg., Sales Practices & Prod. Liab. Litig.)*, No. 11-CV-00310 CRB, 2012 U.S. Dist. LEXIS 111446, at \*216 n.7 (N.D. Cal. Aug. 2, 2012). The court also distinguished its previous decision on the grounds that it “involved allegations of first-party reliance, not misrepresentations made to third-party physicians.” *Id.* In its previous decision, however, the court wrote that “defendants’ alleged deception of the physicians, causing the physicians to prescribe *Celebrex*, is an integral part of the causation chain.” *In re Bextra & Celebrex*,

In 2013, the First Circuit issued opinions in three related appeals in the *In re Neurontin Marketing and Sales Practices Litigation* case, in which it gave its imprimatur to a causal chain of injury that incorporated the decision making of the thousands of physicians who prescribed Neurontin for off-label uses for which the drug was no more effective than a placebo.<sup>274</sup> The three appeals were brought by the Kaiser Foundation Health Plan and Kaiser Foundation Hospitals, respectively a health insurer and health care provider, by Aetna, a health insurer, and by Harden Manufacturing Corporation and others, self-insured employers. The district court granted the defendant Pfizer's motions for summary judgment in the cases brought by Aetna and Harden Manufacturing on the familiar grounds that physicians' independent decision making broke the chain of causation between the prescriptions for which Aetna and Harden paid and the defendants' fraud.<sup>275</sup>

Kaiser, by contrast, was able to overcome the presumption of physician independence by pleading, and then proving over the course of a five week jury trial, (1) that the defendants provided it with false information, (2) that it relied on the information to develop its formulary, and (3) that its physicians in turn relied on the formulary in writing prescriptions.<sup>276</sup> The "jury found that Pfizer engaged in a RICO enterprise that committed mail and wire fraud by fraudulently marketing Neurontin for off-label conditions such as bipolar disorder, neuropathic pain, and migraine, and at doses greater than 1800 mg/day" and the court found that Kaiser also succeeded in proving its claim under California's Unfair Competition Law.<sup>277</sup> After trebling

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2007 U.S. Dist. LEXIS 102340, at \*203.

274. Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (*In re Neurontin Mktg. & Sales Practices Litig.*), 712 F.3d 21, 42–43 (1st Cir.), *cert. denied*, 134 S. Ct. 786 (2013).

275. See Harden Mfg. Corp. v. Pfizer, Inc. (*In re Neurontin Mktg. & Sales Practices Litig.*), 754 F. Supp. 2d 293, 311 (D. Mass. 2010), *rev'd in part and vacated in part*, 712 F.3d 60 (1st Cir. 2013); Guardian Life Ins. Co. of Am. v. Pfizer, Inc. (*In re Neurontin Mktg. & Sales Practices Litig.*), 677 F. Supp. 2d 479, 495 (D. Mass. 2010), *rev'd in part and vacated in part*, 712 F.3d 51 (1st Cir. 2013).

276. *Kaiser Found. Health Plan*, 712 F.3d at 40–41. Kaiser showed that it has a 95% rate of compliance with the Kaiser formulary among its affiliated physicians. *Id.*

277. *Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.)*, No. 04-cv-10739-PBS, 2011 U.S. Dist. LEXIS 99593, at \*4 (D. Mass. Aug. 31, 2011).

pursuant to the RICO statute, Kaiser's award was \$142,089,276.<sup>278</sup>

On appeal, the First Circuit affirmed the verdicts in favor of Kaiser and reversed the district court's grants of summary judgment against Aetna and Harden. The appellate court held that it had not been necessary for Kaiser to show that it itself was a target of and relied on Pfizer's fraudulent promotion in order to establish a causal chain of injury for purposes of RICO or California's Unfair Competition Law.<sup>279</sup> The evidence that the plaintiffs presented regarding Pfizer's fraudulent promotion to physicians was sufficient to establish both but for and proximate causation.<sup>280</sup>

