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Lars Noah
University of Florida

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Doctors on the Take: Aligning Tort Law to Address Drug Company Payments to Prescribers

LARS NOAH†

I know you think you are being generous, but the foundation of gift giving is reciprocity. You haven't given me a gift. You've given me an obligation.

—“Dr.” Sheldon Cooper*

INTRODUCTION

From a very young age, we all learn to crave gifts. Whether to mark milestones (large and small) or holidays (major and minor), children become accustomed to getting stuff that they do not need. At first, some mystery may

† Stephen C. O’Connell Chair, University Term Professor, and Professor of Law, University of Florida; author, Law, Medicine, and Medical Technology (Foundation Press 4th ed. 2017).

* The Big Bang Theory: The Bath Item Gift Hypothesis (CBS television broadcast Dec. 15, 2008) (“The essence of the custom is that I now have to go out and purchase for you a gift of commensurate value and representing the same perceived level of friendship as that represented by the gift you’ve given me. It’s no wonder suicide rates skyrocket this time of year.”). One season later, the show’s eccentric physicist applauded the message of the classic Dr. Seuss book “How the Grinch Stole Christmas!” up until the eponymous character’s change of heart. See The Big Bang Theory: The Maternal Congruence (CBS television broadcast Dec. 14, 2009).
surround the gift givers, from Santa Claus, the Easter Bunny, the Tooth Fairy, a secret admirer on Valentine’s Day, or strangers dressed up in costumes handing out candy on Halloween, but with time most gift-givers want to get some credit for their generosity.

Few of us ever outgrow the desire to receive gifts, though we try to become adept at giving them as well, while persons who prefer to opt out of the madness get rewarded with unkind epithets. Economists occasionally point out the inefficiency of the process,\(^1\) preferring the exchange of cold hard cash (or gift cards) or endorsing the increasingly popular “self-gifting” phenomenon,\(^2\) but our economy would suffer mightily if consumers heeded such advice. In certain contexts, however, the gift relationship has a less benign reputation, particularly when it involves elected officials or others charged with making decisions that should remain free of potential bias.

Doctors like getting goodies as much as the rest of us. Indeed, some physicians bemoan the fact that patients have fallen out of the habit of expressing their gratitude in this fashion.\(^3\) Not to worry, the drug industry has stepped in to fill that void in a big way. In fact, some of the giveaways tie in nicely with the holidays, including complimentary

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3. See Suzanne J. Koven, The Ungifted Physician, 279 JAMA 1607 (1998). Although I avoid health care professionals (and the exchange of gifts) like the plague, one time I gave a physician a signed copy of my casebook (MSRP > $200) in thanks for patiently attending to members of my immediate family. See Dedication from author to Catherine Blackband (Apr. 6, 2013) (copy on file with author).
Christmas trees and bouquets to pass along to that special someone on Valentine’s Day, 4 though lately cash has taken center stage. The apparent generosity of companies that sell therapeutic products has encountered a growing chorus of criticism, however, because these gifts seek to influence physician choices that affect patient health. Although the recipients of industry largesse vehemently deny that their professional judgment could get corrupted so easily, they fool no one but themselves and may endanger their patients in the process. 5

Part I describes the nature and scope of industry payments to health care professionals. These have changed over time as a variety of institutions attempted to crack down on the practice. First, the medical profession issued ethical codes, and the industry adopted voluntary guidelines; next, federal agencies published nonbinding guidance documents and prosecuted some companies; most recently, a handful of states and then Congress imposed reporting requirements and created databases designed to promote transparency. Nonetheless, manufacturers of prescription drugs and medical devices continue to find ways of rewarding physicians for selecting their products, at times adopting creative tactics to evade the limited restrictions that currently exist, while researchers keep documenting the powerful impact of even trivial inducements.


5. Although normally criticized for driving up costs, promotional campaigns at the time of initial product launch may expose patients to heightened risks because unexpected adverse events often turn up during the first few years after approval. See Karen E. Lasser et al., Timing of New Black Box Warnings and Withdrawals for Prescription Medications, 287 JAMA 2215, 2218–19 (2002) (concluding that it may take several years of use to fully characterize a drug’s safety profile); Gordon D. Schiff et al., Principles of Conservative Prescribing, 171 ARCHIVES INTERNAL MED. 1433, 1435 (2011) (suggesting that physicians wait to use a new drug until seven years have passed since its introduction).
Part II, therefore, suggests a couple of modifications in tort doctrine to tackle the problem. First, courts could expand the informed consent duties of physicians to include disclosures of potential conflicts of interest to patients, though in practice such a move might not accomplish much. Second, courts could recognize a novel exception to the “learned intermediary” doctrine, stripping manufacturers of an important limitation on their duty to warn when they have made certain types of payments to prescribers. If sellers of therapeutic products faced the prospect of having to supply adequate risk information directly to patients in such cases, then perhaps they might finally give up on this dubious method of marketing to health care professionals.

I. PHARMACEUTICAL COMPANIES PAYING PHYSICIANS TO PRESCRIBE THEIR PRODUCTS

Manufacturers have found a variety of ways to encourage the selection of their prescription drug products. In response to evolving ethical codes, industry guidelines, and occasional prosecution of unlawful kickback schemes, the methods deployed by pharmaceutical companies have changed over time. For instance, firms have sponsored studies that appear to serve no other purpose than getting physicians into the habit of using a new drug for their patients. Recently adopted reporting requirements and the resulting databases have helped researchers more clearly document the full scope and continued impact of payments to prescribers.

A. Evolving Industry Practices and Guidelines

For at least half a century, manufacturers have lavished various types of gifts on health care professionals in the hopes of generating demand for their products. In an earlier era, the industry hardly tried to conceal its crass efforts to purchase the loyalty of physicians.\(^6\) The first

\(^6\) See, e.g., John C. Nelson, A Snorkel, a 5-Iron, and a Pen, 264 JAMA 742
ethical codes appeared in 1990, with both the medical profession and the pharmaceutical industry expressing their concerns about some of the gifts and prizes offered to prescribers.  

Although not entirely consistent with one another and periodically revised over the years, the guidelines now basically allow gifts of modest value (less than $100 or so) that serve some educational purpose or benefit patients. Nonetheless, because they lack any real force, these guidelines have managed to stamp out only the


9. See Bill Brubaker, Drug Firms Still Lavish Pricey Gifts on Doctors; Ethics Debated As Freebies Flow, WASH. POST, Jan. 19, 2002, at E1 (“Nothing in the AMA guidelines discourages doctors from accepting as many free breakfasts, lunches or dinners as they want... [F]ree meals must be ‘modest’ and have an educational component.”); cf. Douglas R. Waud, Pharmaceutical Promotions—A Free Lunch?, 327 NEW ENG. J. MED. 351, 352 (1992) (“[T]he idea seems to be to stick to bribes that are small enough to be swept under the rug if someone asks questions... Can any physician really believe that patients would be happy to know that their doctors were taking bribes, no matter what the size?”).
most egregious abuses.10

The industry bestows gifts on other parties as well. In addition to ingratiating themselves with physicians, some pharmaceutical manufacturers have enlisted retail pharmacists to help expand market share.11 Although less common, companies may offer financial enticements to patients.12 Sponsors of medical research have used similar inducements, paying physicians to refer their patients to clinical trials,13 and offering various goodies to subjects

10. See Lars Noah, Medicine’s Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community, 44 ARIZ. L. REV. 373, 431 (2002) (“While the payola-style abuses of earlier decades have largely vanished, sales strategies have become more sophisticated, . . . and detail representatives continue to ‘wine and dine’ physicians.”); see also Kirsten E. Austad et al., Changing Interactions Between Physician Trainees and the Pharmaceutical Industry: A National Survey, 28 J. GEN. INTERNAL MED. 1064, 1068 (2013) (finding failures to follow the latest industry code in giving gifts to medical students, which suggests that “voluntary, self-imposed guidelines may not be sufficient to end potentially problematic industry marketing practices”); David Grande, Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention?, 25 J. GEN. INTERNAL MED. 79, 80 (2010) (“[E]vidence from state gift disclosure laws suggests that many physicians do not follow the AMA’s ethics guidelines.”).

11. See Gina Kolata, Pharmacists Help Drug Promotions: Some Doctors Dislike a Link with the Manufacturers, N.Y. TIMES, July 29, 1994, at A1 (“[O]thers complain that when pharmacists make money on particular choices of drugs, they are no longer disinterested parties. It is no different, some say, from the doctor who owns the diagnostic laboratory down the street from his office and so benefits financially each time he sends a patient there for lab tests.”).

12. See Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 GA. L. REV. 141, 169–70 (1997) (“[C]ritics suggest that some recent promotional campaigns, including coupons, rebates, and offers of free gifts in exchange for visits to physicians, are unseemly.”); see also Rhonda L. Rundle, A New Wrinkle in Rewards Programs—Restylane, Botox Offer Incentives for Loyal Patients; Some Raise Ethics Concerns, WALL ST. J., Mar. 2, 2005, at D1 (describing incentives similar to frequent-flyer programs).

13. See Lars Noah, Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy, 28 AM. J.L. & MED. 361, 361–62 (2002) (explaining that sponsors “may offer financial incentives to family physicians for recruiting subjects from among their existing patients”); Kurt Eichenwald & Gina Kolata, Drug Trials Hide Conflicts for Doctors, N.Y. TIMES, May 16, 1999, § 1, at 1 (“There are finder’s fees for those who refer their patients to other doctors conducting research.”); id. (“[T]op recruiters can earn as much as
upon enrollment. Conversely, health insurers sometimes provide financial incentives to prescribers in order to discourage the use of expensive brand-name drugs, which prompted one major pharmaceutical manufacturer to cry foul.

In the face of growing scrutiny of pricey gifts, lavish dinners, and junkets to vacation spots for physicians, the $500,000 to $1 million a year.

14. See Lars Noah, Coerced Participation in Clinical Trials: Conscripting Human Research Subjects, 62 ADMIN. L. REV. 329, 329–30 & n.2, 358 & n.126 (2010) (discussing inducements for participation in medical studies); Rachel Zimmerman, Desperately Seeking Kids for Clinical Trials, WALL ST. J., May 29, 2002, at D1 (“To lure young patients, some trials are offering cash, gift certificates to Toys R Us and Tower records, T-shirts, and use of a Palm Pilot during the study.”); see also id. (“While it’s illegal to pay physicians cash ‘bounties’ for recruiting children, some researchers are rewarded in other ways.”).

15. See Vanessa Fuhrmans, Doctors Paid to Prescribe Generic Pills, WALL ST. J., Jan. 24, 2008, at B1 (reporting that one insurer offered physicians “$100 each time they switch a patient from a brand-name drug,” adding that Pfizer complained about the program to several medical associations, and that the AMA cautioned that such payments might constitute illegal kickbacks); id. (Such approaches “are coming under fire for injecting financial incentives into what some patient advocates and legislators say should be a purely medical decision. Medical societies are also concerned that such rewards may put doctors in the ethically questionable position of taking a payment that patients know nothing about.”). Patients know nothing about such payments only because participating physicians remain silent.

16. See, e.g., Adriane Fugh-Berman & Shahram Ahari, Following the Script: How Drug Reps Make Friends and Influence Doctors, 4 PLoS MED. e150, at 0623 (2007) (“High prescribers receive higher-end presents, for example, silk ties or golf bags.”); Robert M. Tenery, Jr., Interactions Between Physicians and the Health Care Technology Industry, 283 JAMA 391, 392 (2000); Adams, supra note 4, at A1 (“As the drug industry reaches new extremes in its courtship of prescribing doctors, the giveaways are flowing freely . . . [including] flowers, books, CDs, manicures, pedicures, car washes, bottles of wine and cash.”); id. (“mention[ing] ‘gas ‘n’ go’ events, where a doctor drives up, gets his tank filled and hears a drug pitch”); Sheryl Gay Stolberg & Jeff Gerth, High-Tech Stealth
American Medical Association (AMA) launched a campaign—underwritten by drug companies no less—to remind physicians about the existing ethical guidelines. In 2002, the pharmaceutical industry issued a code of conduct to address interactions with physicians, and its latest revision appeared one decade ago. The medical

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17. See Council on Ethical & Judicial Affairs, Am. Med. Ass'n, Guidelines on Gifts to Physicians from Industry: An Update, 56 Food & Drug L.J. 27, 28 (2001) ("[T]he AMA is about to embark on a nationwide campaign to educate physicians about the importance of reducing and eliminating inappropriate gifts from industry."); see also Susan Okie, AMA Criticized for Letting Drug Firms Pay for Ethics Campaign, Wash. Post, Aug. 30, 2001, at A3 ("[D]rug companies often treated doctors to expensive gifts, lavish dinners, trips or cash payments. Publication of the guidelines helped curb such practices in the early 1990s, but more recently, studies and media reports have suggested that gift-giving to doctors by drug companies has increased . . . . [S]urveys indicate many doctors are unaware that the ethics guidelines exist."); id. ("Drug companies’ gifts to doctors typically include such items as pens, notebooks, coffee cups, desk accessories and tote bags . . . [and] golf balls or golf club covers . . . . The AMA guidelines state that doctors should not accept gifts . . . if the gift is an incentive or a reward for prescribing a company’s drug.").

18. See Scott Hensley, Sorry, Doc, No Dinners-to-Go—Drug Sales Reps Begin Building a New Marketing Playbook, Wall St. J., Apr. 23, 2002, at D4 ("The voluntary code, adopted . . . last week, would eliminate a pizza dropoff for the staff unless it is accompanied by an in-person educational session. Entertainment for its own sake would be eliminated entirely."); id. ("No longer will [salespeople] be able to chat up a surgeon during intermission at a ‘Lion King’ performance, or bond side by side in half-court seats at a Lakers game."); Jeffrey L. Seglin, Just Saying No to Gifts from Drug Makers, N.Y. Times, Aug. 18, 2002, § 3, at 4; Cyril T. Zaneski, Medical Sales Reps Arrive Bearing Gifts, Balt. Sun, June 17, 2004, at 1A ("The PhRMA code allows companies to provide meals and gifts of less than $100 in connection with presentations and sales visits. The gifts must be something that can be used in a medical office. A stapler with a drug logo is OK under the code. A box of golf balls or a ticket to a sporting event is not.").

