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Politely Refuse the Pen and Note Pad: Gifts From Industry to Physicians Harm Patients

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Introduction

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Drug companies use many methods to bring their products to the attention of physicians. Most of us are familiar with contacts between drug company representatives, formerly called detail men, stemming from the time when, as medical students, we were beneficiaries of the Eli Lilly Company’s largesse: doctor’s bag, stethoscope, hammer, and tuning fork. Since then, most of us have been offered many other small (sometimes big) gifts that are intended to gain our attention. Decades ago, no one saw much of a problem with this practice; rather, most saw it as a harmless, friendly gesture that led to valuable educational exchanges between detail men and physicians. In recent years, however, there has been a crescendo of warnings that such gifts are not harmless but endanger patients by binding us to the giver of the gift through the elemental human response to gifts: reciprocity, the need to give something back to the giver. Some worry that the impulse of reciprocity may lead us to prescribe products that are not quite right for a particular patient or prescribe an expensive drug in place of an effective drug that is much less expensive. Do we unwittingly endanger our patients by accepting gifts?

The Case of the Detailed Surgeon

Dr John DeNile is always happy to see Cindy, a representative of the NovoCefalo Company, in his office. She is an articulate and attractive brunette who visits Dr DeNile once every month or two with information that has recently become available about the various drugs produced by NovoCefalo. She always brings with her ballpoint pens, note pads, Post-it pads, and other small gifts (most bearing the company’s logo), which Dr DeNile finds useful in his office. On this particular visit, Cindy provides Dr DeNile with information about NovoCefalo’s fourth generation cephalosporin, Cefprophylax. The antibiotic is new, but the United States (US) Food and Drug Administration (FDA) has approved it, and among its approved uses is prophylaxis for surgery. Dr DeNile is impressed with the spectrum and the safety of the drug. He has routinely used cefazolin for antibiotic prophylaxis for 48 hours after his open heart operations, in accordance with practice guidelines from the Society of Thoracic Surgeons and the Surgical Infection Society. After listening to the details Cindy has provided, he thinks that it is a good idea to switch to Cefprophylax.

Dr DeNile uses Cefprophylax after every open heart operation, as he did cefazolin. Two months after changing antibiotics, he does an uncomplicated coronary artery bypass on 62-year-old John Luckless. Mr Luckless is doing quite well at his 2-week follow-up visit, but a month later, he reports that for the last several days he has not been urinating as much as he did previously, has noted that his urine is tinged pink, has vomited several times after meals, and has gained nearly 10 pounds.

These symptoms are of great concern to Dr DeNile, and he orders laboratory tests; the blood urea nitrogen is 36 mg/dL and creatinine is 3.2 mg/dL. He consults a nephrologist colleague, who, after an appropriate workup, makes the diagnosis of interstitial nephritis, probably resulting from an allergic response to the antibiotic Mr Luckless received at the time of his operation. The patient’s interstitial nephritis progresses and he is placed on dialysis. He is worked-up as a possible kidney transplant candidate and is placed on the kidney transplant waiting list.

Dr DeNile is sure this is a rare complication of the antibiotic and continues using it. The nephrologist reports the allergic reaction to the company. Eight months later, Dr DeNile receives notification from NovoCefalo and from the FDA that Cefprophylax has been withdrawn from the market because of a high incidence of kidney damage. He immediately switches back to cefazolin, his former routine prophylactic antibiotic.

At Cindy’s next visit, she gives Dr DeNile a small leather-bound date book with NovoCefalo’s logo on the cover and the surgeon’s name engraved below it. She has some very interesting information on the latest generation corticosteroid, which lacks the fluid retention side effect that has been so troubling with other corticosteroids. While she is talking, Dr DeNile wonders whether the article he read recently on the effect of gifts on
physician’s prescribing patterns might apply to him and whether the small gifts Cindy always brings might have affected his decision to use the now withdrawn Cefprophylax. Although he believes the literature showing that even small gifts produce a sense of obligation to reciprocate and that most physicians are influenced by gifts, he is certain that his dedication to his patients’ welfare prevents any such influence on him. He turns his full attention back to Cindy’s recitation of the new steroid’s pharmacologic details.

