

a Relationship in Flux

Pharmaceutical reps and physicians have always had a symbiotic, if cautious, relationship. With production demands on doctors and new ethical guidelines affecting how reps detail drugs, the old face-to-face may be a thing of the past.

BY WILLIAM ATKINSON

UP UNTIL A COUPLE OF DECADES AGO, when life was simpler, pharmaceutical representatives dropped by physicians' offices, chatted a few minutes about new drugs, dropped off some samples, and left. Things have changed. In the past couple of years, time constraints have caused many physicians to reevaluate how (and even if) they see reps. Even greater changes have occurred in areas related to ethics, such as gift-giving and "shadowing," where reps actually sit in during patient consultations. As a result, many physicians are looking for new direction in how to create and manage functional and ethical relationships with reps.

"We believe that, in the vast majority of cases, relationships between sales representatives and doctors are very constructive," says Jeff Trehitt, a spokesperson for the Washington, DC-based Pharmaceutical Research and Manufacturers of America (PhRMA), which represents about 90 pharmaceutical companies.

In addition, the industry can provide value above and beyond educational information from reps. "Pharmaceutical companies fund research, and not all of it is focused specifically on their own drugs," says Munsey Wheby, MD, the president of the American College of Physicians and a professor of medicine at the University of Virginia School of Medicine in Charlottesville. "For example, they fund medical education in certain hospitals through unrestricted gifts."

However, he continues: "The proper relationship between the individual physicians and medical organizations and the pharmaceutical industry has always been a difficult area for physicians." One reason, according to Wheby, is that there is a variety of opinions about what constitutes a "proper" relationship between physicians and the industry in general, and between physicians and reps specifically.

Scott-Levin, a pharmaceutical research firm, reported in 1999 that, while the industry spent less than \$2 billion in direct-to-consumer advertising, it spent more than \$11 billion in direct marketing and promotion activities to physicians, an average of around \$10,000 per physician per year. The same firm also reported that pharmaceutical industry-sponsored events increased from 80,000 in 1993 to 280,000 in 1999, many of them expensive "junkets" for physicians that included cruises and resort vacations.

By 2002, according to the Kaiser Family Foundation,



a non-profit health research organization, direct-to-physician spending had increased to more than \$13 billion, and direct-to-consumer advertising was at \$2.5 billion.

Recently, according to Wheby, the physician-rep relationships are being more closely examined, in large part due to concerns among the public as to whether physicians and the pharmaceutical industry are too close. For example, are physician prescribing prac-

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tices influenced by pharmaceutical's promotional practices? "The primary responsibility of a physician is to serve the patient's best interest," Wheby says. "The primary responsibility of industry is to promote profitability. This doesn't mean industry is evil. However, it does mean that the differing interests can cause some conflicts."

Michael Goldrich, MD, a New Brunswick, New Jersey-based otolaryngologist and the chair of the AMA's Council on Ethical and Judicial Affairs, adds: "The AMA has a long-standing policy on the relationship between physicians and the pharmaceutical industry. The policy emphasizes the ethical obligations of physicians to the patients." Pharmaceutical reps are one avenue for physicians to gain new knowledge about new products on the market, he acknowledges. However, "Once this shifts over to the realm of marketing, which is where problems such as gift-giving and shadowing emerge, then the ethical concerns about compromising the physician's objectivity really stand in the way of new knowledge and can potentially compromise patient care," Goldrich says.

Wheby shares some specifics of how ethics can be compromised: "Detail people can become quite close to physicians. For example, they may develop friendships and have social relationships. This can lead to improper relationships," he says.

Rodney Sorensen, DO, the chair of the neurology department at the Marshfield Clinic in Marshfield, Wisconsin, says, "I have always had an innate mistrust of whether drug

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reps are really in the business of doing things that are the best for patients. Getting objective data to us about medications is valuable, but so much of it is tainted by marketing.” In his experience, too many reps seem to be saying, “Prescribe this medication, because it will be good for me and my company.”