19. See Pharm. Research & Mfrs. of Am. (PhRMA), Code on Interactions with Healthcare Professionals 13 (July 2008), http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf (forbids offering or providing anything “in a manner or on conditions that would interfere with the independence of a healthcare professional’s prescribing practices”); Howard L. Dorfman, The 2009 Revision to the PhRMA Code on Interactions with Healthcare Professionals: Challenges and Opportunities for the Pharmaceutical
device industry adopted a similar code. Nonetheless, payments to health care professionals have continued under different guises.

For instance, some manufacturers have sponsored so-called “seeding trials” that purport to elicit information about patient experiences from prescribers but in practice seemed to represent little more than financial inducements designed to encourage physicians to use a new drug or device. “Preceptorships” refer to an arrangement that

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Industry in the Age of Compliance, 31 CAMPBELL L. REV. 361, 364–70 (2009) (highlighting modifications to the industry guidelines that related to gifts and payments); see also infra note 52 (discussing the effort to end the giving of trinkets in this latest version of the code); cf. Elizabeth Wager, How to Dance with Porcupines: Rules and Guidelines on Doctors’ Relations with Drug Companies, 326 BMJ 1196, 1196–97 (2003) (comparing codes from around the world).

20. See Advanced Med. Tech. Ass’n (AdvaMed), Code of Ethics on Interactions with Health Care Professionals (July 2009), https://www.advamed.org/sites/default/files/resource/112_112_code_of_ethics_0.pdf; see also Bonnie O’Connor et al., Salespeople in the Surgical Suite: Relationships Between Surgeons and Medical Device Representatives, 11 PLOS ONE e0158510, at 16 (2016) (“The issues and potential pitfalls of excessive industry influence in medical care and physicians’ treatment decision making are at least as urgent for implantable medical devices as they are for pharmaceuticals and prescribing practices, but to date they are far less well studied . . .”).

21. See Christopher Lee, Drugmakers, Doctors Get Cozier: Gifts Continue, Contacts Increase Despite Guidelines, WASH. POST, Apr. 29, 2007, at A3 (“Despite efforts to curb drug companies’ avid courting of doctors, the industry is working harder than ever to influence what medicines they prescribe, sending out sales representatives with greater frequency and plying physicians with gifts, meals and consulting fees . . .’’); id. (“The ties between doctors and drug companies are deepening despite voluntary guidelines to curb excesses . . .’’); see also David Blumenthal, Doctors and Drug Companies, 351 NEW ENG. J. MED. 1885, 1889 (2004) (“[A]s long as such relationships are legal, the parties involved will face constant temptations to test the limits of professional and industry codes and government regulations. One can predict, therefore, that there will be ongoing cycles of scandal and reform for the foreseeable future.’’); Alexander C. Tsai, Policies to Regulate Gifts to Physicians from Industry, 290 JAMA 1776, 1776 (2003) (“Some observers perceived an abatement of marketing abuses, but it was short-lived. Within a few years, commercial detailers and physicians continued to exhibit behavior inconsistent with the guidelines.’’).

22. See, e.g., Gardiner Harris, As Doctor Writes Prescription, Drug Company Writes a Check, N.Y. TIMES, June 27, 2004, § 1, at 1 (reporting that Schering-
allows company representatives to shadow a physician while treating patients; although the industry defends this practice as a way of educating members of its sales force, while the AMA has focused on ensuring safeguards for patient autonomy and privacy, critics view preceptorships as nothing more than another concealed payoff to physicians. Speaking engagements and consulting agreements offer more typical mechanisms for funneling money to prescribers. If these payments reimburse

Plough paid physicians “consulting fees” of $10,000 plus a bonus of up to $1,500 per patient enrolled in a purported trial of Intron A, the company’s expensive hepatitis C drug; Barry Meier, Implant Program for Heart Device Was a Sales Spur, N.Y. TIMES, Sept. 27, 2005, at A1 (“About 80 cardiologists nationwide completed an evaluation run by the Guidant Corporation of one of its products . . . . In exchange for implanting the lead in three patients and completing five survey forms, each physician received $1,000 . . . .”); id. (“Several doctors who took part in the Guidant survey said that they did not tell their patients about the payments they received.”); Gregory Zuckerman, Biovail Tactics on Marketing Focus of Probe, WALL ST. J., Aug. 25, 2003, at C1; see also infra Section I.D (discussing other seeding trials that have come to light).

23. See Bruce Japsen, AMA Says Drug Reps Not Welcome in Exams, CHI. TRIB., June 18, 2003, at A1 (describing a new policy that requires getting consent from patients).

24. See id. (“AMA members say patient shadowing is the latest attempt by pharmaceutical companies to influence physicians’ prescribing habits.”); Melody Petersen, Suit Says Company Promoted Drug in Exam Rooms, N.Y. TIMES, May 15, 2002, at C1 (“Warner-Lambert’s shadowing program [for Neurontin®] involved an estimated 75 to 100 doctors . . . . Each doctor was paid $350 or more for each day they let sales representatives watch as they examined patients, according to court documents.”); Zaneski, supra note 18, at 1A (“Companies can pay several hundred dollars a day to physicians who allow reps into the examining room to learn first-hand about patients’ reactions with medications.”); AMA Turns Down Proposal to Ease Guideline on Gifts; Doctor Says Policy Ignored by Many, CHI. TRIB., June 15, 2004, at C4 (reporting that the AMA had decided to defer action on a “proposal [that] would have urged doctors to refuse payment—sometimes hundreds of dollars daily—for shadowing, which critics say is meant to influence what drugs are prescribed”); see also L. Lewis Wall & Douglas Brown, Pharmaceutical Sales Representatives and the Doctor/Patient Relationship, 100 OBSTETRICS & GYNECOLOGY 594, 598–99 (2002) (arguing that preceptorships are unethical).

25. See Hensley, supra note 18, at D4 (“[S]treching the definition of consultant, sales reps now recruit local doctors, paying them hundreds of dollars for an evening meeting in town . . . . A doctor also can earn a consulting fee by helping a company study a drug or joining a company’s speakers bureau and lecturing colleagues.”); see also JEROME KASSIRER, ON THE TAKE: HOW
physicians for their time and expertise rather than loyalty, then they would represent legitimate compensation as opposed to dubious gifts.26

B. Government Responses to Industry Abuses

Although the U.S. Food and Drug Administration (FDA) has limited authority over verbal statements made by sales representatives,27 it enjoys essentially no power to regulate gifts.28 As a consequence, other actors have become more involved in trying to supervise the practice. For instance, a handful of states enacted laws regulating drug

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26. See Brubaker, supra note 9, at E1 (“The [AMA] guidelines offer some wiggle room. Doctors who have been deemed ‘advisers’ to drug companies, if only for a few hours, can accept honorariums and travel perks, for example. Forest Laboratories calls its advisers ‘advertising/marketing consultants’ in the confidentiality agreements they are asked to sign.”); id. (“The guidelines do not rule out five-star treatment—or honorariums—for doctors who provide ‘genuine’—not ‘token’—services as company advisers.”). See generally Fred Eaton & Jaimee Reid, Mirror, Mirror on the Wall—Evaluating Fair Market Value for Manufacturer-Physician Consulting Arrangements, 65 FOOD & DRUG L.J. 141 (2010).

27. See Noah, supra note 6, at 317–26.

28. See Gardiner Harris, Drug Makers Are Still Giving Gifts to Doctors, F.D.A. Officials Tell Senators, N.Y. TIMES, Mar. 4, 2005, at A15 (reporting a statement by one high-level official that the agency “has no jurisdiction to police such efforts”); see also infra notes 63–65 and accompanying text (noting its limited power over seeding trials). Trinkets bearing brand names qualify as “reminder ads” that face few FDA restrictions. See 21 C.F.R. § 202.1(o)(2)(i) (2017).
and device industry gifts to physicians. The Office of the Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS), acting under its authority to investigate fraud and abuse involving the Medicare and Medicaid programs, issued a guidance document to address industry marketing practices. The OIG guidelines included an expression of particular concern about seeding trials.

29. See, e.g., CAL. HEALTH & SAFETY CODE § 119402 (West 2017) (requiring the adoption of compliance programs that satisfy federal guidelines and PhRMA’s code); 105 MASS. CODE REGS. § 970.008(1) (2017) (barring essentially all gifts); MINN. STAT. ANN. § 151.461 (West 2017) (prohibiting companies from giving gifts worth more than $50 annually); NEV. REV. STAT. § 639.570 (2017) (requiring adherence to PhRMA’s code); VT. STAT. ANN. tit. 18, § 4632 (2017) (requiring annual reports); see also Eric G. Campbell, DOCTORS AND DRUG COMPANIES—SCRUTINIZING INFLUENTIAL RELATIONSHIPS, 357 NEW ENG. J. MED. 1796, 1796 (2007) (noting that Minnesota adopted a reporting requirement in 1993, Vermont joined a decade later, followed by California, D.C., Maine, and West Virginia); Joseph S. Ross et al., PHARMACEUTICAL COMPANY PAYMENTS TO PHYSICIANS: EARLY EXPERIENCES WITH DISCLOSURE LAWS IN VERMONT AND MINNESOTA, 297 JAMA 1216, 1220–22 (2007) (finding the reported data incomplete and inaccessible).


31. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,734–38 (May 5, 2003); Robert Pear, DRUG INDUSTRY IS TOLD TO STOP GIFTS TO DOCTORS, N.Y. TIMES, Oct. 1, 2002, at A1 (“T]he government said that drug makers could not offer incentive payments or other ‘tangible benefits’ to encourage or reward the prescribing or purchase of particular drugs by doctors . . . .”); id. (“While the new standards do not have the force of law, drug makers that flout them are more likely to be investigated and prosecuted for violations of federal fraud and kickback statutes.”); see also Susan Chimonas & David J. Rothman, NEW FEDERAL GUIDELINES FOR PHYSICIAN-PHARMACEUTICAL INDUSTRY RELATIONS: THE POLITICS OF POLICY FORMATION, 24 HEALTH AFF. 949 (2005) (discussing the OIG’s drafting process); David M. Studdert et al., FINANCIAL CONFLICTS OF INTEREST IN PHYSICIANS’ RELATIONSHIPS WITH THE PHARMACEUTICAL INDUSTRY—SELF-REGULATION IN THE SHADOW OF FEDERAL PROSECUTION, 351 NEW ENG. J. MED. 1891, 1898–99 (2004) (discussing the OIG guidelines); id. at 1891 (“[G]overnment policing in this area is likely to intensify.”).

32. See OIG Guidance, 68 Fed. Reg. at 23,735 (“Postmarketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug.”). Technically, however,
Several companies have faced prosecution for violating the anti-kickback law. For instance, Serono pled guilty after it had offered ten physicians a free trip to the French Riviera if they increased their use of an expensive AIDS drug. One year later, Schering-Plough agreed to a substantial fine for paying doctors $500 per patient started on the company’s hepatitis C treatment. More recently, corporate officers at Insys Therapeutics got charged with offering kickbacks to physicians for prescribing Subsys® (fentanyl sublingual spray) more widely than just for its

the OIG guidelines lack the force of law. See id. at 23,731 (“The document is intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers.”); see also Lars Noah, Governance by the Backdoor: Administrative Law(lessness?) at the FDA, 93 Neb. L. Rev. 89, 90–93, 113–22 (2014) (explaining that federal agencies increasingly issue guidance documents even though devoid of any binding effect).


34. See John Gibeaut, Seeking the Cure, A.B.A. J., Oct. 2006, at 44, 46 (“In exchange [for the trip], each doctor was to write 30 new prescriptions . . . .”); Eric Lichtblau, Settlement in Marketing of a Drug for AIDS, N.Y. Times, Oct. 18, 2005, at C1 (reporting that Serono “admitted that it provided what amounted to illegal remuneration to a group of AIDS doctors by paying for them to attend a medical ‘conference’ in Cannes, France, in 1999 in exchange for the doctors’ writing more prescriptions for Serostim”); cf. Zaneski, supra note 18, at 1A (“The U.S. Justice Department says Pfizer provided doctors with weekends at Florida and Hawaiian resorts and trips to the 1996 Olympics in Atlanta with little or no medical education provided on the junkets.”).

35. See Jeffrey Krasner, Drug Firm Hit with 3d Big Penalty in Five Years, Bos. Globe, Aug. 30, 2006, at F1 (“The government cited an illegal kickback scheme Schering-Plough devised for its drugs used to treat hepatitis C. For each patient starting treatment with Schering-Plough’s drugs, doctors would receive up to $500.”).
approved use in treating breakthrough cancer pain, and those on the receiving end of these unlawful payments faced prosecution as well. Members of the medical device industry have gotten caught playing similar sorts of games.

36. See David Armstrong, Drug Firm Accused of Bribing Doctors, Bos. GLOBE, Dec. 9, 2016, at C2; Joseph Walker, Fentanyl Billionaire Comes Under Fire, WALL ST. J., Nov. 23, 2016, at A8; see also Evan Hughes, The Pain Hustlers, N.Y. TIMES MAG., May 6, 2018, at 55 (recounting the following explanation of the Insys speakers program by one former sales rep: “the real target was not the audience but the speaker himself, who would keep getting paid to do programs if and only if he showed loyalty to Subsys. It was a quid pro quo . . . .”); id. (“Some prescribers were paid four figures to ‘speak’ to an audience of zero.”); Katie Thomas, Drug Company Enlists Doctors Under Scrutiny: Big Payments for Top Painkiller Prescribers, N.Y. TIMES, Nov. 28, 2014, at A1 (Insys “reward[ed] high-prescribing physicians with perks like paid speaking engagements. And in at least two cases, the company hired the adult children of top doctors to serve as their parents’ sales representatives.”); id. (“During a five-month period at the end of 2013, Insys paid 20 doctors more than $30,000 each in speaking and consulting fees as well as perks like travel and meals.”).