Pro

Kenneth V. Iserson, MD, MBA

A battle is being waged to win the hearts and minds of the physicians who write 2.2 billion drug prescriptions annually in the United States [1]. Given that virtually all these physicians accept some gifts from pharmaceutical or equipment manufacturers, and the case described demonstrates merely one tragic outcome, what new information might be imparted to change attitudes and behavior toward drug/medical device manufacturers’ sales tactics? Perhaps what might be most useful is to look at the truth behind typical physician responses to such tactics.

The following are common responses physicians give when asked about why they accept gifts, in any form, from drug and medical device companies:

1. **Why do you think that I accept gifts?** And if I do, why do you think that would influence my prescribing habits, which equipment I use, or what I recommend to my hospital or group to buy?

   *Nearly all of you accept gifts.* We know from multiple studies that nearly all physicians accept gifts from the drug detailers whom they meet with an average of four times a month [2, 3]. Many doctors see drug detailers in their offices every day [4]. Those gifts, worth billions of dollars, run the gamut from free pens, pads, and drug samples to high-priced meals, entertainment tickets, trips, and honoraria. In fact, gifts are one of the main reasons physicians meet with drug detailers [5].

   *It does influence you.* These studies also show that physicians believe that company representatives present accurate drug information. And although physicians deny that gifts influence their behavior, those who accept drug samples preferentially and rapidly began prescribing the new drugs—often in lieu of equally effective or less-expensive generic drugs or previously used medications. The studies also showed that interacting with pharmaceutical representatives often led to nonrational prescribing practices [2]. For example, by the time Merck withdrew the antiinflammatory drug Vioxx from the market, more than 100 million prescriptions for Vioxx had been dispensed in the United States, with most written after evidence of cardiovascular risks was known. Internal company documents prove that Merck carefully trained its detailers to mislead doctors about the dangers of Vioxx [4, 6].

   *Even the smallest gifts influence you.* Even the small tokens that physicians receive from pharmaceutical companies may make a large impact. As a prestigious physician group recently wrote in the *Journal of the American Medical Association,*

   Most of the recommendations from medical and industry groups share key assumptions. The first is that small gifts do not significantly influence physician behavior. The second is that disclosure of financial conflicts is sufficient to satisfy the need to protect patients’ interests. Although these two assumptions are widely accepted among physicians, compelling research findings using a variety of methods have called their validity into question. . . . Social science research demonstrates that the impulse to reciprocate for even small gifts is a powerful influence on people’s behavior [7].

   Accepting a gift of any kind forms a relationship, making the recipient indebted to the giver. The strength of this debt varies, but at some level it becomes a bribe when an overgenerous gift is given with “strings attached.” A risk to the surgeon accepting some gifts is that they may meet the definition (in spirit, if not in law) of bribes [8].

   *Receiving industry gifts compromises professionalism and your fiduciary duty to your patients.* Part of the surgeon’s professional role is to manage the patient’s resources for his or her best interest. This so-called fiduciary duty means putting the patient’s interests before personal benefit. Market incentives to surgeons and relationships between them and pharmaceutical companies and medical device manufacturers may compromise this duty. “Conflicts of interest occur when physicians have motives or are in situations for which reasonable observers could conclude that the moral requirements of the physician’s roles are or will be compromised” [7].

   2. **I’m smarter than they are; they can’t fool me.**

   *Devious marketing strategies.* Drug detailing has been a major part of the pharmaceutical industry for more than a century. Although their methods have changed over time, the fact that they continue to spend large sums to promote drugs and devices to the physicians who control access shows that it is working.

   “Devious” may seem like a harsh term to describe the industry’s marketing strategies. Yet, as a result of a federal lawsuit over the marketing of gabapentin, we got a rare glimpse into the real, often deceitful, world of pharmaceutical promotion. The companies involved eventually admitted to violating federal regulations by
promoting the drug for pain, psychiatric conditions, migraines, and other unapproved uses [9].

Their marketing strategy included activities with clear promotional intent (eg, journal advertising, detailing), with mixed promotional intent (eg, speakers bureau lectures, dinner meetings, teleconferences, patient-education, advisory board meetings), and with hidden or unclear intent (sponsored research, sponsored publications, educational grants, funding independent continuing medical education). Their promotion targeted “independent” continuing medical education, “peer-to-peer selling” by physician speakers, industry-funded studies, publications in the medical literature, resident programs, a video case series, and a central nervous system resident course [10].

