Medical Schools Just Say No to Drug Reps' Gifts

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SACRAMENTO — Another medical school has joined what could be a growing movement to ban faculty and residents from accepting gifts from drug company representatives.

The University of California, Davis, Health System decided in late November to forbid its medical staff to accept gifts from drug salesmen, including drug samples, pens, mugs, and meals, however small they might be. Earlier, the school had banned drug company representatives from walking into the clinical areas on a preceptorship.

By taking this action, the school joins a cadre of institutions that includes Yale University, which implemented its policy in 2005, the University of Pennsylvania, which did so in July 2006, and Stanford University, which implemented its policy in October 2006. At UC Davis, the policy goes into effect in July 2007.

From a survey of more than 1,000 medical students, an average third-year student receives one gift or attends one company-sponsored activity a week.

The new prohibition "picks off the low-lying fruit" in an attempt by the institution to create a greater distance between its clinical practice and the pharmaceutical industry, said Dr. Timothy E. Albertson, the university system's executive director of clinical care.

The school has plans to look at the issue of conflict of interest in further detail, particularly in regard to relationships with and practices of other vendors. "We're certainly not trying to change capitalism, but we are trying to redefine the ethics of this type of involvement," he said.

The efforts at UC Davis and the other schools were spurred in part by an article in the Journal of the American Medical Association (2006;295:429-33), which noted that many authoritative bodies, including the Pharmaceutical Research and Manufacturers of America and government agencies, have made attempts to curtail practices that constitute a conflict of interest for physicians. But the article also said those actions have largely failed to change the current climate. Thus, the 11 authors of the paper urged academic medical centers to take the lead by, among other things, banning the acceptance of gifts, samples, and payment for time spent at meetings. Academic medical centers need to adopt such policies because the medical profession looks to them for leadership, the proposal said.

The article noted that 90% of the marketing dollars spent by the pharmaceutical industry were directed at doctors, despite the increase in money spent on direct-to-consumer marketing in recent years.

According to IMS Health, a pharmaceutical information and consulting company, drug companies spent $27 billion on product promotion in 2004, of which $16 billion was for free drug samples and $7.3 billion, including gifts and meals, went to sales representative contacts.

The pharmaceutical industry, which adopted strict guidelines on gift giving in 2002, says that limiting the practices and access of their sales representatives will deprive physicians of the best expertise on their medicines. But gifts, however insignificant, establish an unspoken quid pro quo between physicians and pharmaceutical companies. If gifts did not serve this purpose, companies would not give them, the JAMA authors said. They noted that the research bears this out.

According to a 2003 survey of more than 1,000 third-year medical students, an average third-year student receives one gift or attends one company-sponsored activity a week (JAMA 2005;294:1034-42). That is precisely the point of the no-gift policies proposed by the JAMA article, said one of its authors, Dr. Jerome P. Kassirer, former editor-in-chief of the New England Journal of Medicine.

"These meals and gifts give residents and trainees the idea that pharmaceutical largesse is all right and the way things work, but it taints the profession," Dr. Kassirer said in an interview. "They wouldn't pass out these gifts if it didn't matter."

At the academic medical centers, free meals seem to be the biggest issue impeding acceptance by staff. The free meals allow physicians to attend midday meetings they otherwise would not have time to attend. At the UC Davis Cancer Center alone, it is estimated that companies spend $70,000 a year on free lunches. The center will now pick up those costs, and other departments may have to do the same.

At the University of Pennsylvania Health System, the adoption of its policy caused some grumbling at first, along with the loss of some legitimate educational programs that were sponsored. For the most part, however, physicians and other staff members have adjusted, said Dr. Patrick J. Brennan, the chief medical officer of the university health system.

He said there is "much less evidence" of sales representatives around the clinics and school. At one suburban clinic run by the university, sales reps turned in their identification badges in protest; but, he believes, the sales force may have adjusted. He has lately seen an increasing number of medical education programs offered to faculty and staff sponsored by a third party hired by a drug company.

