Pharmaceutical Marketing Practices Aimed at Physicians

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Case 3-1:

You are a 3rd year medical student about to begin your outpatient medical rotation. The week before your first day, you receive an email from your preceptor welcoming you to the office and explaining some of the basics about your role and her expectations. Your preceptor also informs you that lunch will be provided on your first day.

You show up eagerly on the first day and shadow your preceptor during the morning to get a feeling for the office. At noon, you head with her to the conference room for lunch where gourmet deli sandwiches and a full spread of side dishes, drinks and desserts are neatly arranged along a table. A well-dressed woman introduces herself to you as you take your plate.

"Hi, I'm Sandra from Novartis". She offers you pens, an ID card holder and an article which you take and place in your white coat. "Please let me know if you have any questions about Diovan," she says to you before casually asking your preceptor about her child's birthday party last weekend. Your preceptor signs something on Sandra's clipboard, and she brings a few boxes of samples into the supply room. During lunch you are introduced to the office staff as everyone eats. Sandra offers articles to everyone who enters the room and informally chats with the office staff.

After 20 minutes of lunch, the receptionist informs your preceptor that the first afternoon patient has arrived. You quickly peruse the article that Sandra handed you, and from the title and abstract, you gather that valsartan (Diovan), an angiotensin receptor blocker, has been proven to reduce systolic blood pressure by an average of 10-17 mmHg and is less likely to cause coughing as a side effect compared with the most prescribed ACE inhibitor.

Your preceptor asks if you are ready to see your first patient on your own.

Discussion:

Is there anything wrong with taking the food that was offered? What are the different ways physicians learn about drugs? How much money is spent by the pharmaceutical companies each year in promotion and marketing? What are the methods that pharmaceutical companies use to educate and influence physicians? Who are the pharmaceutical representatives who come to the office?
Pharmaceutical Marketing Practices aimed at physicians

Case 3-2:

The first patient of the afternoon is a new patient who recently moved into the area. After your preceptor asks the patient's permission, you interview and examine him. Following a thorough history and physical, you write the following note with your “Diovan” pen:

53 y.o. male who has been feeling well recently, with occasional back pain that is mild and controlled with ibuprofen (less than 10 pills per month). He had a colonoscopy two years ago with no abnormal findings.

PMH:
- HTN
- back pain (as above)

Meds:
- Reports being on something for blood pressure, but ran out months ago. Asks if he can have some samples since he is just opening a new restaurant and does not have health insurance as a small business owner, so would have to pay out of pocket
- ibuprofen PRN

Allergies: Penicillin - reports a "rash" when he was younger

FHx: Father is 84 and has Alzheimer's, Mother died at 81 of bladder cancer. No siblings.

SHx: Married with 2 children. Moved to town to start new restaurant. Smoked 1 pack per day for 20 years, quit 10 years ago. Social alcohol use (negative CAGE). No illicit drugs. Is knowledgeable about a healthy diet, although occasionally eats unhealthy foods. Uses an exercise bike and lifts weights 3 times/week.

VS: 76, 144/82, 12
Other than some regular nevi on his arms and back, the entire PE is within normal limits, including a normal fundoscopic exam, vascular exam and digital rectal examination.

On your way to present the case to your preceptor, you walk by the supply closet, where a pile of new Diovan sample boxes are prominently displayed.

Discussion:

The first part of the case introduced the pharmaceutical industry and the investment they have in influencing physician prescription practices. The second part of the case digs deeper into the sales rep/physician interaction. Are educated, intelligent physicians actually influenced by the promotional material, small gifts, and food? The patient in the case specifically requests free samples. There are obvious benefits to providing samples, especially in the case of a patient without health insurance, but are there any negatives to providing samples?
Cases 3-3:

You present the patient to your preceptor, suggesting that he be started on valsartan (Diovan) for his HTN, especially given his insurance situation and the fact that there are samples in the office. You also suggest a urine analysis to screen for renal disease in the setting of HTN.

Your preceptor nods at your suggestion, and says, "Let's go take a look." She repeats your H&P and confirms most of your findings.

At the conclusion of the visit, your preceptor recommends valsartan (Diovan) for the patient's HTN and provides him with a one month free sample and a prescription once the sample runs out. A UA is also obtained. The patient agrees to the plan. A follow-up appointment is set up for three months later.