The company not only published its own articles but also contracted with medical education companies to develop review papers, original articles, and letters to the editor about gabapentin, paying $13,375 to $18,000 per article, including $1000 to the physician or pharmacist author. It also paid honoraria, travel, lodging, and amenities at resorts and luxury hotels for physician participants at its advisory board and consultants meetings. These physicians were selected for writing “favorable articles on the topics outlined” [10]. For unaccredited educational programs, the company reserved the right “to probe the faculty further to definitively establish presentation content and make the appropriate changes and/or recruit an alternate speaker” [10]. With much clearer insight than most physicians, an author of a gabapentin business plan noted, “Medical education drives this market!” [10].

In 2006, drug companies were caught blatantly manipulating the physician community again with “Protein C” for sepsis. Aside from standard marketing, they established ethics panels to set rules for using/rationing very expensive medications, such as this one. They also supplied more than 90% of the funding for supposedly independent panels to develop sepsis treatment guidelines that would include this drug. Subsequent controlled trials found no difference in patient outcomes when the medication was used—other than a near doubling of the bleeding risk. None of this was mentioned in a guideline supplement available after the study results were published [11].

3. Why can’t I spend a few minutes talking with the very pleasant (and pretty/handsome) drug rep? They have to make a living, too.

Ever see an ugly drug rep? “Detailing” is sending attractive company representatives (lobbyists) to meet with physicians in their offices or clinics to discuss (push) their newest drugs. These are individuals who are knowledgeable about the drugs they are selling, about how to best interact with physicians, and who have excellent sales techniques. For example, the course to become a Certified National Pharmaceutical Representative includes the topics getting in to see the physician, preparing for the sales call, finding/gathering information, building a relationship, and enhancing the client (physician)—rep relationship [12].

How intense is drug detailing? It costs a great deal for you to receive the drug companies’ largesse. The industry employs 80,000 to 100,000 drug company detailers, a ratio of 1 salesperson for every 5 office-based physicians and an increase of more than 100% from the approximately 42,000 employed in 1996 [4, 13]. During 2003, drug manufacturers spent $22 billion on direct marketing to doctors in the United States alone [14]. That amounts to about $25,000 per physician per year [4]. Between 1996 and 2004, spending on marketing to doctors increased by 275% [14]. In 2002, the big Pharmaceutical Research and Manufacturers of America (PhRMA) companies spent about $22 billion marketing to physicians and only about $26 billion on research. Of course, they also spent about $3.3 billion marketing directly to consumers.

4. Why shouldn’t I have someone to tell me about the newest drugs and devices? I don’t have the time to read all the journals.

Admittedly, about 150,000 medical journals are now being published worldwide. No one can keep up with this deluge of information. However, there are good alternatives, such as the subscriber-supported, rather than advertiser-supported, Medical Letter and Thoracic Surgery Clinics.

5. Anyway, the reps don’t know whether I prescribe their drugs or not.

Of course, they do! Most physicians don’t realize that each week drug detailers receive detailed lists of every prescription written by every physician they visit [15, 16]. Huge data-mining companies purchase information on the millions of prescriptions that physicians write each month and resell it to pharmaceutical manufacturers, who then distribute the information to their detailers. This information allows pharmaceutical reps to target individual doctors and to adjust their sales pitches until they find the one that works best [17]. A number of states have considered legislation banning this practice, including Arizona, Illinois, Kansas, Maine, Nevada, New York, Massachusetts, Rhode Island, Vermont, Washington, West Virginia, and Texas [18]. In 2007, however, a federal court quashed a New Hampshire law that tried to restrict access to this information [19].

6. Are you claiming that I don’t practice elegant, evidence-based medicine?

Elegant medicine is providing patients with the best result that has the lowest cost, the least discomfort, and the fewest and least-risky interventions. Evidence-based medicine is the integration of the best available clinically relevant research evidence with clinical expertise and patient values [20]. Consider whether any alteration in your prescribing habits or use of medical equipment based on interactions with company salespeople or equipment company representatives in the operating room or other clinical areas is consistent with elegant, evidence-based surgical practice.

7. Don’t indigent patients need drug samples?

This is the most frequent defense physicians give for interacting with industry salespeople. It is best viewed by asking three separate questions:

What drugs are given to physicians as samples? Sample medications given to physicians are the most costly gifts.
that pharmaceutical companies distribute. Although individual trips, medical equipment, grants, and consulting fees are more expensive, they are much less commonly dispensed. Samples are never generic and are seldom for inexpensive therapy [8].