The evidence presented included an expert report and testimony from Dr. Meredith Rosenthal, a health economist who is a professor at the Harvard School of Public Health.<sup>281</sup> As Dr. Rosenthal explained at trial, she "use[d] aggregate data and statistical approaches to link patterns in promotional spending to patterns in prescribing for the drug."<sup>282</sup> The promotional spending data on which she relied encompassed expenditures "on detailing of doctors, advertisements in professional journals, and the retail value of samples."<sup>283</sup> While Dr. Rosenthal was able to exclude from her analysis "the many off-label prescriptions by physicians who received legitimate on-label promotion[.]" she was not able to distinguish between off-label promotion that was truthful and off-label promotion that was not.<sup>284</sup> The district court found that, "given the pervasive nature of the publication fraud that infected the nationwide sources of information available to all physicians," it was reasonable to assume that all of the monies the defendant spent on off-label promotion were spent on

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278. *Id.*

279. *Kaiser Found. Health Plan*, 712 F.3d at 37 ("Here, like the defendants in [*Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008)], Pfizer argues that its supposed misrepresentations went to prescribing doctors, and so the causal link to Kaiser must have been broken. Even putting aside the evidence of Pfizer's direct communications to Kaiser, we think *Bridge* forecloses this argument.").

280. *Id.* at 40.

281. *Id.* at 29. There was also "subsidiary evidence" that tended to show causation, including the fact that Kaiser-affiliated physicians "attended conferences where Neurontin was promoted for off-label uses, and after one such conference, in May 1999, new starts of Neurontin increased by 62%." *Id.* at 31.

282. *Kaiser Found. Health Plan*, 2011 U.S. Dist. LEXIS 99593, at \*94.

283. *Id.* at \*94, n.19.

284. *Kaiser Found. Health Plan*, 712 F.3d at 30.

fraudulent off-label promotion.<sup>285</sup> The district court also found that it was reasonable for Dr. Rosenthal to use national data on the number of prescriptions written for each of the off-label uses at issue, based on the assumption “that Kaiser’s patient population and physician distribution are similar to the national mix.”<sup>286</sup>

Dr. Rosenthal performed a regression analysis on the data on spending and sales and found that they were causally related to varying degrees.<sup>287</sup> At the high end, spending on off-label promotion caused 99.4% of Neurontin prescriptions for bipolar disorder, while at the low end, it caused 27.9% of Neurontin prescriptions for migraine.<sup>288</sup> Once Dr. Rosenthal determined the percentage of Neurontin prescriptions caused by Pfizer’s fraudulent marketing, a second expert, Dr. Raymond Hartman, converted the percentages into a damages estimate, using “a list of alternative drugs that ‘were more appropriate for each off-label indication than Neurontin’ in order to determine the average cost of the alternative medications that would have been prescribed in the absence of defendants’ fraud.”<sup>289</sup>

Pfizer argued on appeal that Dr. Rosenthal’s testimony should not have been admitted or credited because “an intervening cause—individual physicians’ independent medical judgment . . . precludes a finding of causation based on aggregate evidence.”<sup>290</sup> The First Circuit responded that “‘the burden of proving an ‘intervening cause’—something which snaps the ‘causal chain’ (that is, operates as a ‘superseding cause,’ wiping out the defendant’s liability) that connects

285. *Kaiser Found. Health Plan*, 2011 U.S. Dist. LEXIS 99593, at \*95.

286. *Id.*

287. *Kaiser Found. Health Plan*, 712 F.3d at 29–30.

288. *Id.* Essentially, then, the First Circuit allowed Kaiser to establish causation by demonstrating what the Second Circuit termed a “‘quantity effect.’” *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 129 (2d Cir. 2010). The First Circuit held that there was no split in authority because

[T]he Second Circuit described the plaintiffs’ aggregate evidence of causation as involving only an extrapolation from the fact that the number of off-label prescriptions for Zyprexa fell after Eli Lilly’s fraud became known. This does not come close to resembling Dr. Rosenthal’s evidence, which examined contemporaneous data that reflected what was actually happening with regard to spending and prescriptions while Pfizer’s fraud was ongoing.

*Kaiser Found. Health Plan*, 712 F.3d at 46 (citation omitted).

289. *Kaiser Found. Health Plan*, 712 F.3d at 30, 32.

