WHEN MONEY TRUMPS TRUST

By || Loren Jacobson and Paul Lawrence

Trust lies at the center of the physician-patient relationship. But this core value of the medical profession has been compromised by the pervasive influence of drug companies and medical device manufacturers.

Americans consistently rank physicians as among the most trusted professionals.[1] Much of that trust is well earned and arises, in part, from the public perception that a doctor's judgment is free of corrupting financial influences. But that confidence has been increasingly compromised by financial incentives that pharmaceutical and medical device companies have given to physicians. Ask doctors whether they are influenced by gifts and payments and they will say that their professional judgment cannot be bought. Ask drug and device sales reps the same question and they will say that even small amounts of money paid to doctors produce significant "returns on investment."

Industry payments to physicians have become a central allegation in many different types of litigation, including qui tam whistleblower actions, products liability suits, securities litigation, RICO actions, and personal injury cases. When a case presents financial ties between a physician and a drug or device company, the plaintiff lawyer must show the judge and jurors that doctors may respond to financial inducements in ways that do not benefit their patients. There is a wealth of research to prove this point.

The influence of pharmaceutical and medical device companies on the practice of medicine

is staggering. According to a 2004 study of the 15 largest drug companies in the United States, the industry spent just under a third of its total budget for marketing on payments to physicians.[2] And a national survey published in the *New England Journal of Medicine* in 2007 found that 94 percent of physicians had some sort of financial relationship with a pharmaceutical company.[3] Of this number, 83 percent reported receiving meals from drug companies, 35 percent reported reimbursement for costs associated with professional meetings or continuing education, and 28 percent said they received payments for consulting, giving lectures, serving on an advisory panel, or enrolling patients in clinical trials.

The drug and device industry provides compensation in many ways. Companies provide grants to cover most of the operating costs of medical societies; they pay physicians to serve as consultants and on advisory boards that review clinical trials and marketing; they give grants to publish case studies and journal articles; and they pay physicians to sign their names to ghostwritten articles and enroll patients in clinical trials.[4] Compensation also may take the form of "preceptorships," where sales representatives "shadow" the doctor for as much as a full day of patient appointments.[5]

Beyond pens and clipboards, drug and device manufacturers work to ensure brand loyalty by providing perquisites such as meetings at resorts, travel and hotel expenses, car service, golf games, and even snorkeling excursions. For example, one judge, ruling on a motion to dismiss in a class action based on state consumer protection laws, noted that Forest Pharmaceuticals "illegally induced physicians to prescribe Celexa through a system of kickbacks, such as honoraria for participation in advisory boards, restaurant gift certificates, lavish entertainment, and research grants."[6]

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In a Texas case against Janssen Pharmaceuticals for its fraudulent marketing of the drug Risperdal, the evidence showed that the state's medical algorithm favored Risperdal as a first-line drug. Physicians involved in developing the algorithm testified that they had received thousands of dollars in

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payments from Janssen, including funding of trips to other states to promote the Texas system.[7]

Ghostwriting is another increasingly common issue in litigation. In a qui tam case the government settled against Novo Nordisk last year, the relators alleged that the company paid Army physicians to author case studies and other articles supporting the off-label use of a drug prescribed for hemophiliacs in trauma situations.[8] Ghostwriting has also been a factor in hormone replacement therapy and Vioxx litigation; in the latter, the evidence showed not only that studies supporting Vioxx's safety and efficacy were ghostwritten, but also that the physician "authors" received hefty sums to put their names on the articles.[9]

Industry influence also extends to continuing medical education, which is mainly sponsored by drug and device companies. Manufacturers not only pay the costs of putting on seminars; they also pay physicians "honoraria" to speak at medical education events and at non-educational promotional events. Professors and clinicians who are considered "key opinion leaders" are added to a company's speaker's bureau, and they give multiple regional and national lectures on a particular drug or device—or on a condition treated by that drug or device. The companies also pay clinicians honoraria just for attending such presentations.[10]

The financial pressure on physicians to prescribe new drugs or use new devices sometimes goes against a patient's best interest. Clinicians prescribe the latest patented medicines and devices they have heard about from industry-funded colleagues and may ignore safer, time-honored products that are less profitable for manufacturers.

Most physicians believe that industry influence and money do not affect their professional judgment, but studies show just the opposite. In a landmark 1992 study, researchers at the Cleveland Clinic in Ohio tracked the prescribing habits of physicians who attended drug companies' "all-expenses-paid trips to popular . . . vacation sites to attend symposia."[11] The researchers looked at each physician's prescribing habits for two intravenous drugs (an antibiotic and a heart medication) for the 22 months before the trip and the 17 months afterward. Prescriptions written for the antibiotic initially increased tenfold after the trip and then leveled off at a rate that was more than three times higher than previous levels. Prescriptions for the heart medication increased to four and a half times what they had been before the trip.