The potential friction and differing goals play out in at least four scenarios: rep visit frequency, the circumstances under which physicians see reps, gift-giving, and shadowing.

Timing of visits

Scott-Levin reported that, in 1999, 62,000 pharmaceutical reps called on physicians, twice as many as just six years earlier. By 2001, this number had increased to 88,000. Verispan, a health-care research firm, reported that the industry employed more than 90,000 reps in 2003. “There is a ‘sales force arms race’ in the pharmaceutical industry,”

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says Briscoe Rodgers, the CEO of Boston-based RepWire (formerly MedMeeting), a rep scheduling firm.

“Companies don’t seem to see any choice other than increasing sales force size in order to maintain market presence and awareness.” However, the explosion has begun to overwhelm physicians, according to Rodgers.

It is causing problems for reps, too. “As the number of reps has increased, productivity levels have plummeted,” says Rodgers. The reason: Physicians are still only seeing the same number of reps they did in the past, or, in many cases, even fewer.

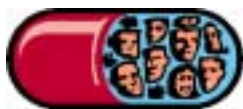
Jeff McGeary, the president of the Philadelphia Area Pharmaceutical Representative Association, says, “Being a drug rep is definitely more challenging these days than it was when I started. For example, I have definitely seen some changes related to stricter access. Physicians tend to run busier schedules these days. They want to keep their hours as full as possible with patients.”

Time is a big issue for physicians, agrees Shannon Ostby, the president of the Metro Detroit Pharmaceutical Representatives Association. “Unfortunately, some reps don’t respect this time,” she admits.

While a rep’s individual approach can be important, some reps have more success seeing physicians than others simply by virtue of what they’re selling. Cambridge, Massachusetts-based Biogen IDEC, for example, is involved in oncology, neurology, and dermatology. “Given that we are in these specialty areas, physicians tend to want to see our reps,” says Irene Hunt, the marketing director for the neurology group. In addition, she says, reps focus exclusively on providing information, services, and other support to physicians and their patients. “Physicians tend to view all of this as value-added.”

Despite the value that reps can provide in terms of education and samples, some reps can “step over the line,” shifting from objective education to questionable marketing practices. “Some detail people can be very aggressive,” says Wheby. “As a result, more and more physicians and hospitals have found it necessary to create rules or guidelines for when and how detail people are seen.”

For example, physicians at Cardiovascular Specialists in Memphis, Tennessee meet with drug reps only on a pre-scheduled basis. “As new drugs are released, there is a need for the physicians to be informed,” says David Jones, the chief operating officer. “However, we have an



✓ *Pharmaceutical industry-sponsored events increased from 80,000 in 1993 to 280,000 in 1999.*

individual who schedules these visits.”

Other facilities have tighter policies. “One of these is Columbus Oncology Associates in Ohio. “Most of the information our physicians need from drug reps can be handled via e-mail or an occasional phone call,” says Ruth Lander, the practice’s administrator. As such, physicians only see reps if they have brand new drugs, and then only for a few minutes at the end of administrative meetings twice a month.

In sum, more reps are jumping through more “hoops” just to get time with physicians. Further, the time the reps have is shorter. Result: Rep effectiveness is suffering. A study by McKinsey and Company found that for every 100 reps who visit physicians’ offices, only 20 get to meet with physicians, and the physicians themselves remember only eight of these encounters.

The price of admittance

Some medical practices have taken limiting rep access one step further—requiring pharmaceutical companies to pay to have their reps meet with physicians. While one result was the opportunity to increase clinic and physician incomes a bit, the main reason was to reduce the number of reps seeking time with physicians. “A few medical practices have tried this—not as a way to make money, but to discourage detail people from visiting,” says Wheby.

One medical practice that experimented with this concept for awhile was Seattle-based Polyclinic, an 80-physician multi-specialty practice. At the time, the group concluded that

In Black and White

The following points represent the position of the American Medical Association on gifts and remuneration to physicians from the pharmaceutical industry:

✓ Gifts should primarily entail a benefit to patients (textbooks, pens and notebooks, stethoscopes, modest meals with an educational purpose) in the general range of \$100.

