An Ethical Perspective on the Marketing of Pharmaceuticals to Physicians

By: Jeff Erman

Tremendous concern has developed in recent years regarding the marketing practices of the pharmaceutical industry. In particular, the interactions between pharmaceutical companies and physicians have been recognized as an area generating conflicts of interest. Professional judgment could be influenced by personal gain resulting from relationships with the pharmaceutical industry. Inappropriate marketing practices by pharmaceutical manufacturers designed to influence physician prescribing can jeopardize patient care, promote the misuse of drugs, increase costs to the healthcare system and distort public opinion of the healthcare industry. These are conflicts of interest that may jeopardize the fidelity the public has invested in the healthcare industry.

Importantly, pharmacists may not be sheltered from these inappropriate marketing practices. As pharmacists continue to make strides into the clinical realm of practice they become open to marketing from the pharmaceutical companies. It is important to recognize and understand the acceptable and unacceptable marketing practices from both an ethical and legal perspective to avoid entering into arrangements that can result in legal actions or at the very least, a compromise of ethical principles. Pharmacists must also understand these outside influences on prescribers when evaluating drug therapy regimens and the appropriateness of prescribing habits.

Throughout history, the public has held healthcare practitioners to a high standard of ethical behavior. Practitioners are endowed with a certain level of trust so that they may inform and educate the public. Professional training inherently comes with a greater degree of ethical responsibility. The pharmaceutical industry is a part of the corporate culture whose primary focus is on profitability. Many times these corporations will practice unethical behaviors sometimes bordering on illegal. Any unethical behavior that a representative of the healthcare community engages in with corporate culture can have lasting damage on the healthcare community at large. Normative principles of justice and fidelity demand that healthcare practitioners remain free from outside influence with regards to decisions about patient care.

The pharmaceutical industry spends about $12 billion every year on gifts and payments to physicians. The goal of spending all this money is to get physicians to write more prescriptions for a particular company’s product. This money can be spent on educational programs, small gifts or meals for the physician. Many times this money ends up being spent for less valid reasons resulting in personal gain derived from the physician’s relationships with the pharmaceutical companies. Monetary kickbacks and expensive gifts or trips are not uncommon benefits a doctor may receive from pharmaceutical sales representatives. Every pharmaceutical company wants to leave a lasting impression on the prescribers mind.

In 2001, a Henry J. Kaiser Family Foundation random survey of physicians found that 92 percent of physicians received free drug samples from pharmaceutical companies; 61 percent received free meals, tickets for entertainment or free travel; 13 percent received "financial or other in-kind benefits"; and 12 percent received
financial incentives to participate in clinical trials. Attitudes of physicians are generally that they are free from influence by these marketing practices. Many studies have indicated otherwise. A study of sampling in a resident practice found that when samples were given and accompanied with a written prescription, the prescription matched the sample 100 percent of the time.

Practitioners must resist the temptations of greed and realize that entering into intimate relationships with large pharmaceutical companies and allowing them to influence decision-making is damaging to the medical community. This damage can make it difficult to maintain public trust and further, make it difficult to provide patient care. If the public begins to wonder if every doctor is making decisions on their healthcare with ulterior motives, they are less likely to listen to that physician. Even when a health care worker has no other interests at stake, patients may begin to wonder if they can trust anything from the healthcare community. If the fidelity of the healthcare community is damaged it will be extremely difficult to repair.

The entire healthcare community can continue to be further damaged eventually beyond a state of repair if actions are not taken by every professional organization with interest in healthcare to condemn the corporate practices being used to promote drugs. When dealing with corporate America, one must remember it often lacks ethical restraints. Many times its sole purpose is financial gain and it will engage in situations that may create conflicts of interest. The healthcare community must stand up to the enticing practices brought forth by the drug companies, publicly denouncing drug company practices that are deemed unethical. Licensing bodies should sanction practitioners who repeatedly engage in unethical behavior through relationships with drug companies. It is in the best interest of the healthcare industry to distance itself from corporate marketing practices. The public must be ensured that the healthcare community is indeed above petty influence and does truly have the public’s health as its’ top priority. The fidelity of the healthcare industry is at risk and must be preserved to avoid dire consequences for medical care in the future.

