What do pharmaceutical companies owe to patient? Examining the (un) ethical aspects of the pharmaceutical industry’s practices

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Abstract: This paper examines the ethically problematic aspects of the pharmaceutical industry’s practices, with particular emphasis on its drug sale promotion and direct to consumer advertising activities. Based on an analysis by Pellegrino and Thomasma, where health care professionals are defined as moral agents indebted to the public, in the first section of the paper I assert that the due to the nature of the drug development processes, the pharmaceutical industry is also morally indebted to the patients and the public and that its current role as a typical free market player can not be justified. Therefore, contrary to the common approaches, which simply try to place limits on the interaction between the pharmaceutical industry and other parties without recognizing any inherent ethical issues in the nature of the promotion and direct to consumer advertising, it is argued that these activities themselves are unethical in the healthcare context and should not be allowed.

In the second section of the paper, I first examine the paradigm shift that took place in the pharmaceutical industry’s recent past and point out that the change was not for the better. I then argue that the pharmaceutical industry needs to be reformed and that both health care professionals and patients can enforce the moral commitments required to reform the industry. Finally, I will address the lack of systematic
approaches in bioethics on the issue and the need for defining a consistent moral framework where the industry practices can be critically examined.

**Key words:** Pharmaceutical industry, drug sale promotion, direct to consumer advertising

**Introduction**

Pharmaceutical companies are one of the most important actors in the health care scene today. However, the ethical aspects of the pharmaceutical industry’s practices (such as drug sale promotions) are usually evaluated from the perspective of the health care professional rather than that of the industry itself. To a certain point, this is understandable: the professional’s duty to promote the patient’s benefit is a well-established one in bioethics and therefore, it is easy to assert that the commitment of the health care professionals should be first and foremost to their patients, and not to the pharmaceutical companies. Furthermore, studies on the issue have been reported to indicate that the physician – pharmaceutical industry interaction is mostly associated with problematic physician practices, such as the rapid prescription of a new drug (1), so it makes practical sense to view the issue from the perspective of the professional’s ethical obligations. This approach is clearly seen in the works of authors like Brody, who have suggested that physicians should ‘refuse to see’ pharmaceutical representatives (2).

There have also been efforts to place limits on the health care professional – industry interaction by focusing on the other end of the spectrum, namely, the drug sale representatives. A typical example of this approach can be found in “Code on Interactions with Healthcare Professionals” by Pharmaceutical Research and Manufacturers of America (PhRMA) (3). This Code in question prohibits offers with entertainment or recreational purposes (such as tickets to sport events or vacation trips…) to health care professionals, as well as the use of non-educational and practice related items (such as pens or note pads with company logos imprinted on them) for promotional purposes.

On the other hand, whether the focus is on the health care professional or the sales representative, there is a common element in both of these approaches: they try to minimize the conflict of interest created by the physician – pharmaceuticals industry relationship and its potential (and sometimes very real) harmful consequences. However, as valuable as these approaches may be, they do not necessarily recognize any of the interactions between the pharmaceutical industry and the professional as inherently problematic. What is even more important is the fact that such approaches do not usually attempt to construct a solid moral framework within which the activities of the pharmaceutical industry can be critically examined. As a result, the ethical obligations of the industry become difficult to define and justify, and the inherent ethical problems in the industry’s practices are hardly recognized, as in the case of drug sale promotion activities and advertising. This paper aims to show that such a moral framework can actually be based on the nature of clinical drug trials with human volunteers and it argues that moral commitments that go beyond the currently accepted standards, including those that apply in drug sale promotion and advertising, should be defined for the pharmaceutical industry.

