

A Bitter Pill: Prescription Drug Costs and Direct-to-Consumer Advertising

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Anyone who watches TV is aware of the dramatic proliferation of direct-to-consumer advertising (DTCA) of prescription drugs (I've noticed that these ads only appear on stations whose demographic includes me. Presumably, millennials are not buying many drugs for urinary urgency or ED). Research shows that total DTCA in the United States (New Zealand is the only other country that allows it) totaled only \$12 million in 1989; it reached \$350 million five years later, tripled by 1998, doubled to \$2.24 billion by 1999 (after the FDA relaxed its advertising rules) and doubled again by 2005.¹

Not all of these ads are the same. The FDA describes three general categories. One the "help-seeking ad" which provides "only information about a medical condition and encourages patients to contact their physician." These ads do not mention a specific product. A second category is "reminder

ads" which include the product name and may provide information about "strength, dosage form, or price, but...[don't] mention indication or make any claims." The third category is a "product claim ad" which mentions the name, the indication, and makes claims about efficacy or safety.² Most of the ads we see on TV today are of this third kind.

DTCA raises several different ethical questions, most of which are subsets of principles related to marketing in general: efficacy, side-effects or limitations of the product, value, truthfulness of claims about benefits, and cost. The matter is further complicated because many ethicists consider drugs (and health care in general) are not just another product but rather "special goods [that] are different from others in the market place." If prescription drugs are in a different category from tires, snowblowers or beer, then the ethical bar for advertising must be raised higher for them.

A review of the literature on DTCA reveals several specific ethical hazards: overselling, over-pricing, re-pricing, informed consent, and the impact on the role of the physician. In addition, these questions must be examined at both a micro and a macro level, since the cost of drugs affects individual

patients as well society's ability to allocate a certain percentage of our total health care dollars to drugs as opposed to other kinds of therapies.

Overselling

This is related to truthfulness in claims about the efficacy of a drug which involve both promises and disclaimers. Even though DTCA has been guided since 1985 by an FDA requirement for a "fair balance" of information³ and "brief summaries" of drug benefits or side effects, ads sometimes overestimate benefits or underplay risks by visual images of happy, carefree patients that do not reflect the seriousness of side effects or even of the illness itself.⁴ In their article on the "vernacular of risk," Greene and Watkins note the difficulty of conveying risks to patients by means of technical information printed in tiny type on a package insert. Indeed, they describe early attempts to be "virtually useless" as information sources.

Another aspect of overselling is creating or identifying a "new" disease and then marketing a drug that will treat it. The most familiar example is Viagra and other treatments for "erectile dysfunction."

Overpricing

There has been a great deal of publicity about the high cost of prescription drugs, especially those designed for relatively rare diseases. A recent study by the Kaiser Family Foundation says that the high price of drugs is the public's top health care priority⁵. The American Medical Association recently called for a ban on consumer advertising of prescription drugs, saying that "marketing costs play a role in fueling escalating drug prices," and that "patient care can be compromised when prescription drugs are unaffordable."⁶ Ezekiel Emmanuel notes that Cerezyme for Gaucher disease (a genetic disorder that causes fat accumulation in organs) and Kalydeco for cystic fibrosis both cost about \$300,000 per year – or almost \$1,000 a day – and have to be taken for the rest of the patient's life. One author describes her own personal experience of seeing the price of Gleevec rise from \$3000 to \$9000 per year between 2007 and 2015.⁷

The price of prescription drugs continues to rise, with the list price rising faster (12% last year) than the net price (the price insurers and employers pay). The latter was only 2.8%. This sounds like good news, but the unintended consequence is that those who might actually end up paying the full list price are often the uninsured or unemployed, who do not have the leverage of volume purchasing. "It's sort of

embedded in the health care system that the price is never the price, unless you're a cash-paying customer, and in that case we soak the poor," says Adam J. Fein.⁸ This should be a major concern to those in Catholic health care if we claim to be advocates for the poor.

Another aspect of overpricing is packaging. In a move that resembles selling 20-ounce bottles of soda to people who only want to drink 12 ounces or selling a package of chips at the same price, even though it contains 10% less product than it used to, some cancer drug manufacturers effectively sell more drug than a patient needs by marketing only one vial size. This results in waste and raises cost.⁹

Other manufacturers have attempted "differential pricing"¹⁰, in which they sell drugs at different prices in different countries in line with the income levels in those countries. Some have cost assistance programs (e.g., "If you have trouble paying for your medication, call us, we may be able to help"), but one researcher says "The public relations benefits [of these programs] for drug companies may outstrip the actual improvement in medical outcomes for patients."¹¹ Another maintains that these offers are designed to make companies look generous so "patients won't complain about the ridiculously unsustainable prices because they won't see them, which in turn allows prices to continue to rise."¹² In addition, only a small percentage of

eligible patients appears to take advantage of these offers, and there is evidence that getting such help is cumbersome and time-consuming.¹³

Repricing is a slightly different issue. It occurs when a manufacturer buys a generic, unpatented drug, patents it, and sells it at an enormously inflated price. This is what happened recently when Martin Shkreli of Turing Pharmaceuticals bought the rights to Daraprim, which treats toxoplasmosis, and raised the price from \$13.50 to \$750 per tablet.

