Comments on Consumer-Directed Promotion

Docket No. 2003N-0344

Marta Wosinska*
Harvard Business School

December 1, 2003

1 Report summary

In response to the FDA's request for comments on consumer-directed promotion, I submit findings from two empirical studies I conducted. While these studies are under review in peer-reviewed journals, they are available as working papers at the Social Science Research Network website:

- "*Just What the Patient Ordered? Direct-to-Consumer Advertising and the Demand for Pharmaceutical Products*,"
  Harvard Business School Marketing Research Paper No. 02-04,
  http://papers.ssrn.com/sol3/papers.cfm?abstract_id=347005.
- "*Advertising and Optimal Consumption Path: The Case of Prescription Drugs*,"
  Harvard Business School Marketing Research Paper No. 03-07,
  http://papers.ssrn.com/sol3/papers.cfm?abstract_id=459100.

This report discusses the study design, findings and generalizability of both studies. Research described here the was funded by the Agency for Healthcare Research and Quality (grant R03 HS11600) and by two centers at the University of California at Berkeley: Center for Health Research and Institute for Business and Economic Research.

*Author's affiliation and contact information: Marta Wosińska, Assistant Professor, Harvard Business School, Boston MA 02163, phone: (617) 495-6548, fax: (617) 496-5853, email: mwosinska@hbs.edu.

2 Effect on Physician's Prescription Choice

In the first study, I focus on the effect consumer-directed promotion may have on physician's choice of drug. More specifically, I address the following questions. What is the role of consumer-directed promotion vis-à-vis physician-directed marketing (so called detailing)? Does consumer-directed promotion undermine the price sensitivity mechanisms used by health plans for cost containment? In particular, does consumer-directed promotion have an impact on demand for drugs insurance companies try to contain?

2.1 Study design

I address the above questions by analyzing prescription decisions for a subset of patients enrolled in a Blue Shield of California PPO plan during 1996-1999. The size of the estimation sample (11,520 prescription decisions for 4,728 patients) is restricted by the availability of copayment data for brands the physician did not choose. Refills are excluded from the analysis because the decision to refill belongs to the patient. These patient-level data are combined with monthly, brand-level consumer-directed promotion data from Competitive Media Reporting (CMR). IMS Health is the source for monthly, brand-level detailing and free sampling data. After combining these three data sources, I estimate the probability that a physician will prescribe a drug given its characteristics: time-invariant brand characteristics (fixed effect), patient's copayment, indicator for previous treatment with the drug, formulary status of the drug, and level (and stock) of the three primary marketing instruments: consumer-directed advertising, physician-directed promotions and lagged free sampling activity. To address the possibility of differential impact of promotions on formulary and non-formulary drugs, I also interact the formulary indicator with the three marketing instruments listed above.

2.2 Findings

The analysis indicates that consumer-directed advertising has a significant positive influence on probability of choice — a $1 million increase in consumer-directed advertising expenditures increases market share by 0.5%. However, this effect is found only for drugs that have preferential status with the insurer (are listed on the formulary). In other words, there is no evidence for a strategic effect to undermine the formulary. Moreover, this effect is significantly larger if physician-directed promotions (detailing) are not taken into account. Thus the oft cited finding that doctors honor 70% - 85% of consumer requests for specific advertised brands may be driven by physicians' preference for these drugs rather than patients' influence. Last, the estimated marginal impact of detailing is found to be significantly larger than the marginal impact of consumer advertising. This is consistent with the ability of consumer-directed advertising to affect total market size substantially more than detailing does — detailing can shift patients from non-drug therapies or increase testing for a particular ailment, but it cannot bring untreated consumers into the office. It is also supported by a steep rise in the total number of prescriptions filled by Blue Shield patients — while the enrollment doubled, the number of cholesterol prescriptions rose 300% between early 1996 and late 1999.

2.3 Generalizability

The generalizability of these findings hinge on the representativeness of the sample used. One consideration revolves around the financial incentives given to patients. Clearly, the differential effect of advertising on formulary and off-formulary drugs depends on the magnitude of price incentive differentials across these two groups of drugs. This study cannot rule out that advertising may significantly increase market share for non-formulary drugs if all the advertised drugs in a category are given less preferred status and therefore assigned higher prices.

Another consideration is the early time frame of the study. In the late 1990s many brands experimented with this newly available marketing instrument. Based on conversations with industry insiders, the realization that return on investment depends on success with physicians (manifested by large market share) has likely led many pharmaceutical manufacturers to rethink their consumer promotion strategies. This may be one of the contributing factors for the slowdown of consumer-directed promotional spending.