As you begin to leave the room, the patient says: "One other thing doctor, I'm having some trouble in bed. Is this stuff any good? I think I'd like to try it." He pulls out an ad for Viagra from Sports Illustrated.

Discussion:

A different but related practice of pharmaceutical marketing is direct-to-consumer advertising (DTCA), which is illustrated in this part of the case as the patient brings in an advertisement for a drug to treat erectile dysfunction. DTCA represents another major avenue that the pharmaceutical industry uses to increase prescription sales in the US. How should you handle the request for sildenafil (Viagra)? How large is the DTCA industry? How does it impact the patient-physician relationship?
After finishing your afternoon at the clinic, you go home and read the article on valsartan more carefully. The design of the study compares valsartan to a placebo and was based on 214 research subjects. Using PubMed, you look up some of the meta-analyses done on anti-hypertensives and realize that hydrochlorothiazide is a cost-effective alternative to valsartan (assuming no other comorbidities such as diabetes) and other classes of medications for HTN. Your research takes you approximately three hours. In order to pass along this information to your preceptor, you copy one of the articles to bring into your next clinic session.

**Discussion:**

In the case, the sales rep handed out an article on the benefits of valsartan (Diovan). Detailers often quote studies and statistics about their products, and it is important to know more about the information that they provide. How should a prescriber critically read promotional material? How can physicians evaluate whether the information (including articles and promotional materials) given to them by sales reps is accurate and unbiased? What about articles in peer-reviewed journals—do readers need to be skeptical about the material published in these reputable journals? What about special journal "supplements" which are sponsored by pharmaceutical manufacturers?
Pharmaceutical Marketing Practices aimed at physicians

Case 3-5:

Your school is reviewing its policy towards allowing pharmaceutical representatives’ access to medical students and residents. Because of the initiative you have taken in your outpatient medicine clerkship, your preceptor nominated you to be one of the student representatives on the committee for medical education reform. You begin preparing for the meeting that will draft recommendations to the Dean.

Discussion:

What will you say to the committee and how will you frame your debate? What are some existing guidelines about protecting medical students and residents from promotional materials from pharmaceutical companies? If you recommend stopping or curtailing pharmaceutical company-sponsored lunches, do you think your recommendations will be popular among other medical students and residents? Among department chairs who will need to make alternative arrangements for lunches, teaching sessions, and continuing medical education? How much would you estimate that it costs to providing lunch to housestaff and medical students at your institution? Have any major programs initiated substantial changes?
Pharmaceutical Marketing Practices aimed at physicians

Discussion section

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Pharmaceutical Marketing Practices aimed at physicians

Case 3-1:

Launching the discussion:

This scenario is intended to present a realistic case of the interaction between medical students (as well as residents and attending physicians) and pharmaceutical sales representatives. Medical students do not often have full control over their schedules, and in an effort to be pleasant and adopt a "go with the flow" attitude among their preceptors - who also have the responsibility of evaluating and grading – students are likely to observe and then adopt the behaviors of those above them in the medical hierarchy. In this instance, the student was told "lunch will be provided". Time to eat is often limited, and a student who objects to eating meals organized by their preceptors, may have to meals entirely (which can make for an uncomfortable afternoon) or make separate arrangements such as leaving the communal eating space to purchase lunch, which can further distance them from their co-workers. Factors such as low budgets and limited time to prepare food ahead of time make the decision to avoid "free lunches" even more difficult for students. You can ask students whether they have ever faced a similar situation.

A helpful way to begin the discussion is to ask participants about their interactions so far with pharmaceutical representatives. Has anyone been to a lunch sponsored by a pharmaceutical company? What was it like? What were the pharmaceutical sales representatives like? Did they acknowledge you as medical students? What did you notice about their interactions with the other physicians and the office staff? The discussion will be much more relevant if participants can identify some of the characteristics of sales representatives and their tactics before learning about the industry from the studies below. The pervasiveness of the pharmaceutical companies' efforts to influence doctors starts early and comes in conspicuous and subtle ways, which are important to identify.

