Financial Conflicts of Interest in Physicians’ Relationships with the Pharmaceutical Industry
Self-Regulation in the Shadow of Federal Prosecution
Legal Issues in Medicine


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THESE AUTHORS NOTE:

“The past two years have witnessed extraordinary regulatory ferment in the area of conflicts of interest involving physicians, especially conflicts arising in relationships with the pharmaceutical industry.”

“Professional regulatory bodies, the pharmaceutical industry, and the government have all decided that physicians and drug manufacturers need stronger advice about appropriate relationships.”

“There is a growing realization, inside and outside medical circles, of the troubling influence that pharmaceutical marketing can have on patient care.”

Also, since Medicare has adopted a prescription-drug benefit, there is widespread concern about the costs of this program.

Therefore, a body of federal law dealing with “fraud and abuse” is being used “by prosecutors to punish pharmaceutical companies and physicians involved in marketing practices that were once fairly common.”

“Apprehension over conflicts of interest in medicine is rooted in a concern that professional judgments about the welfare of patients may be inappropriately influenced by a secondary interest — in this case, the personal gain derived from relationships with pharmaceutical companies.”

“A drug company’s primary interest is to maximize sales of its product. Physicians do not (or should not) share this goal, but they are the chief conduit for sales. Consequently, physicians have been the central target of marketing strategies, and they remain so even after the rise of direct-to-consumer marketing.”

“The pharmaceutical industry spends approximately $12 billion annually on gifts and payments to physicians.” [WOW!]

70% of funding for drug clinical trials is paid by drug companies.

Drug companies absorb over half of the costs of for continuing medical education. [WOW!]
“Financial entanglement has bred close ties between the industry and physicians.”

“Contacts with trainees come early and adhere as physicians move to practice.”

“There is hardly a physician practicing today who has not been the beneficiary of small ‘educational’ gifts such as pens and memo pads or lunch for the office staff.”

“Many physicians attend dinners to hear a hired expert talk about a product, take educational trips to resorts, or receive funds (explicitly without strings attached) in the form of research grants, trainee support, or lucrative consulting fees.”

“Prosecutors have begun to apply the anti-kickback and false-claims laws widely in cases dealing with interactions between physicians and pharmaceutical companies.”

The authors use this illustrative case:

A) In 1997, government investigators began to probe relationships between TAP Pharmaceuticals, and various urologists for the marketing of Lupron, a potent gonadotropin-releasing hormone agonist used in the treatment of prostate cancer.

B) TAP encouraged the urologists to bill Medicare at the average wholesale price for Lupron, which they received free or at discounted prices, netting the urologists a substantial profit.

C) TAP employed doctors as “consultants” without requesting any services in return, took physicians on free trips to attend educational seminars, and awarded educational grants without doing any work.

D) Federal prosecutors charged TAP with criminal violations of the Prescription Drug Marketing Act, alleged that the schemes were intended to induce prescriptions for Lupron and therefore constituted kickbacks, and charged that the practices resulted in false claims.

E) TAP settled with the government for $290 million in criminal fines plus $585 million in civil penalties. The whistle-blowers received $100 million of the damages.

F) TAP also faced a series of class-action lawsuits brought by insurers and patients for unnecessary and costly services.

These aggressive of these as over-the-top marketing practices “are virtual fixtures in medical practice.” [WOW!]

“The outcome of the government’s case against TAP and regulatory-guidance documents issued by the Office of the Inspector General show that the propriety of trips to resorts, consulting arrangements that involve meager or no work products, and open-ended educational grants has stepped beyond the realm of academic debate regarding professional ethics and conflicts of interest.”
Other cases include.

A) In 2003, AstraZeneca settled criminal-fraud charges of $355 million in a case dealing with the drug Zoladex.
B) On July 14, 2004, Schering-Plough pleaded guilty and paid a fine of $350 million for providing grants to private physicians to conduct educational programs, which prosecutors characterized as kickbacks.
C) Schering-Plough faces an ongoing investigation into whether it used sham consulting arrangements and clinical trials to remunerate physicians for prescribing its hepatitis drug, Intron A.

“Clearly, a range of activities that have become ubiquitous within the triangle of pharmaceutical firms, physicians, and academic medical centers may be construed today as illegal inducements to prescribe medications.” [WOW!]

Payment for meals by pharmaceutical companies should meet the following conditions:

1) The meal is modest and is associated with valuable scientific or educational activities.
2) Guests are not included.
3) No takeout meals.