Finally, it is important to consider whether the results may be a function of the particular category used in the analysis — cholesterol-lowering drugs. However, the findings here are consistent across studies of various drug categories. Other researchers have found that consumer-directed advertising primarily increases category sales and has little effect on market share alone (Rosenthal, Berndt, Donohue, Epstein & Frank 2002, Narayanan, Desiraju & Chintagunta 2003, Iizuka & Jin 2003). It has also been confirmed that detailing is significantly more effective at increasing market share than consumer-directed advertising (Narayanan et al. 2003).

3 Effect on Patient Compliance

The second study focuses on the ability of consumer-directed promotions to increase therapy compliance. The potential of drug advertising to improve therapy compliance has been suggested numerous times in the popular press and senate hearings (Smith 1998, Smith 1999, Manning & Keith 2001). The support for these claims often draws upon a set of annual phone surveys by *Prevention* magazine. In these surveys about a third of surveyed patients said advertisements reminded them to take or refill their medication. However, it is difficult to gauge the true magnitude of the reminder effect because of the potentially strong priming. Using unbiased outcomes data, this paper estimates the extent to which consumer-directed advertising induces existing patients to follow their prescribed therapies more closely. It also explores whether patients brought in by advertising are, on average, more or less compliant than the existing pool of treated patients.

3.1 Study design

This project uses the same four-year panel of prescription claims from Blue Shield of California, but this time both new prescriptions and refills are taken into account. The estimation sample includes 16,011 patients who initiated cholesterol lowering therapy at least four months after

they were first observed in the Blue Shield membership database. The analysis is restricted to patients on therapy between January 1996 and September 1999 and does not consider the decision to discontinue treatment (persistency). I compare the number of days between prescriptions to the number of days supplied and account for the stock of tablets from previous prescriptions. This difference corresponds to the number of non-compliant days. These data are combined with monthly, brand-level advertising expenditures from CMR.

I estimate the number of non-compliant days as a function of the brand taken by the patient, the prescribed strength, patient's copayment, refill indicator, new brand indicator, time since therapy onset, channel (mail or retail), and consumer-directed advertising. Because only monthly advertising expenditures are available, I operationalize the advertising effect by weighting the current and last month's advertising expenditures by the day of the month. I also allow for the possibility that advertising by one brand may increase compliance among patients taking other brands if it makes the condition salient. Finally, I test whether the marginal patient brought in by advertising more or less compliant. This effect on patient mix is captured by the level of own and category advertising in the month prior to the patient's first insurance claim for a cholesterol-lowering drug.

3.2 Findings

Advertising is found to have a compliance-improving effect that spills over to competing brands. In other words, advertising by Zocor and Pravachol increases compliance among patients taking Lipitor. The magnitude of this statistically significant effect is not economically substantive — a $1 million change in advertising by other brands changes the conditional mean by 1.4%, which yields an average improvement in compliance of only twenty minutes per month. Back of the envelope calculations suggest that this increase in purchase frequency results in additional $66,000 of revenue for a competing brand with 20 million yearly prescriptions priced at $50 per prescription. In addition, patients who start on drug therapy following high total category advertising tend to be more compliant possibly because they initiated the process and thus are more motivated. As with the spillover effect, the effect is significant statistically, although substantively lower than that of many other variables such as drug attributes and price.

The effect of own-advertising on compliance presents a surprise — own-advertising appears to be significantly less effective than advertising by other brands. In other words, advertising by Lipitor is not effective in increasing average compliance rates for Lipitor patients, but the same advertising by Lipitor does significantly improve compliance across Zocor patients. The paper explores a number of possible drivers behind this asymmetry: seasonal effects, demand shocks, changing patient mix, differential quality of advertising across brands and the possible impact of side-effect warnings. Only the latter two hypotheses cannot be rejected. The found asymmetry is driven by one brand in particular — Lipitor. Zocor's consumer-directed advertising has a positive impact compliance, larger than the spillover effect, however the economic magnitude remains minuscule (the same holds for Pravachol). At the same time, it appears that Lipitor's advertising is, on average, associated with increased number of non-compliant days.

A potential explanation for the negative impact of Lipitor's advertising on compliance emphasizes the unusual feature of drug advertising — the requirement to mention the severe, yet unlikely, side effects and their potential symptoms. If a sufficient number of patients reacts to hearing the possible side effects of their drug by temporarily discontinuing the therapy, then the average number of missed therapy days will increase. Some patients might decide to either contact the physician, talk to their friends, or to simply run an experiment to see if the symptom subsides when treatment is temporarily suspended. Some patients may permanently discontinue therapy, but these infinite days missed are not included in the estimation sample. In that sense, the estimate of the risk disclosure effect is conservative. Note also that the side effect need not be common — it needs to be sufficiently serious or socially embarrassing (ex. flatulence or incontinence). The effect may further be enhanced if the rare side effect has a common symptom as in the case of statins.

