ECONOMICS COMMITTEE NEWSLETTER

Contents

Analyzing Competition in the Pharmaceutical Industry

Rahul Guha
Cornerstone Research
Andrew M. Lacy
Simpson Thacher & Bartlett, LLP
and Sally Woodhouse*
Cornerstone Research

Introduction

Over the past decade the pharmaceutical industry has been the target of numerous antitrust actions by both government enforcement agencies and private plaintiffs. Whether the litigation involves a merger, a patent settlement, or a supply or distribution agreement, a common issue that arises is how to define the relevant product market. The structure of the pharmaceutical industry, as described below, does not easily lend itself to the traditional empirical analysis of competition based on estimating price-elasticities of demand. Furthermore, because certain forms of competition in the pharmaceutical industry are more transparent than others, erroneous conclusions can be drawn about the nature and extent of competition within a therapeutic category. Indeed, it is important to guard against the possibility of using poorly measured and incomplete pricing data to support presumptions about the nature of competition that would not necessarily hold up under a more rigorous analysis.[1]

Competition in the Pharmaceutical Industry

In contrast to situations where a person consuming a good is also the person choosing and paying for the good, the pharmaceutical industry is characterized by a more complex structure of decision making and payment. The choice of which drug is consumed by a patient to treat a particular condition is largely made by the treating physician.[2] Pharmacists cannot substitute a different branded drug within the same therapeutic category without the physician's permission. Pharmacists can, however, substitute generic equivalents of branded drugs—indeed, they are often mandated to do so. For most patients, the costs of consuming prescription drugs are also shared with insurance plans. Insurers and Pharmacy Benefit Managers ("PBMs")[3] can influence drug choice through the co-payments they charge their members. It is within this context that competition between drug manufacturers occurs.

Brand Price Competition

Price competition among branded drugs usually occurs at the level of insurers and PBMs. These entities commonly use drug formularies to drive purchasing behavior. A drug formulary is simply a list of approved prescription drugs that will be reimbursed to the patient and/or pharmacy. Three-tier formularies are commonly used in the industry, where drugs in Tier 1 have the lowest co-payments and drugs in Tier 3 have the highest co-payments. Branded drug manufacturers compete on the prices paid by patients and their insurers by offering rebates to insurers in exchange for more favorable formulary placement, i.e., insurers and PBMs create price competition among various drugs by exploiting their ability to shift demand based on formulary placement. Thus, rebates given to insurers and PBMs are an important aspect of price competition in the pharmaceutical industry. A 1998 study conducted by the Congressional Budget Office suggests that manufacturer rebates to insurers increase with the number of branded drugs within the therapeutic category.[4]

Other Forms of Brand Competition

In addition to competing by offering rebates to insurers and PBMs, branded drugs also compete through promotions that take a variety of forms. Because physicians decide which drug to prescribe, sales representatives of branded drug manufacturers provide information to physicians about new drugs and treatment options.[5] Such information may be valuable and may enhance the quality of medical care received by patients. Branded drug manufacturers also provide free samples of their drugs to physicians, which are then passed on to patients. Free samples effectively act as a price discount for both insurers and patients.[6] Finally, branded drug manufacturers also promote their drugs directly to patients.

Generic Competition

Generic drug manufacturers rely on state substitution laws to take sales away from their branded counterparts. When there are multiple generic versions available for a branded drug, wholesalers and pharmacies decide which generic version is substituted for the brand. Thus, generics have an incentive to provide price discounts directly to wholesalers and pharmacies so that their version is stocked on pharmacy shelves. It has generally been observed that generic prices fall as more generic competitors enter.[7]

Because at least a portion of these lower prices get passed on to insurers and PBMs, these entities have an incentive to encourage generic substitution. They do so by setting low co-payments for generic drugs and often increasing the co-payments for branded drugs after generic entry.[8] The co-payments may increase not just for the brand to which the generic is equivalent, but also for other branded drugs within the same therapeutic category.[9] Even though generics benefit from insurers' and PBMs' efforts to increase generic substitution, generics have little incentive to offer price discounts directly to insurers and PBMs because these entities do not influence which generic version is substituted for the brand by the pharmacist. For similar reasons, generics do not have an incentive to promote to physicians—physicians have no influence over which generic version is substituted for the brand.