At UC Davis and some of the other institutions, efforts are being made to help low-income patients who previously might have received free drug samples or devices. The university is going to try to purchase some of the equipment that has been donated in the past, such as training inhalers for asthma patients and supplies for diabetes patients, Dr. Albertson noted. ■

POLICY & PRACTICE

ASP Decreases Volume for Some

The switch in 2005 to an average sales price (ASP)–based payment method for drugs administered in physician offices under Medicare Part B resulted in substantial price savings for the federal program, according to a report from the Medicare Payment Advisory Commission (MedPAC). The ASP-based system led to an increase in claims volume and total charges; even so, some specialists provided fewer drugs in their offices in 2005, according to MedPAC. Overall, drug spending for Part B fell from $10.9 billion in 2004 to $10.1 billion in 2005. The commission scrutinized how the switch to ASP affected certain specialists. Urologists cut back the most, giving 16% fewer drugs, leading to a 52% decrease in Medicare spending, mostly for hormones that were prescribed for prostate cancer. Rheumatologists increased the drug volume—mostly for infliximab—by 9%; Medicare's spending on that drug was constant, however, according to the report. Infectious disease specialists gave 21% fewer drugs in 2005, possibly because physicians shifted their patients to hospital outpatient and post–acute care settings, the report said. The change may present some patient access and safety issues, according to MedPAC. But there was no reduction in quality of care in other specialties as a result of the switch to ASP.

Monitoring Drug Acquisition

A new law requires the Centers for Medicare and Medicaid Services to keep a closer eye on the Medicare Part B Competitive Acquisition Program. As part of last year's omnibus tax and health care bill (H.R. 6111), Congress established a postpayment review process for CAP, a program under which physicians are paid for administering certain Part B drugs and biologics but do not take on the financial risk of purchasing the drugs. For 2007, only one vendor, BioScrip, has been chosen to participate in CAP. The review program mandated by Congress will be aimed at ensuring that when Medicare pays for a drug or biologic, it has actually been administered to the beneficiary.

Unique New Drugs on Decline

The Food and Drug Administration approved only 18 new molecular entities last year, which is on par with the previous year but close to a historic low. Throughout the 1980s and 1990s, the agency approved at least 20-30 NMEs annually. Among the 18 were four biologic therapies and four new vaccines. The paltry number of approvals and a Government Accountability Office report issued in December may point to a decline in new drug development, according to Representative Henry Waxman (D-Calif.), and Senators Richard Durbin (D-Ill.) and Edward Kennedy (D-Mass.). The legislators requested the GAO report, which found that huge increases in drug industry research and development from 1993 to 2004 were not accompanied by a similar rise in new drug applications—especially for NMEs—to the FDA. From 1993 to 2004, research and development spending increased 147% while NME applications increased by only 7%. NME applications have declined especially since 1995. "These submission trends indicate that the productivity of research and development investments has declined," the GAO report said. In support of that conclusion: Over the same period, the FDA has continued to approve most submissions, but the number approved overall has declined, the GAO said.

FDA Panels Held Less Often

An advocacy group is charging that the FDA is holding outside advisory panel meetings less often than it did a decade ago. Public Citizen's Health Research Group analyzed the 275 advisory committee meetings held from 1997 to 2006. In 1998 and 1999, almost half of approved new molecular entities were preceded by panel meetings; from 2000 to 2006, only 24% (35) of the 147 NMEs approved had a committee meeting first, according to Public Citizen, which put its conclusions in a letter published in the Dec. 23 issue of the Lancet. The group also found that the FDA did not present its scientific opinion as a counterbalance to the drug maker's presentation at 18%, or 49, of the 275 meetings. The FDA overruled the panel conclusions 28% of the time, "a figure higher than is generally assumed," according to Public Citizen.

Easing Use of Experimental Drugs

The FDA is proposing to widen access to experimental drugs. The agency has been accused by patient advocates and some drug makers of obfuscating the criteria that physicians need to seek to use investigational drugs in their patients. In 2003, an Arlington, Va.–based advocacy group, the Abigail Alliance, sued the FDA to get unfettered access to unapproved therapies. The plaintiffs were backed by a federal appeals court in May 2006, and a rehearing of the case is expected to begin in March. In the meantime, the FDA's proposed rule, which was published on Dec. 14, said that the agency was going to make it easier for physicians to access experimental therapies and for manufacturers to make them available. "FDA hopes this proposal will increase awareness in the health care community of the range of options available for obtaining experimental drugs for seriously ill patients," Dr. Janet Woodcock, FDA deputy commissioner for operations, said in a statement. A separate proposed rule would make it easier for manufacturers to recover costs. In a statement, the Abigail Alliance said that the FDA proposals "merely clarify their existing policies."

—Alicia Ault