

IN PRACTICE

NO MORE FREE LUNCH: THE NEW PHARMACEUTICAL GUIDELINES

By Orly Avitzur, MD, MBA

In neurology practice, not a day goes by without several drug reps stopping by hoping for a few minutes of our time. In fact, according to Scott-Levin, a pharmaceutical sales

consulting company, the ratio of pharmaceutical sales representatives to office-based doctors has increased from one per 8.8 in 1996 to one to 4.7 in 2001, and the number of drug sales reps

has more than doubled in five years.

In the past, drug reps came to offices bearing gifts of food, tickets for sporting events, and invitations to all-expense-paid trips to resorts. But on July

1, 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA), an organization of research-based pharmaceutical and biotechnology companies, adopted a voluntary code on relationships with health care professionals. Two months later, the federal Office of Inspector General (OIG) released a draft compliance program for pharmaceutical manufacturers.



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ANTI-KICKBACK LIABILITY

While these standards are not law, drug companies that ignore them are being warned that they could be investigated for violations of federal fraud and kickback statutes. And although this guidance is directed toward pharmaceutical companies, Powers, Pyles, Sutter, and Verville, PC – the Washington, DC, firm that serves as legal counsel for the AAN – advises that the anti-kickback liability “applies both to the payer and receiver of an illegal payment or remuneration. Consequently, physicians are at risk if they have received remuneration which violates these guidelines.”

Rebecca Burke, a health care attorney with the firm, suggests that physicians who receive compensation for consulting services, serve as advisors, or engage in research, understand that these are areas of scrutiny. “These activities may be perfectly legitimate, but they may also be a disguised reward to induce a physician to use a pharmaceutical company’s product,” she said. “Be sure that you are being paid at fair-market value and for bona fide services.”

OIG: RISK AREAS

The OIG detailed three risk areas for pharmaceutical manufacturers: (1) the integrity of data used to establish reimbursement; (2) kickbacks and other illegal remuneration for prescribing practices; and (3) compliance with laws regulating drug samples.

The OIG also described issues relating to relationships with physicians, including "switching" arrangements in which pharmaceutical companies offer physicians cash or other benefits each time a patient's prescription is changed to their product from a competitor; consulting and advisory payments in which payments should be "fair and market value for services rendered" rather than "merely token" arrangements; and other remuneration, which could implicate the anti-kickback statute including "entertainment, recreation, travel, meals, or other benefits" associated with marketing.

The PhRMA code states that financial support should not be offered for travel, lodging, or personal expenses of non-faculty physicians attending meetings, and that funding should not be offered as a compensation for time. It restricts gifts to items \$100 or less, and recommends that they serve primarily for the benefit of the patient. It states that cash payments or the equivalent should not be offered except for bona fide services, and it says that reasonable compensation may be awarded for consultants and identifies factors that support legitimate arrangements.

DRUG SCANDALS

The need for guidelines has emerged in the wake of several scandals – one of which involved the neurological market. Last year, Parke-Davis, a drug company that was acquired by Pfizer in 2000, was implicated for its marketing practices of gabapentin (Neurontin) in a whistleblower case. A civil lawsuit and a separate criminal investigation by the US Attorney in Boston alleged that Parke-Davis and its parent company, Warner-Lambert, paid kickbacks to doctors to prescribe Neurontin for conditions for which the drug was not approved.

According to memorandums and invoices reported in the press, neurologists were allegedly expected to present positive messages about the drug and were paid fees of \$500 to \$2,000 per speech. A March 1996 memo instructed sales reps to target top prescribers of Neurontin for an all-expenses-paid trip to a Florida resort and include a \$250 honorarium.

Other allegations claimed the company paid neurologists \$1,000 to review and sign their names to ghostwritten journal articles, and paid doctors to bring salespeople into exam rooms to meet with patients, review charts, and even recommend medications, a program referred to as "shadowing."

SHADOWY PRECEPTORSHIPS

Alan Kurland, MD, a neurologist in private practice in a Boston suburb, attended

the Parke-Davis trip to Florida. He does not believe the meeting was biased in terms of the presentation of epilepsy data. He recalls hearing about off-label uses of Neurontin at this and other Parke-Davis conferences and said, "We need some way of getting vital, up-to-date information about medication – including efficacy, side effects, dosing but *also* the possibility of benefits in other conditions."

