Regulating pharmaceutical advertising: What will work?

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Abstract

As Dr. Joel Lexchin makes painfully obvious in this issue (see pages 351 to 356), regulatory processes governing pharmaceutical advertising in Canada and elsewhere are seriously compromised. However, the remedial measures Lexchin proposes are not sufficient. Financial sanctions against improper advertising are likely to be regarded by manufacturers as the cost of doing business, and any regulatory body that includes drug industry representatives or individuals receiving financial support from the drug industry cannot be genuinely independent. Moreover, manufacturers are now using promotional strategies that are particularly difficult to regulate. These include providing drugs at lower than the usual cost to ensure their inclusion in managed-care formularies, and using direct-to-consumer advertising to take advantage of the public's lack of sophistication in interpreting scientific evidence. Our best hope of counteracting the power and influence of the drug industry lies in regulation by government agencies, whose interest is the protection of the public.

Résumé

Comme le Dr Joel Lexchin le démontre d'une façon qui n'est que trop évidente (voir pages 351 à 356), les mécanismes de réglementation qui régissent la publicité sur les produits pharmaceutiques au Canada et ailleurs sont gravement compromis. Les mesures correctives que propose le Dr Lexchin ne suffisent toutefois pas. Les fabricants risquent de considérer les sanctions financières entraînées par une publicité indue comme le coût normal des affaires, et tout organisme de réglementation où siègent des représentants de l'industrie pharmaceutique ou des personnes qui reçoivent de l'aide financière d'elle ne peut être vraiment indépendant. De plus, les fabricants ont maintenant recours à des stratégies de promotion particulièrement difficiles à réglementer. Ces stratégies consistent notamment à faire une remise sur des médicaments pour en assurer l'inclusion dans les formulaires de soins dirigés et à utiliser la publicité directe aux consommateurs pour profiter du fait que le public n'est pas assez averti pour interpréter des données probantes scientifiques. Notre meilleur espoir de contrer le pouvoir et l'influence de l'industrie pharmaceutique réside dans la réglementation par des organismes gouvernementaux qui ont pour mandat de protéger la population.

If the practice of medicine is an art, pharmaceutical advertising is its predominant public expression. The $12.3 billion annual budget for drug advertising in the United States exceeds that for all undergraduate and postgraduate medical education and comes close to the entire budget of the National Institutes of Health.[1] Because the goal of advertising is to induce someone to buy (or, in the case of prescribing, cause others to buy) a product that they otherwise would not purchase, there is plenty of opportunity for mischief if that product is potentially harmful or very costly. Only isolated voices contend that we should not regulate drug advertising in some way. The challenge that we face is to develop an approach that will do more than put a face of respectability on reprehensible practices. Somehow, we must maximize the public good and minimize the ability of advertisers to increase sales when evidence of the merits of a product is lacking or when that product poses a health risk or unjustifiably increases costs.

Pharmaceutical companies have taken the initiative in several industrialized

Editorial

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countries to "regulate" promotional activities. The strategic intent is to prevent governments from becoming more involved in regulation. The ultimate goal is to continue business as usual without having to justify one's activities to parties whose primary interest is not the maximization of sales.

What do we know about the effectiveness of self-regulation in assuring the quality of advertising and other forms of promotion? Unfortunately, as Dr. Joel Lexchin makes painfully obvious in this issue (see pages 351 to 356), regulatory processes are seriously compromised. Reviewing the procedures in place in Australia, Canada and the United Kingdom, Lexchin concludes that adjudicating committees often include substantial (or majority) representation from within the industry. In all three countries the monitoring process is relatively passive and consists largely of fielding complaints, although Australia and the United Kingdom have provisions for the review of randomly selected materials. When contraventions of standards do occur, the consequences are trivial. Canada has a system for independent preview of written, audio and visual materials, but it is unclear how effectively it screens out problematic content. Only in the United Kingdom does there seem to be any serious effort to notify the wider medical community about problems with drug promotion.

Lexchin proposes a series of remedial measures, including 1) proactive monitoring for violations, to be financed by a levy on manufacturers, 2) constitution of a monitoring committee which, like that in Australia, would be comprised largely of individuals without any financial ties to the industry, 3) stiffer sanctions and 4) wider reporting of violations. Are these measures justified? Are they sufficient?