37. See Benjamin Weiser & Katie Thomas, 5 New York Doctors Are Charged in a Fentanyl Kickback Scheme, N.Y. TIMES, Mar. 17, 2018, at B2 (“Insy paid the doctors, in some cases more than $100,000 annually, in return for prescribing millions of dollars’ worth of the company’s painkiller product, the indictment said. It charged that Insys funneled the illicit payments to the doctors through a sham ‘speakers bureau’ . . . .”); id. (“Earlier this month, another top prescriber, Jerrold Rosenberg of Rhode Island, was sentenced to more than four years in prison after admitting he took kickbacks from Insys.”). Most of the time, physicians accused of receiving kickbacks from manufacturers suffer absolutely no consequences. See Tracy Weber & Charles Ornstein, This Won’t Hurt a Bit, WASH. POST, Sept. 18, 2011, at G1 (“At least 15 drug and medical-device companies have paid $6.5 billion since 2008 to settle accusations of marketing fraud or kickbacks. However, none of the more than 75 doctors named as participants were sanctioned . . . .”).

38. See, e.g., United States ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 236–37 (3d Cir. 2004) (reversing summary judgment granted to the defendant in a False Claims Act lawsuit where a whistleblower surgeon charged a manufacturer of orthopedic implants with offering kickbacks to a hospital chain for purchasing products later billed to Medicare); see also Jason M. Hockenberry et al., Financial Payments by Orthopedic Device Makers to Orthopedic Surgeons, 171 ARCHIVES INTERNAL MED. 1759, 1762–63 (2011); Reed Abelson, Possible Conflicts for Doctors Are Seen on Medical Devices, N.Y. TIMES, Sept. 22, 2005, at A1 (“[F]ederal prosecutors have begun to investigate some device makers’ deals with doctors, trying to determine if they amount to payoffs for using a product.”); Barry Meier, An Rx for Ethics, N.Y. TIMES, Jan. 24, 2009, at B1
A little-noticed provision in the Affordable Care Act created a federal requirement that health care providers report the receipt of anything worth at least $10 (or several smaller gifts annually if they exceed $100 in the aggregate), though it excluded the value of free product samples.\textsuperscript{39} The resulting compilation of data has revealed substantial industry funds flowing to physicians.\textsuperscript{40} Nonetheless, the prospect of disclosure apparently made companies somewhat less likely to offer—and physicians less likely to accept—covered gifts.\textsuperscript{41}


\textsuperscript{40} See Peter Loftus & Joseph Walker, \textit{Doctors, Hospitals Got $6.49 Billion from Firms in ’14}, WALL ST. J., July 1, 2015, at B3; \textit{see also} Deborah C. Marshall et al., \textit{Disclosure of Industry Payments to Physicians: An Epidemiologic Analysis of Early Data from the Open Payments Program}, 91 MAYO CLINIC PROC. 84, 92–93 (2016) (comparing payments across different specialties); Genevieve Pham-Kanter et al., \textit{Public Awareness of and Contact with Physicians Who Receive Industry Payments: A National Survey}, 32 J. GEN. INTERNAL MED. 767, 771 (2017) (finding a wider impact when measured as the percentage of patients seen by physicians who receive payments); \textit{Which Drug Companies Give Gifts to Your Doc?}, DENV. POST, July 14, 2014, at 2C (reporting that an earlier survey found “nearly 95 percent of U.S. physicians accept gifts, meals, payments, travel and other services from companies that make the drugs and medical products they prescribe”); \textit{id.} (“Although patients will benefit from increased transparency in coming years, the ultimate goal of policymakers is to pressure doctors to give up some of their more egregious relationships with industry.”).

\textsuperscript{41} See Peter Loftus, \textit{The New State of Health Care: Doctors Face New Scrutiny over Gifts}, WALL ST. J., Aug. 23, 2013, at A1 (“Many doctors say the increased disclosures are making them rethink their relationships with industry . . . . Some fear patients will view the payments as tainting their medical decisions . . . .”); Jonathan D. Rockoff & Hester Plumridge, \textit{Drug Firms Curb Ties to Doctors}, WALL ST. J., Dec. 18, 2013, at B3; \textit{see also} Ed Silverman, A
These laws and guidelines do not obligate recipients of industry gifts and payments to disclose their arguable conflicts of interest to patients, and it seems that relatively few patients take the initiative to search the federal database. In contrast, physicians must reveal to patients self-referrals, and, in the pharmaceutical context, they should secure prior consent for preceptorships. At the

Hefty Payday for Hospitals; Drug, Device Makers Paid Billions in 2015 to Care Providers, Bos. GLOBE, July 1, 2016, at C1 (“[C]ompanies increased charitable contributions on behalf of physicians by more than 120 percent. Payments for food and beverage, travel and lodging, and consulting fees were either flat or declined very slightly. Payments for honoraria fell by about 50 percent and by more than 30 percent for gifts . . .”); cf. Lars Noah, \textit{The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards,} 11 YALE J. ON REG. 293, 398 (1994) (“[W]arning requirements occasionally represent a surreptitious form of regulation, for instance, to encourage design modifications or product reformulations without directly mandating the desired changes.”). But see Tong Guo et al., \textit{The Effect of Information Disclosure on Industry Payments to Physicians} (Mar. 27, 2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3064769 (finding that the federal disclosure law has had only a limited impact on payments); Genevieve Pham-Kanter et al., Letter, \textit{Effect of Physician Payment Disclosure Laws on Prescribing,} 172 ARCHIVES INTERNAL MED. 819, 820 (2012) (same for state disclosure laws).

42. See Abigail Zuger, \textit{How Tightly Do Ties Between Doctor and Drug Company Bind?,} N.Y. TIMES, July 27, 2004, at F5 (“[C]alls for transparency have yet to penetrate to the individual doctor’s office, still a black box where conflicts of interest go virtually unchallenged.”); cf. Lars Noah, \textit{When Constitutional Tailoring Demands the Impossible: Unrealistic Scrutiny of Agencies?}, 85 GEO. WASH. L. REV. 1462, 1468 n.21 (2017) (“[T]he Supreme Court invalidated a state law requiring that charitable solicitors disclose what percentage of donations actually reach the charity because the state instead could have published the financial disclosure forms that it already collected . . . Such alternative options hardly seem, however, to work nearly as well.”).


44. See Dennis F. Thompson, \textit{Understanding Financial Conflicts of Interest,} 329 NEW ENG. J. MED. 573, 575 (1993) (“A physician is required, for example, to tell patients about his or her financial interest in the laboratory to which they are being referred and to let them decide whether to go to a different laboratory.”).

45. See Zaneski, \textit{supra} note 18, at 1A (“AMA guidelines and federal privacy
other extreme, far more serious conflicts of interest largely remain hidden from view.\textsuperscript{46} Somewhat remarkably, even though extensive federal rules govern informed consent in the research setting,\textsuperscript{47} nothing demands that investigators alert subjects to potential conflicts in that context.\textsuperscript{48} Then again, some commentators have speculated that disclosure grants a clear conscience to recipients of industry payments who might otherwise harbor ethical qualms about the

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\textsuperscript{48} See Jeffrey N. Gibbs & Gregory A. Guagnano, \textit{Investigator Financial Disclosures and Its Effect on Research Subjects}, 62 FOOD & DRUG L.J. 727, 729 (2007) (“FDA’s disclosure regulations, however, do not require that subjects in a clinical study be told about the potential conflicts of interest.”); Deborah L. Shelton & Jason Grotto, \textit{Patients at Heart of Device Debate; Many Unaware of Potential Doctor Conflicts of Interest}, CHI. TRIB., May 23, 2011, at A1 (reporting that hundreds of patients undergoing heart valve repair unknowingly received investigational annuloplasty rings invented by their cardiac surgeon); see also Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, 69 Fed. Reg. 26,393, 26,397 (May 12, 2004) (suggesting disclosure); Lindsay A. Hampson et al., \textit{Patients’ Views on Financial Conflicts of Interest in Cancer Research Trials}, 355 NEW ENG. J. MED. 2330, 2336 (2006) (finding limited interest among subjects); id. at 2331 (explaining that the AMA and others recommend full disclosure of potential financial conflicts by investigators); Kevin P. Weinfurt et al., \textit{Views of Potential Research Participants on Financial Conflicts of Interest: Barriers and Opportunities for Effective Disclosure}, 21 J. GEN. INTERNAL MED. 901, 904 (2006) (“[W]e found that many participants want to know about financial interests in research, whether or not they report that such knowledge would affect their decision to participate.”).
practice, and centralized reporting—as opposed to informing patients directly—may only magnify this problem.

C. Documenting the Impact of Gifts to Prescribers

If health care professionals simply pocketed such payments without altering their prescribing choices, then gift giving by the pharmaceutical industry would provide no cause for alarm. Although companies might wonder why they persist in wasting this money, and patients ultimately get to pick up the tab, therapeutic decision making by these physicians would remain entirely uncorrupted. In reality, however, gifts to prescribers unmistakably influence treatment choices, and even fairly trivial gifts can have an

49. See Daylian M. Cain et al., The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest, 34 J. LEGAL STUD. 1, 7, 22 (2005); id. at 3 (“Physicians will prefer disclosing gifts from pharmaceutical companies (or disclosing payments for referring patients to clinical trials) to actually eschewing such benefits.”); George Loewenstein et al., The Unintended Consequences of Conflict of Interest Disclosure, 307 JAMA 669, 670 (2012) (“[P]erhaps the most significant likely pitfall of disclosure is . . . a kind of moral licensing on the part of the profession as a whole—the rationalization that, with disclosure, the profession has dispensed with its obligation to deal with conflicts of interest.”); see also Elisabeth Rosenthal, I Disclose . . . Nothing, N.Y. TIMES, at Jan. 22, 2012, at SR1 (“Disclosure has taken on the gestalt of confession: Dump the information and be absolved of further moral or legal responsibility.”).

50. See Noah, supra note 10, at 432 (“Although most doctors express probably unjustified confidence that such sales pitches and freebies do not influence their own prescribing behavior, they do worry about their more gullible colleagues.”); Carl Elliott, The Drug Pushers, ATLANTIC, Apr. 2006, at 82 (“The trick is to give doctors gifts without making them feel that they are being bought. ‘Bribes that aren’t considered bribes,’ [former drug rep turned academic Michael] Oldani says.”); Shelley Murphy, Gifts to Doctors Is Effective Marketing, Some Drug Firm Employees Say, BOS. GLOBE, Nov. 17, 2002, at B1; Zaneski, supra note 18, at 1A (“Few doctors would admit that drug company sales pitches influence their prescribing. But pharmaceutical companies behave as though the reps and their handouts matter very much indeed.”); Abigail Zuger, When Your Doctor Goes to the Beach, You May Get Burned, N.Y. TIMES, Feb. 24, 2004, at F5 (noting that this “is one of the few research topics in medicine that will not attract drug company financing”).
impact. After revisions to the industry code sought to end the practice of distributing trinkets emblazoned with drug brand names and company logos, free food has become the most common coin of this realm. Numerous studies have found a link between industry payments and prescribing behavior. Although previously

51. See Jason Dana & George Loewenstein, A Social Science Perspective on Gifts to Physicians from Industry, 290 JAMA 252, 254 (2003); id. at 252 (“[S]mall gifts may be surprisingly influential.”); David Grande et al., Effect of Exposure to Small Pharmaceutical Promotional Items on Treatment Preferences, 169 ARCHIVES INTERNAL MED. 887, 892 (2009); Dana Katz et al., All Gifts Large and Small: Toward an Understanding of the Ethics of Pharmaceutical Industry Gift-Giving, AM. J. BIOETHICS, Summer 2003, at 39, 41 (“When a gift or gesture of any size is bestowed, it imposes on the recipient a sense of indebtedness. The obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behavior.”); Bernard Lo & Deborah Grady, Payments to Physicians: Does the Amount of Money Make a Difference?, 317 JAMA 1719, 1720 (2017).

52. See Natasha Singer, No Lipitor Mug? Drug Makers Cut out Goodies for Doctors, N.Y. TIMES, Dec. 31, 2008, at A1 (“The sudden scarcity of free goodies, though, could enhance the cachet of collections that some doctors have assembled over the years . . . .”); see also Michael J. Oldani, Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices, 18 MED. ANTHROPOLOGY Q. 325, 336 (2004) (recalling from his time as a drug rep that doctors sometimes would specifically request distinctive pens and mugs); Chris Adams, Student Doctors Protest Largess of Drug Makers, WALL ST. J., June 24, 2002, at B1 (discussing the “Viagra calculator that stood up on a base when the ‘on’ button was pressed”).

53. See Robert Steinbrook, Physicians, Industry Payments for Food and Beverages, and Drug Prescribing, 317 JAMA 1753, 1753 (2017) (“Although the median value of each food and beverage payment is modest, these are by far the most frequent types of gifts and payments that physicians receive from industry, apparently now supplanting the branded black bags, pens, mugs, and other tchotchkes of yore.”); see also L. Lewis Wall & Douglas Brown, The High Cost of Free Lunch, 110 OBSTETRICS & GYNECOLOGY 169, 171 (2007) (singling out the persuasive power of food); Ravi Parikh, If Your Doctor Accepts a Free Meal, Are You Paying for It?, WASH. POST, Sept. 20, 2016, at E6; Stephanie Saul, Drug Makers Pay for Lunch as They Pitch, N.Y. TIMES, July 28, 2006, at A1.

researchers had to conduct surveys of physicians, the federal payments database now offers a goldmine for anyone interested in this question. Several recently published studies have documented an association between drug industry payments and prescribing behavior, including the remarkable discovery that even inexpensive meals might do the trick. Investigative journalists also

marketing literature on all types of advertising directed to doctors); infra notes 57–59 (citing some of the latest studies).