290. *Id.* at 45.

the wrongful act to the defendant's injury—is on the defendant.”<sup>291</sup> The court also pointed to Dr. Rosenthal's testimony at trial that “Pfizer's proposed physician-by-physician analysis of causation was not . . . scientifically valid.”<sup>292</sup> Dr. Rosenthal explained that it is “neither standard nor appropriate to look physician by physician” because it is well-recognized in the field of healthcare economics that “self-reporting from physicians about patterns of practice that may be controversial shows both conscious reluctance and unconscious bias, which lead them to deny being influenced.”<sup>293</sup>

The First Circuit explained its decision as follows:

In fact, the causal chain in this case is anything but attenuated. Pfizer has always known that, because of the structure of the American health care system, physicians would not be the ones paying for the drugs they prescribed. Pfizer's fraudulent marketing plan, meant to increase its revenues and profits, only became successful once Pfizer received payments for the additional Neurontin prescriptions it induced. Those payments came from Kaiser and other TPPs.<sup>294</sup>

“The fact that some physicians may have considered factors other than Pfizer's detailing materials in making their prescribing decisions” could have an effect on the number of prescriptions attributable to Pfizer and, therefore, on the calculation of damages, but it did not “add such attenuation to the causal chain as to eliminate proximate cause.”<sup>295</sup>

#### V. TOWARD AN AMPLIFIED ROLE FOR “LITIGANT REGULATION” OF PHYSICIAN CONFLICTS OF INTEREST

As the preceding discussion suggests, courts can, consistent with at

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291. *Id.* (quoting *BCS Servs., Inc. v. Heartwood 88, LLC*, 637 F.3d 750, 757 (7th Cir. 2011)).

292. *Id.* at 30.

293. *Id.*

294. *Id.* at 38–39.

295. *Kaiser Found. Health Plan*, 712 F.3d at 39.

least a strand of current doctrine, move beyond the “independent physician” litigation heuristic that stands between plaintiffs and recovery in cases brought against drug and device companies. If the doctrine were to evolve in this way, “litigant regulation” could fill in some of the gaps left by the limited public regulation of physician-industry financial relationships. This would bring closer the goal of ensuring that patients and payers are fairly compensated for the harms caused by conflicts of interest. Perhaps more importantly, it would provide an additional incentive to drug and device companies to ensure that the payments they make to physicians are legitimate.

#### *A. Federal and State Regulation of Physician-Industry Relationships*

The regulatory scheme governing physician-industry financial relationships is replete with gaps and characterized by under enforcement. State attorneys general and medical boards have, for the most part, remained on the sidelines.<sup>296</sup> A new federal law, passed as part of the Patient Protection and Affordable Care Act, will, when it is fully implemented, require that financial relationships between the drug and device industries and physicians be disclosed via a public website.<sup>297</sup> A handful of states have adopted similar disclosure regimes.<sup>298</sup> Clearly, however, disclosure requirements, no matter how robust, do not add up to a comprehensive regulatory regime.

Conflicts of interest in clinical research are addressed by regulations promulgated by the FDA and by the PHS, which demarcate overlapping categories of financial relationships that pose the highest

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296. *But see* Press Release, Synthes, Synthes Settles with New Jersey Attorney General and Agrees to Reimburse Investigation Costs of US \$236,000 (May 5, 2009) (announcing settlement between New Jersey Attorney General and device maker pursuant to which device maker agreed to, among other things, cease its practice of compensating physician-investigators with company stock).

297. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689–96 (2010) (codified as amended at 42 U.S.C. § 1320a-7h) (amending Part A of title XI of the Social Security Act by adding section 1128G and requiring pharmaceutical and medical device manufacturers to disclose payments made to physicians and teaching hospitals for, among other things, conducting clinical research).

298. Joseph S. Ross et al., *Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota*, 297 JAMA 1216, 1216–17 (2007).

risk to the integrity of clinical research.<sup>299</sup> These regulations, however, are limited in both scope and effect.<sup>300</sup>

The FDA's regulations only apply to potential conflicts of interest that arise in the subset of clinical studies of drugs and devices that are submitted as part of marketing applications.<sup>301</sup> Under the FDA's regulations, the sponsor of a clinical trial must report to the agency (1) any financial arrangement between the sponsor and any clinical investigator the value of which could be affected by the trial's outcome, (2) any proprietary interest in the tested product held by any investigator, (3) any significant equity interest in the sponsor held by any investigator, with "significant" defined as an interest "whose value cannot be readily determined through reference to public prices (generally, interests in a nonpublicly traded corporation), or any equity interest in a publicly traded corporation that exceeds \$50,000[.]" and (4) any significant payments, defined as payments in excess of \$25,000.<sup>302</sup> The FDA specifically exempts from regulation payments made to compensate investigators for conducting the clinical trial itself, even if those payments are in excess of the investigator's costs.<sup>303</sup> Information about the financial relationships that are covered by the regulations is submitted to the agency after the clinical trials at issue are completed.<sup>304</sup> The FDA reviews the information to ensure the integrity of the trials' results, not to protect the rights and interests of individual trial participants.<sup>305</sup>