**The nature of clinical drug trials: A sound basis for imposing ethical obligations on pharmaceutical companies**

Developing a new drug is a very costly, long and multi-staged process, but for the purposes of this article, the most important stage is the final one which involves clinical drug trials. These trials aim to show whether the new drug is efficient and safe for therapeutic use in a given medical condition and for this purpose, the drug is tested on human volunteers.
While a detailed analysis of the ethical aspects of human research is beyond the scope of this paper, it is essential to understand that these trials, unlike routine health care service, do not primarily aim to benefit the individuals who have volunteered to take part in them; the findings are expected to provide benefits for future patients and for society. While this does not necessarily mean that the patients in these trials will not experience any benefit, one should understand that the main objective of these studies is to document whether any relevant change will be observed as a result of the application of the drug molecule. In other words, the drug tested may or may not be effective and safe; therefore, these trials may not only fail to provide any benefit, but may also include risks or may cause harm for volunteers. Therefore, the volunteers are expected to understand these facts and give valid informed consent before they can participate in these trials. If the research process is mistaken for an individualized health care service, then “therapeutic misconception” may arise, and this misconception prevents the participants from giving a valid informed consent (4). For this reason, some bioethicists indicate that ‘attaching the favorable term therapeutic to research can be dangerous, because it suggests justified intervention in the care of particular patients’ (5).

At this point, it should be clear that volunteers participating in drug trials are actually in a unique position where they may not necessarily experience any direct benefit and may even be exposed to several risks. This is an undertaking which primarily aims to benefit the society and future patients, rather than simply serving the subjects’ own interests. On the other hand, successfully completed drug trials also serve the interests of the pharmaceutical companies, as also indicated by authors such as Beauchamp and Childress, who note that “…the returns from a successful trial are the life-blood of the company” (5). When a drug has been shown to be safe and effective for use in these trials, this means that the pharmaceutical company can now apply for a marketing license. Once the drug is approved for a certain condition and the license has been granted, the company is free to start marketing the drug. In other words, without the voluntary participation of human subjects, a pharmaceutical company can never complete the licensing process for its drug and move on to the marketing stage.

Unfortunately, it is difficult to say that the ethical significance of this consequence has been fully recognized in bioethics, although the significance of similar relationships has been recognized in the health care services long ago. In their influential work in which they establish the idea of ‘medicine as a moral community’, Pellegrino and Thomasma have noted the vital contribution of society to medical knowledge and to the training of physicians, arguing that ‘certain invasions of privacy’, which include ‘actions that would be illegal in circumstances other than medical education’ are allowed by society (6). In this analysis, it is important to realize that the actions in question do not promise any direct benefit for the patients who allow them; the aim is to ensure that ‘society has an uninterrupted supply of trained medical personnel’ (6). Therefore, the authors argue that health care professionals are morally indebted to society and assert that the knowledge physician possess ‘is not proprietary’ and is not intended for ‘personal gain, prestige or power’ (6).

I not only agree with Pellegrino’s and Thomasma’s analysis, but also assert that this line of thinking can and should be extended for the pharmaceutical industry. Successful drug trials conducted with the voluntary participation of human volunteers, where they are not the primary beneficiary, allows the industry to start marketing their drugs; however, the knowledge gained from these trials can not be proprietary to the industry alone. The industry is, in fact, morally indebted to society and this debt can serve as a sound basis upon which the moral aspects of the pharmaceutical business can be constructed and the ethical obligations of the pharmaceutical industry can be formulated. However, the implications of this position appear to have been either deliberately overlooked or have been unnoticed for some reason.
Although the pharmaceutical companies have been expected to meet strict legal and ethical requirements in clinical research, the marketing practice has been left to be governed simply by the dynamics of so-called ‘free market regulations’ where profit making without any obvious violation of the laws in force – and sometimes even at the expense of violating them – is the single motivation. Sadly enough, the industry itself appears to have no complaints about acting out its assigned role. The most obvious indicator of this can be found in the ‘profit-only’ mentality shaping the drug sales promotion activities, as examined below.

