

The Price of Seduction: Direct-to-Consumer Advertising of Prescription Drugs in the US

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Between 1997 and 2000, spending on direct-to-consumer (DTC) advertising of prescription drugs more than doubled to reach \$2.5 billion¹ and, in light of this trend, a conservative estimate for 2003 would be a figure in the region of \$3 billion. Of the 9,900 prescription drugs on the market in 2000, the top 50 most heavily advertised drugs had combined sales of \$41.3 billion, almost one-third (31.3%) of the total retail prescription drug sales that year.² The same 50 drugs accounted for almost one half (47.8%) of the increase in the value of such drug sales from the previous year.³

Spending on DTC advertising of prescription drugs has begun to outstrip mainstream consumer goods. In 2000, for example, \$160 million was spent on the promotion of Vioxx®, significantly more than the sums spent by PepsiCo® and Budweiser® on each of their premier products.⁴ More than half of all expenditures on DTC advertising that year was concentrated on 15 new patented drugs, all of which are for chronic conditions (such as acid reflux, allergies, arthritis, asthma, depression, high cholesterol and impotence) and therefore have the greatest potential to give manufacturers long-term financial return.⁵

Demonstrating clearly the effect of DTC advertising is a little more difficult than one might imagine because direct-to-consumer advertising is usually coupled with promotion to physicians. However, in a recent review of a number of studies, the US General Accounting Office concluded that, on the whole, advertising increased both drug utilization and sales.⁶ Two studies reviewed by the General Accounting Office suggest that a 10% increase in spending on DTC advertising in a particular drug class increased sales by 1%.⁷ At first glance this might appear insignificant. However, in real terms this return could create a substantial increase in profit for the drug company. Applying this rate of return to the top-selling drug in 2000, Prilosec®, which achieved sales of more than \$4 billion with DTC advertising expenditures of approximately \$108 million, an increase in DTC advertising expenditures of \$1 million could increase sales by around \$4 million.

The Targets of DTC Advertising

Some critics of DTC advertising are concerned that it diverts patients from treatment with cheaper but equally effective generic drugs. A recent paper prepared by the National Institute for Health Care Management (NIHCM) on the changing patterns in pharmaceutical innovation reports that the market for generic drugs, which cost between 30 to 60% less than brand name equivalents, has “stalled.”⁸ Although 1,505 new generic products were approved by the FDA between 1994 and 2000, there has been virtually no increase in the overall market share of generic drugs since 1997.⁹ This is due in part to industry practices that include making minor modifications to an existing drug (for example, introducing a slow-release version) in order to retain patent protection and then heavily promoting the modified drug using DTC advertising. It should therefore come as no surprise that the NIHCM found that there is a “disparity between spending and clinical value, with a large increase in recent spending attributable to line extensions providing no significant clinical improvement over older medicines.”¹⁰

Other criticisms of DTC advertising are based on concerns that much of such advertising works by playing on consumers’ anxieties about their health and/or by “medicalising normal human experience”.¹¹ One of the most conspicuous examples of the latter is the opportunistic advertisement for the antidepressant, Paxil®, in the *New York Times* in October 2001 under the headline: “Millions suffer from chronic anxiety. Millions could be helped by Paxil®.”¹² Anxiety following the events of September 11, 2001 was clearly not just an understandable response. It was also an irresistible marketing opportunity.

The Education Fallacy

DTC advertising of prescription drugs is often justified on the grounds that it causes patients to be better informed about potential treatments. However, the principal purpose of product

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advertising is not to educate, but to seduce: to persuade us that our lives will be better when we have the advertised product than they are now. DTC advertising has embraced this ethic of seduction and tends to be more emotive than informative. This is apparent from the most cursory glance at a DTC prescription drug promotion, whether it is a glossy magazine advertisement with its page of unreadable small print or soft-focus television advertisement in which side-effects are read hastily and in monotone.

A study of 320 advertisements for 101 prescription drugs appearing in 18 popular magazines from 1989 through 1998 revealed that most advertisements failed to provide information about the drug's mechanism of action (64%), its treatment duration (89%) or its success rate (91%).¹³ Advertisements also failed to mention alternative treatments (71%) and behavioral changes that could enhance the health of affected patients (76%).¹⁴ A further study of 67 magazine advertisements for prescription drugs appearing in 1998 and 1999 revealed that 67% used emotional appeals, 39% encouraged consumers to consider medical causes for their experiences and 87% described the benefit of medication in vague, qualitative terms instead of relying on data.¹⁵

The data for television advertisements should also cause concern. In a survey of 1,872 viewers, 70 percent thought they had learned little or nothing more about the health condition requiring treatment, and 59 percent thought they knew little or nothing more about the drug being advertised.¹⁶ It should, therefore, come as little surprise that a recent survey of 500 physicians commissioned by the FDA revealed that 75% of them believed that direct-to-consumer advertising caused patients to think the drugs advertised worked significantly better than they actually do.¹⁷