✓ A legitimate conference or meeting is one which is primarily dedicated to promoting objective scientific and educational activities and discourse. The main incentive for bringing attendees together is to further their knowledge on the topic being presented.

✓ Subsidies to underwrite the costs of CME or professional meetings are permissible. They should be accepted by the conference’s sponsor, however, rather than given to individuals.

✓ In general, travel expenses should not be reimbursed by pharmaceutical companies, nor should honoraria be paid for a visiting physician’s time to attend conferences or meetings, unless the physician is providing genuine services to the company, such as research.

✓ No gifts should be accepted if there are strings attached. For instance, companies may not send top prescribers, purchasers, or referrers on cruises. ■

drug reps were too disruptive to the clinic’s workflow and patient flow. “At first, we tried to limit access,” says Lloyd David, the executive director. “We then had an interim program where we charged drug reps for visits with our physicians.” As of 2003, though, the clinic banned reps altogether. “We don’t even allow them into our building,” David says. He says the change in policy allows staff to focus on patients and removes a lot of interruptions for physicians.

Biogen IDEC’s Hunt is familiar with the concept of reps being charged for their time with physicians. “The physicians explain that it should be no different than charging their patients for time,” she says.

However, the practice has come under fire in the last year or so. The AMA’s Goldrich says, “The council’s view is that this is no different than any other kind of gift or payment to a physician.” The rationale: “Pharmaceutical reps should be providing useful information and knowledge to physicians. If this is true, then physicians should value the opportunity to communicate with reps, and there should be no charge.” However, according to Goldrich, if the physician is charging the rep, the implication is that what is valuable is the physician’s time, not the rep’s information.

RepWire’s Rodgers shares another concern. “Pharmaceutical companies giving money to medical groups is considered a conflict of interest,” he says. “For example, for Medicare and

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Medicaid purposes, the federal government considers it a kickback.”

So how can physicians reduce the number of reps they see without getting into the ethical issues of charging them directly? One option is a third-party service which charges reps to schedule appointments with physicians and clinics that are clients of the third-party firm. Two of the most well-known services are RepConnect and RepWire.

Under RepWire's program, the medical practice faxes RepWire a sign-up sheet, where, for example, the first five reps who sign up each day can get in. The medical practice provides RepWire with instructions on what days are appropriate, when the time slots should be during those days, and how often a specific rep and pharmaceutical company can schedule appointments during a month. The reps can then sign up via the company's Web site. “This not only helps the medical practice, but it is more convenient for the reps, because they have specific times when they are expected,” Rodgers says. “As a result, they don't have to sit in the lobby and wait for an hour or more.” The scheduling service is free to medical practices. Reps that use the service pay a flat fee of \$25 a month.

Oh, you shouldn't have!

While visit scheduling has been troublesome, and charging for visits has been controversial, the practice of giving gifts to physicians has been an explosive issue in the last couple of years. Medical groups and the pharmaceutical industry itself have created new guidelines designed to reign in expenditures some critics have

called extravagant excesses.

The concern, of course, is the potential for gifts to dictate, or at least affect, prescribing practices. For example, the January 19, 2000 issue of *JAMA* reviewed studies addressing interactions between physicians and reps. The consensus was that physician prescribing practices did indeed change based on gifts they received, including meals and entertainment. Examples included prescribing brand names over generics and higher-priced new drugs over acceptable older ones.

In mid-2002, the AMA created guidelines on gifts, which are detailed on its Web site (www.ama-assn.org). The American College of Physicians also has guidelines (www.acponline.org). “Our guidelines state that physicians can accept gifts that are limited to things that involve patient care and also meals or social functions that are part of true educational events,” says Wheby.