**Drug sale promotion: Close encounters with the third kind**

The main purpose behind drug sale promotions is to ensure that drugs of a certain company are prescribed more frequently than those of the competitors; the benefit for the patients has no direct significance. This situation has not gone unnoticed by bioethicists. Weber, for instance, notes that ‘although pharmaceutical companies have an interest in promoting good care, marketing practices are designed to sell products’ (10). However, this marketing-based perspective is in total contrast with that of a health care professional, who is expected to promote the patient’s benefit first and this creates a double standard which is difficult to justify: While a health care professional is always required to recommend the best available options to her patients, a pharmaceutical company -and its sales representatives- are never expected to cease promoting their drugs even when a more effective, safer, or cheaper alternative is available. Furthermore, despite this obvious conflict between the position of the drug industry and health care professionals, drug sales representatives can freely access health care professionals and attempt to influence their prescribing habits. The prescriptions, however, affect the life and the health of the patients. Due to the nature of their job, the representatives have to promote the interests of the companies they work for, but they have no apparent duty to promote the patients’ benefits. Last but not least, the patients may have no knowledge about this process and its possible effects on their physicians.

In the light of all these irreconcilable differences between the goals and the positions of the health care professionals and the industry, it is difficult to see how the practice of drug sale promotion has been legalized and perceived as normal for so long and why simple measures such as limiting the interaction of two parties has been considered adequate. This intrusion on the relationship between the patient and the health care professional by the introduction of an agent of the ‘third kind’ is unjust, regardless of the content or quantity of the gifts, promotions or information provided. Therefore, drug sale promotion is ethically unacceptable; the industry should not be allowed to practice it.

**Direct to consumer advertising: Patients as consumers ?**

Direct to consumer advertising (DTCA) of prescription drugs is actually the patient counterpart of drug sale promotion. It is another problematic manifestation of the profit-first mentality of the industry and therefore, there is no fundamental difference between the two. However, while there are those who point out the problematic aspects of this practice and emphasize its marketing-oriented nature (8). DTCA is a popular instrument widely used by the industry today, although regulation policies are reported differ between USA and European countries (9).

The main argument for supporting DTCA appears be built on its potential contribution to patient empowerment; some are reported to claim that DTCA can improve patient care because, ‘through informed questions about specific medications’, patients can ‘assist physicians in avoiding underuse or misuse of drugs’ (7). Such claims, however, are problematic because they are based on a number of false and unjust assumptions. The first of these is the assumption that pharmaceutical companies are in the same position as health care professionals for whom there is a well-established professional duty to
promote the patient’s good; in fact, this is recognized as the primary duty of the health care professional. The problem is that no such duty appears to apply for the current pharmaceutical industry, which is mostly recognized as a typical free market player whose primary goal is to maximize its profits. There is an inherent conflict of interest between this goal and the concept of patient empowerment; the latter would require patients to be truthfully informed about all choices available. However, companies competing for profits do not (or cannot) emphasize the weaknesses of their own products or confess that their product is inferior to something else; this would undermine their profit-making efforts. Furthermore, it is a big mistake to think that all companies can advertise and thus ‘inform’ patients about their products; only those who can afford a budget for advertising can. Therefore, it is practically impossible for DTCA to support a truly informed patient choice; it can only serve to increase the demand for the advertised pharmaceutical agent. For the same reasons, DTCA cannot avoid underuse or misuse of medicines. In fact, this claim seems to be a very poor excuse for incompetence of health care professionals. The problems in question need to be addressed as errors made by health care professionals and they should be treated as such. To claim that these can be remedied by the efforts of the pharmaceutical sector is absurd: Two wrongs do not make a right.

That being said, the most problematic issue regarding the support for DTCA in the pharmaceutical market is the assumption that patients can be considered as typical consumers in an ideal free market environment. This assumption is unjust and erroneous. Normally, consumers not only have the power to choose among different products from competitors (who truly compete to innovate and come up with new and superior products), but also the option of refusing to buy anything at all; through these mechanisms, individuals can exert consumer pressure on the industry and demand that it respond to their needs. However, these dynamics can not apply in the pharmaceutical market since drugs have to be prescribed by a licensed professional and patients may not always be able to refuse to use the products of the pharmaceutical industry; such refusal may even turn out to be a life-threatening or fatal decision. For instance, hypertensive patients would not be expected to boycott anti-hypertensive drugs, when such a decision could cost their lives! Under these circumstances, allowing the use of DTCA, which may include biased and misleading information, only serves to exacerbate the disadvantaged situation of the patients.