Value-based Pricing

Products that perform better are usually more expensive. However, benefit and value are often subjective, and especially so in health care. The benefit of surgery or chemotherapy to me may be a clear burden to someone else. Some drugs, such as Opdivo, promise to add time – about 3.2 months on average -- to a lung cancer patient's life. The problem is that it costs about \$150,000 per year for treatment. Of course the problem here is not the high price, but the patient's perception of the value of an additional 3.2 months. How much is that time worth? This calculation is much easier if someone else -- a private insurer, Medicaid or Medicare -- is paying the bill.

There have been some efforts to establish value-based pricing on prescription drugs, i.e., paying

more for drugs that have fewer side effects or better indications of effectiveness. If this were the case, the widely advertised Jublia, a topical medication for toenail fungus, wouldn't fare too well. A full 48-week course of treatment could cost over \$10,000. The fact that it is fully effective in only 20% of patients is not mentioned in its ads¹⁴. As researcher Peter Bach says, "A drug that works is worth something. One that doesn't is not. If a new drug works no better than an older one, the two have equal worth. If a drug costs a lot, that's OK only if it makes people so healthy that it reduces their spending on other forms of health care."¹⁵

The problem of assessing value and truth claims is exacerbated because ethics and compliance have not kept pace. Although the FDA regularly sends "warning letters" to pharmaceutical companies that stray too far, the number of FDA employees falls far short of what is necessary for adequate monitoring. Indeed, the \$4.8 billion spent by big pharma on DTCA in 2006 is more than double the entire budget of the FDA.¹⁶

Informed Consent

Informed consent is at the heart of ethical medicine. There is little doubt that DTCA provides more information to patients, both about the drugs and about other treatment options. The question is whether there is enough information about the

drug's benefits and side-effects and whether the patient is able to understand that information well enough to make a good choice. Does DTCA really improve patients' understanding of their conditions, or is it designed primarily to influence doctors' prescribing choices? Some researchers believe that DTCA makes patients more informed, more involved and even more compliant. Others fear the risk of misinformation and manipulation is too high.

"Relationship marketing" affects informed consent. It is designed not just to generate a one-time sale, but to create an enduring relationship with the patients so as to create a steady revenue stream. As Alford and Naughton note, the purpose of relationship marketing is "to establish, maintain and enhance (usually but not necessarily long term) relationship with customers and other partners, at a profit, so that the objectives of the parties involved are met. This is achieved by mutual exchange and fulfillment of promises."¹⁷

A strong relationship between health care providers – even a pharmaceutical company – is ordinarily a good thing. In fact, one of the great weaknesses of our current health care system is lack of a medical home and the relationship that goes with it. However, if the relationship is structured for the provider's benefit, then its value to the patient may decline. The ethics of "relationship marketing"

must be measured against an authentic understanding of the virtue of solidarity, by which we are bound to others by virtue of our membership in the human community. Clearly ethical business practices are based on solidarity; cheating, fraud and deception are violations of it. Such practices place self-interest above the value of the human relationship. Relationship marketing can easily short circuit so that we “skim over the fundamentals of relationship building on our rush to cash in on the potential rewards of creating close connections with our customers.”¹⁸

Physician-Patient Relationship

The most dramatic change brought about by DTCA is the change in the relationship between the physician and patient. Until recently, the physician was the exclusive mediator between the patient and prescription medications. Few patients would even have *known about* specific medications, let alone had the nerve to request them by name.

Pharmaceutical companies avoided direct marketing until the 1970s because they did not want to be associated with “patent medicine” which was sold over the counter without a physician’s advice. Early ads referred patients to physicians because physicians gave their products legitimacy. While some physicians feel DTCA gives patients more information and more control, others find it to be

an unwarranted intrusion into their relationships, especially if patient requests are ill-advised or uninformed.

Financial incentives can impact the role of the physician as well. Although pharmaceutical companies cannot pay physicians directly for using their products, they can pay consulting or lecturing fees. These are publicly disclosed.

Currently Medicare pays doctors the average sales prices of a drug, plus a 6% commission. This means that more expensive drugs generate more revenue for the physician. In March of 2016, Medicare announced it was setting up a trial to eliminate this “perverse incentive” to prescribing more expensive drugs by reducing commissions on more expensive drugs and instituting a flat fee for whatever drug is prescribed.¹⁹ If it works, it will become the new standard.

Conclusion

The debate about direct-to-consumer advertising is a complex one that involves health care economics, public policy, marketing, health outcomes, patient autonomy and health care disparities. Supporters of DTCA say that it educates and empowers patients, encourages patients to contact a physician, strengthens the doctor/patient relationship, reduces under-diagnosis and under-treatment, removes the

stigma associated with some diseases and encourages competition and lower prices. Opponents say DTCA can encourage overutilization, overemphasis on benefits, expose patients to risks that may not be known, and leads to inappropriate prescribing, increased cost, and tension between the patient and physician.