Overview of the Pharmaceutical Industry's Marketing Practices aimed at physicians:

Estimated spending on prescription drugs in 2007 was $275 billion, and that number is expected to increase to $500 billion within 10 years (Saul, 2007). Fortunately, it appears as that the rate of increase spending on pharmaceuticals is waning from more frequent use of generics and other market forces (Saul, 2007). A growing body of evidence suggests that commercial sources play a particularly large role in shaping physicians' knowledge about pharmaceutical agents and prescribing decisions (Avorn, Powerful Medicines, 2005). One study found that the largest pharmaceutical manufacturers spend more money on total marketing (which includes both consumer and prescriber marketing) than they do on research and development (Families USA Foundation, 2001).

The most effective commercial marketing strategy is a personal visit from manufacturers' sales representatives (or “detailers”). Pharmaceutical companies spend significant resources on influencing prescriber habits, with estimates of approximately $12 billion per year spent on marketing directly to physicians (Department of Health and Human Services, 2003). There are an estimated 90,000 sales reps (Saul, 2006). This works out to approximately $8,000-15,000 per physician (Blumenthal, 2004). This figure does not include other forms of advertising including direct-to-consumer advertising (more on this later in the case), and cost of providing sample products. Representatives who go to physician offices are known as “detailers,” and it has been estimated that there is one detailer for every 4.7 office-based physicians (Blumenthal, 2004). Although many physicians think they are being
Pharmaceutical Marketing Practices aimed at physicians

guided by industry professionals with high levels of medical knowledge, detailers often have little or no formal scientific training; they are often recruited from the ranks of those who possess qualities important for sales, such as attractiveness, peppiness, and an ability to influence the sales of their product (Saul, 2005). An article written by a former sales rep (Fugh-Berman and Ahari, 2007) describes how pharmaceutical companies define categories for physicians based on their personality characteristics and skepticism of the sales rep. Based on these personality categories, the reps have specific tactics that are known to be effective in changing prescription patterns. Fugh-Berman and Ahari also describe the great lengths that reps go to befriend physicians:

Drug reps are selected for their presentability and outgoing natures, and are trained to be observant, personable and helpful. They are also trained to assess physicians’ personalities, practice styles and preferences, and to relay this information back to the company. **Personal information may be more important than prescribing preferences.** Reps ask for and remember details about a physician’s family life, professional interests, and recreational pursuits. A photo on a desk presents an opportunity to inquire about family members and memorize whatever tidbits are offered (including names, birthdays and interests); these are usually typed into a database after the encounter. Reps scour a doctor’s office for objects – a tennis racquet, Russian novels, seventies rock music, fashion magazines, travel mementos, or cultural or religious symbols – that can be used to establish a personal connection with the doctor.

**One powerful way that pharmaceutical companies enhance the effectiveness of their interactions with physicians is by purchasing access to physician prescription records through data from pharmacies on filled prescriptions** (Steinbrook, 2006). By tracking trends in prescribing habits, companies can determine how specific sales techniques are working by observing the changing volume of an individual physician’s prescriptions. Drug companies spend an additional $1.75 billion annually to purchase these records (Wall, 2007). Fugh-Berman and Ahari (2007) describe how pharmaceutical companies use these records to analyze physicians’ prescribing habits in order to maximize their influence. Physicians are scored on a scale of one to ten, with the goal of identifying those who are high prescribers as well as to identify those who have potential to sell more of the company’s product.

**Interaction between detailers and physicians begins early in physicians’ careers.** A 2004 article (Blumenthal) showed that 41% of residency programs reported allowing pharmaceutical companies to teach residents directly, with 35% of programs allowing residents to receive free samples, and 29% of programs accepting funding to allow residents to travel to meetings. The relationship between physicians and sales reps evolves after physicians pass through residency. One survey found that 92% of physicians receive free drug samples; 61% receive free meals, tickets to entertainment, or free travel; 13% receive financial benefits; and 12% receive money to participate in clinical trials. Continuing medical education is also another avenue where physicians interact with pharmaceutical representatives. **In 2003, pharmaceutical manufacturers supported 90% of all continuing medical education programs (CME), at a cost of almost $900 million** (ACCME, 2003).
Pharmaceutical Marketing Practices aimed at physicians

Sources:

- Blumenthal D. Doctors and Drug Companies. NEJM. 2004;351 (18): 1885-1890.
- Steinbrook R. For sale: physicians’ prescribing data. NEJM 2006; 354(26) :2745–7
Pharmaceutical Marketing Practices aimed at physicians

Case 3-2:

Launching the Discussion:

This second part of the case is designed to get students to think about how effective pharmaceutical companies are with the resources they invest in influencing physicians. Many students and physicians believe they are not likely to be influenced, and it is important to elucidate students’ beliefs before reading through the evidence below. If it was not covered in the first part of the case, the issue of students with small budgets and limited time can be revisited, as many believe they are entitled to free food, especially since many believe small gifts and food can have no influence on them. Additionally, the relevance of this material can be driven home by asking if any of the participants have any gifts on them. Who has a pen (or any other item) with a brand name pharmaceutical on it? Where did they get it? Do you think you’re more likely to remember the name of the product as a result of having the pen?