Impact on Prescribing Practice

Those who support direct-to-consumer advertising sometimes dismiss these concerns by relying on the intervening role of the physician. However, studies suggest that DTC advertising has an impact on the exercise of clinical judgment by physicians. The US General Accounting Office estimates that 8.5 million consumers annually request and receive from their physician a prescription for a particular drug in response to seeing a direct-to-consumer advertisement.¹⁸ The FDA's recent survey of 500 physicians considered the effect of a patient's request for a specific drug. In 61% of cases the physician felt some pressure to prescribe a drug and in 57% of cases the encounter actually resulted in a prescription for the requested drug.¹⁹ Such data should cause concern, particularly when read in conjunction with the results of a further study which suggests that physicians are ambivalent about the treatment in half the cases in which they prescribe drugs requested as a result of direct-to-consumer advertising.²⁰

Human Costs

The unrealistic expectations created by direct-to-consumer

advertising may come at an extremely high price, beyond mere financial or social costs. Two incidents demonstrate the actual and potential human costs. A survey of 997 male patients in an STD clinic in San Francisco showed that some respondents were less likely to practice safe sex because DTC advertisements for antiretroviral therapy (which often used images of mountain climbing and javelin-throwing)²¹ suggested that HIV could be effectively controlled or overcome and was therefore a less serious condition.²² Advertisements may therefore not simply fail to educate, they can actually encourage dangerous or unhealthy conduct.

In 1997, a new drug for the treatment of type II diabetes, Rezulin®, was introduced into the US and heavily promoted by DTC advertising. It was then introduced into the UK and withdrawn six weeks later, when it was linked to six deaths and 135 cases of severe liver toxicity.²³ In spite of this, the manufacturers continued to promote the drug heavily in the US using DTC advertising. Rezulin® was not withdrawn from the US market until March 2000, more than two years later, by which time it had been identified as the probable cause of 556 deaths, including 68 from liver failure.²⁴ By this time, Rezulin® had also earned its manufacturers \$2.1 billion in sales revenue. Such conduct, of which this is only one particularly egregious example, demonstrates that pharmaceutical companies cannot always be relied upon to act in the interests of public health, let alone to take on the role of public health educator.

Regulation in the US and Abroad

In Europe, the direct-to-consumer advertising of prescription drugs is prohibited.²⁵ Recent proposals by the European Commission²⁶ to relax the prohibition and permit the provision of consumer information by manufacturers of drugs for the treatment of AIDS, asthma and diabetes were overwhelmingly rejected by the European Parliament²⁷ and by EU health ministers.²⁸ The prohibition on advertising is, however, not simply a European phenomenon. The United States is the only industrialized nation that permits the DTC advertising of prescription medicines, apart from New Zealand.²⁹ In New Zealand, however, there have been recent calls for the introduction of a ban on DTC advertising of prescription drugs, and its future is uncertain.³⁰ It should also be noted that the World Health Organization has stated that DTC advertising should generally not be permitted for prescription drugs³¹ and has recognized the "inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way."³²

In the US, however, DTC advertising is considered "commercial speech" protected by the First Amendment and the recent jurisprudence of the Supreme Court indicates that it would currently consider a ban on DTC advertising to be unconstitutional.³³ Existing rules do not authorize the FDA to require prior approval of a prescription drug advertisement except in very limited circumstances.³⁴ Although they do permit the voluntary submission of advertising materials for comments

by the FDA,³⁵ much of the work of the FDA involves sifting through a backlog of advertisements which are already being disseminated. If an advertisement is found to be in breach of the rules, the FDA issues a regulatory letter (either a warning letter or a letter giving notice of a less serious violation).³⁶ A recent report by the US General Accounting Office indicates that half of these letters cite advertisements for making misleading claims about a drug's efficacy.³⁷ Of equal concern, the issue of these letters has recently been taking up to 78 days, by which time many of the advertisements, particularly those on television, are no longer being aired.³⁸ The report also makes clear that although regulatory letters halt the dissemination of misleading advertisements, they do not deter pharmaceutical companies from making misleading claims in subsequent advertisements, even those for the same drug.³⁹

Conclusion

The Supreme Court has said that "[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort."⁴⁰ In the context of public health, such an approach may come at an extremely high cost. This has been recognized in Europe where it is expressly acknowledged that freedom of expression may be subject to restrictions for the

protection of public health⁴¹ and where the precautionary principle has been adopted.⁴² According to this principle, in the face of threats of serious or irreversible damage to human health or the environment, lack of full scientific certainty should not be used to postpone cost-effective measures to prevent such damage.

The primary, legitimate interest of pharmaceutical companies is to maximize profits. This interest will not always coincide with the protection of human health, particularly where a pharmaceutical company has invested hundreds of millions of dollars developing a drug and is anxious to recoup its costs. It is the responsibility of the FDA to ensure that the interests of the former not triumph at the expense of public health. In the US, the doctrine of commercial speech (as currently interpreted by the majority of the Supreme Court) puts advertising first and thereby undervalues the importance and complexity of government regulation in the sphere of public health, ties the hands of legislators, and threatens to undermine the efficacy of the FDA. In spite of this, there is clearly room for more effective regulation. And if we are serious about keeping the public informed of important healthcare issues and about empowering patients to participate in decisions concerning their own healthcare, we should also consider a publicly-funded information program motivated by concerns to educate its audience rather than to maximize profits.

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