

The Ethical Implications of Direct-to-Consumer Pharmaceutical Advertising

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Anyone watching television these days is all too familiar with the barrage of product advertisements for beer, potato chips, non-pest strips, and a plethora of other products. Generations of television viewers have seen myriad ads, and we all know that this is what pays for news and entertainment programming. What is new, or at least recent, is the direct-to-consumer television advertisementst of prescription medications.

I can recall the first time I saw one of these new kinds of ads on television. The advertisement showed an attractive young woman windsurfing through a cornfield, and the voiceover of the narrator directed me to ask my doctor about a certain prescription medication. I found the advertisement puzzling. Why was the woman windsurfing in a cornfield? Why was she so ecstatic? Why should I ask my doctor about this particular medication? In a later version of the same commercial, the narrator listed in rapid-fire order the numerous possible side effects that the drug might cause, and which would require immediate medical attention. In this later ad, I now seemed to have too much information—and too little. I could remember some of the dire possible side effects of the medication, but I still had no idea of what the prescription medication was supposed to do. The main point of the ad, it seemed to me, was to be sure to ask my doctor about the medication. Of course, the suggestion was that I should ask for a prescription.

Although I did not know it at the time, I was watching a fundamental change in the marketing of pharmaceuticals. Traditionally, direct advertising took the form of pharmaceutical “detail” men making periodic visits to physicians in their territories in order to tout the virtues of various prescription medications. The Food and Drug Administration (FDA) permitted phar-

maceutical advertisements directed to the public, but only with a full disclosure of the information on a warning label, which included a list of possible side effects, contraindications, and effectiveness. While the FDA’s requirement was suitable for print advertisements in magazines and other popular periodicals, the thirty- to sixty-second air time limit for commercials on television was too restrictive to meet the FDA’s guidelines for pharmaceutical ad placement.

Everything changed in 1997, when the FDA relaxed its standards. According to the Code of Federal

Regulations (Section 202) direct-to-consumer advertisement of prescription drugs may mention the product’s proprietary name and the disease it is used to treat, so long as major risks are summarized and adequate provision is made for the dissemination of full product label information. The thirty- to sixty-second advertisement spot was now sufficient.

Some might contend that the relaxation of the FDA regulations finally allows for full patient autonomy. The advocates of television advertising of prescription-only medications argue that ads contribute to the education of an active consumer-patient, who now might be able to describe ailments more effectively and to participate actively in a treatment plan. In fact, so this view advocates, denying consumer-patients access to the kind of information provided by ads limits autonomy and encourages a paternalistic doctor-patient relationship, because patients must rely too much on doctors for information.

But I suggest that the power to prescribe is in danger of erosion by the influence of direct-to-consumer marketing of pharmaceuticals. Prescription-giving might be influenced too much by consumer demand, and, if so, then all that stands between the marketing departments of pharmaceutical companies and consumers



are prudent physicians who can fend off the increasing pressure to provide prescriptions to patients influenced by advertising. The strength to withstand the pressure of marketing comes in part, I will argue, from acceptance—even welcome—of the role of paternalism in the physician-patient relationship.

The Power to Prescribe

Physicians are licensed to practice medicine only after approximately a decade of schooling, training, and internship. Among their lifesaving skills is the power to prescribe. Some, among them medical ethicist Alan Goldman, argue that both the process of licensing physicians and their power to prescribe drugs are paternalistic. Paternalism—the systematic control of a person or group that is similar to a parental relationship over children—characterizes the doctor-patient relationship because patients have no control how doctors are licensed—that is the role of the American Medical Association (the AMA)—and no control over what chemical compounds are deemed controlled substances. That power belongs to governmental bodies such as the Food and Drug Administration (the FDA), and to bodies of experts. The consumer's access to controlled substances lies in the power of physician prescription. While citizens can influence some workings of government, they have no say in how the FDA does its job, whom the AMA will license and according to what standards, and what chemical substances are to be restricted.

But this sort of paternalism, one could argue, is both practically necessary and morally permissible. Since

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everyone wants high quality healthcare, we need an infrastructure that consistently provides experts properly trained to provide that care. Further, since some substances are dangerous, though helpful for some medical conditions, citizens leave it to experts to describe the potential dangers of substances and to limit access to them via prescription. Government agencies, private and quasi-private bodies indirectly—and physicians most directly—have the power to treat us, heal us, and medicate us rather than allow us to risk the dangers of doing so ourselves. In short, the liberty to self-treatment and free access to any and all medically active compounds are restricted—a paternalistic practice that is necessary if the public is to be spared

the dire consequences of treatment in ignorance and the dangers of self-medication.

Although paternalism is acceptable in matters of licensing, expert opinion, and prescribing, some seem to believe that the ideal doctor-patient relationship should have no aspects of paternalism. Although Goldman explores such elements as informed consent, many ethicists seem to ignore the point that *whenever* someone is in charge of *some* aspect of our lives, we have relinquished at least some control. While medical practice attempts to include the patient in treatment decisions, paternalism is to some degree inescapable—and, I argue, even paternalism in the doctor-patient relationship is to some extent unavoidable, and it is morally acceptable.