PhRMA also has a new comprehensive marketing code developed by member companies and introduced in April 2002. This addresses which gifts are acceptable, which meals are appropriate, and says entertainment is out. According to Trewhitt, “It is very difficult to have a meaningful discussion about a medicine, its side effects, and its characteristics sitting on the third base line at Wrigley Field in Chicago watching the Cubs play the Giants and waiting for Barry Bonds' next home run. As such, we strongly discourage sales representatives from member companies from engaging in entertainment.”

Inexpensive lunches are acceptable.

The code also states that the value of gifts should not exceed \$100. and

the gift should help the medical practice. “For example, a really nice silver serving tray for \$65 is inappropriate,” says Trewhitt. “However, a stethoscope or medical dictionary under \$100 is appropriate.”

More and more pharmaceutical companies are exercising care in gift-giving practices. Biogen IDEC's Hunt reports: “We used to provide folios to physicians. Now, with the new PhRMA guidelines, which specify less than \$100 and medically relevant, we provide the most current textbooks in our areas of specialty. We may also offer gift certificates that physicians can use at medical stores.”

The Marshfield Clinic recently implemented a policy where it no longer allows even the traditional lunch program, where drug reps brought in lunch and conducted marketing programs. “We felt it was sending the wrong image to our patients, who would see reps carrying large bags of food into the clinic,” explains Sorensen. In addition, the clinic no longer accepts any gifts—even pens—that do not have direct patient education value. “For example, we can accept anatomical wall charts that educate patients, but nothing that has direct value to us as physicians,” says Sorensen.

Out of the shadows

For the most part, “shadowing,” which began to proliferate two or three years ago, is now being viewed as ominously as the word itself implies. The pharmaceutical industry prefers the term “preceptorships.” The concept involves reps sitting in on actual consultations between physicians and patients.

“The practice involves sales repre-

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sentatives trying to get to know doctors better and how they practice medicine, so they can better know what doctors need,” explains PhRMA’s Trewhitt. “In the vast majority of cases, they stay in the background and are not invasive. They simply observe the doctors.”

Biogen IDEC’s Hunt adds, “Overall, preceptorships are a very valuable way to understand how physicians operate and interact with patients. For example, we can go into a multiple sclerosis center to see how patient care, physical therapy, and counseling take place in order to provide better support. With current HIPAA guidelines, though, preceptorships can still take place, but they must be in different areas from where the patients are.”

Wheby says, “Shadowing is definitely on the wane, especially as concerns about patient privacy have become more important. However, I don’t see how this practice could have ever gotten started in the first place, even before the privacy rules.”

David Fassler, MD, a member of the governing council of the American Academy of Child and Adolescent Psychiatry (AACAP), adds, “My own opinion is that physicians are better off not doing this. The idea of bringing someone such as a drug rep into the interaction, where there is really no chance of benefit for the patient, seems quite inappropriate.”

What are the concerns? There are at least three. First, having reps sit with physicians can influence what physicians prescribe to the patients. Second, patients are likely to feel too embarrassed or “on the spot” to refuse a physician’s request to have a

rep sit in, even if they do not want the rep to do so. Finally, and of greatest concern, is that if patients do agree, they may end up withholding sensitive or embarrassing medical information from the physician, given the presence of a third party.

Two years ago, when the AACAP began receiving calls from its members about this still-new practice, it began questioning other members. “It became clear to us that this was becoming a widespread practice,” says Fassler. “Dozens of our members had been approached about becoming involved in these programs, and some had even participated.”

As a result of its concerns, the AACAP and the American Psychiatric Association co-sponsored a resolution for discussion at the AMA House of Delegates meeting in 2003. Following, the AMA delivered a policy statement on the practice of shadowing, which says that the AMA opposes “the presence, inclusion, or involvement of pharmaceutical sales representatives in clinical situations without the full knowledge and informed consent of patients.” It did not ban the practice.

For many medical practices, shadowing is not even a consideration. “We are not involved in shadowing,” says Columbus Oncology Associates’ Lander. “One reason is that it violates HIPAA guidelines.”

