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The Devil Is in the Details: The Pharmaceutical Industry's Use of Gifts to Physicians as Marketing Strategy

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Marketing costs exceed 30% of revenues for the pharmaceutical industry, with over 90% of the effort aimed at physicians. Although there are currently unprecedented numbers of regulatory activities focusing on relationships between the pharmaceutical industry and the medical profession, such legislation is often unrecognized or flouted. The potential influence, although minimized by both parties, must not be ignored. Physicians and drug companies will need to re-evaluate their responsibilities to their patients and their shareholders, and both groups should assume proactive and guidance roles in the transformation.

INTRODUCTION

What did you have for lunch today, or breakfast? Check your pocket for pens, and those notepads you scribble on during conference calls. Chances are that some, maybe all, are courtesy of a pharmaceutical or surgical equipment representative. Are those pens, pads, doughnuts, or pizza capable of influencing your decision-making? How about free seats at a sporting or theatrical event? Can those free antibiotics you distribute to your poor or noncompliant patients, and maybe take home yourself, influence your prescribing habits? The answer is probably yes for most of us, despite our convictions otherwise.

Nearly half of Americans over 45 years old and three-quarters of senior citizens require prescription medications [1]. Prescription drugs are the largest out-of-pocket expense for the elderly, with almost 10 million seniors claiming that their medication expenses compromise their other basic needs of life [2]. Over 154 billion dollars were spent domestically in 2001 on prescribed drugs, with yearly increases far exceeding the annual rates of inflation [3]. Consequently, the pharmaceutical industry amassed 400 billion dollars in revenue in 2002, making it the most profitable industry in the United States in terms of return on revenues, return on assets, and return on equity [4].

Patients have historically depended on their physicians for advice, administration, and prescribing of medications, but are now relying also on the Internet and direct marketing by the pharmaceutical industry. For doctors, requisite information about pharmaceuticals originates from many sources, as the physician must remain current about the new or revised drugs that enter the market every year, in addition to the over 11,000 Food and Drug Administration (FDA)-approved drugs already on the market. According to the FDA, up to 76% of "new" drugs represent modest changes in existing drugs, despite 2-fold increases in price [1]. Prior to FDA approval, the average drug has been tested on an average of 3000 patients, with an overall cost to the company per drug estimated at between 223 and 800 million dollars [5]. Nevertheless, the importance of accurate pharmaceutical information is essential, as an estimated 98,000 hospitalized patients die from adverse events annually, with most attributed to medication errors [4].

Marketing costs exceed 30% of revenues for the pharmaceutical industry [2], with over 90% of the effort aimed at physicians [6]. Favored marketing techniques include continuing medical education (CME) and direct contact with physicians. Pharmaceutical company representatives (PCR), also known as drug detailers or detailers for short, distribute much pharmaceutical in-

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formation to physicians. Approximately 90,000 detailers (or one per every five office-based physicians in the U.S.) are currently used, whose job is to meet with physicians individually and promote their products [2]. Described as "missionary sellers" by standard marketing textbooks [7], these detailers perform an estimated 60 million visits annually [8]. Recent estimates are that $4.7 billion are spent per annum in traditional detailing, with $2.8 billion spent in traditional consumer marketing, and $2 billion expended toward educational (CME) events [9]. In 2000, 314,000 events were sponsored that were specifically aimed at physicians [6]. An estimated 40% of detailer visits end without direct contact with a physician, making detail calls extremely time and revenue expensive [7].

The pharmaceutical industry also spends an estimated 12–15 billion dollars annually on gifts and payments to physicians, or an astonishing $10–15,000 per physician per year [2, 10]. This effort is the source of much confusion, exploitation, and recent public and professional outcry and will be the principal topic for the remainder of this discussion.

GIFTS

Gifts from the PCR can be as innocuous as pens, note pads, medication samples, and fast food, or as substantial as travel, cash honoraria, and research support. Egregious, and recent noteworthy, examples include trips to lap-dancing clubs and cash awards for active prescribers of target drugs [11]. Irrespective of the content, gifting is ubiquitous. A 2001 survey from the Kaiser Foundation noted that 92% of physicians had received free drug samples, 61% had received meals, free access to entertainment, sporting events or travel, and nearly one in seven had received financial benefits [12].