The PHS regulations govern institutions that apply for funding for clinical research from PHS agencies, including the National Institutes of Health, as well as the individuals who conduct the research.<sup>306</sup> The PHS regulations are both more and less restrictive than are FDA's. Government-funded investigators must disclose to their institutions

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299. 42 C.F.R. § 50.602 (2011); 21 C.F.R. § 54.1 (1999).

300. *See generally* 42 C.F.R. § 50.602; 21 C.F.R. § 54.1.

301. 21 C.F.R. § 54.1.

302. *Id.* §§ 54.2(b), (f) & 54.4.

303. *Id.* § 54.2(e).

304. *Id.* § 54.3.

305. 21 C.F.R. § 54.5(a) (providing that the information disclosed to the FDA is reviewed "to determine the impact of any disclosed financial interests on the reliability of the study").

306. 42 C.F.R. § 50.602.



significant financial interests, defined to include (1) remuneration in excess of \$5,000, (2) equity in excess of \$5,000 in a publicly-traded entity, (3) any equity in a non-publicly-traded entity, and (4) intellectual property rights, but only upon receipt of income related to such rights.<sup>307</sup>

Public ex post regulation of physician-industry relationships is similarly limited. The FDA and PHS regulations are, at least arguably, under enforced. Both agencies have been the subject of highly-critical investigative reports conducted by the Office of Inspector General of the United States Department of Health and Human Services.<sup>308</sup> Congressional and media investigations have uncovered multiple instances of high-profile investigators who failed to make required conflicts disclosures but suffered no serious consequences.<sup>309</sup> Academic medical centers and private practice physicians who conduct large numbers of industry-sponsored clinical trials are likely to be audited by the FDA, but the FDA's review is broad-based.<sup>310</sup> The financial disclosures that investigators are required to make to sponsors are not a specific focus of the agency.<sup>311</sup>

The Department of Justice, working in concert with the FDA and the Office of Inspector General of the Department of Health and Human Services, enforces the Anti-Kickback Act against drug and device manufacturers.<sup>312</sup> This includes criminal prosecution, with

307. *Id.* § 50.603.

308. OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., THE FOOD AND DRUG ADMINISTRATION'S OVERSIGHT OF CLINICAL INVESTIGATORS' FINANCIAL INFORMATION 15, 21, 23 (2009) (finding that the FDA responded inconsistently or not at all to the financial information that drug and device companies disclosed to it, that the agency did not keep careful track of the information once disclosed, and that fully 42% of the marketing applications it approved were missing required information); OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., NATIONAL INSTITUTES OF HEALTH: CONFLICTS OF INTEREST IN EXTRAMURAL RESEARCH ii–iii (2008) (leveling similar criticisms against the NIH including that the agency failed to track the conflict of interest reports it received and that its response to them was inconsistent and infrequent).

309. *See, e.g.*, Paul Basken, *As He Worked to Strengthen Ethics Rules, NIMH Director Aided a Leading Transgressor*, CHRON. HIGHER ED. (June 6, 2010), (reporting that Dr. Charles Nemeroff, who failed to disclose \$1.2 million in payments from drug and device companies, “has largely avoided NIH restrictions for [his] actions”), available at <https://chronicle.com/article/While-Revising-Ethics-Rules/65800/>; Tracy Weber & Charles Ornstein, *Doctors Avoid Penalties in Suits Against Medical Firms*, PROPUBLICA (Sept. 16, 2011), <http://www.propublica.org/article/doctors-avoid-penalties-in-suits-against-medical-firms>.

310. Boozang et al., *supra* note 39, at 21.

311. *Id.*

312. *See* Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033, 1048 (2012).

settlements implemented via non-prosecution or deferred prosecution agreements, both often overseen by independent monitors, and civil enforcement, with settlements implemented via corporate integrity agreements and also overseen by monitors.<sup>313</sup> The Anti-Kickback Act is also enforced through civil False Claims Act (FCA) suits brought by private qui tam relators, joined, in some cases, by the DOJ.<sup>314</sup> The Patient Protection and Affordable Care Act clarified that a claim for reimbursement for a prescription written by a physician who was paid a kickback is a “false claim” for FCA purposes.<sup>315</sup> Through FCA suits, then, the government can recover the losses it incurs as a result of physicians being paid to prescribe.<sup>316</sup> Losses to private payers and to patients resulting from the same payments, however, go unredressed.