Post-case discussion, part I:

Do Promotional Practices Regarding Prescription Drugs Actually Work to Change Physicians’ Prescribing Habits?

Many medical students, residents, and physicians believe that they are not susceptible to being manipulated to prescribe anything but the most appropriate drug for each individual patient. After all, by the time a physician is finished with training, he or she has seven (sometime 10 or even 12) years of classroom and clinical experience including specific classes on pharmacology and often epidemiology that should enable them to accurately evaluate research on pharmaceuticals. However, one should consider why pharmaceutical manufacturers would spend so much money on detailing, physician advertising, and acquiring prescription records if the endeavor is not effective. There is evidence to show that physicians are indeed strongly influenced by these practices. Chren (1994) has found that physicians who interact most frequently with sales reps are the prescribers most likely to request the addition of new drugs to hospital formularies, a key factor for hospital-based drug sales. Additionally, the drugs that these prescribers requested were produced by the same manufacturers that the prescribers interacted with most frequently. Avorn et al. (1982) studied physician understanding of the efficacy of an over-the-counter analgesic (aspirin) as compared to heavily marketed propoxyphene products (such as Darvon). At the time, research had demonstrated that propoxyphene was in fact a less effective analgesic, with potentially dangerous side effects. However, the propoxyphene products were very heavily marketed. Even though the majority of physicians in the study reported that drug ads and sales reps were “minimally important” factors in influencing their prescribing, while scientific papers and training and experience were “very important” for influencing prescribing, almost half (49%) reported that propoxyphene was pharmacologically more effective than aspirin. These results and many other similar studies suggest that physicians are in fact strongly influenced by pharmaceutical advertising and sales rep interactions.

In a meta-analysis of 29 studies that analyzed the effect of drug company interactions with physician prescribing, Wazana (2000) found that there are a number of negative
outcomes associated with increased interactions with sales reps including: 1) an inability to identify incorrect information about a medication, 2) more favorable attitudes toward representatives, and 3) making increased formulary requests based on non-rational prescription habits, with decreased writing of generic prescriptions. Wazana’s review identified that no studies reported how patient outcomes may vary based on the level of interactions between physicians and detailer. This is an important research question that needs to be investigated.

An often-cited study that demonstrated the direct effect of large gifts on physician prescription practices is from Orlowski and Wateska (1992) who studied a small group of physicians who received an expense-paid resort vacation offered by a drug company. The physicians who accepted the vacation had statistically significant increases in their prescription practices for the two drugs that were promoted on the vacation. Surveys of the physicians showed that the majority did not believe that they could be influenced by such practices.

In 2002 new restrictions were created to limit pharmaceutical manufacturers from making large expenditures on physicians’ gifts, such as the trip studied by Orlowski and Wateska. These restrictions stopped previous practices of lavish golf and resort vacations, expensive dinners, athletic tickets, and other expensive engagements. Until recently, sales reps relied heavily on bringing meals and snacks to offices and hospital-based physicians, which also creates the opportunity to have time to interact with physicians in their otherwise busy clinical schedules. Beyond lunches, coffee, and snacks, there are small items such as pens, sticky tabs, paper weights, and a wide array of other products have been offered to consistently remind prescribers about a product. While there is pressure to curtail such practices, pharmaceutical manufacturers continue to support dinners, national meetings, journal supplements, and continuing medical education sessions (Blumenthal, 2004). In a comprehensive review of the social science literature on gift giving, bias and decision making, Dana and Loewenstein (2003) report that even small gifts, such as food and pens, “can bias how arguments are evaluated (pg. 254).” The conclusion is that these gifts are surprisingly influential, causing many to argue that the only logical policy implication is that all gifts, no matter how small, should be prohibited.