**What happens to these samples?** Although the medical community likes to assert that drug samples are used for patients, either because they are indigent or for the convenience of being able to start the medication immediately, this often is not true. Physicians, their families, and office staff often use these samples. Many samples are stolen and resold [21].

**What does giving these samples accomplish?** Samples prod physicians to prescribe newer, generally more expensive drugs much faster than they would otherwise. They also result in prescribing new drugs, often using it for off-label indications, and using them rather than other, less expensive or generic drugs that may be just as effective. Overall, the cost of these samples (production cost $2 to $3 billion annually) is factored into the drug’s high price, thus harming everyone who must purchase the medication and raising the overall cost of medical treatment. Prescription drug spending is now the fastest rising segment of all health care expenditures. Of the 50 drugs most commonly prescribed to seniors between 1998 and 2003, nearly three-quarters of them increased in price by at least one and one-half times the rate of inflation; more than half increased by at least three times the rate of inflation. In 2004, seniors paid an average of $2322 for their medications [22].

8. Don’t medical journals, medical societies, and fellowship programs need funds from the pharmaceutical and medical device industries to survive? Journal publishers become anguished when anyone suggests that they eliminate drug and medical equipment advertising. In 2003, the pharmaceutical industry spent $448 million on advertising in medical journals, a relatively paltry amount given the $5.3 billion spent on detailing aimed at physicians and the $16.4 billion (market value) on providing free drug samples [3]. (The real value of the sample drugs is estimated as $2 to $3 billion per year [23].)

Consider two things: First, how do most nonindustry magazines survive? They solicit advertisements from industries that sell products to their readers—not to their readers’ clients (patients). In the case of medical journals, this might be the high-priced automobile, electronics, travel, and food/restaurant industries. Second, although a select few medical journals now rely solely on subscriptions (eg, The Medical Letter), the effect of banning pharmaceutical/medical equipment advertising would be to sharply decrease the number of medical journals. With about 150,000 medical journals worldwide, we can afford to eliminate quite a few.

9. Doesn’t the pharmaceutical industry regulate itself? How about government regulations? Aren’t there enough controls on pharmaceutical/equipment marketing to physicians to prevent abuses?

* Aren’t there industry and medical association guidelines? The PhRMA adopted voluntary ethical guidelines in 1990, and slightly revised them in 2002. Those guidelines prohibit gifts worth more than $100. The Advanced Medical Technology Association (Advamed), a manufacturers’ trade group, developed a similar code in 2003 [24]. But industry self-regulation has failed [4].

The American Medical Association’s (AMA) Council on Ethical and Judicial Affairs developed a policy on gifts to physicians from industry in 1990. They conformed to the same standard of allowing gifts only if they “primarily entail a benefit to patients and should not be of substantial value” (less than $100) [25]. Although we focus on the industry, prominent physicians have recognized that “physicians’ behavior is a large part of the problem and industry efforts to date have not resolved the crisis. The standing of the profession, as much as the integrity of the pharmaceutical and medical device industries, is jeopardized by allowing obvious conflicts to continue” [7].

Although current PhRMA, Advamed, and AMA guidelines prohibit most expensive gifts to physicians, three types of more expensive gifts survive: meals, medication and equipment samples, and educational items. Each is engineered to establish a relationship with the physician: meals with their socializing; medication samples with their seeming patient benefit—and not-so-obvious benefits to physicians and staff; and educational items, which represent substantial, useful gifts [8].

**What guidelines does the US government have?** In April 2003, the Office of the Inspector General (OIG) for the US Department of Health and Human Services issued final federal guidelines for physician-pharmaceutical industry relations, including the gray areas that they said had a “significant potential for abuse”: funding for education, research and consulting, as well as gifts and gratuities [26]. The OIG continued to insist that gifts, regardless of value, “potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company” [26]. However, it provided questions that drug companies (and, in turn, physicians) could use to identify dubious arrangements:

Does the arrangement or practice have a potential to interfere with, or skew, clinical decision making? . . . to increase costs to the federal healthcare programs, beneficiaries, or enrollees? . . . to increase the risk of overutilization or inappropriate utilization? . . . Does the arrangement or practice raise patient safety or quality of care concerns? [26].

