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Ethical Considerations Of Pharmaceutical Sales In The Primary Care Arena

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Abstract

The conflict of interest between pharmaceutical sales and the ethical practice of medicine has long existed. While pharmaceutical companies have lost much of their ability to financially incentivize clinicians, they continue to have undue influence over prescribing practice by means of "detailing." In an attempt to gain large market shares, these companies exploit this mode of medical information dissemination, creating enormous endorsement bias, and ultimately placing patients at the mercy of these manipulation tactics. Jonsen et al. have established the four topic method of ethical discourse which includes medical indications, patient preferences, quality of life, and contextual features. These topics allow for an intelligent discussion concerning the ethics of pharmaceutical business practices. The integrity of evidence-based medicine as well as the safety and welfare of patients are at risk. How clinicians respond to these pressures will have positive or negative impact on this medical ethics dilemma.

INTRODUCTION

The conflict of interest between pharmaceutical sales and the ethical practice of medicine has long existed. Since the 1950s, educators, administrators, researchers, and clinicians have fought for corrective action (Podolsky & Greene, 2008). Pharmaceutical companies have spent approximately $21 billion dollars on marketing while 90% of this budget has gone toward directly influencing physician practice (Brennan et al., 2006). Physicians and other health care practitioners have a fiduciary duty to act in the best interest of their patients. Jonsen, Siegler, and Winslade (2006) define this duty as, "[owing] undivided loyalty to clients and [working] for their benefit" (p. 163). Furthermore, according to these authors, it is especially important that fiduciaries avoid financial conflicts of interest that "prejudice their clients' interest" (p. 163).

Now that pharmaceutical companies have lost much of their ability to financially persuade practitioners with large monetary gifts, the focus on ethics behind their influence has shifted more toward the issue of "detailing" (Huddle, 2008). "Detailing" is loosely defined as the process of face to face contact between a medical provider and drug company representative ("drug rep") for the purposes of educating the medical provider on all of the details of a particular drug, service, or device. Many argue that a conflict of interest still exists for patients, despite a cap on monetary incentives (Brennan et al., 2006; Higgins, 2007; Spurling & Mansfield, 2007). They contend that any gift, large or small, may still influence the decision making process of a medical provider, and thus conflict with the better interest of the patient. They often site social science research which has demonstrated the powerful impulse to reciprocate for even small gifts (Brennan et al., 2006). Indeed, from their standpoint, pens and lunches strongly count toward that influence. For those who seem to believe that little influence can be generated from such small gifts, the persuasion is thought to stem from the dissemination of biased information (Huddle, 2008). These conflicting viewpoints have stirred an ongoing battle between the unbiased better interest of patient care and the financial self-interest of multibillion dollar pharmaceutical companies. The integrity of evidence-based medicine and ultimately the safety and welfare of patients hang in the balance as the battle wages on.

Through the litmus of Jonsen et al. four topic method, the far reaching implications of this subject will be explored.

MEDICAL INDICATIONS

Medical indications are defined as "the facts, opinions, and interpretations about the patient's physical and/or psychological condition that provide a reasonable

justification for diagnostic and therapeutic interventions." (Jonsen et al., 2006, p. 14) The concepts of beneficence and nonmaleficence must be considered regarding what is medically indicated for patients. These concepts define what is necessary to create maximum benefit and avoid harm to the patient. The conflict of interest caused within the drug rep/provider relationship, through the use of detailing and gifting providers, sheds suspicion on what is truly medically indicated for patients. Clinicians often have enormous choices when it comes to what medicine or device they may chose for a patient. Unfortunately, many providers succumb to the pressures placed upon them by drug or device representatives when it comes to patient care. This may not be in the patient's best interest.

Evidence-based practice has emerged as the new standard of patient care. As such, many higher educational institutions have begun to shun pharmaceutical influence in the way they provide care for their patients. For example, Yale, Stanford, and the University of Pennsylvania have limited relationships between member healthcare providers and pharmaceutical companies (Higgins, 2007). Yet other institutions embrace these types of symbiotic relationships. At the forefront of this practice is the Weill Medical College of Cornell University, who recently opened the Clinique Skin Wellness Center (Higgins, 2007). Created mostly from a $4.75 million dollar grant from Clinique, the center justifies its existence through the education of skin cancer prevention. While this is a noble effort, physicians in this setting will find it difficult to convince patients the care they are receiving is unbiased (Higgins, 2007). In other words, providers in this setting might find it difficult to provide medically indicated and evidence-based care when that evidence points away from the use of Clinique products. What are the plans in case of therapeutic failure should Clinique products and educational materials bring detriment to patients? The probabilities of success of Clinique products should have been weighed against the larger body of evidence based medicine before this relationship of biased synergy was struck.