### *B. Moving Beyond the “Independent Physician” Litigation Heuristic in Personal Injury Cases*

In personal injury cases, the inquiry into whether the learned intermediary doctrine applies or not should be expanded to encompass not just the effect of a financial relationship on a physician’s decision making but also the drug or device company’s intent in entering into the relationship. If even one purpose of the payment or payments was to reward the physician for prescribing the company’s drug or device—that is, if the Anti-Kickback Act’s intent requirement is met—then the learned intermediary doctrine should not apply.<sup>317</sup>

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313. Kathleen M. Boozang & Simone Handler-Hutchinson, “Monitoring” Corporate Corruption: DOJ’s Use of Deferred Prosecution Agreements in Health Care, 35 AM. J.L. & MED. 89, 92–93 (2009); see, e.g., Press Release, U.S. Dep’t of Justice, Minnesota-Based Medtronic Inc. Pays US \$23.5 Million to Settle Claims That Company Paid Kickbacks to Physicians (Dec. 12, 2011), available at <http://www.justice.gov/opa/pr/2011/December/11-civ-1623.html> (announcing settlement to resolve allegations that device maker used post-market studies and device registries as vehicles to pay physician-investigators kickbacks to implant the company’s pacemakers and defibrillators); Press Release, U.S. Dep’t of Justice, Minnesota-Based St. Jude Medical Pays U.S. \$16 Million to Settle Claims that Company Paid Kickbacks to Physicians (Jan. 20, 2011), available at <http://www.justice.gov/opa/pr/2011/January/11-civ-078.html> (same).

314. Kathleen M. Boozang, Note & Comment, *The New Relators: In-House Counsel and Compliance Officers*, 6 J. HEALTH & LIFE SCI. L. 16, 21–22 (2012).

315. 42 U.S.C. § 1320a-7b(g) (2010).

316. See United States *ex rel.* Wilkins v. United Health Group, Inc., 659 F.3d 295, 304 (3d Cir. 2011).

317. Tim Drake, Alexandra Kanu & Nick Silverman, *Health Care Fraud*, 50 AM. CRIM. L. REV. 1131, 1144 (2013) (“Most courts have adopted the ‘one purpose’ standard, whereby the Anti-Kickback Statute is violated if one purpose of the offer or payment was to induce referrals.”).

What, one might ask, justifies affording special treatment to kickbacks? Congress chose not to provide for a private right of action to enforce the Anti-Kickback Act. Moreover, the FCA ensures that taxpayers' interest in suppressing kickbacks is protected. In fact, there is doctrinal support for "special" treatment for kickbacks. A central justification for the learned intermediary doctrine is that physicians independently weigh the costs and benefits of drugs and devices and then make independent prescribing decisions. Clearly, the manufacturer cannot warn itself of the dangers of its products and avoid liability thereby. Similarly, manufacturers should not be able to avoid liability by providing warnings to doctors they pay to prescribe. Courts should presume that a physician who was paid a kickback is not independent of the manufacturer making the payment, and so cannot function as a learned intermediary.

On the other hand, where a plaintiff alleges not a kickback but a facially legitimate financial relationship between manufacturer and doctor, the burden of proving that the doctor was not independent should remain with the plaintiff. Physician-industry financial relationships pose a risk to the quality of the advice that physicians provide to their patients and that physician-investigators provide to participants in clinical trials. This does not mean, however, that any particular patient or clinical trial participant received bad advice, even if the individual suffered personal injury.

In the *Murthy v. Abbott* case discussed above, the court initially found as a matter of law that a facially-legitimate financial relationship between a doctor and a drug company so undermined the doctor's independence that the company had to direct any and all warnings about the drug's safety directly to the doctor's patients.<sup>318</sup> The *Murthy* court reached this conclusion without apparent regard for the nature, size, or scope of the financial ties at issue.<sup>319</sup> On the one hand, this approach—which the *Murthy* court eventually stepped back from—

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318. See *supra* text accompanying notes 11–16.