Paternalism and the Physician-Patient Relationship

Medical ethicists Ezekiel and Linda Emanuel examine four models of the physician-patient relationship: the paternalistic, the informative, the interpretive, and the deliberative. The “paternalistic” model requires little examination; at its worst, patients receive little, or false, information from their doctors, who take no account of the patient's values and wishes, and who decide what is for the patient's “own good” in designing and implementing a treatment plan. When one looks closely at the other models of the patient-physician relationship, however, one also finds in them paternalistic aspects.

The informative model. The “informative” model calls for the “physician to provide the patient with all relevant information, for the patient to select the medical interventions he wants, and for the physician to execute the selected interventions.” This model seems the farthest from medical paternalism. However, realistically, no doctor, because of time constraints or difficulty of putting complex medical jargon into laymen's terms, can give patients all of the facts. The “facts” here might include chemical interactions of a two-drug regimen, possible side effects, and the reasons why these side effects occur. Understanding most of this would require substantial scientific training the typical patient neither has nor cares to undertake. However, to be informative in the strictest sense of the model, all of the facts need to be presented in order for the patient to make an educated decision. If a physician is to be informative, he must be thorough, and since he cannot strictly be *completely thorough*, paternalism has crept in the moment a doctor decides that certain facts either are or are not necessary to divulge to the patient.

Degrees of paternalism are present in the “interpretive” and “deliberative” models as well.

The interpretive model. The “interpretive” model requires the doctor to present the facts to her patient, to

understand the patient's values, and to consider treatment options in light of those values. In addition to the paternalism that occurs because disclosure of full information is an impossibility, paternalism also creeps in because complete and correct interpretation of patient values is also an impossibility. Suppose, for instance, that the patient is shy or fearful; his values might be hidden or expressed in a muddled way. Because patient values must be surmised, the physician can only interpret, or make an educated guess about, those values.

The deliberative model. The "deliberative" model also contains paternalistic elements. This model attempts to help the patient "develop" her value systems with her physician during the office visit. But here, too, the physician's own opinions, values, and priorities inevitably will creep in.

All three models, in short, show that paternalism is present even in well-intentioned and sensitive patient-physician relationships. Again, however, this is not to cast aspersions on physicians for their paternalism. One visits a physician for assistance, recognizing her wealth of knowledge, and wanting a firm opinion and a discussion of treatment options. Goldman focusses on the paternalism that exists in the procedural aspects of training and licensing doctors, and in the power to prescribe restricted pharmaceuticals. Unlicensed individuals are barred from exercising their full autonomy, because a limit to autonomy is preferable to the possibly disastrous consequences of self-diagnosis and self-treatment. The Emanuels focus on the physician-patient relationship. But their characterizations of the various models show that, even when physicians are informative, offer medical opinions, and discuss treatment options, the relationship is paternalistic because the physician must choose what information to give, in what form, and influenced by the physician's values and priorities, based on suppositions about those of her patient.

My contention is that *all* interactions between physician and patient are paternalistic to some degree, and that they *should be* so. The degree of paternalism might be in question, but not its existence or appropriateness. If paternalism exists, and it is practically necessary and morally permissible, then the question remains: How does direct-to-consumer advertising and marketing of pharmaceuticals influence the power to prescribe and, more broadly, the the necessarily paternal relationship between doctor and patient?

The Power of Suggestion: Marketing and Commercialism

All humans have needs and desires. While needs are required to survive, desires can include needs, but, in addition, desires include those things we seek out to

make life more pleasant or satisfying. Among the strategies of advertising and marketing are: 1.) to show the consumer ways to fulfill already-existing needs or desires (the new or improved cleaning agent), or 2.) to create new needs or desires in the consumer (try this particular allergy medication so you'll feel free like you're surfing on dry land), or 3.) to challenge a pre-existing belief about a product (Brand X pain relief product is no longer dangerous because the bottles are now tamper resistant).

Radio, television, the Internet, in addition to written media, are all marshalled to sell both necessary and unnecessary products. The result of ubiquitous and insistent advertising is what one might call *commercialism*, which is the subconscious or conscious effect of manufacturing a desire or perceived need in someone through the power of suggestion. Who has not felt that she must have something she has just seen for the first time in an advertisement, never mind that she has no use for that product, and in fact, has never felt a need that the item supposedly fills?

The desire for some items might be harmless—wanting a certain kind of car, shoes, or mouth wash. But some manufactured desires are not so innocuous. Consider tobacco products. Even today, with smoking being the habit of the damned, advertising is limited but still plentiful. The images portrayed—rugged outdoorsmen, willowy and glamorous women—are meant to encourage admiration and emulation. Because tobacco products are unhealthy and addictive, governmental policy now restricts its promotion via advertisement, with the goal of reducing the number of new adult smokers, and preventing the acquisition of the habit among young people. The right of the manufacturer to advertise is limited because the potential harm to the public and to public health is so catastrophic. If the harmfulness of tobacco products justifies limits to marketing, should other potentially hazardous products be treated differently? Alcohol consumption is legal for adults, yet here too, advertisement of alcohol products is restricted for the public good. Can a similar case be made for direct-to-consumer advertising of pharmaceutical products?