Many physicians feel their interactions with pharmaceutical manufacturers and their representatives are not inappropriate and actually beneficial. Physicians feel their interactions are educational, keeping themselves informed about new therapeutic agents. However, it has been shown in social studies that gifts create a sense of indebtedness and this creates feeling of obligation of the receiver to the giver. This indebtedness and feeling of obligation, even if unconscious and trivial can influence behavior. Pharmaceutical representatives do provide a lot of information about new products but most of this information is heavily biased in the products favor.

The important issue with this type of marketing is the increase in costs. As each company attempts to outdo the previous one, costs continue to increase. These costs are then added into marketing budgets of the pharmaceutical companies. These costs ultimately appear in the prices of the drugs increasing healthcare costs for everyone. Another problem which adds to increasing costs is that pharmaceutical companies usually focus their marketing efforts on their "latest" and "greatest". These medications tend to be more expensive than the existing drugs which may be more effective. Indeed, increased exposure of primary care physicians to drug representatives has been associated with higher prescribing costs. These increased costs become a burden on the already taxed United States healthcare system.
It is evident that the marketing of the pharmaceutical industry is having an impact over prescribing patterns. The pharmaceutical companies know it works or they would not engage in this extra expense. The ethical implications are damaging both to the healthcare industry and to the pharmaceutical industry. Both the healthcare and pharmaceutical industry provide a tremendous benefit to the public. Their products and services provide better health outcomes and improve quality of lives. When the public perception changes due to unethical practices this is forgotten. Eventually the public demands action against these practices in the form of litigation. An increase in scrutiny and litigation further increases the costs for the healthcare industry and continues to damage its ability to provide a service.

The pharmaceutical industry begins to establish relationships early in a physician’s career. Pharmaceutical representatives have direct interaction with both residents and medical students. The industry often provides small gifts and sponsors meals, conferences and educational meetings. The influence is started early in an attempt to influence prescribing patterns. The industry is clearly trying to establish a foothold in the prescribing of these young physicians who may be in a more influential stage of their career. Medical residents, who are overwhelmed with the rigors of medical training, are being influenced with drug companies’ biased educational and marketing campaigns. Early on, conflicts of interest are already developing. The gifts and sponsorships may be exciting to new physicians but these gifts may develop a sense of indebtedness to the companies providing them. At the very least, the representatives are placing their medication at the forefront of these young physicians’ minds. Often this marketing translates into a false belief that a particular medication is first line treatment for a disease when, in fact, it is not.

The American Society of Health-System Pharmacists conducted a survey regarding pharmacist’s opinions of the pharmaceutical industry. In this survey, more than 60% of respondents agreed or strongly agreed that pharmaceutical sales representatives provided gifts that had no relationship to patient care. It is clear that many pharmacists understand the influence the industry holds over physician prescribing. This is important to pharmacists for two reasons. First, pharmacists are assigned the task of evaluating physician prescriptions for appropriateness. Understanding the outside influences can give pharmacists further understanding of how they must approach the evaluations. It is important for the pharmacist to go beyond just making sure the drug is safe and effective. They must make sure it is indicated, cost effective and appropriate. Second, pharmacists must be careful not to fall into the position physicians find themselves in now. If pharmacists are to evaluate drug therapies effectively, it must be done objectively. Allowing outside influence from marketing campaigns and petty gifts to influence their practice will jeopardize the profession’s progress. Pharmacists have an opportunity to learn a lesson to avoid conflicts of interest when dealing with the product we have been trusted to dispense in an unbiased manner.

There is a fine line that must be drawn between what is acceptable and what is excessive gain or influential marketing. A healthcare worker’s time is limited, especially with increasing demands for meticulous documentation. Therefore, a physician is likely to be unwilling to give time to a pharmaceutical sales representative simply to hear about a new product that may or may not be an advantageous addition to a physician’s medication arsenal. For example, it could be reasonable to allow educational events to provide a practitioner with some comforts such as dinner. What kind and how much influence the pharmaceutical companies can provide through these types of interactions are at question. Several
organizations have made an attempt at defining the line between harmless expenses on educational activities and excessive expense to influence prescribing habits.