When supporting meetings, pharmaceutical companies should do the following:

1) Provide no compensation to participants for attendance time.
2) Provide no support for non-faculty attendees.
3) Meals must be modest.
4) Do not cover travel, lodging, time, or other personal expense of physician attendees who are not faculty.
5) Faculty honoraria and reimbursement must be reasonable.
6) No payments to physicians for listening to product presentations.
7) Disclose commercial support in printed materials.
8) Require that faculty disclose any relationships with commercial entities.
9) Ensure that educational events are not eclipsed by commercially supported social events.
10) Ensure that honoraria and reimbursement for faculty are reasonable.
11) Do not compensate or reimburse non-faculty attendees.
12) Industry-sponsored hospitality should be modest and arranged so that social activities don’t compete with educational events.

Pharmaceutical companies may provide reasonable compensation and reimbursement to bona fide consultants.
“Suspicious arrangements with consultant physicians include compensation for services related to marketing and sales activities, compensation received by physicians for time spent listening to marketing, and ghostwritten papers or speeches.”

“Physicians may accept gifts from pharmaceutical companies under the following conditions:

A) The gift must be primarily for the benefit of patients and be primarily related to the physician’s work
B) The gift must be of insubstantial value and may not be cash.
C) The gift must come with no strings attached.
D) Drug samples permitted for non-retired physicians; personal and family use of the samples also permitted. [THIS IS BIZARRE]

Extravagant gifts and no-strings-attached consulting relationships is commonplace and should be discouraged.

The literature shows that “even small gifts create a sense of indebtedness, which can lead to inappropriate prescribing.” [WOW!]

Important questions are:
1) How likely is the arrangement to interfere with clinical decision making by diminishing the objectivity of professional judgment?
2) How likely is the arrangement to increase the use of a company’s products?
3) How likely is the arrangement to increase costs to federal health care programs?
4) “Finally, does the arrangement raise concern about patient safety or the quality of care? [Interesting that patient safety is their last concern].

“With respect to educational programs, the guidance document clarifies that physicians and researchers face potential exposure to liability whenever a manufacturer has influence over the substance of a program.”

Paying physicians as consultants to attend meetings and engaging physicians to work in manufacturers’ marketing and sales activities are improper.

“Entertainment, recreation, travel, meals, gifts, and gratuities are all potentially subject to anti-kickback prohibitions.”

“From an ethical perspective, most physicians would regard ghostwriting practices as unacceptable, no matter what the legal implications.”

Federal authorities are using the powers granted them under the anti-kickback and false-claims statutes to step up their policing efforts.
“With the continuing publication of studies showing that even minor gratuities can influence the behavior of physicians, the government will grow more aggressive in anti-kickback enforcement.”

“As the cost of drugs continues to rise and Medicare becomes an increasingly prominent payer (owing to the prescription drug benefit and the aging of the population), the government will seek any means available to reduce the overuse and cost of drugs.”

KEY POINTS FROM DAN MURPHY

1) Conflicts of interest between drug companies and medical doctors is widespread and include attending dinners to hear a hired expert talk about drug products, take educational trips to resorts, or receive funds (explicitly without strings attached) in the form of research grants, trainee support, or lucrative consulting fees that involve no actual work; financial kickbacks to doctors to prescribe certain drugs. Sometimes the drug company will pay for the doctor’s travel expenses, lodging, and meals, and all at resort locations. Drug companies may ghostwrite scientific papers or speeches for doctors.

2) Drug company marketing exerts a troubling influence on patient care, and the problem is worse since Medicare has adopted a prescription-drug benefit. [Does this surprise any of us?]

3) There is the concern that judgments by doctors concerning the welfare of patients may be inappropriately influenced by the personal gain derived from relationships with pharmaceutical companies.

4) A drug company’s primary interest is to maximize sales of its product for profit, not the health of patients.

5) Physicians are the chief conduit for drug sales and therefore the central target of marketing strategies.

6) Drug companies have escalated their direct-to-consumer drug marketing.

7) The pharmaceutical industry spends about $12 billion annually on gifts and payments to physicians. [Incredible! This is significantly more money than all practicing chiropractors combined collectively earn in a year]

8) 70% of funding for drug clinical trials are paid for by drug companies.

9) Drug companies supply over half of the costs of for continuing medical education.

10) Financial entanglement has bred close ties between the drug industry and physicians.
11) Essentially all physician practicing today have been the beneficiary of ‘educational’ gifts such as pens and memo pads and lunch for the office staff.

12) Over-the-top marketing practices (often bordering or outright illegal, “are virtual fixtures in medical practice.”

13) Even small gifts from drug companies create a sense of indebtedness by the doctor to the drug company, which can lead to inappropriate drug prescribing.

COMMENT BY DAN MURPHY

Some of these practices may apply to some of the marketing of products within the chiropractic profession.