56. See, e.g., Scott E. Hadland et al., Industry Payments to Physicians for Opioid Products, 2013–2015, 107 AM. J. PUB. HEALTH 1493, 1493 (2017) (“For the first time, exhaustive data on payments are now available through the Open Payments program . . .”); id. at 1494 (finding that one out of twelve physicians received payments from sellers of opioids during the study period, totaling over $46 million); Kathryn R. Tringale et al., Types and Distribution of Payments from Industry to Physicians in 2015, 317 JAMA 1774, 1780 (2017) (“The current population-based analysis of industry-to-physician payments in 2015 shows the far-reaching extent (more than 10 million transactions totaling $2.4 billion) of these reported financial relationships.”).


58. See Colette DeJong et al., Pharmaceutical Industry-Sponsored Meals
have uncovered similar linkages in the federal database.

D. The Seedy Aspects of “Seeding Trials”

Seeding trials have drawn particular criticism. Once largely just a matter of speculation, researchers have documented their growing use. In 1994, FDA officials summarized the attributes of these “studies” as follows:

Features that distinguish such trials from scientifically rigorous studies include the use of a design that does not support the stated research goals, the recruitment of investigators not because they are experts or leading researchers but because they are frequent and

and Physician Prescribing Patterns for Medicare Beneficiaries, 176 JAMA INTERNAL MED. 1114, 1120 (2016) (finding “that receipt of a single industry-sponsored meal, with a mean value of less than $20, was associated with prescription of the promoted brand-name drug at significantly higher rates,” and that “the relationship was dose dependent, with additional meals and costlier meals associated with greater increases in prescribing of the promoted drug”); id. at 1121 (noting caveats); see also Peter Loftus, Study Says Gifts Affect Physicians’ Drug Choices, WALL ST. J., June 21, 2016, at A1 (reporting on this study).

59. See, e.g., Charles Ornstein, Public Disclosure of Payments to Physicians from Industry, 317 JAMA 1749, 1749–50 (2017) (discussing the work of ProPublica); Aaron Kessler et al., The More Opioids Doctors Prescribe, the More Money They Make, CNN (Mar. 11, 2018), https://www.cnn.com/2018/03/11/health/prescription-opioid-payments-eprise/index.html; see also Dennis Thompson, Drug Firms’ Gifts Linked to Docs’ Choices, BALTIMORE SUN, June 22, 2017, at C1 (reporting that payments of a few hundred dollars influenced selections among equally effective cancer treatments even though patients might face more bothersome side effects as a result of the choice).

60. See David Malakoff, Allegations of Waste: The “Seeding” Study, 322 SCIENCE 213, 213 (2008) (“Although seeding trials may be a longtime open secret in the industry, the authors [of a new article in the Annals of Internal Medicine] write that the Merck documents [involving Vioxx®] ‘provide the first strong documentary evidence of the practice.’”); Bob Fernandez, Journal Takes on Drugmaker “Seeding Trials,” PHILA. INQUIRER, Aug. 20, 2008, at C1 (“Seeding trials had been an ‘open secret’ in the drug industry, but there had been no hard proof to show they existed.”); see also id. (Dr. Harold Sox “said seeding trials betrayed the trust patients had in doctors and drug companies. Patients say they believe they are participating in a bona fide drug trial to determine health benefits of a drug. But drug companies have other goals: selling pharmaceuticals.”). At least temporarily, seeding trials may manage to dodge federal reporting requirements: CMS allows delayed disclosure (for up to four years) of payments related to non-clinical trials designed to investigate potential new uses of approved products. See 42 C.F.R. § 403.910 (2017).
prescribers of competing products in the same therapeutic class, disproportionately high payments given to “investigators” for their work (although the only work may be to write prescriptions for the drug), sponsorship of the studies by the company’s sales and marketing division rather than its research department, minimal requirements for data, and the collection of data that are of little or no value to the company.61

Their article offered a pair of examples that the agency had encountered, including one seeding trial for a new antihypertensive agent that tasked the manufacturer’s sales force with recruiting 2,500 frequent prescribers of such drugs who would agree to enroll a dozen patients each, which earned participating physicians $85 per patient (up to $1,050 total).62 The FDA could do little, however, other than deliver a slap on the wrist, “inform[ing] the sponsor that no data from this trial could be used to promote the product,”63 even though the authors had recognized that the trial itself rather than any collected results represented the central aspect of this promotional campaign.64

Over the last decade, more such illustrations have

62. See id.; see also id. (quoting an internal company memo about another antihypertensive seeding trial that also sought 2,500 physicians though to enroll only ten patients each).
63. Id. In contrast, the agency managed to prevent a planned seeding trial of an anticonvulsant—which intended to recruit 500 prescribers to enroll five patients each (and earn $100 per patient)—because it had represented “a thinly disguised” effort to promote the drug for an unapproved use (i.e., panic disorder) and, for that reason, would have violated federal law. See id.
64. See id. (calling these studies “thinly veiled attempts to entice doctors to prescribe a new drug,” aimed at “undoing physicians’ comfortable habits of prescribing a competing, more established product”); see also Bruce M. Psaty & Drummond Rennie, Editorial, Clinical Trial Investigators and Their Prescribing Patterns: Another Dimension to the Relationship Between Physician Investigators and the Pharmaceutical Industry, 295 JAMA 2787, 2788 (2006) (discussing a slightly more rigorous trial of an approved asthma drug that remained unpublished but “had the desired outcome of seeding studies and improved market share among trial-conducting practices”); id. at 2787 (“The umbrella of a research study allows the sponsor to pay the physician investigators in a way that circumvents rules against direct inducements to prescribe.”).
emerged after again escaping regulatory oversight. First, documents uncovered in litigation against Pfizer revealed that a predecessor company had conducted a seeding trial for the anticonvulsant Neurontin® (gabapentin), recruiting more than 700 physicians to enroll an average of three patients each (and receive $300 per patient) in order to try higher-than-approved doses of the drug in treating epilepsy. A couple of years later, researchers discussed a similar campaign that Merck undertook to encourage the use of Vioxx® (rofecoxib), which the company later withdrew from the market after discovering that this prescription analgesic posed heightened cardiovascular risks. Apart from objections to promotion masquerading

65. See Carl Elliott, Op-Ed., Useless Studies, Real Harm, N.Y. TIMES, July 29, 2011, at A27 (complaining that, “even after particularly egregious seeding trials have been exposed, the F.D.A. has not issued sanctions,” adding that subjects may suffer serious injuries but institutional review boards “don’t typically pass judgment on whether a study is being carried out merely to market a drug”).

66. See Michael Steinman et al., Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents, 145 ANNALS INTERNAL MED. 284, 289–90 (2006) (discussing this seeding trial as just one among many of the seller’s questionable marketing tactics); see also Samuel D. Krumholz et al., Study of Neurontin: Titrated to Effect, Profile of Safety (STEPS) Trial: A Narrative Account of a Gabapentin Seeding Trial, 171 ARCHIVES INTERNAL MED. 1100, 1104–05 (2011) (offering more details about this seeding trial); id. at 1103 (“[C]ompany sales representatives rewarded some investigators for achieving specific recruitment milestones; physicians were given a free lunch after recruiting 3 patients and a free dinner after 7 patients.”); id. at 1105 (arguing provocatively that the participating physicians represented the true and unwitting subjects of this company-sponsored research).

67. See Kevin P. Hill et al., The ADVANTAGE Seeding Trial: A Review of Internal Documents, 149 ANNALS INTERNAL MED. 251, 252, 256 (2008) (explaining that the company recruited 600 physicians to serve as investigators, enrolling over 5,500 of their patients, half of whom received Vioxx); see also Philip Greenland & Donald Lloyd-Jones, Critical Lessons from the ENHANCE Trial, 299 JAMA 953, 954 (2008) (speculating that a study of Vytorin® [ezetimibe with simvastatin], another Merck drug, was nothing more than a seeding trial).

68. See Alex Berenson et al., Despite Warnings, Drug Giant Took Long Path to Vioxx Recall, N.Y. TIMES, Nov. 14, 2004, § 1, at 1.
as scientific investigation,\textsuperscript{69} seeding trials unmistakably influence the prescribing choices made by participating physicians.\textsuperscript{70}

\section*{II. Refashioning Tort Doctrine to Combat Inappropriate Drug Marketing Tactics}

What, if anything, might guard against the problems associated with pharmaceutical industry payments to prescribers? Some commentators have called on health care professionals to stop accepting such gifts altogether.\textsuperscript{71} Given the apparent failure of self-regulation, however,

\begin{itemize}
\item 69. See C. Seth Landefeld & Michael A. Steinman, \textit{The Neurontin Legacy—Marketing Through Misinformation and Manipulation}, 360 NEW ENG. J. MED. 103, 105 (2009); Joseph S. Ross et al., \textit{Promoting Transparency in Pharmaceutical Industry-Sponsored Research}, 102 AM. J. PUB. HEALTH 72, 72–73 (2012); Harold C. Sox & Drummond Rennie, Editorial, \textit{Seeding Trials: Just Say “No,”} 149 ANNALS INTERNAL MED. 279, 279 (2008) (“Why would a drug company go to the expense and bother of conducting a trial involving hundreds of practitioners—each recruiting a few patients—when a study based at a few large medical centers could accomplish the same scientific purposes much more efficiently?”).

\item 70. See Morten Andersen et al., \textit{How Conducting a Clinical Trial Affects Physicians’ Guideline Adherence and Drug Preferences}, 295 JAMA 2759, 2764 (2006) (concluding that “physician involvement in clinical trials is a powerful tool for influencing company-specific drug preferences”).

\end{itemize}
other commentators have called for greater legislative and regulatory intervention. This Part suggests, instead, that the judiciary might have a productive role to play. Relatively minor adjustments to medical malpractice and products liability rules could make physician payments less attractive to both recipients and companies.

A. Informed Consent Duties of Health Care Professionals

Physicians may face civil liability if they fail to secure the informed consent of their patients. In a few jurisdictions that continue to focus on the origins of the doctrine in the tort of battery, consent obligations attach only in cases of surgical and other invasive procedures, thereby excluding therapeutic interventions such as pharmaceutical products recommended by a physician.

For the most part, however, physicians also must secure informed consent when they recommend noninvasive treatments, particularly when they prescribe or

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72. See Rikin S. Mehta, Why Self-Regulation Does Not Work: Resolving Prescription Corruption Caused by Excessive Gift-Giving by Pharmaceutical Manufacturers, 63 FOOD & DRUG L.J. 799, 820–21 (2008); id. at 808–10 (critiquing the internal compliance programs adopted by two large pharmaceutical manufacturers); Joshua Weiss, Note, Medical Marketing in the United States: A Prescription for Reform, 79 GEO. WASH. L. REV. 260, 273–76, 292 (2010); see also Susan Chimonas et al., Physicians and Drug Representatives: Exploring the Dynamics of the Relationship, 22 J. GEN. INTERNAL MED. 184, 185 (2007) (“[P]hysicians have so many ways of justifying their relationships with detailers that conflict-of-interest policies based on self-regulation are unlikely to succeed.”); id. at 189 (“Given physicians’ attitudes, even these minimal [voluntary] standards are not likely to succeed . . . .”).


74. See Morgan v. MacPhail, 704 A.2d 617, 619–20 (Pa. 1997); see also Shadrick v. Coker, 963 S.W.2d 726, 732–33 (Tenn. 1998) (treating the failure to secure informed consent as a claim for battery); cf. Shuler v. Garrett, 743 F.3d 170, 173–75 (6th Cir. 2014) (holding that the administration of heparin against the patient’s wishes and in spite of her known allergy to the drug qualified as a medical battery under Tennessee law).

75. See Matthies v. Mastromonaco, 733 A.2d 456, 460–61 (N.J. 1999) (holding that a physician who prescribed bed rest as treatment for a fractured
administer pharmaceutical products. Financial conflicts of interest generally have not, however, required disclosure.

1. Types of Information That Doctors Must Disclose

Before subjecting a patient to a diagnostic or therapeutic intervention, health professionals must describe its general nature. More importantly, they need to reveal any significant risks known to accompany the medical procedure. In addition, physicians must disclose reasonable alternative courses of action to the patient. Some courts would include among such alternatives the likelihood of a better outcome if treated by a more skillful physician (in effect, a duty of referral), but other

76. See, e.g., Hutchinson v. United States, 915 F.2d 560, 562–63 (9th Cir. 1990); Summit Bank v. Panos, 570 N.E.2d 960, 967–68 (Ind. Ct. App. 1991); see also Schilling v. Ellis Hosp., 906 N.Y.S.2d 187, 188–89 (App. Div. 2010) (holding that a psychiatrist may have breached a duty to warn the patient of a rare risk of developing gynecomastia from use of the antipsychotic Risperdal® (risperidone)).


79. See, e.g., Doe v. Johnston, 476 N.W.2d 28, 31 (Iowa 1991); Herrington v. Spell, 692 So. 2d 93, 100 (Miss. 1997); Jandre v. Wis. Injured Patients & Families Comp. Fund, 813 N.W.2d 627, 666 (Wis. 2012). The duty to disclose alternatives does not, however, include telling patients about the availability of experimental treatments. See, e.g., Moore v. Baker, 989 F.2d 1129, 1133 (11th Cir. 1993); Schiff v. Prados, 112 Cal. Rptr. 2d 171, 182–84 (Ct. App. 2001).

