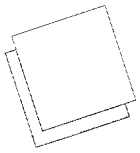

Misplaced marketing

Misplaced fears of off label prescription drug marketing

Chester S. Galloway
Assistant Professor, School of Accountancy, Auburn University, Auburn, Alabama, USA

Keywords *Drugs companies, Marketing, Marketing management, USA*

Abstract *The United State Food and Drug Administration gives approval for prescription drugs that are shown to be safe and effective to treat specific conditions. But once the drug is available, physicians can prescribe it for other "off label" uses, the positive therapeutic side effects that are discovered by the medical communities' own information networks. The pharmaceutical manufacturers would like to be able to tell other doctors about these positive side effects, but they are barred from such "off label marketing" practices except under very narrow conditions.*

Prescription drug approval

In the USA, once a prescription drug is given approval by the Food and Drug Administration (FDA) it may be legally marketed only for specific purposes. However, pharmacological compounds often have unanticipated therapeutic impacts known as "side effects". While side effects are commonly thought of as negative, they can be positive, too. Doctors can legally write prescriptions "off label" for these side effects even though these are uses other than those that gained the drug its initial approval. Yet to many critics of the pharmaceutical businesses, the manufacturer is acting improperly if the sales staff or marketing efforts promote the drug for these off label uses. Known as off label marketing, this creates an inherent conflict between the marketing desire to provide information doctors need or want and what the company is allowed to provide.

To understand unexpected and positive side effects better, consider the drug alcohol. Besides its euphoric effects, recent studies indicate that moderate and a frequent consumption has beneficial cardiovascular effects (Ashley *et al.*, 2000). It is also quite common for physicians to recommend patients to take a daily dosage of aspirin to promote cardiovascular health, which everyone must know is not an FDA approved use. Off label prescribing is part of the normal and accepted practice of medicine. In pragmatic terms, off label marketing is usually precipitated by off label prescriptions and any off label marketing is telling other doctors of what their colleagues are doing. The art of medicine is far from an exact science. Focused on the best interest of their patients, doctors prescribe that medicine which they believe will be most efficacious.

Off label marketing

Off label marketing, however, raises different questions and concerns in that it involves the selling of a product for use other than as approved by the FDA or for a population, such as children, who were not approved by the FDA to use the drug (*The (California) Sacramento Bee*, 2002; Pande *et al.*, 2000). Doctors can write prescriptions for off label uses, and consumers are often helped by such physician innovations, but the companies who make the product are supposedly acting improperly if they inform customers of

successful off label uses. The problem comes down to what business critics consider marketing abuse.

It is important to note that despite the growth of direct to consumer (DTC) marketing by pharmaceutical companies, there does not exist any examples of off label DTC marketing. To the extent any off label marketing is performed, it is to very well educated and sophisticated physician intermediaries, highly educated professionals who are not motivated by profit in the prescribing decision. That is the whole reason why we have classes of drugs that are available only by prescription (Rotfeld, 2002).

Exchange of information

Many off label uses of drugs are discovered and advocated by organizations other than the drug manufacturer, a third-party exchange of information not considered by many as encompassed in the term off label marketing but is the strongest factor in off label practices. In many instances these informal networks work better than clinical testing, catching errors in initial approval decisions as well as broader uses. Clinical trials are by no means foolproof. In one recent instance a company did not do anything improper and received FDA approval for a drug that could be prescribed for the treatment of a irritable bowel syndrome. But after several patients died apparently from taking the drug for that purpose, the company withdrew the drug from the market (*FDA Consumer*, 2002). Informal networks were largely responsible for discovery of the problem, not the FDA and not the manufacturer's pre-approval drug trials.

In 1997 US Congress passed the Food and Drug Administration Modernization Act that specifically authorizes the off label marketing of drugs under certain limited guidelines. Generally, a manufacturer may market a new use of an approved drug by giving doctors unabridged peer reviewed or refereed scientific publications. The manufacturer must report to the FDA on off label marketing activities and concomitantly submit a supplemental application for such a new use. This broadens the ability of companies to inform doctors of new uses of an existing product, but these changes in the law are limited and cumbersome, expecting new and expensive product testing, plus the slow process of review and publication of new refereed journal articles, while the clock on the drug's patent keeps ticking.

Costs of development

As with any new product, to recoup the substantial costs of development new drugs receive patent protection for exclusive sales rights under US and international patent law for a period of 20 years from the date of the application for the patent, and patent approval generally takes about two years. However, patent approval is separate and distinct from FDA approval which may takes another two years and requires its own expensive costs for product testing (e.g. DiMasi *et al.*, 2003). The costs of controlled scientific studies of drugs can be expensive and time-consuming. Drug makers must recoup their R&D costs and make a profit on newly approved drugs during the patent period – once that protected time period ends, generic copies flood the market substantially reducing or even removing the profitability of the drug. To the company, the potential for profit pretty much ends when the patent period expires.

Admittedly there exists a potential for unscrupulous manufacturers to overreach the marketing of drugs without sufficient scientific evidence of efficacy and safety. The more uses to which a drug can be put, the more prescriptions will be written and the more profit will be made. This creates economic incentives for pharmaceutical companies to suggest to physicians

uses for patented drugs other than those approved by the FDA, but they are not encouraged to invest the time and expense in more testing. These pressures could result in off label marketing recommendations despite questionable scientific evidence for the use.

Reform of patent law

Resolution of this problem, to the extent it exists, lays not in tighter drug regulation, but a reform of patent law that might provide an incentive for additional off label product testing by the companies. Where a manufacturer has invested in substantial additional testing to discover and prove the safety and efficacy of a new use, additional patent protection is warranted especially if the new use proves to be substantially better than any existing off patent drugs.

As noted, off label marketing can provide beneficial information for many doctors. The use of selected, or worst, pseudo-scientific articles as a basis for off label marketing is both deceptive and illegal, but the fear of it being a major problem or danger for consumers is probably unfounded. Substantial cases of abuse are likely to be rare and when they occur will be short lived due to the gate keeper role of the physician.

References

Ashley, M.J., Rehm, J., Bondy, S., Single, E. and Rankin, J. (2000), "Beyond ischemic heart disease: are there other health benefits from drinking alcohol?", *Contemporary Drug Problems*, Vol. 27, pp. 735-77.

(The) (California) Sacramento Bee (2002), "Walking a medical tightrope with few drugs tested for children, physicians rely on trial and error", *The (California) Sacramento Bee*, 24 June, available at: http://infoweb.newsbank

DiMasi, J.D., Hansen, R.W. and Grabowski, H.G. (2003), "The price of innovation: new estimates of drug development costs", *Journal of Health Economics*, Vol. 22, pp. 151-85.

FDA Consumer (2002), "FDA approves restricted marketing of Lotronex", *FDA Consumer*, Vol. 36, July/August, p. 4.

Pande, A.C., Crockatt, J.G., Janney, C.A., Werth, J.L. and Tsaroucha G. (2000), "Gabapentin in bipolar disorder: a placebo-controlled trial of adjunctive therapy", *Bipolar Disorder*, No. 3, Pt. 2, 2 September, pp. 249-55.

Rotfeld, H.J. (2002), "Information you can't use", *Journal of Consumer Affairs*, Vol. 36, Winter, pp. 299-302.