319. *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 972 n.5 (S.D. Tex. 2012) (noting that “[a]ccording to researchers, physicians may even be influenced by ‘token gifts’: ‘Social science research continues to show that the impulse to reciprocate from even a token gift can be a powerful influence on behavior, thereby producing a possible conflict of interest for the recipient (physician)’” (citation omitted)).

took seriously the risk that even seemingly-benign financial relationships could bias prescribing. On the other hand, it transformed a difficult factual question into a question of law and, arguably, gave the research compensation at issue too much weight in the process.

As the *Murthy* court held on reconsideration, it may or may not be appropriate to apply the learned intermediary doctrine in cases in which the plaintiff alleges that there was a facially legitimate financial relationship between the defendant manufacturer and the plaintiff's doctor.<sup>320</sup> The factual questions raised when a plaintiff plausibly pleads that his or her doctor had a financial relationship with the defendant manufacturer are many.

Among the questions raised by physician-industry relationships are the following. Is there a *de minimis* amount below which concerns about bias recede? Are there relevant temporal parameters? How does the type of financial relationship affect the calculus? Some observers, for example, would argue that compensation for conducting research—of the sort that was at issue in *Murthy*—is either untroubling or on net a social good that should be encouraged. Others believe that per capita payments for conducting research are particularly problematic, especially where the physician investigator is responsible for recruiting and enrolling his or her patients into the clinical trial.<sup>321</sup> That these questions lack easy answers argues in favor of determination as a matter of fact, not law. A motion to dismiss on learned intermediary grounds should rarely be successful in the face of allegations that the defendant manufacturer had a financial relationship with the plaintiff's physician.

There are potential practical objections to the proposed doctrinal approach. For one, to the extent that it opens the proverbial floodgates to litigation, it could further strain judicial resources and unfairly and undesirably handicap the life sciences sector. One response to this objection is that courts would still have a plethora of tools for disposing of drug and device cases at an early stage of litigation wherever appropriate. In particular, it is important to note that in order

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320. See *supra* text accompanying notes 21–23.

321. Boozang et al., *supra* note 39, at 10.

to benefit from the presumption that a physician who was paid a kickback is not independent, a plaintiff must plead and later prove that the defendant manufacturer paid the plaintiff's physician to prescribe.<sup>322</sup> This seems likely to be more straightforward than pleading and proving a physician's internal decision making process, which should work to the benefit of plaintiffs, but plaintiffs will continue to bear a heavy burden.

Another potential practical objection is that an exception to the learned intermediary doctrine that rested on a case-by-case evaluation of financial ties between a manufacturer and the many physicians with whom it works would be difficult to implement. At least one court has opined that it would be difficult or impossible for a company to determine who the patients of the physicians it compensates are, let alone to warn each of them directly of the risks posed by its drug or device.<sup>323</sup> Here, one could respond by challenging the premise that drug and device companies could not, in a data-centric age in which direct-to-consumer marketing is ubiquitous, convey adequate warnings directly to patients.

Finally, an exception to the learned intermediary doctrine for physician-industry relationships could be criticized on policy grounds. Clearly, such an exception would serve the individual plaintiffs whose cases would be dismissed without it. The question arises whether it would also serve the larger goal of ensuring that patients have the information and advice they need to make the best possible decisions about their healthcare.

The exception would create an incentive for manufacturers to warn patients directly of the risks posed by drugs and devices, but patients are unlikely to do a better job weighing the benefits and risks of a drug or device than doctors are.<sup>324</sup> For example, patients are much more

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322. *Cf.* United States v. Mathur, No. 2:11-cr-00312-MMD-PAL, 2012 U.S. Dist. LEXIS 143197, at \*20 (D. Nev. Sept. 13, 2012) (discussing the Anti-Kickback Act's stringent specific intent requirement).

323. Ruling on Plaintiff's Motion for Directed Verdict on Defendant's Learned Intermediary Doctrine Defense, *supra* note 134, at 5.