Social science research continues to show that the impulse to reciprocate from even a token gift can be a powerful influence on behavior, thereby producing a possible conflict of interest for the recipient (physician) [1, 5]. This conflict of interest exists when there is an inconsistency between an ethical or professional interest and self-financial concern. This becomes evident when pharmaceutical companies persuade physicians to write prescriptions, an act not only with financial and health sequelae for the patient, but with possible financial consequences for the physician [1]. A classic study has shown that most physicians (61%) believe that they are not influenced by detailers' gifts; however, they believe the same is true for only 16% of their colleagues [13]. Medical students acknowledge gifts as more difficult ethically for professions other than their own [1]. Such findings echo social science research, demonstrating that, although bias is identifiable, it tends to be preferentially attributed to others [1, 5].

Nevertheless, there is strong evidence that bias behaviors exist. Physicians are more likely to prescribe a drug if they had recently attended a sponsored event by the manufacturer [14]; they are more likely to prescribe a drug that is not clinically indicated [15] and have a drug placed on a hospital formulary [10]. In academia, an article whose outcome is favorable to the sponsoring company's drug is four times more likely to be published than an unfavorable study [16]. Physicians who are given free samples to distribute to needy patients are far more likely to write subsequent prescriptions for that drug [17]. A newsworthy illegal exploitation of drug samples includes the famous "Lupron" case of 1997, whereby free samples of this expensive prostate cancer drug were administered to patients and subsequently billed to Medicare, an arbitrage of sorts that netted the urologists a healthy profit, and subsequent heavy fines and prison sentences [18]. Despite all of this evidence to the contrary, most doctors do not believe that they are biased, and recent large physician surveys have shown a disturbingly permissive attitude toward pharmaceutical gifts [19].

RESPONSES

Thus far, we have established the magnitude and importance of the pharmaceutical industry and its resources and direct-marketing efforts toward physicians. This effort includes billions of dollars spent in gifts—tangible and intangible. We have also identified the influence that gifts have on physician decision-making, the consequences of that decision-making, and a cognitive dissonance of the potential bias exhibited by most physicians. Despite this apparent lack of concern, there have been responses mounted on both sides of the issue.

MEDICAL STUDENTS

Medical students, the most junior of the health care professionals to be discussed, are prime targets for detailers. Although unable to prescribe drugs legally, they are young, impressionable, loyal, financially stressed, and under the supervision of senior physicians. In fact, 93% of medical students surveyed had attended at least one drug-sponsored event at the instruction of a medical school faculty member [8]. Another study found that 56% of medical students had three or more professional conversations with pharmaceutical representatives during medical school [20]. As with physicians, medical students also perceived their own bias to be much less than their fellow medical students, despite the reporting of an average of one gift (often a free meal) per week, and that many (80%) felt "entitled" to such gifts [8].

Wake Forest University recently reported their experience with a single workshop intervention whereby both school faculty and a detailer educated medical students about industry interactions. Issues discussed

were typical detailer–physician interactions, the uses of samples and gifts, the scientific validity and legal restrictions of PCR information, and ethical issues [20]. A posttest revealed that students acknowledged the PCR's educational value as well as the possible impact on prescribing. The authors recommend similar educational endeavors be uniformly applied.

A formal response has been organized by the American Medical Student Association (AMSA), which represents over 30,000 students, interns, and residents in the United States. The AMSA has organized PharmFree, a initiative to end gift-giving, free lunches, sponsored education, and honoraria for public speaking [21]. This national organization was motivated by smaller groups such as the New York entity "No Free Lunch" that champions the motto "Just say no to drug reps," as well as an Australian assembly called Healthy Skepticism, which also implores doctors to avoid industry-sponsored education, information, and gifts. These international campaigns are signals that a deep-seated redescription of the affiliation between physicians and pharmaceutical companies is imminent [10]. PharmFree goes as far as to urge medical students to sign a pledge and has offered a revised Hippocratic oath, that includes such pledges as "I will make medical decisions . . . free from the influence of advertising or promotion . . . money, gifts, or hospitality that will create a conflict of interest in my education, practice, teaching, or research" [21].