On the other hand, it is difficult to contest the idea that patients should be able to access reliable information whenever they need; physicians or other health care professionals do not have to be the only available source of information on pharmaceutical agents. Therefore, despite the objections I have presented above against the use of DTCA, I appreciate the efforts of those who try to defend it through its possible contribution to patient empowerment on condition that ‘the presentations provide fair and balanced information on the benefits and risks of therapy’ (10). In its current state, however, the pharmaceutical industry can not be expected to serve this purpose. As I argue in detail below, the industry needs to be reformed if it is to become a source of reliable information.

**From competitive innovation to innovative competition: Why the pharmaceutical industry needs to be reformed**

Up to this point, I have examined the problematic aspects of specific activities of the pharmaceutical industry, and have pointed out the need for and justification of a pharmaceutical industry that dedicates itself primarily to promoting patient welfare ahead of profit-making. In order to strengthen the argument and address the possible practical implications of my approach, here I will look at the bigger picture of the pharmaceutical industry.
The modern pharmaceutical industry is a giant sector investing heavily in marketing. In a JAMA article published in 2000 by Wazana, the industry was reported to have spent more than 11 billion dollars for promotion and marketing (1). However, the works of several scholars of history of medicine suggest that this focus on marketing (rather than research and development for novel treatments or innovation) is a relatively new trend. Porter, for instance, points to the contrast between ‘the cornucopia of truly effective drugs’ that had become available by the 1960s and ‘the last few decades’ where ‘… many recent preparations are “me-too drugs”, minor variants on existing ones, designed to win a rival manufacturer a share of the market‘ (11). On a similar note, Bynum observes that ‘small firms get swallowed up in larger ones and contemporary budgets for advertising and sales are larger than those for research and development (12).

One might be tempted to dismiss these comments simply as the personal concerns of the scholars on the issue, but facts and figures verify their observations. In their thought-provoking analysis of the pharmaceutical industry and arguments against drug patents and monopolization, Boldrin and Levine (both academic economists) cite data from a National Institute of Health Care Management Report (13) based on FDA applications between 1989-2000 and indicate that ‘about 77% of what the FDA approves is “redundant” from the strictly medical point of view’ (14). This conclusion is in line with Porter’s observation and it suggests that “me too” drugs (and not innovation) are now playing a major role in the market. Boldrin and Levine’s analysis also provides support for Bynum’s observations, pointing to the monopolization that followed the patenting of drug molecules (14) while also noting that the sector’s ‘top 30 firms spend about twice as much in promotion and in advertising as they do in R&D…’ (14).

These findings suggest that a paradigm shift has recently taken place in the pharmaceutical industry: innovation is no longer essential. In fact, it might even be more profitable to avoid it. However, this change was obviously not for the better and it is the major culprit in the development of the ethically problematic marketing practices for drugs discussed above. In fact, the defining characteristic of this new paradigm appears to be its focus on the development of newer and more cunning – if not at times entirely unethical and even illegal– marketing strategies rather than novel drug molecules. In other words, the industry is now behaving as if treatments for all major threats to human health have already been discovered and there is no urgent need for innovation. This perspective is not only unrealistic but also dangerous, since it implies that the pharmaceutical industry is now free to pursue primarily its own profits and interests.

Opposing this current paradigm of the industry is an ethical duty of uttermost importance; the pharmaceutical sector must undergo a reformation process and acknowledge that the fulfillment of its moral duties to the patients and the public is its primary goal. However, this is certainly a most challenging task and some would doubt whether this could be possible at all. I address this issue in detail below and argue that despite the financial strength the industry possesses, the health care community and the patients still have the power to enforce moral commitments on the industry in case it refuses – as it does now – to re-evaluate and reform itself.