If the answers were no, the practice could continue [1]. Concerning the practice of “pay-to-detail” arrangements, wherein physicians receive compensation for listening to sales talks or reading marketing materials, the OIG wrote:

Recently, some entities have been compensating physicians for time spent listening to sales representatives market pharmaceutical products. In some cases, these payments are characterized as “consulting” fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing
The history of the relationship between industry and medicine is long and productive. It is marked by many great achievements. Millions of Americans and patients all around the world have benefited greatly from this partnership. The facts are clear. Many more patients have benefited from this partnership than have the pockets of doctors or members of industry. A plethora of examples illustrate just how well this relationship works and how it has helped a large number of patients. Here are a just a few examples of the fruits of a healthy relationship.

- Insulin was discovered by a team of Toronto physicians in May 1921, but mass production was not possible until industry, Eli Lilly and Company, intervened in June 1922. Within 6 months the production problem was solved and large quantities of insulin were produced and sold [27]. Millions of patients were helped.

- The clinical applicability of research in molecular genetics has exploded in the past several years thanks to the camaraderie between academic researchers and venture capitalists. This has produced products such as the hepatitis B vaccine. It was developed by doctors but delivered to thousands by industry. This provides another shining example of the benefits of this relationship [28].

The list is long and impressive.

The interaction between industry and physicians takes place on many different levels, but in general, there are two distinct levels. The first interaction is the most common. It takes place on a small scale but occurs almost daily, in thousands of hospitals all over the United States and throughout the world. It involves one or a few company representatives offering educational sessions to physicians, often while lunch or dinner is provided. Food has a unique way of bringing busy, reclusive physicians—especially young physicians in training—out in the open. Industries as well as hospitals and most medical societies have established strict guidelines to help govern these interactions. In 1990 the American Medical Association developed specific guidelines regarding gifts from industry and these guidelines were endorsed by the Pharmaceutical Manufacturers Association, now called the Pharmaceutical Research and Manufacturers of America [29]. These types of meetings represent minor problems, if any, in the industry-physician relationship.

The second type of interaction occurs mostly at academic centers and involves research projects or studies. These types of interactions can involve large dollar amounts and are more problematic. Once again, strict rules and regulations exist on both sides and help promulgate rules to protect both sides. The specific rules vary for each academic hospital and for each drug company but can be easily viewed at the Web sites of each university or industry. Yet, it has been this latter relationship that has been the focus of great debate and controversy lately. We will focus our discussion on this second type of interaction.

Any relationship between two large, diverse groups that are composed of many different individuals gives rise, unfortunately, to negative events as well as positive. The negative events often gain quick overnight national attention. A complicated issue becomes compressed into a perfunctory 10-second sound bite by the media. Irrational exuberance often follows, sometimes leading to sweeping legal changes. One or two egregious cases that receive national attention can quickly and permanently overshadow the thousands of previous positive stories that go untold.

One example involved a teenage boy who died after participating in a study at the University of Pennsylvania. The boy was injected with genes engineered to make enzymes that the patient genetically lacked. However, he died of multi-organ system failure. One of the study investigators who helped founded the company and thus had a financial interest in the company’s success [30] was involved in the patient’s care. An accusation was levied

to avoid prosecution. The pharmaceutical and medical equipment industries are increasingly targeting physician-customers using electronic media, including Web sites, e-mail, Web-based “surveys,” instant messaging, and personal digital assistant programs.

Given this onslaught, what individual practitioners do matters enormously. We serve as role models for colleagues and trainees, and as examples to our patients. Compromising our values for any reason diminishes our self-worth and our professionalism.

To know what to do, we need only ask ourselves. Are we adequately protecting our patients’ interests?
that his relationship with the company contributed to the boy’s tragic death. This unfortunate death became a high-profile case and received an enormous amount of media attention. However, no evidence was ever offered to support the claim that the physician’s relationship with industry contributed in any way to the teenager’s death. The link or smoking gun to prove this claim was never provided. The accusation and the mere hint of impropriety led to an assumed verdict as it does so often in today’s society. Hence, many academic centers reacted out of the fear of subsequent legal reprisal in their centers and for their physicians. Hysteria, based mainly on legal overtones (and make no mistake, it is the legal ramifications that have led the charge for most of these changes) led to sweeping changes at many institutions.

In 1988, a news report suggested misconduct at a Harvard-affiliated hospital in an industry-supported clinical study. The immediate response from the Harvard administration, as it has to be in today’s legal climate, was to tighten its academic-industry research rules and regulations, even though not all of the facts behind the case had been fully discovered or evaluated [31]. Similarly, the National Institutes of Health (NIH) mandated that their 20,000 employees sell all of their investments in stocks and bonds in any health-related industry [32]. These types of internal changes at many academic institutions illustrate the climate that exists within these centers. Indeed, it serves as the philosophic backdrop for this entire debate and explains why the physician–industry relationship is now so often discussed at scientific medical meetings—it has changed our life and forced us to attend mandatory classes.