Lipitor is unique in that it did not begin to advertise until a large share of patients in the Blue Shield panel was built up. The ads were perhaps the first salient exposure Lipitor patients had to the potential liver problems and to the threat of rhybdomyolisis — a serious and rare condition with common symptoms (muscular pain and weakness). Accordingly, it is TV and not print advertising that is associated with higher counts of missing pills. In addition, the result holds only for patients that started on Lipitor before the onset of its 1999 television campaign. This further supports the hypothesis that the first set of Lipitor TV ads effectively provided new information.

3.3 Generalizability

The findings presented above may not be representative of every advertising campaign. First, hypercholesterolemia is asymptomatic and therefore we would expect the reminder effect to possibly be larger than in conditions where symptoms are salient. In addition, the perceived severity of side effects will drive differences in the ability of advertising to affect compliance. Finally, the effect may differ with quality of the ad copy, as well as the type of ad. In particular, patients are unlikely to learn much about the benefits and risks from a reminder ads. Help-seeking ads are more likely to affect all patients in the category. Last, product-claim ads are the only ones that mention side effects, which opens up the possibility for a negative effect on observed compliance.

The side-effects argument assumes that patients are not exposed to this information through other sources. In that sense, later Lipitor advertising campaigns may not have had the same effect. This new information effect is quite plausible because neither physicians nor pharmacists are required to verbally describe side effects to patients. Instead, side effects are listed on package inserts or leaflets attached to the dispensed pillboxes and thus more likely to be ignored by patients. The effect of this new information on compliance is likely a function of the severity of the condition, especially if the side effect has a common symptom as in the case of statins. However, the side effect need not be common — it probably needs to be sufficiently serious or socially embarrassing (ex. flatulence or incontinence).

In contrast to the previous project, the findings stand out in a relatively small academic literature on the topic. Donohue, Berndt, Rosenthal, Epstein & Frank (2003) look at consumer-directed advertising in the context of quality of care. They focus on the effect of consumer-directed advertising and physician-directed detailing on compliance with antidepressant treatment guidelines. They find that high levels of advertising (captured by monthly brand-level expenditures) have a small positive effect on the probability that a patient will have at least four prescriptions within six months of diagnosis. Bowman, Heilman & Seetharaman (2003) study the determinants of product use compliance behavior using a set of patient diaries. Aside from various satisfaction measures, these patients report whether they had seen ads (the questionnaire does not clarify whether the ads were only for the brand they are taking). Their latent class linear model yields mixed effects of advertising on compliance across various market segments. Both papers find advertising effects with magnitudes significantly lower than those suggested by the *Prevention* magazine surveys.

These findings could greatly benefit from patient and physician surveys. Existing surveys have asked whether patients are concerned about the side effect warnings and a small percentage of patients said they were. However, to my knowledge, no surveys ask patients whether patients talk to physicians about side effects they hear through advertising. How often are they concerned that their generic symptoms are actually driven by the drugs they are taking? Do they experiment by temporarily discontinuing the therapy to see if the symptoms subside? Where do they turn to for more information? Most importantly, if patients respond to the side effect warnings by seeing more information, which is observed as an increase in the number of non-compliant days, should it be called non-compliance?

References

Bowman, D., Heilman, C. M. & Seetharaman, P. B. (2003), 'Determinants of product use compliance behavior', *Working paper* .

Donohue, M. J., Berndt, E. R., Rosenthal, M., Epstein, A. M. & Frank, R. G. (2003), 'Effects of pharmaceutical promotion on adherence to guideline treatment of depression', *Working paper* .

Iizuka, T. & Jin, G. Z. (2003), 'The effects of direct-to-consumer advertising in the prescription drug markets', *Working paper* .

Manning, R. & Keith, A. (2001), 'Prescription drug advertising: Empowering consumers through information', *Economic Realities in Health Care Policy* **2**(1). Pfizer Inc.

Narayanan, S., Desiraju, R. & Chintagunta, P. K. (2003), 'Roi implications for pharmaceutical promotional expenditures: The case of second-generation antihistamines', *Working paper* .

Rosenthal, M. B., Berndt, E. R., Donohue, J. M., Epstein, A. & Frank, R. G. (2002), Demand effects of recent changes in prescription drug promotion. Working paper.

Smith, D. (1998), 'Can DTC programs improve patient compliance?', *DTC Times* pp. 14, 17.

Smith, D. (1999), 'DTC ads: Promoting compliance a win-win prospect', *Pharmaceutical Executive* **19**(12), 84.