**Revisiting clinical drug trials: What should health care professionals do and what can patients do?**

The recent change in the pharmaceutical industry summarized above is probably causing many people to consider the industry as morally corrupt today. This idea becomes even more difficult to refute when one considers the scandals involving the big players of the sector and the huge sums of monetary fines these
players are willing to pay as a result of their marketing practices (14). Therefore, the idea of a pharmaceutical industry morally committed to promoting patient welfare as its primary goal may not seem like a realistic idea. However, while I do not by any means think that the reformation process I propose is an easy undertaking, I think that it is quite possible to enforce moral commitments on the industry. In order to prove this, I would like to note a number of vital points which the pharmaceutical industry apparently does not recognize: first, the more “me too drugs” and similar products are produced, the harder it becomes to justify clinical drug trials with human volunteers. The industry has to understand that if the current trend for refusing innovation for the sake of profit-making continues, the ethical (and perhaps even the legal) status of clinical drug trials will have to be challenged. This means that in time, the role of health care professionals as researchers in industry-sponsored trials will become more and more questionable. In fact, they may have to refuse that role altogether in the near future. Furthermore, if health care professionals are genuinely dedicated to promoting the interest of their patients first and foremost, then they will also be required to start advising against participation in clinical drug trials (and particularly against those that do not involve the development of innovative treatments). Needless to say, the practical implications of this approach may also require professional organizations, state authorities and legislators (as well as bioethics and health law scholars) to take action, but the change can best be initiated by the health care professionals.

The second point to be emphasized is the key role the patients may play in the process. The power patients hold is not something understood well by the pharmaceutical industry, because the industry is not driven by consumer pressure. Instead of focusing on what patients need and answering their demands, the industry mostly relies on its promotion activities through which they can change and shape the decisions of health care professionals. Naturally, this environment also causes the industry to forget the fact that patients still play a key role in clinical drug trials, which is the critical step the industry must complete before the drug can be marketed. While many patients today probably still believe that they will be worse-off without the development of new drugs, if that belief is once lost and patients start thinking that the industry is basically making huge profits through their participation in drug trials without making a significant contribution to the already existing treatment choices, they may start refusing to take part in drug research and the industry may soon find itself on slippery ground. Normally, such a consequence would be expected to cut both ways and become a significant threat to human health and not only to pharmaceutical industry’s profits. The problem is that the current practices of the industry do not appear to be based upon the idea of mutual beneficence. While it is true that the industry needs patients to make profits, whether patients really need what it provides (and whether the industry really cares for what patients need) is not clear anymore. Therefore, it becomes increasingly difficult to claim that patients will be worse-off without ‘new’ drugs, which may in fact not be promising anything new. This means that companies that do not promise to innovate can perish soon. Patients indeed possess the power to make that happen, particularly if their actions are combined with those that can be taken by the health care professionals noted above.

Conclusion: Practical implications and limitations

My criticism of the pharmaceutical industry may appear undeserved to some, therefore I would like to clarify my position. I do not see the industry as an “evil to fight against” by any means; such views are not rational. The pharmaceutical industry is without a doubt one of the major actors of the health care scene. Its function as an innovator of new treatments can not be denied and it has helped many ‘dream’ cures of modern medicine come true. However, the industry is in a serious moral crisis today, because it has failed
to embrace the moral implications of its practice. It is a fact that the industry is a for-profit one and there are responsibilities a pharmaceutical company owes to its shareholders. However, these responsibilities cannot have priority over the industry’s moral duties to patients and the public, because, due to the unique nature of the drug development process, the industry is indebted to the patients and the public: without the contribution of human volunteers and the risks they take, licensing of drug molecules would not be possible.

Establishing the promotion of the patient’s good first and foremost as the sine qua non of the health care worker’s professional integrity has a long history in biomedical ethics. In the light of the analysis presented in this paper, I do not see any reason why the same standard should not apply to the pharmaceutical industry and its employees. Unfortunately, the current focus of the industry on profits fails to acknowledge the moral value of the contribution of the human volunteers and patients to clinical drug trials. Furthermore, the industry assumes that patients are just like other consumers in a typical free-market environment where the buyers can freely choose among different brands and products, demand refunds or boycott the products entirely to exert consumer pressure. These assumptions are wrong because of the vital role licensed professionals (physicians and pharmacists) play in the process and the limitations diseases may exert on people: not choosing to buy any drug can be a fatal decision and therefore, the patients may have no choice. Sadly enough, instead of acknowledging the possible effects of these vulnerabilities and admitting the need for much higher moral standards than those other for-profit industries utilize, the pharmaceutical industry chooses to ignore the moral aspects of its business and exploits the vulnerabilities of patients through drug sale promotion and DTCA of prescription drugs. This environment is unjust and therefore, unethical.