Research shows that physicians who receive payments and perks from a pharmaceutical company also are more likely to ask that hospitals, practice groups, and insurers use that company's drugs. A review of physician-industry relationships in 2000 found evidence of a significant relationship between physicians "benefiting from sponsored meals" and their requests that drugs be added to formularies.[12] The researchers also found a similar result when physicians received honoraria.

Patient safety may be at risk in clinical trials of new drugs—at least 70 percent of which are funded by industry—because every aspect of a trial can be influenced.[13] Judge Jack Weinstein of the Eastern District of New York has explained that "not only does commercial bias affect the probable outcome" of these studies, "but it also often controls whether and when a study is published."[14] This commercial influence is pervasive in medical journals; three-quarters of all clinical trials published in the four most respected medical journals are commercially funded.[15]

Judge Weinstein cited expert testimony showing that "the odds are 5.3 times greater that commercially funded studies will conclude that the sponsor's drug is the treatment of choice compared to non-commercially funded studies of exactly the same drug."[16] The testimony also showed that the odds of a trial favoring a drug greatly increase if the trial's researchers had a financial conflict of interest with the manufacturer. For studies that have both industry sponsorship and at least one author with a conflict of interest, the odds are 8.4 times higher that the study will favor the sponsor's drug.[17]

The Issue in Litigation

Payments to physicians have received considerable scrutiny in qui tam cases—cases brought pursuant to the False Claims Act and its state counterparts. Many courts agree that a prescription written by a doctor who receives remuneration from the drug's manufacturer is a "false claim" when the claim is submitted to Medicare or Medicaid because it violates the federal Anti-Kickback Statute, but this theory has not been universally accepted.[18] Many large pharmaceutical companies and medical device manufacturers have settled kickback claims under the False Claims Act.

The issue of financial conflicts of interest in clinical trials has featured prominently in products liability cases, securities class actions, and RICO suits.[19] From Avandia to Vioxx, the story behind many of the most dangerous drugs and devices—including those pulled from the market—often involves industry-funded clinical trials, ghostwriting, and manipulated clinical trials.[20]

In any products liability case, it is worth determining whether the clinical trials for the drug or device involved were funded by the industry, and this inquiry should extend to researchers involved in the publications supporting the product. This information may help prove that the drug or device was neither safe nor efficacious, even for its intended use. It may also prove that the company

manipulated information and paid key opinion leaders to promote the product despite evidence of its harm or lack of efficacy. Under such circumstances, there is some support for the argument that potential defendants should include not only the drug company but also "authors" and key opinion leaders who received kickbacks to promote the drug or device.[21]

Similarly, it is important to know whether a drug company's expert witnesses have received funding from the company or other pharmaceutical manufacturers. Even if the evidence is not sufficient to disqualify the expert, it can help impeach his or her credibility. A recent study by *Consumer Reports*, for example, revealed that 51 percent of respondents said "even a payment of $500 or less from a drug company would make them concerned that a 'doctor's judgment might be influenced by the dollars.' "[22]

In some medical malpractice cases (such as those involving the implantation of medical devices), it may be fruitful to investigate whether the doctor has received payments from the medical device company or profited from using the device through royalties or other financial incentives. Such payments may have influenced the doctor to perform an unnecessary or risky medical procedure, or they may at least help you challenge the physician's professional judgment.

These avenues are worth exploration because you need the jury to understand the physician's motivations. Was the physician persuaded to perform a risky procedure because a device company paid him or her? If so, the company may be a viable defendant under a conspiracy theory. At least one court has held that physicians who accept kickbacks without disclosure to their patients may be liable for medical malpractice on the theory that they have withheld information that patients need to give informed consent.[23]

Finding the Money Trail

Where can you find information about industry payments to physicians? Well-crafted discovery and pointed deposition questions can go a long way, but other sources can be useful. ProPublica, an investigative journalism organization, hosts a massive database of pharmaceutical industry payments to physicians that includes $761.3 million in disclosed payments from 12 drug companies.[24] Several states, including Massachusetts, Minnesota, and Vermont, also have "sunshine" laws that require physicians and industry interests to report payments. The information is available in public databases and reports.[25]

Information about conflicts of interest often can be found in the journal articles themselves. Many medical

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journals require authors to publish conflict of interest information that can be found either in a "conflicts" section at the end of the article or in footnotes to the authors' names.

A Google search can turn up a gold mine of information because physicians and medical researchers often post their CVs online and list the industry grants they have received. And beginning in 2013, all drug and medical device manufacturers must begin collecting and reporting payments to physicians and teaching hospitals pursuant to the federal Physician Payments Sunshine Act, which is part of the Patient Protection and Affordable Care Act.[26]

Uncovering financial connections between big pharma and physicians is time well spent. These resources can help expose physicians' financial conflicts of interest, but disclosure is only half the battle. Plaintiff lawyers must use these tools to help remove the industry's improper influence on the medical profession and protect patient safety.