PATIENT PREFERENCES

The central theme of patient preference is the constant tension between the ideas of autonomy and paternalism. Autonomy has been defined as, "the moral right to choose and follow one's own plan of life and action (Jonsen et al., 2006, p. 52)." The idea of paternalism rests in assuming a position of authority over what is thought to be in the patient's best interest and thus ignoring that patient's preferences (Jonsen et al., 2006, p. 54). Unscrupulous clinicians, armed with biased information given to them by drug companies, might assume a paternalistic stance with their patients if those patients aren't convinced the drugs or products their provider is promoting are equal or on par with alternative, less expensive treatments. If the relationship between the drug rep and clinician is severely biased, either through close friendship or substantial financial incentive, the clinician may feel compelled to use his or her position of authority to override patient preference.

For example, a patient may come to the clinician wanting to control her hypothyroidism with a cost effective, generic brand of medication, but the clinician may be incentivized to recommend the "more accurately dosed" brand name. Despite evidence that there is, in this case, no significant difference between generic and brand name medication, the clinician will stand on the authority of his drug rep biased influence and convince the impressionable patient there is a "significant and clinically felt" difference. The patient may not have the money to afford the name brand, but now he or she is convinced that they must have the superior name brand if they are to "feel better." Under this undue influence, the patient is now ready to over-extend his or her budget to secure the medication. Of course, the clinician will attempt to ease the initial cost of the medicine with samples or coupons, but the patient will ultimately be made responsible for its costs when samples and coupon offers run out or expire.

Furthermore, because the clinician is in a position of authority, he or she will substantially contribute toward achieving a placebo effect in patients through the mere suggestion that a particular drug is better than another, thus strengthening the patient's belief in the fallacy. The patient may feel better not because of an actual drug effect, but by the mere suggestion of its superiority. Patients will thus continue to spend their money needlessly because they have been misled by their medical providers.

While it seems obvious to most that this kind of practice constitutes an obvious breach in medical ethics, it occurs all the time in clinical practice. It's this author's humble opinion that this kind of ethic continues to exist because it has been tolerated for so long and has been comfortably categorized as a "grey area" in medical ethics. Even while the patient has the full capacity to decide what he himself prefers, his preferences are ignored and overridden, and he is duped into believing the all too expensive or sometimes deadly (Vioxx) lie. All the while, through continued

promotional campaigns, trumped up clinical trials, and paid physician endorsements pharmaceutical companies and clinicians share in the financial fanfare.

This breach of ethics brings to mind the ethical concepts of scope of disclosure, comprehension, and informed consent. It is important for patients to fully comprehend the decisions they are making. They can make these decisions if all the pertinent facts are fully disclosed them. If they are being intentionally or unintentionally misinformed, how then are they to fully comprehend the impact of their decisions? How are they to make informed consents? The sad fact is this—they are making misinformed consents.

QUALITY OF LIFE

The concept of quality of life is difficult to define. Quality is an elusive term, which means many different things to many different people. In other words, a judgment of quality must be made. This judgment will differ considerably based on the one making the judgment. Some will judge quality based on the "sanctity" of life, which implies that "physical life be sustained under any condition for as long as possible (Jonsen et al., 2006, p. 111)." Quality of life is understood from both personal and observer evaluation. For example, the life of a one legged man may be judged not worth living by the athletic observer, who measures the quality such a life by the ability or inability to run, while the one legged man may have come to fully enjoy such a life now that he has discovered his intellectual prowess (Jonsen et al., 2006).

The medicine of enhancement is ethically suspicious. This area of medicine is full of judgment calls as to what should be considered improved quality of life. Whether it's the ability to enhance sexual or athletic performance or diminish the effects of aging, pharmaceutical companies are there to remind us all what the standard of quality "truly" means. We see the ads on television as constant reminders that we really shouldn't "disappoint our sexual partners" or "begin to show the 'ugly' signs of aging." Who hasn't seen a commercial describing the signs and symptoms of depression and thought, "Hey, that's me." It's no coincidence that the commercials always end with their projected emotional quality of life "standard," in which the now medicated patient is running through a field of daisies. The pharmaceutical industry is a master of thrusting these judgment calls upon us to the point where we can't help but feel completely inept and unsatisfied with our lives.