RESIDENTS

Nearly 100,000 residents work in the teaching hospitals of this country at any given time and are one of the most highly educated, overworked, and inadequately compensated professional groups in the work force. Resident physicians are frequently the targets for PCRs, who may exploit their needs for free food, educational materials, and even social events for the ability to discuss or advocate their products. Many residents divulge that the PCRs are considered reliable sources of medication information [21]; only 10% in one survey admitted to having sufficient training in dealing with the detailers [22], despite receiving an average of six gifts per year [2]. "Dancing with porcupines" is how one author describes the tenuous relationship between detailers and house staff [23], and such notable institutions as the University of California, San Francisco and the University of Pennsylvania have recently eliminated free lunches and sponsored educational conferences from pharmaceutical companies [24].

The internal medicine residency of the University of Chicago has just completed a longitudinal study of resident exposure and perceptions of PCRs over a 3-year period [25]. Surprisingly, residents were likely to perceive small gifts (lunch, pens, etc.) as *increasingly* appropriate as they progressed through residency, but larger gifts—rounds of golf, travel—were increasingly perceived as inappropriate. As with Wofford's study with medical students [20], an intervention led to modest changes in perception and behavior.

PRACTITIONERS

Physicians and drug companies are reasonable colleagues in health care but each must realize their respective motivations. The physician's primary goal is to improve the welfare of the patient, whereas that of industry is to maximize shareholder profit [26]. It takes "two to entangle"; however, and practicing physicians are equally complicit [27]. Gift giving and acceptance is considered endemic, and the willingness to receive gifts of high value is proportional to sympathy for the practice [28]. Brett *et al.* recently used an 18-scenario questionnaire to demonstrate that physicians have a lenient view on the ethical propriety of gifts and activities extended to them by detailers. In this study, practicing physicians were found to be less tolerant than residents. The authors believe that this difference is presumably a result of both age-related cynicism and improved socioeconomic status [19]. Similar results were described by Watson *et al.* in another anonymous survey of attitudes about conflict of interest with the pharmaceutical industry, although both groups—medical residents and the medical school faculty—wanted full disclosure of gifts and sponsorship, especially for CME events [29].

Within this rampant indifference is found some of the most highly educated professionals in the world, with arguably some of the most vulnerable clients (patients), who continue to ignore the probabilities that their judgments and decisions may be biased. Over 20 years ago, Rawlings, commenting on detailer gifts, stated, "No big company gives away its shareholders' money in an act of disinterested generosity" [30]. Although it may be challenging to dissect scientific fact from marketing "spin," doctors should not be wined, dined, or entertained to facilitate their medical decisions [4, 15].

PHARMACEUTICAL INDUSTRY

The pharmaceutical industry's stance is that it is not a nonprofit entity and should not be vilified for its capitalistic basis. The industry manufactures products that benefit human health and longevity, but foremost is designed to expand and maximize shareholder equity. Direct marketing to physicians and physicians in training, a multibillion dollar investment, is used precisely *because it is successful*, as described previously in this report. Pharmaceutical companies, such as Novartis, which spends 36% of its revenues on marketing [2], explain this impetus on several factors. First, al-

most 70% of drugs that are developed fail to recoup the 223–800 million dollar cost of development [5]. Second, the brief time available to attain profit margins needed for shareholder investment requires rapid dissemination of information directly to physicians. Third is the provision of free drug samples to patients, many of whom may not be able to afford nor be inclined to fill a prescription. Compliance is improved, especially for low-income families [10]. This altruism however is counterbalanced by the knowledge that physicians who are given free samples to distribute are more likely to prescribe the drug [17]. Fourth, educational gifts to physicians, such as textbooks and even conference attendance, can improve patient outcomes by broadening the knowledge base of their caregivers. Again, as discussed, the ethical slippery slope of receiving gifts, which historically are a means of initiating and sustaining relationships, is well-documented [28].

The growing negative response to direct physician marketing has also been met with counter-strategies by the pharmaceutical industry. First, E-detailing, or online drug promotion, is increasing and accepted by 65% of online physicians. Incentives are a driver for these as well, as 85% of online doctors favor "compensation" to increase their time using e-detailing [9]. Second, direct-to-consumer or -patient marketing has increased over 7-fold since the FDA relaxed its regulations in 1997 [4]. An estimated 60 million people have sought medical advice and treatment for medical conditions they may have never discussed or recognized prior to seeing the advertisements. Of this 60 million, 25 million were reportedly speaking to a doctor for the first time [31]. Editing or review by the FDA is not required for this advertising, nor does the FDA have authority to fine companies for inaccurate or misleading information, despite 564 warning letters being sent since 1997 [4]. Indeed, direct-to-consumer marketing may even be empowering normal patients to discuss "diseases" like erectile dysfunction, premenstrual dysphoric disorder, and relationship disorders to sell medications [4, 31].