Loren Jacobson is a partner with Waters & Kraus in Dallas. She can be reached at ljacobson@waterskraus.com. Paul Lawrence is of counsel in the firm's Washington, D.C., office. He can be reached at plawrence@waterskraus.com.

Notes

1. *See* Jeffrey M. Jones, *Record 64 Percent Rate Honesty, Ethics of Members of Congress Low*, Gallup Politics (Dec. 12, 2011), www.gallup.com/poll/151460/Record-Rate-Honesty-Ethics-Members-Congress-Low.aspx.
2. Carl Elliott, *White Coat, Black Hat: Adventures on the Dark Side of Medicine* 78 n.3 (Beacon Press 2010).
3. Eric G. Campbell et al., *A National Survey of Physician-Industry Relationships*, 356 N. Eng. J. Med. 1742, 1746 & 1746 tbl. 2 (Apr. 2007).
4. *See e.g. In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 751 F. Supp. 2d 277, 284 (D. Mass. 2010); *U.S. ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 675 (E.D. Pa. 2010).
5. *See* Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It* 127 (Random House 2004).
6. *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 751 F. Supp. 2d at 284; *see also In re Zyprexa Prod. Liab. Litig.*, 2008 WL 2696916 at *36 (E.D.N.Y. July 2, 2008).
7. *See St. of Tex. ex rel. Jones v. Janssen LP*, No. D-1-GV-04-001288, Tr. Transcr. of Alexander Miller & Steven Shon (Tex. Dist. Travis Co. Jan. 11, 2012).
8. *See* Press Release, U.S. Dept. Justice, Danish Pharmaceutical Novo Nordisk to Pay $25 Million to Resolve Allegations of Off-Label Promotion of Novoseven (June 10, 2011), www.justice.gov/opa/pr/2011/June/11-civ-764.html.
9. Joseph S. Ross et al., *Guest Authorship and Ghostwriting in Publications Related to Rofecoxib*, 299 JAMA 1800 (2008).
10. For attorneys, this would be the equivalent of having all continuing legal education activities underwritten by insurance and investment companies who have structured settlement or investment products they want members of the bar to promote.
11. James P. Orlowski & Leon Wateska, *The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch*, 102 Chest 270, 270 (1992).
12. Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?* 283 JAMA 373, 376 (2000).
13. Thomas Bodenheimer, *Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry*, 342 N. Eng. J. Med. 1539, 1539 (May 2000).
14. *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 2696916 at *35; Katharine Greider, *The Big Fix* 78–86 (PublicAffairs 2003).
15. John Abramson, *Drug Profits Infect Medical Studies*, L.A. Times (Jan. 7, 2006), http://articles.latimes.com/2006/jan/07/opinion/oe-abramson7.
16. *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 2696916 at *35.
17. *Id.*
18. *Compare U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377 (1st Cir. 2011), *with Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318 (11th Cir. 2009).
19. *See In re Neurontin Mktg. & Sales Pracs. Litig.*, 2011 WL 3852254 (D. Mass. Aug. 31, 2011).
20. *See* Catherine D. DeAngelis & Phil B. Fontanarosa, *Ensuring Integrity in Industry-Sponsored Research*, 303 JAMA 1196 (2010); Steven E. Nissen, *Setting the RECORD Straight*, 303 JAMA 1194 (2010).
21. *See e.g.* Xavier Bosch et al., *Challenging Medical Ghostwriting in U.S. Courts*, 9 PLoS Med. 1 (Jan. 24, 2012).
22. Nicholas Kusnetz, *Consumer Reports: Most Patients Worry About Pharma Payments to Doctors*, ProPublica (Oct. 18, 2010), www.propublica.org/article/consumer-reports-most-patients-worry-about-pharma-payments-to-doctors; ConsumerReports.org; *CR Investigates: Dangerous Medical Devices* (May 2012), www.consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm.
23. *See e.g. D.A.B. v. Brown*, 570 N.W.2d 168, 170-71 (Minn. App. 1997).
24. *See* Dan Nguyen et al., *Dollars for Docs: How Industry Dollars Reach Your Doctors* (Sept. 7, 2011), http://projects.propublica.org/docdollars.
25. *See* Mass. Exec. Off. of Health & Human Servs., Pharmaceutical Code of Conduct: Data & Reports, www.mass.gov/eohhs/provider/licensing/programs/pharm-code-of-conduct/data; Minn. Bd. of Pharm., Payments to Practitioners Documents, www.phcybrd.state.mn.us/main_pay.htm; Vt. Off. of the Atty. Gen., Disclosures by Manufacturers of Prescription Drugs, Biological Products and Medical Devices, www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php; *see also* Charles Ornstein et al., *Minnesota's Pharma Payment List*, ProPublica (Dec. 10, 2010), http://projects.propublica.org/tables/minnesota-dollars-for-docs.
26. The Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010) (codified at various sections of 42 U.S.C.). The Physician Payments Sunshine Act is found in §6002 of the Act; it is codified at 42 U.S.C. §1320a-7h(a).

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