324. *See* Talley v. Danek Med., Inc., 179 F.3d 154, 163 (4th Cir. 1999) ("Even if the manufacturer could be assured that the patient received the warnings, this practice might not be beneficial because 'the information regarding risks is often too technical for a patient to make a reasonable choice.' . . . One of the important functions of the physician is to determine the risks and explain them to the patient in a way

likely than their doctors are to under-appreciate prospective benefits and overreact to potential risks. As Christopher Robertson notes, where there is “epistemic asymmetry[,]” as there is between a doctor and his or her patient, expert advice, even if conflicted, may be preferable to no advice.<sup>325</sup> A partial response to this criticism of a conflict of interest exception to the learned intermediary doctrine is that such an exception would not force patients to weigh the benefits and risks of drugs and devices alone, without the guidance of their personal physicians. Manufacturers would continue to be obligated to provide physicians with safety information about their products, and physicians would continue to be responsible for factoring that information into their prescribing decisions. All that would change is that, in cases in which a physician had a conflict of interest, manufacturers would also be obligated to provide the safety information directly to the physician’s patients.<sup>326</sup>

### C. Moving Beyond the “Independent Physician” Litigation Heuristic in Economic Injury Cases

In economic injury cases, courts should follow the First Circuit’s decision in *Kaiser Foundation Health Plan v. Pfizer* and allow plaintiffs to use standard statistical methods such as regression analysis to demonstrate that kickbacks or other financial relationships influenced physicians’ prescribing decisions in the aggregate. As the

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that can be understood.”); see also Jeremy A. Blumenthal, *Expert Paternalism*, 64 FLA. L. REV. 721, 750 (2012) (“[A] range of studies show experts’ superiority. Experts do make accurate, well-calibrated judgments, using appropriate amounts and types of information.”).

325. Christopher Tarver Robertson, *Biased Advice*, 60 EMORY L.J. 653, 677 (2011).

[W]here epistemic asymmetry is high, a ban on conflicted advice would be very bad policy, unless the policymaker can be confident that non-conflicted advisors would replace the conflicted advisors. Such replacement is not an obvious outcome of a ban on conflicted advice. To the extent that an advisor has a conflicting interest, the advisory services are being subsidized by some outside source. . . . Thus, policymakers must ask whether the asymmetry is greater than the bias ratio, and whether there is a viable alternative epistemic and economic relationship.

*Id.*

326. Note that one could also argue that a conflict of interest exception would not go far enough and that, given the changes that have taken place in the practice of medicine, patients should in all cases be directly informed of the benefits and risks of drugs and devices. See *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 912–13 (W. Va. 2007) (relying heavily on the existence and increasing prevalence of direct-to-consumer advertising in deciding not to adopt the learned intermediary doctrine at all).

First Circuit held, “regression analysis is a well recognized and scientifically valid approach to understanding statistical data, and courts have long permitted parties to use statistical data to establish causal relationships.”<sup>327</sup>

Allowing plaintiffs to prove causation in the aggregate would lead to significantly more “litigant regulation” of physician conflicts of interest. For one, it would make class action lawsuits, whether brought by patients or third-party payers, possible.<sup>328</sup> As Maria Glover has explained, “the class action device is likely able to function in the context of RICO fraud claims if parties can allege causation or reliance by means of statistical or aggregate proof.”<sup>329</sup> Glover opines that “[f]or small-value RICO claims . . . mechanisms like the class action device are critical to facilitate private enforcement.”<sup>330</sup>

Even in traditional lawsuits brought by individual third-party payers, resort to aggregate proof is a practical necessity given the large number of prescriptions likely to be at issue. Aggregate proof is particularly appropriate in this context. If a third-party payer establishes that it paid for more prescriptions than it would have absent a defendant manufacturer’s fraudulent promotion, it is not relevant which physicians contributed to the increase and which did not.

Allowing for aggregate proof of causation will not mean that all harms caused by conflicts of interest will be redressed. In a case, for example, in which the defendant manufacturer paid kickbacks to doctors but did not make false or misleading representations about its drug, a plaintiff may not be able to plead or prove the typical RICO predicate acts of mail or wire fraud.<sup>331</sup> Other RICO elements could also prove difficult for plaintiffs to plead and prove.<sup>332</sup>

327. *Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.)*, 712 F.3d 21, 42 (1st Cir.), *cert. denied*, 134 S. Ct. 786 (2013).

328. Richard A. Nagareda, *Class Certification in the Age of Aggregate Proof*, 84 N.Y.U. L. REV. 97, 101–02 (2009).

329. J. Maria Glover, *The Structural Role of Private Enforcement Mechanisms in Public Law*, 53 WM. & MARY L. REV. 1137, 1191 (2012).