Several researchers have set out to uncover trends in physician attitudes toward sales reps, and results have been inconclusive. Manchanda and Honka (2005) reported that physicians have a generally negative to neutral attitude toward such detailers. Several factors seem to influence their overall opinion of sales representatives: physicians are more likely to have favorable opinions if the sales reps offer a high degree of educational support. Other opinions of sales reps are based on social factors such as the rep’s personality and style. Those sales reps that are overly forceful with their pitches were not looked upon favorably. Factors associated with the physician that influenced their opinions of sales reps included less access to physician colleagues, which was associated with a higher approval of sales reps, and belonging to a practice that restricted sales rep access was associated with more negative views of them. The authors concluded that sales rep interactions with physicians are an inexpensive and convenient source of information for many physicians, and that this interaction has a significant impact on their prescription behaviors.
Other studies have found that physicians have generally favorable attitudes towards drug companies – believing that the drug companies offer education and samples, which both benefit their patients (Chren 1999 & Brett et al., 2003)

Medical students have been found to underestimate the influence of pharmaceutical promotion. Monaghan et al. (2002) reported that on average physicians and sales reps begin interacting in medical school and average four interactions per month throughout their professional lives. Students were typically unaware of pharmaceutical marketing expenditures, and did not see conflicts in receiving company travel funding for CME or in using professional samples for personal needs. Students also were unaware of the limitation of data and studies provided by detailers (such as pamphlets, studies and verbal information). The study of medical students by Monaghan showed that those students who were educated at institutions where there were policies restricting access to drug companies had a more critical assessment of drug-company provided literature, suggesting that policies to restrict sales rep access can be successful in creating more awareness among students about their vulnerability to marketing.

What about the Decision to Provide the Patient with Valsartan (Diovan) Samples?
Launching the discussion, part II:

In the case, the patient did not have health insurance and requested samples. Conveniently enough, the Novartis sales representative had restocked the supplies of samples. In many ways it seems to makes sense to provide the patient with the samples. The patient has hypertension, and Diovan is known to be an effective antihypertensive with a side effect profile similar to other medications within its class. The patient has no known allergies to the medication. Additionally, the insurance status and financial situation of the patient make it all the more appropriate to start the patient on Diovan, right?

Students should be encouraged to speak about any interactions they have had when samples were offered or requested. Questions about the patient demographics (SES/insurance status) are relevant to examine who is receiving samples. Samples seem like a win-win situation, where physicians have a supply of free medications that they can give out to those who need them. Can the students identify (either from experience or just theoretically) any drawbacks or potential limitations of the benefits of samples?

Post-case discussion, part II:

In 2005 pharmaceutical manufacturers spent over $18 billion dollars on free samples, a greater amount of their revenue than advertising and promotions to physicians and consumers combined (Donohue et al. 2007). Strategically, these expenditures can increase the number of patients who are placed on the products for the long term, thereby creating a reliable and substantial future source of revenue. The intention is to influence physician to begin patients on medications as a result of available samples. Chew et al. (2000) examined whether physician prescription practices were influenced by the availability of samples for patients with hypertension. In a self-report survey, the researchers found that when samples were made available, 27% of respondents would opt for beginning the
sample even if the drug were not a first line treatment as recommended by nationally accepted guidelines for the treatment of hypertension. The study also found that the same prescribers were likely to write prescriptions for the same medications once the samples ran out.

Monane et al. (1995) conducted a retrospective study of elderly patients taking antihypertensive medication. Overall, they noted a decrease in the frequency of thiazide prescriptions even though there was strong evidence for the efficacy of this class of medication in elderly patients. In addition, 25% of patients report difficulty paying for their antihypertensive medications, making the case for a thiazide agent, available in less expensive generic formulations, more compelling. The authors suggest that the introduction of newer, more expensive classes of antihypertensives create a paradox in which physicians are prescribing what they think are better medications, but patients have worse blood-pressure control since they cannot afford to fill their prescriptions once the samples run out. More recent research on the use of appropriate antihypertensives by Fischer and Avorn (2004) has estimated that adhering to evidence-based prescribing guidelines could result in savings for the health care system of approximately $1.2 billion annually just for managing hypertension in the elderly. These savings could have significant impacts on the viability of prescription drug plans as well as the affordability of medications on an individual basis. Other analyses have found that physicians typically do not possess accurate knowledge about prescription costs (Shrank et al., 2006).