This debate, for which no true scientific data exist to support either side, is as much about the promulgation of laws and the protection of academic institutions from lawsuits as it is about the protection of physicians’ morals or patients’ rights. Because no prospective randomized data support either side in this debate, decisions must be based on common sense and experience.

Although I am not privy to our opponent’s article in advance, the supporting literature offered by Kenneth Iserson in his oral debate at the Southern Thoracic Surgical Association meeting in 2006 was all retrospective and subjective. There is no prospective data that industry and greed have led to increased mortality secondary to compromised ethics by physicians or industry members. In fact, the death rate in industry-sponsored research has held constant over the past decade, even though the level of involvement between industry and academia has significantly increased [33]. Thus, the only objective evidence available implies the opposite conclusion.

In an amusing but tragically accurate article that appeared in The Wall Street Journal on February 21, 2006, Thomas P. Stossel equates the witch-hunts of the 16th century to the call by the Journal of the American Medical Association (JAMA) and the NIH to outlaw all industry from their society. Stossel shows the similarities between the hysteria of the two events: lack of logic, absence of data, and subsequent actions out of fear and ignorance. Stossel writes:

The witch hunters of “The Hammer” and of the JAMA paper propose extreme remedies that promise great but practically unattainable rewards. The Hammer recommended torture to elicit confessions from witches and severe punishments following convictions . . . . The JAMA authors want all commercial contributions removed from academic health centers. The JAMA article badly states “that a system review of the medical literature on industry gift[ing] . . . found that an overwhelming majority of industry interactions had negative results on patient care.” Although the sources it cites explicitly say “No study used patient outcome measures” The JAMA article reminds us that industry marketing influences the prescribing habits of physicians . . . but it repeatedly neglects documented evidence that physicians fail to prescribe appropriate drugs according to evidence-based guidelines . . . . The Hammer predicted that eliminating witches would cleanse the world of ills . . . . But witches burned and the problems persisted. The JAMA article says that abolishing the commercial interface in academic health centers will lower the cost of drugs by encouraging prescriptions of cheaper ones. Since physicians not in academic centers write by far the most prescriptions the basis of this hypothetical cost savings is unclear. Even stranger is the idea that companies would sponsor research of no direct benefit to them . . . . They wield the hammer of a new witch hunt. [34]

The facts and data that supported burning witches at the stake are strikingly similar to the facts and data presented on the malevolent effect that industry has on physicians. There exist no data for either, only hysteria.

What does common sense tell us about this issue? How many of us really believe that the daily decisions we make to treat our patients are swayed by the company’s logo on the pen in our pocket? Do we truly believe that the care of our patients is affected or subconsciously altered because a drug company sponsored a lunch that we attended earlier in the day or last week? If we answer no, it is possible that we are completely blind to the unconscious effect the drug companies are having on our free will? However, if we receive a cash bonus each time we place a certain type of cardiac valve or chest wall prosthetic in a patient’s chest are we sure we are not biased toward using that company’s product?

Common sense guides us in our answers to these questions. In my experience, members of industry often supply me with important peer-reviewed scientific articles and educational pamphlets. They are well informed and provide sound educational information to me and my residents and fellows. Regulations and restrictions already in place help monitor our interaction and keep us both honest and ethical. These rules and regulation have been specifically sited earlier in this article and are found in every academic university in the United States (although each center’s rules slightly vary). In addition, each industry has specific guidelines for its employees as well.

There are, however, obvious differences between us. Our main objective during our training (a long road that entails 12 grueling years of education and training after college) is to learn how to best care for the sick. The main objective of members of industry is to make money for...
their companies. This difference uniquely positions us to handle our interaction with members of industry and to ensure it remains responsible and ethical. This is not to imply that members of industry do not want physicians to provide outstanding patient care; we all know that the vast majority of them do—in fact, I have never meet a single one who did not. They know that the optimal way for them to maximize their profits is to provide us with products that help us improve the care of our patients.

What if we decided at the conclusion of this debate that the relationship between industry and physicians just cannot exist? What would health care look like in the third millennium without the industry-physician relationship? Given health care’s current structure and its cost, we are as dependent on industry for research funding and development as they are dependent on us for providing expertise and patients for clinical studies. Do any of us believe that we could fund our research without industry?