This "thrusting" of values upon us by the pharmaceutical industry has its origins in the current sad state of pharmaceutical big business. A recent LA Times article by Melody Petersen (2008), regarding "Big Pharma" reports:

Only now is it becoming clear that this business model couldn't work forever. The strategy had a flaw that executives have long ignored: It required extraordinary amounts of promotion at the expense of scientific creativity. To make the strategy work, the drug industry put its marketers in charge; scientists were given a back seat. Is it any wonder that executives at many companies have watched their pipelines of new drugs slow to a trickle? (p. 1)

While "Big Pharma" has run out of brilliant new drugs, slated to replace the old, they have stepped up their efforts to remarket their existing drugs under new indications or new formulations. Indeed, when new drugs are scarce, simply lower the bar and serve them to a larger population or reformulate to make them "better, faster, stronger." Instead of beefing up efforts to push the envelope of scientific discovery, drugs makers have replaced the scientist with the Harvard MBA (Petersen, 2008). As a result, they have been left scrambling to manage the financial fallout of such business practice. Indeed, according to Petersen, "…the strategy that has made the pharmaceutical industry one of the wealthiest and most powerful on Earth is finally starting to betray it." (Petersen, 2008)

Nothing could be more ethically suspect than the promotion of a drug on the basis of sheer profit, but this is exactly what Big Pharma is doing when they seek and find FDA approval for new indications. Such an example is the new indication for Cialis (a sexual performance drug akin to Viagra) to be taken every day rather than as needed for sexual intercourse.

If quality of life was truly important to pharmaceutical companies they would be interested in creating drugs for all socioeconomic groups, but this not the case. They typically target those markets with expendable income. The "blockbuster" sales tactic wins out when choosing which drug to place their bets on. Categories such as cholesterol management, depression, and constipation are the mainstays of choice (Petersen, 2008). For example, malaria is killing a child every 30 seconds in developing countries, yet the poor cannot support the high prices a blockbuster drug demands, hence very little money is earmarked for development of such drugs (Petersen, 2008). Moreover, medicines that treat diseases that afflict only a small number of patients are often left on the back burner because they cannot achieve the numbers necessary to sustain market share and momentum (Petersen, 2008).

This became clear when Bristol-Myers Squibb executives announced at a news conference in 2000 that they were embarking on what they called the "MegaDouble" business plan. To enhance the company's profits, executives ordered its scientists to work only on "mega-blockbusters," such as Lipitor. Scientists with blueprints for drugs promising a mere $100 million in annual sales had little choice but to box up their work and send it to the warehouse. (And executives are now perplexed about why they don't have enough new drugs) (p. 1).

There is no improvement in patient quality of life when drugs become more expensive and more people are dying from understudied medications. As companies struggle to meet the bottom line, they may lay off employees and place more of the financial burden onto the customer in the form of raising medication costs. There is enormous pressure placed on the pharmaceutical industry by stock holders to compete fiercely in the market place. This fierce competition often leads to premature launching of medicines. Indeed, in much the same way new movies are released, new "blockbuster" drugs must garner a large share of the market upon initial release or they could be doomed to a lesser market share (Petersen, 2008). But unlike the movies, some of these drugs are killing people by the thousands. Some drugs have been studied with only a few thousand subjects before they are launched. In many of these studies the data is barely marginal enough for FDA approval. Indeed, FDA "fast tracking" of certain products is not uncommon practice. Vioxx is perhaps the most notable and recent example of this unfortunate recipe for disaster. It was prescribed to over 20 million patients before Merck pulled it from the market in 2004 after reports that it doubled the risk of heart attack (Petersen, 2008). One FDA scientist estimated that Vioxx might have caused heart attacks or strokes in roughly 139,000 Americans and that 30% to 40% of them died (Petersen, 2008).