First, what is the extent of the problem? Many promotional practices have not been observed in great detail, but we do know quite a bit about some of them. One US study[2] examined the quality of advertisements published in leading general and specialty medical journals. For each of 106 full-page advertisements, 2 clinicians in the relevant field with experience in peer review and 1 academic clinical pharmacist were asked to provide a detailed review in the light of relevant federal regulations. The reviewers identified many inaccuracies, misrepresentations and other deficiencies. A large proportion of the advertisements minimized concerns about adverse reactions, were misleading with respect to efficacy, used statistics inappropriately, promoted the use of products in inappropriate populations and used headlines and subheads that were not supported by the remainder of the written text of the advertisement. Reviewers were asked to rate the appropriateness of the advertisements for publication in the form in which they actually appeared. Where there was consensus by at least 2 of the 3 reviewers, 28% of the advertisements would have been rejected and 34% would have required major revision before publication.[2] In another study, 42% of materials distributed by pharmaceutical manufacturers directly to physicians were found not to comply with relevant US federal regulations.[3]

None of this is very surprising. Although pharmaceutical manufacturers often contend that their promotional activities are largely educational, it is not in their interest merely to provide data that can then be used for rational decision-making. There is every reason to believe that activities that are even more difficult to monitor than published advertisements are more likely to seriously misrepresent products. How does this measure up against the complaint mechanisms generally used to detect violations? Complaints are relatively uncommon, even when regulatory violations are widespread. If a process is to succeed in minimizing violations it must set out first to identify those violations, or at least to put culpable manufacturers at risk of being found out.

Regulation will accomplish little unless the manufacturer has something to lose. A company may view a fine of a few thousand dollars for an occasional violation as the price of doing business, a cost that can be tacked on to the price of the product. When penalties are minimal, there is no deterrence. But can economic penalties, even large ones, work at all? There is little evidence that economic penalties have much effect unless they are extremely high. But even a very large fine might be worth paying if the advertisement or activity in question generates substantial revenue. A more promising approach would be to impose a penalty that really affected the manufacturer's ability to sell the product. This could take one of two forms: a concerted campaign to make it widely known that the manufacturer had misbehaved and cannot be trusted, or a prohibition against selling the misrepresented product at all. To accomplish the former, copies of detailed reports need to be circulated to all physicians as well as to general and medical media. Funds would have to be allocated to ensure that the message reached the general public. It is unlikely that the more severe measure of banning a product from sale would ever be taken.

That the body overseeing the regulatory process should not be comprised of industry employees is obvious. The industry should have nothing to do with the constitution of such a board, and the board's members should not include physicians who receive support from the pharmaceutical industry. Likewise, neither consumer nor professional representatives should own any stock in companies whose products might be reviewed. Finally, there should be proactive data collection on all forms of promotional activity.

Would such a beefed-up regulatory process reduce the

mischief that manufacturers can do? Perhaps minimally, but we cannot be too optimistic given the enormous amount of money that is marshalled in the pursuit of market share. Indeed, manufacturers are developing strategies to move their products through the marketplace by means that are even less susceptible to regulation. Two such trends in the United States deserve comment. First, the movement of large numbers of Americans into managed-care organizations has led these organizations to develop limited formularies. Getting one's product into a formulary is potentially very lucrative. The decision to include a given product on a formulary list appears to be based largely on economic considerations. Granted, managed-care purchasers are often able to negotiate better prices for products (although not necessarily any better than that obtained by government purchasers), but the optimization of health care is not always of paramount concern in the selection of product lines. Manufacturers have, at times, provided drugs to hospitals at very low cost in order to introduce them into physicians' practices; similarly, physicians who are required to prescribe certain drugs for their managed-care patients may be more likely to generalize their prescribing behaviour to other patient populations.

Second, drug advertising targeted directly to the consumer is becoming common. A recent advertisement contended that a particular lipid-lowering agent was the only one shown to prevent certain serious complications of coronary artery disease. This prompted a number of my patients (who were on an equally good drug that had not been used in the clinical trial cited by the advertiser) to ask why they were not on the product that could save their lives. Direct-to-consumer advertising has the potential to stimulate demand by playing on the consumer's relative lack of sophistication about the evidence that supports the use of one treatment over another.

The pharmaceutical industry is resistant and resilient. It has a great deal at stake and passionately believes that its promotional practices must be maintained. The industry is also powerful. When a leading clinical journal published the article, discussed earlier, on peer review of pharmaceutical advertisements[2] with editorial comment by the administrator of the US Food and Drug Administration,[4,5] advertising revenue in that journal dropped precipitously. Although it could never be proved that a drop in advertising was a deliberate attempt to punish the journal, this was widely considered to be the case. Unfortunately, so many academic physicians depend on the pharmaceutical industry for funding that they tend to be reluctant to speak out about abuses of which they are aware.

The pharmaceutical industry has too much at stake to monitor its own promotional activities in a reliable manner. Government is in a better position to represent the consumers' interests, to allocate the necessary resources to monitor evolving marketing strategies and to crack down in a meaningful way on offenders. Lexchin's recommendations make sense only in the hands of an entity that, at the end of the day, is trying to protect the consumer, not increase profits. Even with such an approach, the prospects for overcoming the enormous power and influence of the pharmaceutical industry are dismal.

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