Physicians are held in high esteem by the American public. Recently, the USA Today pollsters reported doctors to be the most trusted of all professions by the American public [35]. Scientists were second. Importantly, lawyers, politicians, and newspaper reporters were ranked the lowest on this list. To maintain the public trust, the importance of which cannot be overstated, we must avoid all controversy. The mere hint of impropriety must be prevented. One negative scandal can unwind all the progress derived from 1000 positive examples of industry-physician relations.

A healthy interaction is a critical pathway towards achieving the best medicine, medical equipment, and care that our patients deserve. If we eliminate our contact with our friends and colleagues from industry; that is, if we “refuse the pen and notepad,” the repercussions on future research and development would be severe. Most importantly, the impact on our patients would be profound. Our health care system, which is already financially strapped, is ill positioned now more than ever to avoid all contacts with industry. President Bush recently called for further reduction in the federal funding of cancer research. Industry and physicians need one another to further improve patient care. Thus, a relationship between us is needed on all levels. But further refinements and education of these existing laws and regulations are needed to ensure that the relationship remains appropriate, honest, and open to peer review.

So, “refuse the pen and notepad?” Of course not. We should accept them and be willing to discuss our knowledge with local members of industry. We should be able to learn from them as well as allow them to learn from us. Together, we can share each other’s expertise and strength and together develop better medicines and medical devices for our patients. We should maintain an amicable relationship, but ensure it is appropriate and is carefully regulated by sensible rules that are open and subject to review. Our patients have reaped the benefits of this relationship in the past and they deserve to continue to enjoy the fruits of a healthy physician-industry relationship in the future.

Concluding Remarks

Robert M. Sade, MD

Kenneth Iserson has made his case by producing voluminous evidence that gifts, even small ones, can influence prescription writing, to the detriment of patients. He cites other methods used by pharmaceutical companies to induce physicians to prescribe their products: direct to consumer advertising, Web-based surveys, and personal digital assistant programs, among others. Very little of the evidence he cites, however, is “reliable in the scientific sense,” as Robert Cerfolio points out. Most of the data are observational, gathered from surveys and retrospective examination of databases, without controls or compensation for confounding factors. Some of the evidence comprises extrapolation and inference from anthropologic and sociologic observations and from the psychology literature. The case against gifting has apparently been built as Cerfolio suggests, on circumstantial evidence, but to many observers, the case is nevertheless strong.

Industry, physicians, and patients have benefited from physicians’ interactions with drug and device representatives for decades, as Cerfolio has summarized, and at least some harm has been done, as Iserson has documented. The possibility that the benefit-harm ratio has diminished or perhaps even reversed, producing a net harm, raises important ethical issues. The principle at the core of medical ethics is this: we, as physicians, owe our first allegiance to our patients. There is no question, therefore, that we should do whatever is necessary to protect the interests of our patients. Iserson alerts us to the harm he sees being done to patients and urges us, as individuals, to maintain our professionalism. He stops short, however, of recommending banning drug representative interactions with physicians, as others have. For example, Stanford, Pennsylvania, and Yale Universities, among others, have pioneered a policy of excluding drug representatives entirely from their academic medical center campuses [36]. The extent to which this policy has protected patients has yet to be demonstrated.

We might consider following their example, but before we go beyond Iserson’s hortatory conclusion and take more severe measures, we must recognize that the evidence impelling us in that direction is not strong in any
scientific sense. In science, we have a generally accepted standard of validity: the probability that a proposition is true is less than 5%, or $p < 0.05$. In the law, decisions are made under several standards of evidence, depending on the nature of the charge: preponderance, clear and convincing, and beyond reasonable doubt. The preponderance of evidence on the effects on physicians of gifts from industry favors harm over benefit, in my view, but the truth of this conclusion is far from beyond a reasonable doubt.

There will be a wide spectrum of views on whether the evidence is clear and convincing. It seems simple enough merely to do as Iserson suggests: maintain sensitivity to potential ill effects of gifts and do not compromise professional values. Others have suggested far more draconian responses to the information we have on the effects of gifts from industry on physicians, as I have noted. An important question arising from the exchange between Iserson and Cerfolio is this: How strong must be the evidence of harm to patients before we should be willing to undertake such drastic measures as locking drug and device representatives out of our teaching hospitals?

References

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