A recent analysis by Mabins et al. (2007) was conducted to observe the effects of beginning indigent patients on prescription drugs for which the physicians had samples. The researchers found that among indigent patients, significant interruptions in therapy occurred once the samples were finished. Patients went an average time of two months without treatment before being restarted, and were more likely to be restarted on the same drug that they originally received as a sample. Other recent work (Cutrona et al., 2008) on the demographics of patients who receive free samples from physicians found that the poor and uninsured are actually less likely to receive free samples.

Collectively these studies emphasize the complex array of factors that should enter into the decision to provide a patient with the free sample and the need for physicians to be well-informed of cost and drug efficacy in order to promote the health of their patients in the most cost effective way. Samples, although they may initially appear to benefit the finances of a patient, can actually cost more to the patient and the entire health care system in the long-term.

Sources:
Pharmaceutical Marketing Practices aimed at physicians

Pharmaceutical Marketing Practices aimed at physicians

Case 3-3:

Launching the Discussion:

DTCA is ubiquitous in American media, and an informal way to begin the discussion is to ask participants about what ads they have seen recently. What classes of medications and what conditions are most frequent? These include drugs for erectile dysfunction (ED), depression, allergy/sinus, bladder control, arthritis, benign prostatic hyperplasia (PBH). What are some of the commercials that people have seen? Who are the celebrities endorsing products? What does every ad have to contain? (A list of side effects and a mention of other treatments that may be effective.) Before delving into the discussion below, it might be useful to have participants brainstorm a couple of pros and cons to DTCA.

Additionally, what if the patient is having ED because of an underlying and treatable medical condition? If the physician accepts the self-diagnosis by the patient without probing his symptoms further, there is the possibility of missing a serious health problem. The end of the post-case discussion attempts to lead readers in this direction.

Post-case discussion:

In 1997, the FDA began allowing DTCA on television, which set the stage for enormous annual spending by pharmaceutical companies on DTCA. The US is currently the only industrialized nation that allows DTCA, which has been banned in Canada and the EU and most recently in New Zealand. The amount spent on DTCA increased by 330% between 1996 to 2005, with $4.2 billion spent in 2005 (Donohue et al.). Donohue et al. (2007) concluded that there have been three confirmed effects of DTCA: 1) pharmaceutical sales have increased for promoted drugs; 2) medications to treat chronic diseases are less likely to be underused; and 3) there has been some overuse of medications. Other major studies, such as one that dealt with antidepressants (Kravitz et al. 2005), found that DTCA influences patients who then have a “profound effect on physician prescribing practices.” Kravitz et al. did not come to a conclusive standing as to whether this “profound effect” found that this probably results in both overuse and preventing underuse of heavily-marketed antidepressants. Curtiss (2005) reported that for every $1 spent on DTCA, the pharmaceutical industry obtains a $4.20 return.

With a condition such as erectile dysfunction, many men would not seek treatment because of embarrassment or because they are unaware that there are medical treatments for the disorder. Among physician visits that were generated directly by DTCA, erectile dysfunction was the most frequently cited condition (16%), with anxiety second (9%) and arthritis third (7%). Allowing DTCA increases public awareness of both diseases and treatment options, which can be useful in diseases with high amounts of social stigma (such as erectile dysfunction and depression). The information presented in DTCA also educates patients which can be empowering and bolster the physician-patient relationship. Other positive outcomes cited for DTCA include having patients “talk to their doctors about advertised drugs and frequently obtain prescriptions for them; often receive prescriptions for other drugs, recommendations of over-the-counter drugs, and lifestyle advice; frequently talk to their doctor about conditions not previously discussed; sometime receive unexpected

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On the other hand, critics of DTCA argue that the drugs that are heavily marketed to consumers are only those that are new and expensive, whose safety profiles may not be fully understood. In light of the recent rofecoxib (Vioxx) debacle, many argue that DTCA can inappropriately promote rapid demand for new prescriptions before there is time to fully assess a drug's safety. According to Donohue et al. (2007), DTCA is centered on a few specific costly drugs within newer classes of medications. In one recent year, 54% of all the DTCA spending was for only 20 drugs, and almost all of those drugs (17/20) were heavily advertised within one year of FDA approval. Donohue also highlights the actions taken by the FDA against pharmaceutical marketing practices in DTCA for minimizing risk (including myocardial infarction, in the case in rofecoxib) or exaggerating effectiveness of specific drugs. Recent trends have shown a decrease in the number of regulatory actions taken by the FDA, but Donahue et al. were uncertain if this reflected a true decrease in infractions or simply worsening FDA oversight (p. 679).