But Dr. Kurland draws the line at what he considers to be the most blatantly flagrant marketing techniques – the shadowing programs, which have been pitched to him as preceptorships. "They make it sound educational for the reps and offer to pay \$500-\$1,000 for a half or full day. I know some academic departments and community-based physicians accept these offers, but I personally view this as an inherent conflict of interest and an intrusion into my patients' privacy." He has had several requests to participate in these programs, but he has always declined.



Dr. Alan Kurland

NEED FOR GUIDELINES

Jan D. Wallace, MD, Senior Vice President of Clinical and Regulatory Affairs at Neuronyx, served as a neurologist at Yale and the West Haven VA Medical Center, prior to joining the pharmaceutical industry in 1986.

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"Sales reps influence drug sales, a fact confirmed to me as I moved to industry, but the scope surprised and disappointed me," he said. "Over the years, drug companies presented incentives that created an increasing appearance of impropriety as companies competed for prescriptions. These new guidelines will place companies on an even footing, and should relieve confusion about what is acceptable."

UNDUE INFLUENCE

But how do we address the issue of undue influence? "Physicians sometimes

think we can control bias in ourselves, yet paradoxically we know full well the need for placebo-controlled clinical studies to avoid bias in interpreting data," Dr. Wallace said. "It would be naïve to think excessive payments could be accepted without bias in prescribing. But most neurologists do not believe that our prescribing habits are influenced by dinner programs or by the acceptance of an occasional logo-embossed pen."



Dr. Jan D. Wallace

"Most, if not all, physicians are somewhat skeptical of info provided by pharmaceutical companies," Dr. Wallace continued. "We recognize that they have hidden agendas when they come to our office to speak about their drug. We are aware that invitations to nice dinners, shows, and events are all done for marketing – and knowing this from the outset puts it into the proper context."

CLINICAL JUDGMENT

Dr. Kurland believes the same reasoning applies to expert presentations at meetings. "The various experts state that one agent is positively superior to another in treating multiple sclerosis, migraine, Parkinson disease, or Alzheimer disease,

for example. But once you've heard a few authorities speak, you are so confused by all of it, you resort back to your best clinical judgment for a specific patient and problem."

Wesley Dennis, MD, a neurologist who works in a group practice with five other neurologists in Arlington, TX, agrees. "I always view their presented information with 'a grain of salt.' I know ahead of time that their research may very well be biased and I never look to these meetings as a sole source of information whenever I decide to prescribe a drug."

MARKETING PRACTICES

Even some bioethicists believe that not all marketing practices necessarily predispose us to partiality. Sheldon Krinsky, a Tufts University Professor who holds joint appointments at the School of Medicine and the Department of Urban Policy and Planning, addresses ethics and conflicts of interest in science in his forthcoming book – *Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research?* – due to be published by Roman Littlefield Publishing later this year.

He said that there is no evidence that, if a physician accepts a trinket from a pharmaceutical company, it will affect the quality of patient care. However, he said scientific studies have demonstrated that "other kinds of relationships – research funding, honoraria, service on advisory boards, and equity interest in companies *can* have an effect on physician behavior."

And what about free trips? "There are no studies that show this causes bias, but if a drug company takes an entire family to a junket, that does raise some issues," Dr. Krinsky said.

Dr. Dennis also takes issue with such trips. "Having pharmaceutical companies pay for recreational outings and junkets without any educational component is simply unethical." He believes that limiting gifts to under \$100 for items such as pads and pens and useful materials that will help in the education of patients is a good idea but adds, "I do think the new guidelines may make physicians more reluctant to meet with drug reps."

Professor Krinsky also points out that in other professions – journalism and the law, for example – certain relationships and behaviors are simply prohibited. There are clear standards regarding even the *appearance* of impropriety. "A judge should simply not be taken out to lunch by a lawyer who appears in his court," he explained.

Gifts to physicians by pharmaceutical companies have also been likened to politicians receiving gifts to influence votes or investment analysts recommending the stocks of clients who have paid fees to their firms. While it is perhaps difficult to change the mindset of physicians who have long been recipients of lavish trips and fine meals, perhaps the guidelines provide food for thought.

"I intend to be much more cautious about my interactions with drug companies and more cognizant of the potential ramifications of accepting dinner invitations and consulting fees," Dr. Kurland said.

Efforts may also be successful if they begin earlier. In fact, the American Medical Student Association (AMSA) created the AMSA Pharm-Free Campaign to educate and train their members to professionally and ethically interact with the pharmaceutical industry. ★