80. See, e.g., Barriocanal v. Gibbs, 697 A.2d 1169, 1173 (Del. 1997); Goldberg v. Boone, 912 A.2d 698, 717 (Md. 2006); Johnson ex rel. Adler v. Kokemoor, 545 N.W.2d 495, 504–10 (Wis. 1996); see also Grubbs ex rel. Grubbs v. Barbourville Family Health Ctr., P.S.C., 120 S.W.3d 682, 687–88 (Ky. 2003) (“If the patient’s ailment is beyond the physician’s knowledge, ability or capacity to treat with
characteristics related to the provider rather than the underlying course of treatment generally would not necessitate disclosure.\textsuperscript{81}

The duty to secure informed consent only requires that physicians communicate “material” information to their patients.\textsuperscript{82} Traditionally, courts asked what a reasonable physician would have disclosed under the circumstances,\textsuperscript{83} but many states have replaced this professional standard with a patient-based test of informed consent,\textsuperscript{84} asking whether a reasonable person would have regarded the information as important.\textsuperscript{85} Whatever the standard used for reasonable success, the physician has a duty to disclose the situation to the patient and to advise the patient to consult a specialist.”).

\textsuperscript{81} See, e.g., Duffy v. Flagg, 905 A.2d 15, 20–22 (Conn. 2006) (poor prior outcomes); Albany Urology Clinic, P.C. v. Cleveland, 528 S.E.2d 777, 780–82 (Ga. 2000) (substance abuse); Ditto v. McCurdy, 947 P.2d 952, 958–59 (Haw. 1997) (lack of special credentials); Jarrell v. Kaul, 123 A.3d 1022, 1034–35 (N.J. 2015) (lack of mandated liability insurance coverage); Duttry v. Patterson, 771 A.2d 1255, 1258–59 (Pa. 2001) (surgeon’s relative inexperience); see also Whiteside v. Lukson, 947 P.2d 1263, 1265 (Wash. Ct. App. 1997) (“Even medical school grades[,] could be considered material facts . . . .” We conclude that a surgeon’s lack of experience in performing a particular surgical procedure is not a material fact for purposes of finding liability predicated on failure to secure an informed consent.”).

\textsuperscript{82} See, e.g., Harrison v. United States, 284 F.3d 293, 299–302 (1st Cir. 2002); Dunn v. Yager, 58 So. 3d 1171, 1200–02 (Miss. 2011).

\textsuperscript{83} See, e.g., Willis v. Bender, 596 F.3d 1244, 1254–56 & n.7 (10th Cir. 2010); Paul v. Lee, 568 N.W.2d 510, 514–16 (Mich. 1997); Robinson v. Bleicher, 559 N.W.2d 473, 478 (Neb. 1997).

\textsuperscript{84} See, e.g., Canterbury v. Spence, 464 F.2d 772, 781 (D.C. Cir. 1972) (“[I]t is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie.”); Shannon v. Fusco, 89 A.3d 1156, 1170 (Md. 2014); see also David M. Studdert et al., Geographic Variation in Informed Consent Law: Two Standards for Disclosure of Treatment Risk, 4 J. EMPIRICAL LEGAL STUD. 103, 105, 119–21 (2007) (evaluating the split of authority on this question).

\textsuperscript{85} See Truman v. Thomas, 611 P.2d 902, 905 (Cal. 1980) (“Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject the recommended medical procedure.”); Carr v. Strode, 904 P.2d 489, 494–99 (Haw. 1995); Pauscher v. Iowa Methodist Med. Ctr., 408 N.W.2d 355, 361–62 (Iowa 1987). A few other courts opt for a more subjective test, which inquires about the perhaps idiosyncratic prior knowledge
judging materiality, plaintiffs also must prove causation, which typically means asking whether a reasonable patient would have declined a treatment had the physician disclosed the additional information.\textsuperscript{86}

2. Obligating Physicians to Reveal Conflicts of Interest

Perhaps the informed consent doctrine should include a duty to reveal potential conflicts of interest. Although arguably immaterial as a provider characteristic,\textsuperscript{87} financial conflicts that bear directly on the choice of treatment certainly should qualify as relevant information.\textsuperscript{88} Many physicians seem to have an ethical blind spot on this score:

86. See, e.g., Bernard v. Char, 903 P.2d 667, 671–76 (Haw. 1995); Ashe v. Radiation Oncology Assocs., 9 S.W.3d 119, 122–24 (Tenn. 1999); Backlund v. Univ. of Wash., 975 P.2d 950, 957–59 (Wash. 1999); see also Martin v. Lahti, 809 S.E.2d 644, 650 (Va. 2018) (upholding the dismissal of a deceased patient’s informed consent claim for lack of proof on causation after concluding that her daughters’ “testimony is nothing but speculation about what Starr’s thought process might have been if various items of information had been provided to her with respect to this specific surgery”).


88. See Margaret Z. Johns, Informed Consent: Requiring Doctors to Disclose Off-Label Prescriptions and Conflicts of Interest, 58 HASTINGS L.J. 967, 1019–24 (2007); Nadia N. Sawicki, Modernizing Informed Consent: Expanding the Boundaries of Materiality, 2016 U. ILL. L. REV. 821, 841–43. Half a century ago, in the course of rejecting challenges to a state law that barred physician ownership of pharmacies, a California court explained that “the doctor who has a financial interest in where his prescriptions are filled may be tempted to prescribe unnecessary medicine, or to prescribe a drug which yields a greater margin of profit or to keep a patient on drugs for an unnecessary period of time.” Magan Med. Clinic v. Cal. State Bd. of Med. Examin’rs, 57 Cal. Rptr. 256, 262 (Ct. App. 1967) (adding that “a sick patient deserves to be free of any reasonable suspicion that his doctor’s judgment is influenced by a profit motive”).
insofar as they refuse to recognize the possibility that gifts and payments might influence their treatment decisions,89 these doctors see no need for disclosure. Several studies have, however, demonstrated that goodies and money affect prescribing choices,90 and patients evidently want to know about it.91 In a similar vein, when health care professionals make use of experimental treatments or otherwise engage in research using their patients, concerns about the potential for conflicts of interest help to explain demands for fuller disclosure about this aspect of the encounter.92

89. See Allan S. Brett et al., Are Gifts from Pharmaceutical Companies Ethically Problematic? A Survey of Physicians, 163 ARCHIVES INTERNAL MED. 2213, 2216–18 (2003); Howard Brody, A Matter of Influence, 21 HEALTH AFF. 232, 232 (2002) (bemoaning “how blind we are to the fact that we are being influenced”); Campbell, supra note 29, at 1796 (“[P]hysicians vehemently deny that their industry relationships have any of these negative effects—but they are less convinced that the same is true of their physician colleagues.”); Michael A. Steinman et al., Of Principles and Pens: Attitudes and Practices of Medicine Housestaff Toward Pharmaceutical Industry Promotions, 110 AM. J. MED. 551, 555–56 (2001); see also Michael Booth & Jennifer Brown, Doctors Still Received Big Fees from Drug Companies to Speak, DENV. POST, Mar. 26, 2013, at 1A (“Some of the doctors said they disclose these payments to patients, but many doctors declined to answer questions about their fees.”).

90. See supra notes 54–59 and accompanying text.

91. See Michael A. Steinman, Gifts to Physicians in the Consumer Marketing Era, 284 JAMA 2243, 2243 (2000) (“Surveys show that as many as 70% of patients believe these gifts significantly impact prescribing, and . . . 24% of patients reported that their perception of the medical profession changed after learning about drug company gifts to physicians.”); see also Robert V. Gibbons et al., A Comparison of Physicians’ and Patients’ Attitudes Toward Pharmaceutical Industry Gifts, 13 J. GEN. INTERNAL MED. 151, 153 (1998) (“Patients are more likely than their physicians to believe that acceptance of pharmaceutical gifts may influence prescribing behavior.”); David Grande et al., Pharmaceutical Industry Gifts to Physicians: Patient Beliefs and Trust in Physicians and the Health Care System, 27 J. GEN. INTERNAL MED. 274, 277 (2012) (“[P]atients that believe physicians accept pharmaceutical industry gifts are significantly more likely to report . . . distrust.”); Marian Wolston, An MS Patient Loses Trust When She Finds out Her Doctor Is Paid by Drug Companies, 30 HEALTH AFF. 2449, 2451 (2011) (“I find it inexcusable that doctors aren’t routinely required to disclose their conflicts of interest to their patients.”).

92. See, e.g., Estrada v. Jaques, 321 S.E.2d 240, 255 (N.C. Ct. App. 1984) (“The psychology of the doctor-patient relation, and the rewards, financial and professional, attendant upon recognition of experimental success, increase the potential for abuse and strengthen the rationale for uniform disclosure.”); see
Even if seeding trials do not represent genuine research, they undoubtedly create financial pressures that may influence treatment choices.\textsuperscript{93}

In the move from its origins in the law of battery, the duty of doctors to secure informed consent extends well beyond the standards of professional negligence and resembles an obligation owed by fiduciaries.\textsuperscript{94} Indeed, several commentators have defined the physician-patient relationship in precisely such terms.\textsuperscript{95} Although this therapeutic relationship does not countenance broader expectations of safeguarding the nonmedical interests of patients,\textsuperscript{96} physicians as fiduciaries should scrupulously

\textit{also} Noah, \textit{supra} note 13, at 371 ("\textit{S}everal arguments support the imposition of more rigorous informed consent requirements in the research context . . . [including] heightened concerns about conflicts of interest, which means that the researcher may have goals other than doing what is best for the subject."); \textit{id.} at 379 (speculating that a requirement to disclose experimental status "alerts patients to the need for exercising greater vigilance about the potential for conflicts of interest"); \textit{id.} at 393 ("\textit{P}hysicians may face some of the same conflicts of interest that researchers encounter.").

\textsuperscript{93} See \textit{supra} notes 22, 60–70 and accompanying text.

\textsuperscript{94} See, e.g., Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972); Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 483, 486 (Cal. 1990) (distinguishing the fiduciary obligations of the plaintiff's physicians from the more limited duties of several other named defendants); Gomez v. Sauerwein, 289 P.3d 755, 759 (Wash. Ct. App. 2012), aff'd, 331 P.3d 19 (Wash. 2014); see also Peter H. Schuck, \textit{Rethinking Informed Consent}, 103 \textit{Yale L.J.} 899, 916 (1994) ("Physicians may not deal with their patients at arm's length; they owe their patients a fiduciary duty, which includes an obligation to act exclusively in the patient's interests and to disclose all information material to those interests."); \textit{id.} at 921 ("\textit{T}he physician must go so far as to \textit{prefer} the patient's interests to her own, acting as the patient's selfless, scrupulous, dutiful agent."); \textit{id.} at 927–28 (discussing the conflicts of interest rationale for demanding informed consent).


\textsuperscript{96} See Arato v. Avedon, 858 P.2d 598, 608–09 (Cal. 1993) (holding that the duty to disclose did not extend to information material to a patient's financial or
avoid—or at least reveal the existence of—financial interests that might taint their treatment recommendations. In a handful of cases, courts have construed the duty to secure patient consent as encompassing such disclosures. If recognized more broadly, then patients might enjoy greater protection from questionable prescribing choices.

Even if courts embraced the idea that industry payments provided a basis for asserting informed consent

97. See Hafemeister & Bryan, supra note 71, at 519–32 (advocating the recognition of claims for a breach of fiduciary duty whenever physicians accept industry payments that might taint their therapeutic recommendations).

98. See, e.g., Shapira v. Christiana Care Health Servs., Inc., 99 A.3d 217, 220–22 (Del. 2014) (rejecting an objection to the relevancy of evidence that a catheter manufacturer had paid the defendant physician to join its speaker’s bureau because the jury could treat this potential conflict of interest as material in resolving the patient’s informed consent claim); id. at 222 (“The conflict created a risk that [Dr.] Shapira wanted to perform the procedure because it would benefit him personally, and not because it was the most appropriate procedure. Likewise, the conflict created a risk that Shapira did not disclose or consider all reasonable alternatives.”); id. (“This is not a case where a doctor fails to disclose that she owns some stock in a publicly-traded medical company. Shapira was making a name for himself, and earning money, by promoting the On-Q procedure. In addition, he was gathering data about the procedure’s efficacy.”); D.A.B. v. Brown, 570 N.W.2d 168, 171–72 (Minn. Ct. App. 1997) (recognizing that a prescriber who received kickbacks from the distributor of Protropin® (human growth hormone) could face liability for malpractice (failure to secure informed consent) but not for breach of fiduciary duty, and dismissing the claim on other grounds); see also Moore, 793 P.2d at 483–86 (holding that a leukemia patient could assert informed consent and breach of fiduciary duty claims against his physician for failing to disclose a research interest in cells removed during and after a splenectomy); id. at 484 (“The possibility that an interest extraneous to the patient’s health has affected the physician’s judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment.”).
claims, it would probably do little to guard against physician conflicts of interest. Financial conflicts have become endemic in medical research, but disclosure requirements have not worked terribly well. Unless health care professionals find themselves embarrassed to confess about the industry gifts that they receive and respond to a disclosure obligation by avoiding the conflict in the first place, simply sharing this information with patients will not accomplish much. Upon hearing such disclosures, some patients might become wary about their physician’s treatment recommendation (perhaps unnecessarily so) or at least first decide to get a second opinion, but in most cases the revelation of a potential conflict of interest will likely go the way of so much other information made an aspect of consent obligations—namely, in one ear and out the other.


100. See Noah, supra note 10, at 409 (“Even if authors conscientiously adhered to the disclosure requirements, this mechanism for dealing with conflicts of interest may have only limited value.”); Shirley S. Wang, Simply Disclosing Funds Behind Studies May Not Erase Bias, WALL ST. J., Aug. 4, 2006, at A11; see also Lisa A. Bero, Editorial, Accepting Commercial Sponsorship: Disclosure Helps—but Is Not a Panacea, 319 BMJ 653, 654 (1999) (“Disclosure does not necessarily eliminate the influence of industry funding on research or doctors’ behaviour.”).