The position I presented in this paper can have numerous practical implications. While a detailed examination of such implications can not be attempted on a single article and is therefore beyond the scope of this paper, I would like to elaborate on the issues of drug sale promotion and DTCA of prescription drugs. These instruments belong to an ideal free market environment as defined above, but their use can not be justified in the health care context and particularly for prescription drugs. For this reason, terms like ‘ethical drug sale promotion’ are actually absurd; promotion and advertising activities of the pharmaceutical sector can not be considered as reliable sources of information. Physicians and other healthcare professionals can (and should) access data on new drugs through more reliable means, such as peer-reviewed journals, expert panel reports etc. For the patients, however, the issue is more problematic, because they need to be provided information that is free from medical jargon and scientific terminology. Nevertheless, this task can easily be assigned to state bodies and/or independent panels and non-governmental patient rights organizations -provided that they do not have conflicts of interests- but certainly not to the current pharmaceutical industry. However, if any of these measures can not be taken and DTCA and drug sale promotion activities can not be prohibited, then, at the very least the industry should be required to declare the inherent conflict of interest in any of these activities. Patients must be made aware that advertisements and promotional activities are devices designed primarily to serve the profit of the industry. Providing information is not their actual function and they can be biased. In the age of the internet, even this seemingly small measure can be a big step forward.

I also realize that the issue I have examined is interrelated with several other issues and most notably the status of the health care professional as the sole individual who has the authority to prescribe drugs. The contemporary debate on the problems of this status voiced by authors such as Veatch, who points out the ‘irrational’ nature of prescribing (15) and proposes alternatives such as ‘patient certification’ (15) is certainly important. However, this debate focuses on the role of the health care professional whereas this
paper’s primary focus is the pharmaceutical industry’s role and its moral obligations. I decided to limit the paper to the latter perspective, but I welcome any change that can contribute to patient empowerment. That being said, it should also be noted that changes such as those proposed by Veatch would probably increase the need for a pharmaceutical industry dedicated to patient welfare instead of profit-making, because even when patients are given the freedom to choose their drugs on their own, they still will be vulnerable – if not more vulnerable – to commercial exploitation by the industry.

Last but not least, I would like to note the need for better and more systematized inquiry on these issues in bioethics; a consistent moral framework within which we can examine the practices of the industry must be formulated. Unfortunately, in contrast to the depth and the complexity of the scholarly works that define and examine the moral foundations of the health care service and particularly the dynamics of healthcare professional-patient relationship in biomedical ethics, the majority of the approaches to the practices of the pharmaceutical industry and its employees are somewhat one-dimensional and shallow. Most of the time, the pharmaceutical industry appears to be understood and analyzed only (or primarily) as a typical free-market actor whose responsibilities to shareholders outweigh any other moral duties, whatever these may be. While the inadequacy of the current standards are realized and criticized by some, (16) there is a serious lack of systematic ethical inquiry which attempts to treat the industry as a moral enterprise in its entirety and establish a moral foundation for its practices. I would like to note that this lack is perhaps as problematic and alarming as some of the pharmaceutical industry’s marketing efforts. Therefore, I hope my approach in this paper makes a difference and contributes to what seems to be a seriously underworked and neglected area. In his famous article, Stephen Toulmin explained how ‘medicine saved the life of ethics’ (17). Whether ethics can now do the same for the pharmaceutical industry remains to be seen; but considering the past achievements of the pharmaceutical industry and its services to human health, there can be no doubt that bioethicists are morally obliged to take the challenge and try.

References