Customer Relationship Management, or CRM, is another strategy being applied to physician marketing. Highly refined and comprehensive information about a doctor's prescribing patterns can be longitudinally tracked. Physicians can be identified as "high-value target," whether their patients are compliant, and which strategy worked [32]. Interactive marketing to physicians will combine direct mail, physician-to-physician marketing, on-line exposures, and sample distribution in individual or "customerization" models to maximize return [32].

The drug industry also has the one of the most robust lobbies in Washington, with an annual combined budget exceeding 200 million dollars [4]. Senator David Pryor (D-Ark.) commented that he believed that "the drug industry is more feared than respected by congress" [3]. Many former staffers and top aides now lobby for Pharmaceutical Research and Manufacturers Association (PhRMA) and individual companies. Such efforts attempt to squelch the industry's "gouging" reputation, but are belied by such information as the average doubling of prices in the U.S. *versus* Europe, identical medicines used in veterinarian and physician practices with 100-fold price differences, and research and development budgets that are usually exceeded by marketing budgets [3].

GOVERNMENT

The aforementioned "Lupron case" stimulated an outbreak of self-regulatory activity evident by 2003, as its settlement identified real and potential anti-kickback law violations. In 2002, the Office of the Inspector General offered a draft document "Compliance Program Guidance for Pharmaceutical Manufacturers" that underwent major revisions by both industry and organized medicine before completion in May 2003 [33, 34]. This exhaustive 13-page document delineates the requirements for an effective compliance program, the guidelines, and compliance program elements [34]. More importantly, the industry practices that could incite prosecution under frauds-and-abuse laws are codified [18]. Other organizations followed suit and also set policy, included the venerable AMA, the American College of Physicians, and the central CME governing body, the Accreditation Council for Continuing Education. Interestingly, some of the most stringent policy is by the industry itself, via its PhRMA lobbying group [18]. Despite such policy and law, this risky behavior still exists and is commonplace, and continued calls for complete severance of industry–professional relationships are present [35].

Thus, there are at least two aspects to the bond between industry and medicine, and many benefits are shared. However, conflicting goals are also present, primarily the maximization of patient welfare *versus* the maximization of shareholder value. This permeation of commercial values into medicine "clearly threatens the basic goals of medical practice and research" [26].

CONCLUSIONS

There are currently unprecedented numbers of regulatory activities focusing on relationships between the pharmaceutical industry and the medical profession. Other than for federal and state employees, however, such legislation is either unrecognized or flouted. The available policies have not had a measurable negative impact on the frequency of modest gifts from PCRs to physicians, and it is unlikely that such activity will ever stop. Their potential influence, although minimized by both parties, must not be ignored [27]. Phy-

TABLE 1

Suggested Strategies for Physician and Detailer Interactions

1) Yearly workshops for new or incoming residents, involving representatives from both the faculty and the pharmaceutical industry.
2) All gifts from detailers should have educational, training, or program support linkage (i.e., no theater or sporting tickets etc.)
3) Patients should be asked to sign a disclaimer stating that they are aware they are receiving free samples from a pharmaceutical company and have been offered an alternative.
4) When possible, physicians should meet with detailers at "drug fairs" where there are multiple vendors present to provide information.
5) Detailers should be able to produce peer-reviewed research supporting their product on physician request.

sicians and drug companies will need to reevaluate their responsibilities to their patients and their shareholders, and both groups should assume proactive and guidance roles in the transformation. A suggested list of strategies is listed in Table 1.

Finally, a possible analogy to physician/PCR behavior is contained in an anecdote attributed to George Bernard Shaw [27]. Shaw was spoken to in a flirtatious manner by an actress at a social event, and after a while inquired if she would spend the night with him for 50,000 pounds. She responded yes, but when he asked if she would do so for 10 pounds, became indignant, asking if he had mistaken her for a prostitute. "We have already established that, my dear," replied Shaw, "we are now merely haggling over price."

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