Other researchers (Wilkes et al., 2000) assert that the rapid rise of DTCA since 1997 is eroding the patient-physician relationship by artificially creating unnecessary and distracting conversations about advertised products. Patients often enter into these conversations with unrealistic expectations, and request drugs that may not be necessary and which can place the patient at risk for harm. Wilkes et al. also highlight how lifestyle modifications are often ignored by patients when they enter a clinical encounter requesting a drug. Many of the concerns raised by Wilkes et al. have not been empirically studied.

One of the most important points that Wilkes et al. raises is that the changes brought about by DTCA are likely to impact many aspects of the health care system, but the responsibility of the clinician should not be undermined. In the case of the patient who requests sildenafil, one ideal outcome may be that the physician takes the time to investigate the patient's problem and ensure that the symptoms are not a sign of a significant health problem. If the patient does in fact have symptoms of erectile dysfunction, and once the physician has ruled out other more serious causes, then it might be appropriate to prescribe a drug such as sildenafil or a comparable agent. The physician must not be distracted by the patients request and self-diagnosis based on DTCA and overlook other conditions that may be contributing to the problem, or ignore solutions apart from the one specifically requested by the patient that may be more appropriate.

Sources:

Pharmaceutical Marketing Practices aimed at physicians


Pharmaceutical Marketing Practices aimed at physicians

Case 3-4:

Launching the Discussion:

The pharmaceutical industry’s influence in research sponsorship, journal article writing, and other avenues of information dissemination is not widely publicized or known among students or many practicing physicians. Most students and practitioners believe that findings published in peer-reviewed journals are free of commercial influence and should be accepted as state-of-the-art knowledge.

Post-case discussion:

In a 1995 study, Ziegler et al. analyzed information provided by sales reps to prescribers and found that 11% of the material contained inaccurate information, and that all of the inaccurate information was in favor of that company’s product. There were no positive statements made about any of the competitive drugs. Additionally, the study found that 26% of the physicians surveyed recalled some of the false data in the material and believed it to be true. In a more recent analysis, Cardarelli et al. (2006) analyzed promotional material that was sent into various physician offices. Independent reviewers found that 25% of studies were invalid, 80% of studies were funded by pharmaceutical companies, and few of the materials presented relative or absolute risks. The authors concluded that physicians need to be critical and cautious when using pharmaceutical marketing brochures to influence prescription practices. The studies that the sales reps report are often funded by the companies that sell the drug and sometimes feature studies designed to produce a favorable outcome for that manufacturer’s product. The goal of all literature distributed by sales reps is to highlight the benefits of their product to increase sales. As a result, all such material provided should be read with skepticism.

For many years, some peer-reviewed journals have published “supplements” whose articles are centered on a specific theme. Supplements are typically sponsored by private industry, including pharmaceutical companies. A 1994 JAMA article (Rochon et al.) found that randomized controlled trials published in journal supplements were of inferior quality compared with RCTs published in non-supplement issues of the same journal. Within the past ten years, some prestigious journals (JAMA, NEJM, Lancet) have abandoned the practice of private sponsorship of supplements, but other editors have defended the credibility of publishing supplements (Block, 2000).

More recently, it has been revealed that several papers submitted to major peer-reviewed journals were written entirely by the pharmaceutical company sponsoring the research (Laine & Mulrow, 2005). In an editorial about such “ghostwriting,” Laine and Murlow explain that a paper that was accepted and published in the Annals of Internal Medicine was entirely written by Merck, and the only responsibility of the author was to edit the document. Further investigation has shown that practices such as ghostwriting occur quite frequently. In a survey of major medical institutions, Mello et al. (2005) report that because 70% of funding for clinical trials is currently sponsored by industry sources, the sponsor is often allowed to own and even store the data. Sixty-two percent of institutions
Pharmaceutical Marketing Practices aimed at physicians can alter the study design after an agreement is reached between the researcher and the sponsor, 96% permitted the sponsor to review manuscripts for some agreed-upon time period between 30 days to one year. Half of research offices surveyed permitted the sponsor to write up the trial results for publication, with the investigator’s only role to review the manuscript and suggest changes.