330. *Id.*

331. Such a plaintiff might be able to plead other RICO predicate acts such as bribery or honest services fraud. *See, e.g., Clark v. Conahan*, 737 F. Supp. 2d 239, 267–68 (M.D. Pa. 2010) (holding plaintiffs could bring civil RICO claims because they alleged honest services fraud).

332. *See supra* note 225.

Establishing a concrete economic injury could also be difficult for plaintiffs in conflict of interest cases, particularly where the drug in question was safe and effective. In *Kaiser Foundation Health Plan v. Pfizer*, the First Circuit emphasized that the district court's damages determination was based on evidence Kaiser produced—including evidence from gold-standard, double-blind randomized controlled trials—that Neurontin was not effective for the four off-label conditions as to which the district court and jury found liability.<sup>333</sup> A plaintiff might allege, for example, that, if the defendant had not paid doctors to prescribe its branded drug, the doctors would have prescribed the drug's much cheaper generic equivalent. Many courts have held, however, that a patient who is prescribed a safe and effective drug “has received the benefit of his bargain,” even if, in the absence of the defendant's illegal promotional efforts, the patient would have been prescribed a less expensive drug that was equally safe and effective.<sup>334</sup>

Finally, even if aggregate proof is permitted, plaintiffs will continue to face challenges related to the element of causation. It will not always be possible, as it was in *Kaiser Foundation Health Plan v. Pfizer*, to use national data based on the presumption that a plaintiff payer's patient population and physician distribution were representative. It will also not always be possible to presume that all of the promotion a defendant engaged in was fraudulent. Distinguishing prescriptions written by physicians who received legitimate promotion from those written by physicians who received illegitimate promotion will also not always be possible.

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333. *Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.)*, 712 F.3d 21, 49 (1st Cir.), *cert. denied*, 134 S. Ct. 786 (2013).

334. *District 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 523 (D.N.J. 2011) (“[W]ithout alleging that a product failed to perform as advertised, a Plaintiff has received the benefit of his bargain and has no basis to recover purchase costs.” (citations omitted)). The plaintiffs categorized their “concrete financial loss” as overpaying for Risperdal for off-label uses due to defendants' allegedly fraudulent and deceptive marketing practices, which inflated the number of prescriptions of Risperdal written and filled and increased plaintiffs' co-payments and out-of-pocket costs. *Id.* at 519. The plaintiffs did not plead that Risperdal was inferior to competitor drugs. *Id.* at 520.



## CONCLUSION

The recommendations set forth in this Article would, if adopted, result in courts moving past the “independent physician” litigation heuristic. In personal injury cases where there is a financial relationship between a physician and the defendant manufacturer, the question of the physician’s independence would become one of fact, to be determined in light of factors such as the nature, size, and scope of the relationship. Where the defendant manufacturer is alleged to have paid kickbacks to a physician, however, plaintiffs would benefit from a strong presumption that the doctor was not in fact independent of the manufacturer and that the learned intermediary doctrine therefore did not apply. In economic injury cases, courts would move beyond the heuristic by allowing plaintiffs to use standard statistical methods to demonstrate that physicians’ prescribing decisions were not independent in the aggregate.

As Joel Demski has noted with regard to conflicts of interest in business, “as with other economic activities, we balance tensions and shy away from attempting to create a situation of zero failures as a result of conflicts of interest, simply because pursuing such an extreme goal would be uneconomic.”<sup>335</sup> Demski goes on to express the following fear:

[W]e have failed to appreciate, or have forgotten, the delicacy of a well-crafted web of controls for managing conflicts of interest. We tend to think in terms of a specific conflict or specific control applied thereto: for example, assuring greater independence for auditors or more outsiders on boards of directors. Yet reality is multiple conflicts among multiple players, in the context of an enlarged, interactive web of controls.<sup>336</sup>

In the medical treatment and clinical research contexts, allowing “litigant regulation” to play an amplified role would move us closer to

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335. Joel S. Demski, *Corporate Conflicts of Interest*, 17 J. ECON. PERSPECTIVES 51, 52 (2003).

336. *Id.* at 53.

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the goal of “a well-crafted web of controls” that would fairly compensate patients and payers for the harms caused by conflicts of interest without deterring desirable collaboration between physicians and industry.