102. See Katrina Armstrong & Andrew A. Freiberg, Challenges and Opportunities in Disclosing Financial Interests to Patients, 317 JAMA 1743,
B. Disclosure Duties of Prescription Drug Manufacturers

Whether or not physicians might face liability for failing to inform their patients of potential conflicts of interest, the companies that intrude upon that relationship should shoulder responsibility. Indeed, given the inherent shortcomings associated with litigating informed consent claims, courts might do well to focus on the sources rather than the recipients of gifts. It would not make sense, however, to obligate manufacturers of prescription products to disclose physician payments, as these companies rarely owe any duty to communicate directly with patients. Instead, courts could expand the limited tort duties of manufacturers to warn in a way better calibrated to the consequences of their efforts to inappropriately influence prescribers: in those cases where they have offered rewards to a particular physician in exchange for selecting their therapeutic products, those companies should lose the benefit of the learned intermediary doctrine, which would then obligate them to supply adequate warnings of prescription drug risks directly to the patients of these conflicted doctors.

1. Obligations to Warn Learned Intermediaries

Traditionally, manufacturers satisfied their duty to warn of the hazards associated with prescription drugs or implanted medical devices by communicating risk information to physicians, under the so-called “learned intermediary” rule. Insofar as it imposes a duty to warn health care professionals, the doctrine hardly provokes any

1744 (2017) (“The amount of information could easily become overwhelming, making it more likely that it will be ignored in decision making.”); see also Omri Ben-Shahar & Carl E. Schneider, The Failure of Mandated Disclosure, 159 U. PA. L. REV. 647, 667–70 (2011); Christine Grady, Enduring and Emerging Challenges of Informed Consent, 372 NEW ENG. J. MED. 855, 857 (2015) (Patient’s “decisions are driven more by trust in their doctor or by deference to authority than by the information provided.”). Actually, consent to medical treatment has become primarily about signing lengthy forms without managing to read or understand them.
controversey. The affiliated absence of a duty to warn patients, however, continues to raise eyebrows. Courts have justified this rule on a number of grounds: physicians must make the judgment about whether to administer or prescribe a medication or use a device; manufacturers should not intrude on the doctor-patient relationship (for instance, by providing information that contradicts the physicians’ advice to the patient or unnecessarily alarms the patient, possibly leading to noncompliance with the prescribed therapy); physicians can better tailor their communication of important and complex information in ways understandable to their typically less-educated patients; and manufacturers have no practical means of conveying risk information directly to patients, apart from drugs that pharmacists dispense in unit-of-use packaging with enclosed leaflets for patients.

103. See Lars Noah, This Is Your Products Liability Restatement on Drugs, 74 BROOK. L. REV. 839, 892 (2009) (“[E]ven critics of the rule do not suggest that pharmaceutical companies should provide warnings only to patients and have no tort duty to warn physicians.”); id. at 892 n.226 (“Indeed, the first judicial opinion to use the ‘learned intermediary’ terminology did so in a case where the prescription drug manufacturer had argued that it owed no duty to warn the physician.”). Courts also have found duties to warn physicians, nurses, and other health care professionals who may treat or advise patients in the aftermath of someone else’s earlier prescribing or treatment decision. See, e.g., Bee v. Novartis Pharm. Corp., 18 F. Supp. 3d 268, 295–96 (E.D.N.Y. 2014) (dentists); Wyeth-Ayerst Labs. Co. v. Medrano, 28 S.W.3d 87, 92–93 (Tex. App. 2000) (nurses).

104. See Noah, supra note 103, at 894 (“The learned intermediary doctrine has attracted its share of critics who argue, among other things, that the defense reflects an anachronistic and excessively paternalistic model of the physician-patient relationship and fails to take into account changes in the delivery of health care services.”); see also Stevens v. Novartis Pharm. Corp., 247 P.3d 244, 259 (Mont. 2010) (“The realities of modern medicine increasingly conflict with the learned intermediary doctrine’s underlying premises. Unsurprisingly, the doctrine is in a state of flux as it adapts to new medical practices.”).

105. Noah, supra note 12, at 170; see also id. at 155–61 (elaborating on these rationales with copious citations to the case law and commentary available more than twenty years ago); id. at 180 (“In the past, the learned intermediary rule protected manufacturers of prescription drugs from tort liability if they conveyed an adequate warning to physicians. Some commentators have argued
Mass immunizations represented the classic exception to the learned intermediary doctrine: when vaccines are administered in such a program, no health care professional makes any sort of an individualized medical decision or engages in a dialogue with their patient. A few courts have extended this exception to other products, such as prescription contraceptives, for which a physician may play a reduced role in helping patients to select among available options. The overwhelming majority of courts do not, however, recognize any exception for contraceptive drugs or devices. Courts occasionally have crafted still other (ad hoc) exceptions where the rationales underlying the learned

that the rule no longer serves a legitimate purpose and should be eliminated altogether or at least reduced in scope by recognizing a number of new exceptions.

106. See, e.g., Plummer v. Lederle Labs., 819 F.2d 349, 356 (2d Cir. 1987) (“If the drug is given under clinic-type conditions the manufacturer is obligated to warn consumers directly.”); Stanback v. Parke, Davis & Co., 657 F.2d 642, 647 (4th Cir. 1981) (limiting the mass-immunization exception to massive, nationwide immunization programs where it would have been foreseeable by the manufacturer that the “vaccine would be dispensed without a physician’s consideration of individual needs and circumstances”); Allison v. Merck & Co., 878 P.2d 948, 958 n.16 (Nev. 1994).


intermediary doctrine no longer apply.\textsuperscript{109}

When it appeared two decades ago, the \textit{Products Liability Restatement} grudgingly endorsed the learned intermediary doctrine in its special rules governing sellers of prescription drugs and medical devices.\textsuperscript{110} An accompanying comment explained that the blackletter formulation attempted to capture the mass immunization exception, discussed the debate about possible exceptions where the FDA has required the use of patient package inserts (PPIs) or manufacturers have decided to engage in direct-to-consumer advertising (DTCA), but left to developing case law the adoption of these or still other exceptions.\textsuperscript{111}

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110. \textit{See Restatement (Third) of Torts: Prods. Liab.} § 6(d) (AM. LAW INST. 1998). Learned intermediary concepts undergirded adjacent blackletter provisions related to design defects and the liability of non-manufacturing sellers. \textit{See id.} cmt. d (“When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device is best for specific patients.”); \textit{id.} cmt. f (“Learned intermediaries must generally be relied upon to see that the right drugs . . . reach the right patients.”); \textit{id.} cmt. h (explaining that retailers “should be permitted to rely on the special expertise of . . . prescribing and treating health-care providers”). Two years after publication of this volume, however, one state’s high court rejected the new design defect standard while endorsing the learned intermediary rule on failure-to-warn claims. \textit{See} Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827, 839–42 (Neb. 2000).

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Just as this volume of the *Restatement of Torts* made its debut, I elaborated on the curious twists and turns that had occurred during the drafting process in relation to the learned intermediary doctrine,112 before explaining at length some of the serious flaws in proposals to recognize a DTCA exception.113 Indeed, insofar as it effectively would impose a penalty for engaging in commercial speech whether or not it has any potential to mislead listeners, state action crafting such an exception arguably violates the First Amendment.114 Apart from a decision of the New Jersey Supreme Court in 1999,115 several courts confronted with efforts to adopt a DTCA exception have appropriately declined to do so.116 One decade ago, however, the high court of West Virginia took its concerns about such advertising a step further and rejected the learned intermediary doctrine altogether.117 Nonetheless, apart

112. See Noah, supra note 12, at 161–68.

113. See id. at 168–79; see also id. at 173 (“Proponents of an advertising exception cannot rebut the two central rationales underlying the learned intermediary doctrine: patients cannot lawfully purchase a prescription drug without receiving authorization from a physician, and physicians are far better situated than manufacturers to communicate with patients.”); id. at 175 (“[P]harmaeutical manufacturers would have to find a way of disseminating [PPIS], ensure that these inserts contained references to all possible side effects in nontechnical language, and, in the unlikely event that they managed to design such an unassailable warning, hope that a jury would not decide that continued advertising to consumers diluted the effectiveness of that warning.”); id. at 180 (concluding that “no persuasive case exists for recognizing an advertising exception”).

114. Cf. Lars Noah, *Truth or Consequences?: Commercial Free Speech vs. Public Health Promotion (at the FDA)*, 21 *Health Matrix* 31, 54–57 & nn.110–12 (2011) (pointing out the U.S. Supreme Court’s surprising use of the unconstitutional conditions doctrine in a drug advertising case); id. at 85–89 (explaining that most restrictions on DTCA would violate the First Amendment).


116. See, e.g., Watts v. Medicis Pharm. Corp., 365 P.3d 944, 950–51 (Ariz. 2016) (declining to recognize the DTCA exception, “which has been adopted only in New Jersey”).

117. See State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 908–
from these outliers, the rule continues to represent a durable feature of failure-to-warn litigation involving therapeutic products that remain accessible only through health care professionals.\textsuperscript{118}

2. Crafting an Exception to Cover Conflicted Physicians

When manufacturers of prescription products reward physicians for patronizing their wares, at least some of the rationales thought to justify the limited duty to warn break down. In contrast to the exceptions referenced in the \textit{Products Liability Restatement}, however, this suggestion has only recently and almost imperceptibly surfaced.\textsuperscript{119} In

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\item \textsuperscript{118} See \textit{In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.}, 884 F.3d 746, 752 (7th Cir. 2018) (concluding that “there is good reason to think that given the opportunity, the Wisconsin Supreme Court would join the vast majority of state supreme courts and adopt the learned-intermediary doctrine”); Diane S. Kane, Annotation, \textit{Construction and Application of Learned-Intermediary Doctrine}, 57 A.L.R.5th 1, § 2.5 (1998 & 2018 Supp.) (collecting almost one hundred decisions from just the last decade); cf. Lars Noah, \textit{Treat Yourself: Is Self-Medication the Prescription for What Ails American Health Care?}, 19 HARV. J.L. & TECH. 359, 378–83 (2006) (discussing the liability questions that arise after powerful drugs switch to nonprescription status).

\item \textsuperscript{119} See \textit{Lars Noah, Law, Medicine, and Medical Technology: Cases and Materials} 799 (4th ed. 2017) (“What, however, if a prescriber receives industry funding—should that provide a new basis for recognizing an exception?”). One year after publication of the \textit{Products Liability Restatement}, a federal appellate court largely dismissed the idea in a case involving a spinal fixation device in spite of the fact that the surgeon received substantial sums as a consultant to the manufacturer—including 25,000 shares of company stock and $250,000 annually—as his work related to a device unrelated to the plaintiff’s treatment.
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light of the previously discussed scope and consequences of industry payments to health care professionals, coupled with the general failure of other institutions to tackle the resulting potential conflicts of interest, judges should seriously consider recognizing a novel exception to the learned intermediary doctrine in these circumstances.

In 2012, a pair of federal district courts squarely confronted this question but arrived at conflicting results. Both cases considered failure-to-warn claims involving the anti-inflammatory biologic Humira® (adalimumab), which treats various autoimmune conditions such as rheumatoid arthritis and psoriasis, and both judges had to guess whether the highest courts in their respective states would craft an exception when pharmaceutical manufacturers had compensated prescribers, though they did so in tandem with efforts by the plaintiffs to urge adoption of a DTCA exception. The payments in these cases came from the postapproval “Humira Efficacy Response Optimization” (HERO) study, which the plaintiffs had portrayed as amounting to little more than a seeding trial.

See Talley v. Danek Med., Inc., 179 F.3d 154, 157, 163–64 (4th Cir. 1999) (rejecting the plaintiff’s argument that the “learned intermediary doctrine should not apply because Dr. Mathews was not independent of [the manufacturer] in view of his financial connection with Danek as a consultant”).


122. See Brief of Petitioners at 18–20, Jones v. Abbott Labs., No. M2013-00769-SC-R23-CQ (Tenn. Apr. 15, 2013) (on file with author); id. at 34
In *Murthy v. Abbott Laboratories*, a federal district court in Texas endorsed the idea of an exception to the learned intermediary doctrine when prescribers receive drug industry compensation. Referencing some of the research and commentary available at that time, the court explained that such payments undercut assumptions supporting the rule. The federal judge in *Murthy* plainly felt emboldened to take this step by a then-recent opinion of the state’s intermediate appellate court favoring the DTCA exception, but the Texas Supreme Court soon thereafter reversed, reiterating its adherence to the learned intermediary rule at least given the facts of that case. Although Judge Ellison’s analysis of the issue hardly depended on the state appellate court’s earlier decision, the intervening signal from the state’s high court suggests that *Murthy* offers little precedential value for those advocating

(Referring to the “payment by Abbott of patient ‘bounties’ to prescribing physicians”).

123. 847 F. Supp. 2d 958.

124. See *id.* at 972–73 nn.5–6.

125. See *id.* at 971 (“[W]hen a physician is compensated by a drug company, some of the assumptions underlying the learned intermediary doctrine no longer hold.”); *id.* at 973 (“[W]hen a physician receives compensation or gifts from drug companies, his or her role as the neutral decision-maker may be diminished.”).

126. See *id.* at 971 (citing *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 499 (Tex. App. 2010)). Separately, however, the court dismissed most of the complaint because of a statutory presumption of adequacy for FDA-approved warnings. See *id.* at 973–77. Upon further consideration and review of additional evidence, the court vacated this part of its order and allowed the plaintiff to file an amended complaint. See *Murthy v. Abbott Labs.*, No. 4:11-cv-105, 2012 WL 6020157 (S.D. Tex. Dec. 3, 2012).