The practice of providing gifts or rewards to physicians for ordering a company’s product or services has been the main focus of attention. Legally, the Anti-Kickback Statute and False Claims Act have been used by the government to protect Medicare and Medicaid programs from excessive and inappropriate expenditures.\(^1\) The Anti-Kickback Statute was passed in 1972 and makes it illegal to give, accept or offer “remuneration” for ordering of products or services from a particular supplier.\(^1\) “The False Claims Act imposes civil liability on people or entities who knowingly submit a fraudulent claim for payment to the federal government.”\(^1\) Legally these two acts have been linked by prosecutors in an attempt to claim that billing Medicare or Medicaid for a service or product obtained as part of a kickback agreement constitutes a false claim under the False Claim Act.\(^1\) Here it is clear that legal action is stepping in where ethical codes have failed.

The Office of the Inspector General has issued statements regarding acceptable practices involving the relationships between healthcare professionals and the pharmaceutical industry. The Office of Inspector General has stated that “any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer’s product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals”.\(^8\) It further states that, under the Anti-kickback Statute, even a seemingly legitimate arrangement such as physician education is not protected if the arrangement is for the purposeful inducement of business.\(^8\) This applies to abuses in federal healthcare programs and is designed to protect the federal government from unnecessary healthcare expenditures. The government, as Medicare becomes an increasing payer in drug expenditures, will continue to take actions against increases in these federal healthcare expenditures.\(^1\)

The American Medical Association guidelines for ethics with regards to gifts to physicians from industry makes statements regarding what is acceptable and unacceptable.\(^9\) Specifically, they state gifts should be minimal and related to patient care or physicians work (i.e. pens, notepads) and that “no gifts should be accepted if there are strings attached”.\(^9\) The guidelines further make statements as to what constitutes legitimate educational activities or meetings. They state that subsidies should not be accepted directly or indirectly from industry to pay for travel, lodging or entertainment. The attempt to eliminate conflicts of interest from physicians practice and association with the pharmaceutical company is clear.

Critics have branded the American Medical Association guidelines as “general and vague”.\(^3\) In reviewing the guidelines it is apparent that many of them are left open to interpretation. The potential for abuses are still present and conflicts of interest are still present especially in the area of educational events. For example, pharmaceutical manufacturers are still permitted to sponsor Continuing Medical Education events and it is stated “appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses.”\(^9\) Defining the terms reasonable and minimal is difficult. They are subjective terms that must be defined by current standards. Due to the overwhelming support of the pharmaceutical industry for physician education it may also be impractical to limit physician and pharmaceutical industry interaction extensively.\(^2,3\)

The Pharmaceutical Research and Manufacturers of America have issued a code to follow to avoid unethical practices and possible legal actions. The preamble
states “The Code is based on the principle that a healthcare professional’s care of patients should be based, and should be perceived as being based, solely on each patient’s medical needs and the healthcare professional’s medical knowledge and experience.”

The code has been written as an attempt to protect its’ membership from liability and legal action and deals with appropriate marketing techniques and interactions between healthcare professionals and the pharmaceutical industry. Here it is clear that the Pharmaceutical Research and Manufacturers of America are attempting to define ethical practices in its’ marketing practices. The code outlines practices and defends certain practices as necessary, beneficial and ethical. By doing so the Pharmaceutical Research and Manufacturer’s have outline what they believe will avoid conflicts of interest in marketing its’ products to physicians.

The incredible power and influence of the pharmaceutical industry cannot be ignored. Pharmaceutical companies have had available to them physician-prescribing data which they can purchase from various information companies. These information companies compile data on physicians from pharmacies and the American Medical Associations masterfile. This information has been used in the past by sales representatives to target physicians for increased sales pressure. In response to this, physician complaints have spurred the American Medical Association to create a Prescribing Data Restriction Program. This program allows physicians to deny all sales representatives access to their individual prescribing data but this will only apply to sales representatives and their immediate supervisors. Several states are considering legislation which would create tougher restrictions on prescribing data. This purchasing of physician prescribing data may be construed as an invasion of privacy. At the very least it leaves physicians vulnerable to targeted marketing from pharmaceutical representatives.

