

## *Virtual Mentor*

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### HEALTH LAW

#### **Is it Legal for a Physician to Receive Payment for Prescribing a Drug?**

Kristin A. Sorenson

Colin Mudd, MD, specializes in pediatric endocrinology. He began prescribing a growth hormone, GrowTall, to a number of patients whose parents were worried about their children's projected adult statures. The parents were pleased with the results—their children rose to mid-percentiles in growth rate—and told other parents about Dr. Mudd. His reputation spread rapidly by word of mouth throughout the community and beyond, and soon he was treating dozens of patients with the hormone. Dr. Mudd's prescribing habits came to the attention of GrowTall's manufacturer, DrugCo, Inc, who approached Dr. Mudd and asked him to enter into an exclusive marketing agreement, under which he would help them in their post-market research by prescribing only GrowTall and reporting patient outcomes to DrugCo. Dr. Mudd, who was generally satisfied with the results his patients were achieving on GrowTall, agreed to the exclusive arrangement. He did not tell the parents of his patients about his financial arrangements with DrugCo, Inc. Over the next 8 years, Dr. Mudd treated more than 200 children with GrowTall. During this time, DrugCo, Inc paid him more than \$1 million under the marketing agreement in the form of research grants and consulting fees. None of his patients' parents complained about the treatment or its cost, nor did their insurance companies issue any complaints.

#### **Legal Analysis**

The above facts are adapted from *US v Brown*<sup>1</sup> and *D.A.B. v Brown*.<sup>2</sup> Dr. David Brown was one of the largest prescribers of Protropin, a genetically engineered human growth hormone made by Genentech and distributed in the US solely by Caremark, a home health care company. Over an 8-year period, Dr. Brown was paid more than \$1.1 million by Genentech and Caremark, including \$509,000 in research grants, \$110,000 labeled as a marketing agreement, \$224,468 paid to the office and staff, and various "consulting" fees.

In *US v Brown*, the government prosecuted Dr. Brown, Genentech, Caremark, and Caremark executives for violating the Medicaid/Medicare anti-kickback statute.<sup>3</sup> Under this statute, it is illegal for a physician to receive remuneration for referring a patient for a service that will be paid in whole or in part by a federal health care program or for prescribing or recommending the purchase of a drug that will be paid in whole or in part by a federal health care program. Violation of this statute is a felony. The person or entity that pays the remuneration is also guilty of a felony

under this statute. Illegal remuneration includes kickbacks, cash, rebates and discounts, even alcohol.<sup>4</sup>

Before the *US v Brown* trial, Caremark pleaded guilty and paid \$161 million in fines and restitution. As part of the plea agreement, Caremark stipulated that it made payments to Dr. Brown to induce him to refer patients for Protropin use. After deliberations, the jury determined that Brown was guilty of soliciting or receiving kickbacks in violation of the statute. However, the district court ended up granting a new trial for Dr. Brown because jurors had been exposed to outside information about the fines paid by Caremark, despite the judge's instruction not to consider that fact. The Court of Appeals for the Eighth Circuit affirmed the order of the court for a new trial.

In *D.A.B. v Brown*, the patients of Dr. Brown brought a private suit against him for breach of fiduciary duty, fraud, negligent misrepresentation, and violation of a Minnesota state statute that prohibits doctors from receiving compensation for prescribing a manufacturer's drugs. The trial court dismissed the case for failure to state an acceptable claim, and the patients appealed. The Court of Appeals found that Dr. Brown was in violation of the Minnesota state statute that prohibits a physician from accepting compensation for prescribing a manufacturer's drugs. Violation of this statute subjects a doctor to state disciplinary action by the Board of Medical Examiners, but does not allow patients to bring private legal action against the doctor. The court declined both the "breach of fiduciary duty" and the fraud claims because, according to Minnesota law, both claims need to be supported by allegation of injury or harm. In this case, the plaintiffs (patients) alleged no harm from the prescriptions or improper treatment, no increase in premiums or co-payments; no monetary damages for the price difference between Protropin and another drug; nor did they allege that they would have stopped treatment or purchased another drug if the physician had disclosed his financial arrangements with DrugCo, Inc. Therefore, the case was dismissed.

### **Conclusion**

There are several causes of action against physicians for taking kickbacks. The federal government has a cause of action for violations of the Medicare/Medicaid statute. If a physician participating in a kickback scheme has Medicare or Medicaid patients, then the physician is subject to this law. Also under new HIPAA regulations, the Department of Health and Human Services may fine a physician who provides a patient's protected health information for marketing purposes without specific authorization and disclosure of the remuneration involved.<sup>5</sup> State governments have their own statutes governing kickbacks, such as Minnesota statute §147.091, subd 1 (p)(1), under which a physician is prohibited from receiving compensation for the referral of patients or the prescription of drugs. A violation of this statute subjects the physician to disciplinary action by the state Board of Medical Examiners. Patients may have a private legal claim against the physician if the kickback scheme caused either monetary or physical injury to the

patient. Such claims fall under malpractice or negligence if injury was caused by the breach of a duty.

### **Questions for Discussion**

1. Does receiving money from the pharmaceutical industry necessarily mean that a physician's medical judgment is compromised? Can you think of situations when no conflict of interest would arise?
2. Do you agree that a physician has a duty to disclose to patients payments of any kind they are receiving from a drug company? Does a physician have a duty to disclose receiving gifts from industry?
3. The Medicare/Medicaid statute says a violation of its kickback statute is a felony, punishable by fines not to exceed \$25,000 and 5 years in prison. Are these appropriate punishments for doctors who receive kickbacks for prescribing one medication rather than others?

### **References**

1. *US v Brown*, 108 F3d 863 (8th Cir 1997).
2. *D.A.B. v Brown*, 570 NW2d 168 (Minn Ct App 1997).
3. 42 USC sec 1320a-7b(b).
4. *US v Perlstein*, 632 F2d 661 (Mich Ct App 1980).
5. 46 CFR sec 164.508(a)(3)(ii).

Kristin A. Sorenson is a contributor to *Virtual Mentor*.

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