127. See *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 162–64 (Tex. 2012) (declining to decide, however, “whether Texas law should recognize a DTC advertising exception when a prescription drug manufacturer distributes intentionally misleading information directly to patients or prospective patients” or “any of the other exceptions to the learned intermediary doctrine”); see also *id.* at 162 n.22 (calling out *Murthy* for its erroneous prediction about Texas law).
an exception whenever drug companies pay prescribers.\textsuperscript{128}

Just nine months after \textit{Murthy}, in \textit{DiBartolo v. Abbott Laboratories},\textsuperscript{129} a federal district court in New York declined to recognize an exception to the learned intermediary rule for physician payments. Judge Buchwald simply pointed to the lack of any local precedent, adding that the “plaintiff has not demonstrated that \textit{Murthy} is part of any trend supporting an exception.”\textsuperscript{130} In an accompanying footnote, the judge elaborated somewhat confusingly about why she remained unpersuaded on the merits:

Looking more broadly to [the doctrine’s] rationale, plaintiff has not demonstrated that an exception . . . would be justified even if one assumes that physicians compensated by Abbott would be more likely to prescribe Humira than to prescribe a competitor drug. Such physicians would not be absolved of their duty to prescribe drugs to patients only when medically appropriate. It is not clear, moreover, that manufacturer-compensated physicians would in fact neglect their professional duties to an extent that would undermine [the learned intermediary doctrine].\textsuperscript{131}

\textsuperscript{128} Nonetheless, one federal court subsequently relied on \textit{Murthy} in declining to apply the learned intermediary rule to dismiss a failure-to-warn claim asserted by a subject allegedly injured while participating in a clinical trial of an investigational hepatitis C drug. See \textit{Rodriguez v. Gilead Scis., Inc.}, No. 2:14-CV-324, 2015 WL 236621, at *5 (S.D. Tex. Jan. 16, 2015) (explaining that the plaintiff had pled that his personal physician and investigator “was not acting within a physician-patient relationship during the clinical study but was rather an extension of Gilead, incentivized to act as a drug marketer rather than as a treating physician”).

\textsuperscript{129} 914 F. Supp. 2d 601 (S.D.N.Y. 2012).

\textsuperscript{130} \textit{Id.} at 616 (adding that the learned intermediary “doctrine [is] firmly established in New York law”).

\textsuperscript{131} \textit{Id.} at 616 n.6. This passage made an assumption but then questioned the assumed premise, mixed unresolved questions of facts peculiar to the case before the court and broader (“legislative”) factual disputes about the potential influence of industry payments (ignoring the page long footnote in \textit{Murthy} that discussed some of the relevant research), and implausibly suggested that a physician's decision to prescribe a medically inappropriate drug would be so wildly unforeseeable to the company that paid him or her as to represent a superseding cause (as opposed to giving the plaintiff a parallel malpractice claim).
Separately, in responding to Abbott’s motion to dismiss, the plaintiff conceded that she had not yet discovered whether her physician had received any payments from the manufacturer of Humira.\textsuperscript{132} \textit{DiBartolo}, therefore, hardly represents a carefully reasoned rejection of the payment exception, though a couple of months later it helped to persuade a federal judge in Massachusetts not to follow Murthy’s lead in still another Humira case.\textsuperscript{133} Otherwise, however, the issue has attracted essentially no further attention.\textsuperscript{134}

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\textsuperscript{132} See id. at 616 (“[P]laintiff’s allegations that Abbott compensated Dr. Cui are completely speculative, based entirely on what Abbott allegedly did in other cases involving other physicians.”). I have found only one commentator who previously has addressed this question. See Kate Greenwood, \textit{Physician Conflicts of Interest in Court: Beyond the “Independent Physician” Litigation Heuristic}, 30 Ga. St. U. L. Rev. 759, 789–94, 815–19 (2014). Although she usefully pointed out that the published opinion in Murthy represented a watered-down approach to the learned intermediary issue when compared with the court’s original (superseded) opinion, she then dismissed even that discussion as dicta, \textit{see id.} at 763–65, failing to realize that the court later revisited its decision to dismiss on other grounds, \textit{see supra} note 126. Ms. Greenwood entirely ignored the contemporaneous decision \textit{DiBartolo} and never mentioned seeding trials by name.
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\textsuperscript{134} Five years ago, the Houston-based plaintiffs’ attorney involved in both of the federal Humira lawsuits contacted me about this issue, attaching the briefs of the parties in a case then pending before the Tennessee Supreme Court. See E-mail from Andy Vickery to author (June 5, 2013, 18:51 E.D.T.) (on file with author). As explained in my reply to him, “I was intrigued by your suggested LI exception in cases of co. payments to Drs. and will be curious to see how it all turns out.” E-mail from author to Andy Vickery (June 6, 2013, 07:19 E.D.T.) (on file with author). In further response, he added that “we have unbelievable record to change law in that arena in numerous Humira cases. Just tried case to verdict in Chicago. Jury cringed, visibly, when depo of prescribing doctor was played and she testified (a) was ok to take Abbott money, and (b) ok not to tell patient about it.” E-mail from Andy Vickery to author (June 6, 2013, 08:42 E.D.T.) (on file with author). This use of such evidence at trial struck me, however, as more about atmosphere than doctrinal change, and it also

Although the learned intermediary doctrine is often framed in terms of the greater relative expertise of health care professionals, courts also assume that these professionals will exercise their judgment independently. When that assumption no longer holds true by virtue of the actions of therapeutic product manufacturers, then the latter parties arguably should owe heightened duties to communicate with patients. Alternatively, plaintiffs could argue that overpromotion by the seller had undermined an otherwise adequate warning directed to their physicians. In the context of promotion by remuneration as opposed to misinformation, however, prescribers will have a greater inclination to deny that gifts or grants in any way polluted their judgment. Removing the learned intermediary doctrine in the event of payments to prescribers offers a more straightforward approach.

represented the last that I have heard to even hint at any successful efforts at using such an exception.

135. See Ackermann v. Wyeth Pharm., 526 F.3d 203, 207 (5th Cir. 2008); Eck v. Parke, Davis & Co., 256 F.3d 1013, 1018 (10th Cir. 2001) (emphasizing the assumption that the prescriber “exercise[d] independent judgment”); Marcus v. Specific Pharm., 77 N.Y.S.2d 508, 509–10 (Sup. Ct. 1948) (“There is no reason to believe that a physician would . . . substitute for his own judgment that of a drug manufacturer.”).


If courts adopted this exception, then they also would have to resolve various practical issues.\textsuperscript{138} Mere inclusion in the federal disclosure database would not suffice for several reasons: (1) it suffers from inaccuracies,\textsuperscript{139} (2) it includes providers who have received fairly small gifts and payments,\textsuperscript{140} and (3) it covers a wide range of corporate donors. Plaintiffs would have to undertake discovery to confirm suspicions based on the federal database or some other source; courts may want to define a threshold amount before they would consider the medical judgments of

\textsuperscript{138} See Greenwood, supra note 132, at 817 (“The factual questions raised when a plaintiff plausibly pleads that his or her doctor had a financial relationship with the defendant manufacturer are many.”); id. at 822 (“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.”).

\textsuperscript{139} See Neil M. Kirschner et al., Health Policy Basics: The Physician Payment Sunshine Act and the Open Payments Program, 161 ANNALS INTERNAL MED. 519, 520 (2014) (discussing opportunities to dispute information before the CMS); Loftus & Walker, supra note 40, at B3 (reporting that a sizeable fraction of recipients lodged disputes for the first full year of reports, but that the AMA nonetheless complained about the failure to otherwise validate the data); Schencker & Richards, supra note 43, at C1 (The AMA “has long criticized the accuracy of the data.”).

\textsuperscript{140} Federal law uses a $10 (or $100 aggregate annual) threshold, see supra note 39 and accompanying text, while some states opted for thresholds of $25 or $50, see Susan Chimonas et al., Show Us the Money: Lessons in Transparency from State Pharmaceutical Marketing Disclosure Laws, 45 HEALTH SERV. RES. 98, 102 (2010). In addition, the likely impact of a payment might vary depending on what percentage of a particular provider’s income it would represent; for highly paid specialists, getting $500 from a company would amount to petty cash, while an overextended general practitioner in a rural area might genuinely appreciate such generosity. Cf. Bimal H. Ashar et al., Prevalence and Determinants of Physician Participation in Conducting Pharmaceutical-Sponsored Clinical Trials and Lectures, 19 J. GEN. INTERNAL MED. 1140, 1144 (2004) (“Our study suggests that dissatisfaction with income partially explains participation in these activities.”). Lastly, even modest individual payments may cumulate and become more consequential when viewed in the aggregate. See Loftus, supra note 41, at A1 (“Consulting and speaking fees are an important source of income for some physicians, who can be paid tens of thousands of dollars a year for such services.”). See generally Thompson, supra note 44, at 574.
physicians potentially corrupted;\textsuperscript{141} and even sizeable payments would have to get linked to choices about prescribing or use that allegedly resulted in an injury to a particular patient.\textsuperscript{142} Seeding trials might simplify the task of satisfying such evidentiary burdens,\textsuperscript{143} while more general consulting agreements with the parent company of a subsidiary producing therapeutic products selected by a health care professional suggest that such inquires could become rather complicated.\textsuperscript{144}

\begin{footnotesize}
\begin{enumerate}
\item See Murthy v. Abbott Labs., 847 F. Supp. 2d 958, 973 (S.D. Tex. 2012) (“[T]he Court would have to examine the factual circumstances surrounding the compensation of Murthy’s physician in order to evaluate whether application of the learned intermediary doctrine is appropriate.”). The industry codes, though voluntary, might help in this task. Cf. Robinson v. G.G.C., Inc., 808 P.2d 522, 526–27 (Nev. 1991) (upholding the admissibility of an ANSI standard adopted after an accident). Although they use the term “modest” and a rough threshold of $100 per gift, and do so for purposes of a prohibition, see supra notes 9, 19–20, and accompanying text, courts could decide that aggregate annual payments to a physician exceeding such thresholds would deprive donors of the learned intermediary doctrine’s protections.
\item Cf. Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551, 554 (N.D. Tex. 2006) (granting defendant summary judgment because the plaintiff had no evidence linking the company’s sales calls to decisions by his physicians to prescribe OxyContin® (oxycodone)). See generally supra note 5 (explaining the heightened risks associated with new drugs when initially launched).
\item See Eichenwald & Kolata, supra note 13, at 1 (“Doctors with money at stake may persuade patients to take drugs that are inappropriate or even unsafe.”); see also Krumholz et al., supra note 66, at 1105 (pointing out that, during the seeding trial of Neurontin, which had enrolled 2759 subjects, “11 patients died, 73 experienced serious adverse events, and 997 experienced less serious adverse effects”). Conversely, in seeding trials and similar studies, sponsors typically would supply consent forms with detailed risk disclosures and an expectation that physician-investigators get signatures from their enrolled patient-subjects. See, e.g., Murthy, 847 F. Supp. 2d at 964. In those circumstances, an exception to the learned intermediary rule would have little impact on sellers.
\item Cf. Talley v. Danek Med., Inc., 179 F.3d 154, 164 (4th Cir. 1999) (pointing out that “Dr. Mathews’ consulting relationship with Danek involved devices other than internal fixation devices” used on the plaintiff). Indeed, product sellers might simply respond by funneling more of their grants to doctors through seemingly independent third-party organizations such as patient advocacy groups. See Noah, supra note 96, at 290–94; Thomas Ginsberg, Donations Tie Drug Firms and Nonprofits, PHILA. INQUIRER, May 28, 2006, at A1 (“[M]any patient groups and drug companies maintain close, multimillion-
Critics of the DTCA exception worried that it might prompt a counterproductive response. If faced with the threat of expanded tort liability, prescription drug manufacturers would not supply warnings to patients; instead, they would cease engaging in such promotional campaigns, thereby depriving patients of potentially useful, even if incomplete, information. Proponents of the DTCA exception might not have minded such a response, so it depends on whether one sees anything of value in pitching prescription products to patients. This question seems less

145. See Noah, supra note 12, at 177–78; id. at 144 (“[F]aced with the prospect of significantly enhanced tort liability, pharmaceutical manufacturers may choose to discontinue most promotions directed to persons other than medical professionals.”); id. at 169 (“[R]ecognition of an exception in such cases might be counterproductive insofar as manufacturers react to the expanded duty to warn by conveying far less rather than more information to patients.”); id. at 178 (“Direct advertising encourages active participation by consumers in prescribing decisions, a favorable development that courts should not ‘reward’ by expanding the tort duties of drug manufacturers and, thereby, discouraging such advertising in the future.”); see also id. at 179 (“[C]ritics of the learned intermediary rule often emphasize the value of communicating additional information to consumers and then simply assume that expanding the duty to warn will best promote this goal. Eliminating the doctrine altogether would do so, but carving out only an advertising exception may do nothing to improve communication with consumers.”).

146. See id. at 170 (“[P]roponents of an advertising exception seem to rest their position on what they perceive as crass, profit-motivated advertising of prescription drugs. Once pharmaceutical manufacturers stoop to direct consumer advertising, the argument goes, they no longer deserve the special treatment that they have enjoyed under tort law.”); cf. id. at 177 n.135 (“Even critics concede that direct advertising provides significant valuable information to consumers.”).
contestable here: if faced with an exception to the learned intermediary doctrine, manufacturers would probably not start supplying warnings to patients; instead, they would stop lavishing gifts and money on physicians.147 Unlike other forms of industry advertising directed toward health care professionals, rewarding those who select a company’s therapeutic products lacks any communicative value.148 Some physicians might complain about the loss of these bonuses and mementos of appreciation,149 but in no sense would patients find themselves worse off. Insofar as this

147. If, instead, manufacturers did supply risk information directly to patients, then another rationale favoring the learned intermediary rule would come into play—namely, concerns about intruding upon the doctor-patient relationship. See id. at 157 (“Warnings that contradict information supplied by the physician will undermine the patient’s trust in the physician’s judgment.”). Again, however, in cases where a prescriber has a conflict of interest, rattling a patient’s naive confidence in the judgment of their physician might represent “just what the doctor ordered.”