Cardiovascular Specialists engaged in shadowing in the past, and it had some benefits, according to Jones. “However, we are no longer involved,” he says. “One reason is that we heard about some abuses that took place in other offices, and we just felt it was appropriate to stop doing it here.”

Shadowing also occurred at the Marshfield Clinic. “It didn’t occur very often, and even when it did occur, there was always a lot of nervousness, because we always questioned the value of it,” says Sorensen. “As a result, it is no longer done here at all.” The only exception is when a physician might want a medical supply rep to demonstrate how patients can use specific equipment.

McGeary, of the Philadelphia-area reps association, says, “I have done preceptorships in the past. They gave us a chance to learn more about physicians and their interactions with patients. We are no longer doing them, though. I think we can learn just as much through discussions with physicians during meals.”

The ethical debate over shadowing is not over yet, though. One reason is that, in many cases, money changes hands, with physicians accepting payments from reps for the opportunity to shadow. Fassler is familiar with direct payments to physicians as high as \$500 per day. Because of payment issues and other ethical considerations involved in shadowing, the AMA’s Council on Ethical and Judicial Affairs is continuing to review this practice.

One of Sorensen’s concerns: “If physicians are accepting payments from drug reps for shadowing and also from patients for their consultation services, the physicians are actually selling their services to two different people at the same time. This strikes me as being unacceptable.”

A few observers have suggested that, if shadowing does occur, and if money changes hands, the money should go to the patients. Goldrich says that is an interesting idea.

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“Certainly, if there is an educational benefit to the pharmaceutical representative, as the industry claims, then it is the patient who is being inconvenienced by the presence of a third party.” From an ethical point of view, paying the patient removes concerns about physicians’ objectivity being threatened.

What’s ahead?

In light of all the controversy the last two or three years, where do relationships between physicians and pharmaceutical reps stand? And what will the relationships be like in the years to come? Opinions are mixed.

“I think most of the major concerns have been addressed, and most of the flagrant problems, such as pharmaceutical companies paying for physicians to take trips under the guise of medical education, have been eliminated,” says Wheby.

Goldrich also sees progress, but he still sees problems. “Relationships between pharmaceutical representatives and physicians create ongoing concerns,” he says, adding that these are often cyclical. “Offenses can become more egregious over a period of time, until a medical group, a consumer

group, or the government puts the brakes on it.” Recently, the industry and the AMA have gotten together to try to create coordinated restrictions inside the marketplace. “As such, we are in a period where some of the more egregious cases have fallen into the background. This doesn’t mean that there aren’t proposals by individual companies which are still ‘way out on the margins.’ However, these are much less frequent than they were in the recent past,” says Goldrich.

Others envision more substantive changes in the works. “I think there will be some major changes in the way physicians and pharmaceutical reps interact in the future,” suggests Biogen IDEC’s Hunt. “While rules and regulations have changed, what still needs to change in some cases is for the reps to make sure they focus on providing education and support. Physicians just don’t have time any more for anything else.”

Probably the most significant possibility is that electronic communication (e-detailing) will replace face-to-face communication. According to Rodgers, electronic communication between physicians and drug reps is already increasing. “My view is that it

will gain a lot of popularity in rural areas, where reps don’t want to take the time to drive to many of these remote locations,” he says.

Columbus Oncology Associates’ Lander isn’t so sure about the future of face-to-face of any kind. “My belief is that the concept of reps knocking on the door will disappear,” she says. “There will be Internet portals where virtually all of the communication can take place.”

If and when that comes to be, a whole host of scheduling and ethical issues may arise. A look into the crystal ball may include on-line educational events after which physicians can “click a key,” automatically triggering a gift to be sent to them? Will the pharmaceutical companies “shadow” physicians by placing video cameras in rooms where physicians meet with patients, while a host of pharmaceutical employees to watch and listen via a television screen hundreds of miles away? Will physicians charge fees for these visits? We’ll know in five years—maybe sooner. ■

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