What's interesting here is that this author prescribed hundreds of tablets of Vioxx during its "glory days." Every one of his patients enjoyed an improved quality of life through significant reduction of musculoskeletal pain and luckily no one was harmed in this small subset of patients. However, 139, 000 patients in the general population suffered an adverse event or died from using the drug. While there was no indication in earlier studies that the drug would cause harm to such a large number of patients, perhaps a larger original study sample would have accounted for this deadly propensity and prevented this pharmaceutical catastrophe from occurring in the first place.

CONTEXTUAL FEATURES

Clinicians face many contextual features such as social, political, economic, religious, institutional, and family considerations. At the same time, the physician has the fiduciary duty to provide undivided loyalty to her patients and "must work for their benefit (Jonsen et al., 2006, p. 163)." The concept of "conflict of interest" has already been discussed above, but needs to resurface here again to underscore the importance of avoiding such conflicts when caring for patients within the above contexts. Under the role of other interested parties, the patient and physician must navigate together the waters of best interest for the patient. Federal and local authorities, managed care organizations, public health authorities, third-party payers, and pharmaceutical companies all claim an interest in the care of patients (Jonsen et al, 2006, p. 166). All of which may even attempt to dictate how care is rendered. This places the clinician in the middle, between the patient's interest and outside influences. Thus the clinician must serve as intermediary between the two, serving both interests simultaneously, keeping the betterment of the individual and the whole in mind. This, of course, is no easy task.

In an effort to minimize the effect of undue influence by the pharmaceutical industry, grass roots organizations have emerged to empower the clinician to stand against such influence. One such organization is the No Free Lunch organization (No Free Lunch (NFL), n.d.). They have launched a website known as "www.nofreelunch.org" which educates and assists physicians in standing against this conflict of interest. This organization encourages medical providers to pledge to eliminate this influence in their workplace by boycotting pharmaceutical industry promotional activity on their turf. Indeed, all paraphernalia, such as pens, pamphlets, note paper, posters, and other "educational" material provided by the drug industry are to be confiscated and discarded and then replaced with No Free Lunch materials. Becoming a member of this organization proves to patients that your organization takes this conflict of interest very seriously and is doing something about it.

This organization is a viable solution to the current crisis. However, it could be construed to be too representative of the "unrestricted advocacy" approach to patient care. In this approach, whatever is required by medical indications and personal preference should be avoided (Jonsen et al., 2006, p. 178). Perhaps the patient has no problem with or even

prefers to have a physician who has access to free samples. Many patients within this author's practice have stated such and enjoy the ability to obtain free samples, many of which are on a continuous basis, so long as the drug is still under patent and available to the clinic. Many drug reps understand that there exists a small subset of underserved patients in every practice and will allocate to the medical provider a certain amount of medications to serve this portion of the population. Of course, this activity will never make it to the books as such, but it does occur. They do this knowing that this will help the physician maintain some balance in access to care. This is also a tactic they employ to further entwine the provider into writing more of the product under other, more profitable circumstances. In essence, the clinician feels less conflict of interest by helping disenfranchised patients, but must then reciprocate even further by writing the drug for patients who can afford it. Either way, the conflict still exists and is unavoidable. It's essentially an all or nothing decision to engage in the activities or not. Sadly, because this kind of practice is so ubiquitous, most primary care medical centers have come to accept it as the norm. This ambivalence spurs the conflict of interest forward with no end in sight.

CONCLUSION

Many argue that a conflict of interest still exists for patients, despite a cap on monetary incentives provided by pharmaceutical companies. Citing social science research, they contend that any gift, large or small, may still influence the decision making process of a medical provider, and thus conflict with the better interest of the patient. Jonsen et al. have provided an excellent framework upon which ethical arguments can be constructed for or against this industry-wide dilemma. The principles of medical indications, patient preferences, quality of life, and contextual features have proven to be the perfect litmus through which tough questions may be challenged and hence emerge far better understood and appreciated.

As the art and practice of medicine forge on, it is imperative that financial conflicts of interest stay far removed from the scientific process. Market share concerns have too often tainted the purity of scientific inquiry. This has had profound effect on patient safety. Moreover, corporate sales tactics have replaced the better judgment and unbiased concerns physicians once had for their patients. There are enormous obstacles in the way of changing the current state of affairs. Perhaps there will be power found in the increasing number of grass roots physicians who are choosing to stand against this type of influence. But until then, the current landscape, overshadowed by pharmaceutical big business is, at best, ethically suspect.

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