In recent years, journals have adopted stricter guidelines indicating awareness of some of the deceptive practices that can bias research. A number of guidelines that the Annals editors have adopted to ensure higher integrity include: 1) ensuring that authors are guarantors of the content and integrity of the work; 2) examining to see if the authors were "advised" by professional writers, 3) assuring transparency if professional writers were involved, and 4) ensuring that any professional writer who does assist has the credentials and expertise to write in that field (p.611-612). Many other journals do not require these safeguards.

Where can medical professionals go for sources of unbiased information? There are several sources for evidence-based reviews of medications:

- The Independent Drug Information Service [www.rxfacts.org]
- Therapeutics Letter (Canada) [www.ti.ubc.ca]
- Drug and Therapeutics Bulletin (UK) [www.dtb.org.uk]
- Medical Letter [www.medletter.com]
- Prescriber’s Letter [www.prescribersletter.com]
- No Free Lunch [www.nofreelunch.org]

Sources:
Pharmaceutical Marketing Practices aimed at physicians

Case 3-5:

Post-case discussion:

In recent years, the lay and academic presses have written about changing policies among academic medical institutions to restrict access of pharmaceutical company gifts and sponsorship. In an article in *The New York Times* (Saul, 2006) reported that the University of Michigan followed the University of Pennsylvania's initiative to completely restrict industry sponsored lunches. Saul reports that the cost of providing lunch to its staff after restricting pharmaceutical sponsored lunches at the University of Michigan was approximately $2.5 million per year. Stanford University School of medicine has adopted a similar policy (Croasdale, 2006).

In one of the most sweeping recommendations to be published in a major medical journal, Brennan et al. (2006) laid out a set of guidelines for academic medical centers aimed at removing the overt and subtle influence that industry has gained within the medical field through decades of questionably ethical practices. In order to restore the waning professional integrity of the medical field, the authors suggested the following: 1) Rejecting of all pharmaceutical company gifts and meals and payments for time, travel, or participation in CME. 2) A complete prohibition of the dispensing of samples. The authors conclude that samples directly cause physicians to prescribe medications that are more expensive, yet not necessarily more efficacious. The use of samples also increases the exposure of sales reps to physicians, creating more opportunity for influence on physicians. They suggest instead establishing a low-cost supply of medications for patients with limited or no prescription drug coverage. 3) Physicians who have any financial connections with pharmaceutical companies should not be members of committees that create formularies. 4) Pharmaceutical companies should be removed from any direct connection to CME. If a company is interested in sponsoring CME, the authors proposed that they deposit funds in a centralized account that will be used to fund CME but without direct promotion of the drugs that the company produces. 5) All funds for physician travel (including for residents and fellows) should be restricted. As with CME, if the pharmaceutical industry would like to continue to support physician travel without receiving direct recognition, they would place funds in a centralized location that will disburse funds for physicians without a direct connection to the company. 6) Faculty at academic medical centers should abstain from participating in pharmaceutical speakers’ bureaus, with no exceptions. The authors argued that the faculty’s role in educating students and residents obligates them to be free of this conflict of interest. 7) There should be increased transparency of consulting and research contracts made with pharmaceutical manufacturers. All agreements should be publicly available to ensure that the agreements are ethical. Brennan et al. acknowledged that many innovations in drug development come from academic partnership with private industry, and they made recommendations to allow such partnerships to flourish, but with provisions to limit conflicts of interest.

Brennan et al argued that the adoption of these recommendations will restore integrity to the profession, improve the use of evidence based medicine, and may have unintended positive
outcomes such as decreased health care costs. Their recommendations have yet to be adopted on a large scale, but they represent a lofty set of goals that academic institutions can strive to accomplish. **At least one well respected academic institution (Yale) has adopted a similar set of guidelines** (Coleman et al., 2006). There is evidence (Monaghan et al. 2002) that medical students trained at institutions that restrict the promotional access of pharmaceutical companies are more critical in their ability to assess pharmaceutical sponsored educational materials. Limiting the influence of drug company marketing within academic institutions will help students and practicing physicians understand the pervasive influence of such promotion and can help lead to higher standards in medical education.

**Sources:**