148. See Lars Noah, Permission to Speak Freely?, 162 U. PA. L. REV. ONLINE 248, 250–54 (2014) (discussing the constitutional protections that apply when companies seek to communicate potentially valuable therapeutic information to physicians); see also Noah, supra note 114, at 68–84 (elaborating). Although efforts to discourage companies from handing out money in exchange for prescribing would not seem to raise any First Amendment issues, trying to punish companies for bankrolling others to communicate (or collect) information might do so. See id. at 84–85 n.217. Nonetheless, companies argue that gifts represent an essential part of their communicative encounter, providing a means for their agents to “get a foot in the door” of busy physicians, and that otherwise they could not effectively deliver their constitutionally protected messages. See Gardiner Harris, Minnesota Limit on Gifts to Doctors May Catch on, N.Y. TIMES, Oct. 12, 2007, at A25 (reporting such arguments in response to one state’s move to ban free meals for physicians); cf. Sorrell v. IMS Health Inc., 564 U.S. 552, 578–79 (2011) (“Vermont may be displeased that detailers who use prescriber-identifying information are effective in promoting brand-name drugs. . . . The State may not burden the speech of others in order to tilt public debate in a preferred direction.”); IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163, 173 (D.N.H. 2007) (quoting an anecdote about a sales rep regularly delivering coffee to a clinic and then complaining to a nurse that this had failed to increase their use of her company’s drug), rev’d, 550 F.3d 42 (1st Cir. 2008).

149. See Chimonas et al., supra note 72, at 186 (“Regulatory efforts irritated the physicians [participating in focus groups]. They resented limitations on entertainment and other personal-use gifts . . . . They particularly objected to excluding spouses from industry-sponsored events.”); see also supra note 3 (explaining that some doctors miss getting gifts from patients).
exception would have the effect of discouraging companies from giving sizeable gifts to persons responsible for selecting therapeutic products, so much the better.

Furthermore, if companies want to continue engaging in generous outreach efforts to the medical community, then they would have a ready means of fulfilling their expanded duty to warn. Unlike the proposed DTCA exception, which—contrary to the misconceptions of some courts and commentators—could not get satisfied simply by communicating fuller risk information through that medium, manufacturers have the power to contractually obligate recipients of their largesse to disseminate warnings to patients under the care of those (and only those) health care professionals. In the event of a physician’s neglect in doing so, the manufacturer could seek indemnification if later held liable for failing to warn a patient directly. Thus, another common objection lodged against suggested exceptions to the learned intermediary doctrine has no particular force in this setting.

Product sellers may face vicarious liability for the tortious conduct of their employees. These issues have

150. See Noah, supra note 12, at 174 (“Once the duty to warn expands, risk information contained in the advertisements would not satisfy a drug manufacturer’s duty to warn patients directly.”); Noah, supra note 103, at 901–03; id. at 900 (“What the plaintiffs wanted, however, was not clearer risk information in advertisements that they may not have seen (or remembered); instead, they sought printed warnings to accompany the drugs when later dispensed to them.”).

151. Cf. Mazur v. Merck & Co., 964 F.2d 1348, 1365–69 (3d Cir. 1992) (holding that a vaccine manufacturer had satisfied its duty to warn by delegating to the U.S. Centers for Disease Control and Prevention the responsibility for disseminating patient labeling). But cf. In re Vioxx Cases, No. JCCP 4247, 2006 WL 6305292, at *4 (Cal. Super. Ct. Dec. 19, 2006) (rejecting the argument that the learned intermediary doctrine did not apply to a prescriber previously paid by Merck to serve as an investigator and speaker, adding that “if such payments alone sufficed, a manufacturer would have to obtain the patient list of every physician it pays for research in order to somehow provide direct warnings”).

152. See, e.g., Delfino v. Griffò, 257 P.3d 917, 928–29 (N.M. 2011) (allowing vicarious liability claims to proceed against the employers of pharmaceutical
become more important as industry salespersons occasionally insinuate themselves in patient care. When drug and device manufacturers hire practicing physicians to serve as consultants, speakers, or investigators, one can make the argument that these doctors have become agents of the manufacturer. Nonetheless, because the physicians


153. See, e.g., Sanchez-Scott v. Alza Pharm., 103 Cal. Rptr. 2d 410, 418–19 (Ct. App. 2001) (allowing an invasion of privacy claim against a drug manufacturer where a breast cancer patient had not consented to the presence of one of its salesmen during an exam as part of a preceptorship); Hurley v. Heart Physicians, P.C., 898 A.2d 777, 787–88 (Conn. 2006) (allowing a claim against the manufacturer where one of its salesmen allegedly had adjusted the settings of an implanted pacemaker in an improper manner); see also Christiana C. Jacxsens et al., Beyond the Basics: Expanding Theories of Liability and Defenses for Claims Involving Medical Device Sales Representatives, 39 Wm. Mitchell L. Rev. 1087, 1112–16, 1143–50 (2013); Abigail Zuger, Fever Pitch: Getting Doctors to Prescribe Is Big Business, N.Y. Times, Jan. 11, 1999, at A1 ("[T]hey begin to blend into the health care team. Salesmen who sell surgical devices have long been present at operations to guide doctors using new equipment."); id. (Harrisburg Hospital’s “Dr. Shaughnessy said he once found residents actually presenting cases to a pharmaceutical representative for treatment advice, apparently finding him more pleasant and accessible than their supervising physicians.").

154. See Margolis, supra note 71, at 1236 (worrying about “the loss of autonomy as physicians become the agents of pharmaceutical manufacturers”); id. at 1237 (arguing that seeding trials pose such concerns even more clearly); Daniel Carlat, Dr. Drug Rep, N.Y. Times Mag., Nov. 25, 2007, at 64 (recounting that the author, a practicing psychiatrist, had earned almost $30,000 in extra income one year on the speakers circuit pitching Wyeth’s antidepressant Effexor® (venlafaxine)). Thus, when a company enlists independent physicians to communicate information that it could not share, the government has on rare occasions brought conspiracy charges against the health care professional. See Alex Berenson, Indictment of Doctor Tests Drug Marketing Rules, N.Y. Times, July 22, 2006, at A1 (reporting the arrest of a psychiatrist accused of conspiring with the manufacturer of Xyrem® (gamma hydroxybutyrate) to publicize off-label uses of this narcolepsy drug at continuing medical education events); Weber & Ornstein, supra note 37, at G1 (noting that this physician pled guilty to a misdemeanor count of drug misbranding and got sentenced to a year of probation before committing suicide); cf. United States v. Caronia, 703 F.3d 149, 156–58, 168–69 (2d Cir. 2012) (dismissing prosecution of the sales rep involved in that case on First Amendment grounds). In some cases, the arrangements become almost incestuous. See Thomas, supra note 36, at A1 ("In
technically would qualify as independent contractors rather than regular employees, manufacturers normally would not have to fear vicarious liability. In particular, courts have rejected efforts to hold pharmaceutical companies that sponsor clinical trials vicariously liable for the actions of principal investigators.

addition to paying high-prescribing doctors to speak on behalf of Subsys, Insys also hired the doctors’ family members.

155. See Talley v. Danek Med., Inc., 179 F.3d 154, 163–64 (4th Cir. 1999) (“[I]f Dr. Mathews were not merely a consultant but an employee of Danek or so closely related to Danek that he could not exercise independent professional judgment, a question could legitimately be raised as to whether he was an intermediary. The resolution of that complex question would depend on the nature of the relationship between the manufacturer and the physician . . . .”); cf. Weber & Ornstein, supra note 37, at G1 (repeating allegations that a frequent prescriber of the antipsychotic Zyprexa® (olanzapine) felt underappreciated by the payments he had received from the manufacturer for speaking engagements and switched his loyalties after Eli Lilly refused to hire his son as a sales rep).

156. See, e.g., Tracy v. Merrell Dow Pharm., Inc., 569 N.E.2d 875, 879 (Ohio 1991) (rejecting the plaintiff’s argument that a physician became the agent of a drug manufacturer for accepting $15 to enroll patients in a trial of a prescription smoking-cessation product so as to make the learned intermediary doctrine inapplicable). See generally Pusey v. Bator, 762 N.E.2d 968, 972 (Ohio 2002) (explaining that “an employer is generally not liable for the negligent acts of an independent contractor”); RESTATEMENT (SECOND) OF TORTS § 409 (AM. LAW INST. 1965).

157. See, e.g., Abney v. Amgen, Inc., 443 F.3d 540, 548–50 (6th Cir. 2006); Suthers v. Amgen Inc., 372 F. Supp. 2d 416, 425 (S.D.N.Y. 2005); Kernke v. Menninger Clinic, Inc., 173 F. Supp. 2d 1117, 1121–22, 1124 (D. Kan. 2001) (applying the learned intermediary doctrine in granting summary judgment to the manufacturer of an investigational drug for schizophrenia, adding that the other named defendants owed duties to the subject); see also Vinion v. Amgen Inc., 272 F. App’x 582, 584 (9th Cir. 2008) (agreeing that the consent documents made no promise of continued access to the study drug at the conclusion of the clinical trial and that the investigator was not the manufacturer’s apparent agent); cf. id. at 585–87 (Fletcher, J., dissenting) (suggesting that a reasonable jury could regard the investigator as an implied agent of the manufacturer sufficient to commit the companies to supply Enbrel® (etanercept) free of charge). But cf. Mink v. Univ. of Chi., 460 F. Supp. 713, 718–19 & n.6 (N.D. Ill. 1978) (allowing battery claims to proceed against a manufacturer of diethylstilbestrol for sponsoring a clinical trial at a teaching hospital that...
Even without the prospect of vicarious liability, physicians paid to market prescription drugs and devices might find themselves treated as members of the chain of distribution. Although health care professionals need not fear strict liability for defective products that they use or recommend,158 they might open themselves to such claims if viewed instead as conduits for the sale of drugs and devices.159 The more forgiving standards used for judging claims of professional negligence would give way to the more demanding standards of products liability; moreover, physicians on the (intermittent) payroll of sellers might face the prospect of liability for any defects introduced upstream of them (typically at the level of the finished good manufacturer) even if they had no way of knowing that such flaws existed in the products.160 The ultimate financial responsibility would flow back to those manufacturers—at least barring bankruptcy—by the operation of express or implied rights of indemnification,161 but, depending on the language of their contracts with such consultants,162 they

administered the drug to hundreds of its patients without their knowledge), aff’d mem. after further proceedings, 727 F.2d 1112 (7th Cir. 1984); Darke v. Estate of Isner, No. 022194E, 2005 WL 3729113, at *14 (Mass. Super. Ct. Nov. 15, 2005) (holding that evidence of a financial relationship with the principal investigator might suffice to make gene therapy trial sponsor vicariously liable).

158. See Noah, supra note 103, at 918–19; see also id. at 923–24 (explaining that hospitals enjoy a similar exemption).

159. Cf. Jacxsens et al., supra note 153, at 1136–40 (explaining that salespersons employed by a company might get recharacterized as downstream sellers subject to strict liability).

160. See Heredia v. Johnson, 827 F. Supp. 1522, 1524 (D. Nev. 1993) (rejecting a pharmacy’s motion for summary judgment on a strict liability claim for an alleged failure to transmit the manufacturer’s warning to a consumer about a prescription drug’s risks); cf. RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(e) (AM. LAW INST. 1998) (limiting downstream liability for prescription products to manufacturing defects); Noah, supra note 103, at 917–22 (discussing ambiguities in this provision).


also may now face what amounts to vicarious liability for the failures (negligent or innocent) by health care professionals to pass along adequate warnings in a way that the learned intermediary rule would have barred and made solely a matter of potential malpractice liability. If this convoluted scenario represents a plausible account of how responsibility for failures to warn patients ultimately might get charged to therapeutic product manufacturers, then why not accomplish the same result more forthrightly by recognizing an exception to the learned intermediary doctrine in cases of physician payments?

III. CONCLUSION

The pharmaceutical and medical device industries aggressively market their wares to health care professionals, and gift giving has become a fixed feature of this process. Most observers regard offers of financial incentives to select therapeutic products as crossing the line, but the practice has continued in different guises. Various institutions have taken fairly tepid stabs at combating inappropriate gifts and payments to physicians: more than a quarter century of voluntary industry guidelines and ethical codes for medical professionals, fifteen years of nonbinding federal guidelines, or the still newer state and then federal reporting laws. Self-regulation, threats of prosecution, and transparency initiatives may have curbed the most egregious abuses, but manufacturers always have found clever new ways of

Lilly’s promise to indemnify physicians sued for prescribing the antidepressant Prozac® (fluoxetine)).

163. See, e.g., Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 105 (Fla. 1989) (affirming summary judgment for a drug manufacturer on failure-to-warn claim notwithstanding prescriber’s alleged failure to share that information with his patient); Humes v. Clinton, 792 P.2d 1032, 1043 (Kan. 1990) (granting summary judgment to the manufacturer of an IUD where the physician had neglected to hand out its patient labeling in favor of a homemade leaflet); Niemiera v. Schneider, 555 A.2d 1112, 1119–22 (N.J. 1989) (absolving drug manufacturer but remanding claim that physician failed to warn patient).
purchasing the loyalty of prescribers.

As presently configured, tort law has essentially nothing to say about industry payments to physicians. Fairly minor modifications to doctrine could, however, make a big difference. Courts could include potential conflicts of interest as material information that physicians must reveal when securing consent from their patients, but such professional negligence claims would offer a difficult mechanism for effectuating such disclosures and, therefore, probably not do much to discourage gift taking. Instead, courts could expand the duties of manufacturers. By depriving therapeutic product sellers of the learned intermediary doctrine when they provide financial incentives to those intermediaries, manufacturers of prescription drugs and medical devices would face enhanced exposure to inadequate warning claims. The prospect of having to communicate risk information directly to patients might make companies think twice before lavishing gifts and payments on physicians, which in turn would help to ensure that those learned intermediaries continue to serve the best interests of their patients.