Combatting Commercialism with Paternalism

Some might say that pharmaceutical product advertising *is* sufficiently restrictive. But recall my experience with the television ad of the the young woman on the surfboard. A seed is planted: Could the touted allergy medication have the same salutary effect on me? Was this the magic I was looking for? Perhaps it would be, if I suffered from significant allergies. The victory of marketing genius begins the moment I call my physician at the suggestion of the advertisement's sponsors. Victory is assured when I visit my doctor,

especially if my experience of the advertisement leads me to apply pressure to my physician for a prescription. Further, because my doctor is a responsible, knowledgeable person, he describes the medication's uses and effects. It may be the case, however, that his description allows me to deceive myself into believing that I have the symptoms that will be alleviated by prescription. I leave my doctor's office, prescription in hand; the marketing victory is complete.

But medications can be used improperly. If marketing and advertising create new needs or desires, then prescription-only medications can also be the object of manufactured need or desire, and the public clamor for them can result in suffering dire side effects and result in long-term harm. Cholesterol-lowering medications, for instance, can damage the liver; anti-depressants can effect sexual dysfunction, and medications for erectile dysfunction can cause heart attack or stroke. Manufactured needs can result not only in damage to health, but people who are seduced by direct-to-consumer advertising of pharmaceuticals also might never explore the safer and efficacious options possible with lifestyle changes, such as healthy diet, exercise, or stress reduction. Consumers, finally, in emphasizing the severity of symptoms or by manufacturing symptoms, could lose the important skill of "listening" to their bodies and seeking health care sensibly and when necessary.

In prescription medication commercials, patients are encouraged to ask their physicians about certain drugs and, by implication, they are encouraged to request a prescription. If the medication is not needed, or is dispensed based on the description of a non-existent condition, then harm—even dire harm—might be the result. Even more worrisome is the availability of prescription medications ordered from the Internet and without a doctor's office visit. The doctors who prescribe through the Internet do no service to any patient (if one can call a person a "patient" when he or she has never been examined by the physician in question). Any time a patient succeeds in obtaining unneeded prescription medication, the marketing campaign is the winner.

However, if the issue began and ended in the physician's office, paternalism would serve the true interests of the patient. The patient who demands prescriptions based on an appealing ad is not autonomous or actively involved in her health care. A physician-patient relationship that is based on an informative discussion leads to patients who are truly informed and therefore better capable of making free and educated decisions. Advertising is selective in the information it provides because its sponsors hope to generate desire for the product. Physicians are selective in giving patients information, based on judgments about the efficacy of some treatment options and judgments about the patient's ability to make

informed choices among those options. This sort of selective presentation of information is paternalistic, or so I have argued. However, it is practically necessary, morally justified, and it should not be confused with the selectivity of information in advertising directly to consumer-patients. Advertisement selectivity serves not the patient, but the corporate sponsor; but when a physician selects among all the information she has in educating her patient, she does so with the patient's best interest in mind. Direct-to-consumer advertising of pharmaceuticals intrudes on the physician-patient relationship. It conflates the differences between selective presentation of medical information by ads and by doctors, it confuses the strong urges of consumer product desire with taking responsibility for one's health care.

Assuming that no further substantial governmental intervention is on the horizon, and that drug manufacturers will continue to directly advertise to consumers, such advertising can usefully inform consumers of the existence of prescription medications that might help genuine maladies. Certainly, patient-consumers should be encouraged to involve themselves in their treatment to the extent that they feel confident and comfortable doing so. However, it is also important to remember that we seek out physicians for their expertise and guidance, and that this relationship is to an extent paternalistic. If physicians falter in exercising their power to prescribe—that is, if they shirk from this aspect of the necessarily paternalistic doctor-patient relationship—then in effect doctors will be relinquishing the power to prescribe, and they will be transferring that power, not to patients, which is also inappropriate, but to pharmaceutical manufacturers. The patient's true condition becomes almost irrelevant; what he or she *wants* becomes primary. The role of the physician is transformed into that of mere prescription dispenser in the consumer's search to realize a health fantasy. The practice of medicine could become just that, practice, in the worst sense of the word.

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Sources: Ezekiel J. And Linda L. Emanuel: "Four Models of the Physician-Patient Relationship" in *Journal of the American Medical Association*, 267, no.16, April 22/29, 1992, pages 2221–2226; Alan Goldman, *The Moral Foundations of Professional Ethics*. (Rowman and Littlefield, 1980); United States Food and Drug Administration, Center for Drug Evaluation and Research: *Guidance for Industry: Consumer-Directed Broadcast Advertisements*. (Food and Drug Administration, 2003).