The conflict of interest occurs between the AMA revenue, which is substantial, from the sale of information found in the masterfile database, and the AMA’s duty to protect and respect the privacy of its membership. The AMA received $44.5 million in revenue in 2005 from sales related to its database but it is unclear how much of this was related to prescribing data. The AMA has stated that restrictions may lead to reductions in the number of offers physicians receive from the pharmaceutical companies, including drug samples, CME programs and speaking engagements. How this will end up in years to come is unclear but sales of physicians prescribing data allows the pharmaceutical companies to place undue pressure on physicians to prescribe their products. This practice denies the physician autonomy and freedom from scrutiny of prescribing practices by marketing and sales forces. The power of the pharmaceutical companies is also illustrated here. Even an agency supposedly with physicians’ best interest in mind is influenced by the financial power of the pharmaceutical companies.

Direct relationships are not the only way in which pharmaceutical marketing influence reaches physicians. The pharmaceutical industry also funds greater than half of the costs for continuing medical education (CME). They are responsible for providing more than 70 percent of the funding for clinical trials. Many have highlighted the incredible impact medical journals have had as marketing tools for the pharmaceutical industry. These two areas provide a great potential for influence over prescribing habits.

Through advertising within medical journals, pharmaceutical companies are attempting to further influence prescribing habits. It may be that much of what makes up these ads is less than fact. A US congressional inquiry reported that from August 1997 to August 2002 the Food and Drug Administration (FDA) issued 88 letters accusing drug companies of advertising violations.
companies overstated the effectiveness of the drug or minimized the risk.\textsuperscript{13} The drug companies litter the journals with colorful full page advertisements intended to influence prescribing habits. Clearly many ethical and even legal principles are violated if these ads contain false or purposely misleading information. Advertisers also publish “advertorials,” advertising that is mostly words meant to look like editorial material.\textsuperscript{13} This is obviously a deceptive tactic in order to make biased advertisements appear as legitimate scientific material. Overall, the advertising in medical journals is often misleading, but the profits for the journals are worth millions.\textsuperscript{12}

How can it be expected that a company who sponsors continuing medical education will not try to influence in favor of their product? In fact, studies show that pharmaceutical company sponsored CME always preferentially highlighted the sponsor’s drug.\textsuperscript{2} Continuing Medical Education is meant to inform physicians in an unbiased manner. Through drug company sponsorship of these programs, it has become more of a marketing tool for the pharmaceutical companies. Changes in prescribing practice (self reported) in favor of the sponsor’s drug have been noted.\textsuperscript{2} CME sponsored by pharmaceutical companies afford the drug companies the opportunity to market its’ products by disguising the marketing as an educational event.

The relationship between the authors of clinical practice guidelines and the pharmaceutical industry has the potential to impact the prescribing patterns of a large number of prescribers.\textsuperscript{14} Influence authors of clinical practice guidelines receive from the pharmaceutical industry has the potential to be magnified through the effects on the practice of a large number of physicians.\textsuperscript{14} Many times these potential conflicts of interest are not disclosed. In a study of forty-four published guidelines, forty two made no statements on potential conflicts of interest between the authors and pharmaceutical companies.\textsuperscript{14} In that same study, 87% of the authors responded to a survey and stated they had a relationship with the industry.\textsuperscript{14} Greater than half of the respondents also indicated they received travel funding/honorarium, speaker honorarium, educational program support or research support.\textsuperscript{14} Clearly, conflicts of interest exist and are not being stated in the clinical guidelines physicians rely on as expert advice and evidence of best practices.\textsuperscript{14}

It is almost impossible to completely avoid conflicts of interest in the healthcare environment of today. The issue is not that these conflicts exist, but that they are not disclosed. Full disclosure of any conflicts of interest is necessary and appropriate. This allows anyone who is reviewing literature to have a clear understanding of how the work came about. This is not to say that conflicts of interest automatically render a work illegitimate, but disclosure is necessary so the reader can make a decision as to whether or not bias has entered into a study. Just as a study should disclose its methods for the reader to review, it should also identify any potential conflicts of interest for the reader to evaluate as well. By presenting conflicts of interest, the author or authors have fulfilled their ethical obligation to discuss any possible outside influences involved in the study.