I have only drawn attention to a few of the most prominent issues. I have not addressed the ownership of drugs and drug research and the ways in which we try to protect pharmaceutical intellectual property rights. This important question deserves its own thorough treatment.

Rising expenditures on drugs and health care in general make it certain that both policy and ethical evaluation will continue to evolve.

¹ Two studies cite the same statistics. C. Lee Ventola, “Direct to Consumer Pharmaceutical Advertising,” *Pharmacy and Therapeutics* (October 2011): 669-674, 681-884; and Jeremy A. Greene and David Herzberg, “Hidden in Plain Sight: Marketing Prescription Drugs to Consumers in the 20th Century,” *American J of Public Health* (May 2010): 793-803. It is important to note that while spending on DTCA has increased dramatically, it is still a relatively small percentage of pharmaceutical promotion overall. Much more is still spent on traditional marketing to physicians, which is often a combination of promotion and education.

² Ventola, “Direct to Consumer.” See also Greene and Herzberg, who track the graduation evolution from general ads in the early 20th century which simply linked the manufacturer to praiseworthy qualities and professionalism (to distance themselves from less respectable “patent” medicines) to the much more detailed ads we see today. Further information about FDA advertising categories found at www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072077.htm. Accessed March 21, 2016.

³ Jeremy Greene and Elizabeth Watkins, “The Vernacular of Risk – Rethinking Direct-to-Consumer Advertising of Pharmaceuticals,” *NEJM* (September 17, 2015): 1087-89. See also Ventola, for a fuller description of the history of direct to consumer advertising.

⁴ Ventola, 15, at “Overemphasizes Drug Benefits.”

⁵ “Prescription Drug Costs Remain Atop the Public’s National Health Care Agenda, Well Ahead of Affordable Care Act Revisions and Repeal,” KFF news release, October 28, 2015, <http://kff.org/health-costs/press-release/prescription-drug-costs-remain-atop-the-publics-national-health-care-agenda-well-ahead-of-affordable-care-act-revisions-and-repeal/>, accessed March 21, 2016.

⁶ American Medical Association, “AMA Calls for Ban on Direct to Consumer Advertising of Prescription Drugs and Medical Devices,” news release, November 17, 2015, accessed March 21, 2016.

⁷ Erin Havel, “Name Brand Drugs Costs Are Too High and Generics Are Growing Out of Reach,” <http://www.huffingtonpost.com/erin-havel/name->

[brand-drug-costs-are-too-high-and-generics-are-growing-out-of-reach_b_9161066.html](#), accessed 3/21/2016.

⁸ Mr Fein is quoted by Katie Thomas, “Drug Prices Keep Rising Despite Intense Criticism”, *New York Times* (April 26, 2016). Andrew Pollack cites a similar problem that arises from an attempt in California to keep state programs from paying more for any drug than the Veteran’s Administration does (they get a favorable rate). Again, it sounds good, but AIDS advocacy groups are wary, claiming that lowering the price paid by the state might increase the cost for others. The article notes that lack of transparency in pricing is a major problem. “California Drug Price Plan is Criticized by Patient Advocates,” *New York Times*, July 4, 2016.

⁹ Gardiner Harris, “Waste in Cancer Drugs Costs \$3 Billion a Year”, *New York Times*, March 1, 2016, citing a study done by Memorial Sloan Kettering Cancer Center and published in February by the *British Medical Journal*.

¹⁰ Sara Parker-Lue et al, “The Ethics and Economics of Pharmaceutical Pricing,” *Annual Rev of Pharmacol and Toxicol* (2015:191-206) at 199. This article presents an excellent overview of several ethical issues in pharmaceutical pricing.

¹¹ *Ibid.*, 195.

¹² Erin Havel, “Name Brand Drugs Costs Are Too High”.

¹³ Parker-Lue et.al., 195.

¹⁴ Jublia’s website indicates that 15-18% of patients achieve complete cure after 48 weeks of treatment.

<http://www.jubliarx.com/efficacy-side-effects>, accessed March 21, 2016.

¹⁵ “A New Way to Define Value in Drug Pricing,” *NEJM Catalyst*, February 24, 2016. Cites “DrugAbacus” which enables patients to make a more objective assessment of value.

¹⁶ Greene and Herzberg, “Hidden in Plain Sight,” 801.

¹⁷ *Managing As If Faith Mattered*, p. 183, quoting C. Gronroos. Relationship marketing is the result of trying to replace the “4 Ps” of marketing (product, price, place, promotion) with “4 Cs” (consumer need, consumer cost, convenience and communication, [p. 188]).

¹⁸ Alford and Naughton, 184-185, quoting S. Fournier et al, “Preventing the Premature Death of Relationship Marketing.”

¹⁹ Margot Sanger Katz, “Medicare Tries an Experiment to Fight Perverse Incentives,” *New York Times*, March 10, 2016.