The indirect marketing practices highlighted above represent a difficult problem. On one hand there is clear and deliberate marketing and influence from the pharmaceutical industry. The problem is that the pharmaceutical industry is funding a large portion of these events. In 2003 pharmaceutical companies were providing $900 million of the $1 billion spent annually on continuing medical education in the United States.\textsuperscript{3} Three fourths of randomized clinical trials reported in major medical journals are paid for by the pharmaceutical industry.\textsuperscript{13} On the other hand, the pharmaceutical industry clearly has a strong role in supporting
clinical research and education. It is also important for healthcare practitioners to remain informed of the latest developments in the pharmaceutical industry. Without the marketing campaigns of the drug companies much of this information would not exist. The difficulty comes in recognizing what is legitimate useful information and what is corrupt marketing propaganda.

In an ideal world the pharmaceutical industry would support clinical research and educational programs without strings attached. All clinical trials would be completely free from bias and educational events would be without promotion of particular products. The world does not work this way and is not likely to change anytime soon so we must understand how things work and always look at everything with a keen sense. Understanding this influence will help us view prejudiced information with an objective clarity and allow us to remain free from manipulation.

Understanding of the corrupt methods and conflicts of interest present in many clinical trials and Continuing Medical Education programs is a key to remaining free from undue influence. Physicians tend to feel that they are immune from influential bias present in educational content from the pharmaceutical industry.\(^3\) It is unreasonable, in this author’s opinion, to expect anyone to remain free from influence with the volume of misinformation constantly being propagated. The influence of the pharmaceutical industry is incredibly powerful and reaches several areas of clinical practice education that should remain as objective as possible. It may be more reasonable to understand the influence exerted upon oneself and recognize the fact that it must be consciously disregarded. Without a conscious effort to dispel the incredible influence of the drug companies, it is easy to fall for such powerful persuasiveness. Simply ignoring this outside influence, as it appears many physicians have, will only allow it to subconsciously influence medical practice.\(^3\)

In addition to the legitimacy of educational events, one may question the knowledge base of the pharmaceutical sales force. Pharmaceutical sales representatives are in fact employees of the company whose product they are trying to promote. They are also often not actual healthcare practitioners. Their sole training and education about the product they are promoting may have come entirely from the company they work for. Their knowledge of other products on the market or medicine in general may be limited and at the least, biased. The representatives make their living promoting the product for the company for whom they work. Human nature will push them to do what it takes to sell more of the product they are representing. An understanding of this will allow any healthcare provider to understand that anything a representative has to say is suspect.

As pharmacists there are several ways to deal with the conflicts of interest and corruption created and propagated by the pharmaceutical industry. To deal with this, pharmacists must uphold core values of patient care. Pharmacists must know their patients and recognize the autonomy of every patient. Through knowing the patients we must ensure that they are receiving the appropriate medication. If it is deemed that a more appropriate, more efficacious and less expensive medication is available for that patient, we must not be afraid to confront the physician about it. A quick phone call to the prescriber may yield a change. By doing so, we will have let the physician know that there are better alternatives than the high priced medications that the pharmaceutical companies are pushing. We will also help to portray our value to both the medical community and our patients. This action goes to our core values and simply standing by and doing nothing would be an act of non-maleficence.
Pharmacists have many roles in abating this outside influence from the pharmaceutical industry. Pharmacists need to remain vigilant in their educational efforts as to the appropriate medication for a particular condition. One study of family practice residency programs found that those with pharmacists on the faculty were more likely to have guidelines for interactions with pharmaceutical representatives and were more likely to include methods for evaluating the representative’s promotional materials. Continued education on appropriate drug therapy is another core value that we can uphold to counteract the misguided influence from the drug industry.

As healthcare costs continue to climb and populations of people cannot pay for their needed medications, it is unacceptable for the pharmaceutical industry to frivolously spend on these unethical marketing practices. Buying influence for profit when an individual’s health is at stake is simply deplorable. Objectivity in medicine is a key to achieving the best outcomes. When this objectivity is compromised the entire healthcare system suffers. There is no place in healthcare for this waste and illegitimate influence but it is not likely to be eliminated any time soon. Therefore, all healthcare practitioners must understand and avoid engaging in practices, which incur unnecessary costs and represent unethical practices for healthcare professionals.

References