Implications for Market Definition Analysis

IMS Health and Verispan are two commonly used vendors of pharmaceutical data. However, the prices captured by these vendors do not represent the amount paid by patients (i.e., co-payments).[10] Nor do they reflect rebates to insurers or PBMs by branded drug manufacturers. Instead the prices represent either the amount pharmacies pay for the drug ("wholesale prices")[11] or the total price pharmacies charge for the drug ("retail prices").[12] Because branded drug manufacturers offer rebates directly to insurers and PBMs, the prices of branded drugs in IMS Health and Verispan data are likely to be less accurate than the prices of generic drugs.[13]

Furthermore, data from commonly used sources such as IMS Health and Verispan do not account for the effect of free samples on the overall price paid for branded drugs. Even harder to measure and value are the non-price benefits of free samples and other pharmaceutical promotions.

The implication to be drawn from these data imperfections is that, while generic competition is easy to observe and measure using commonly available data sources, brand competition in the form of rebates, free samples, and promotions can be considerably more difficult to observe and measure. This, in turn, can lead to erroneous conclusions

about the nature of competition within a therapeutic category. A cursory examination of the relationship between imperfect and incomplete price measures and quantities sold can lead to conclusions about the extent of competition within a therapeutic category that may not be warranted without a more complete analysis of the aspects of brand competition that are more difficult to measure.

Incorrect conclusions about the extent of competition within a therapeutic category can be reinforced by another consequence of the regulatory and institutional framework of pharmaceutical markets: the ability of generic drugs to "free ride" on branded drug promotional efforts. As already noted, state substitution laws allow or mandate generic substitution. As a result, branded drug manufacturers lack the incentive to promote their drugs after generic entry because additional prescriptions resulting from such promotional efforts will be substituted largely with the generic version of the drug. Thus, promotions for branded drugs, including the provision of free samples, usually decrease or end after generic entry. In addition, because the rebates paid by branded drug manufacturers to insurers and PBMs often depend on the sales volume of the branded drug, such rebates may decrease after generic entry. Lower rebates combined with a reduction in free samples may cause the net price of branded drugs to substantially increase after generic entry at the same time that promotions decrease.[14] Thus, while generic entry can increase competition to supply a particular drug because there are now multiple versions of the same drug available, it can potentially lessen competition between different branded drugs within the same therapeutic category.

The result is that generic entry for a particular brand may not have the effect of reducing the quantity sold of other branded drugs within the same therapeutic category. This has sometimes been interpreted to mean that branded drugs within the same therapeutic category do not compete, when the reality may be much more complicated than that. The effect of having a lower priced generic alternative may be offset by the reduction in brand promotions. Indeed, the fact that generic entry often leads to a *decline* in the total quantity sold of a particular drug formulation—despite the lower prices that generics may offer—demonstrates the complex nature of pharmaceutical markets and the need to examine those markets carefully to draw appropriate conclusions about the relevant product market.

Conclusion

The unique structure of the pharmaceutical industry implies that the most commonly available pricing data, which do not reflect patient co-payments, rebates paid to insurers and PBMs, or the effective price discounts provided by free samples, are poorly measured for branded drugs. Such data imperfections can lead to erroneous conclusions about the nature and amount of competition between drugs within a therapeutic category. The institutional and regulatory framework guides the manner in which drug manufacturers compete and must be taken into account when analyzing price competition in the industry. A clear understanding of this framework combined with an analysis of its implications based on the specific characteristics of the therapeutic category at issue can provide considerable insights into the nature and extent of competition.

---

* The authors would like to thank Seth Sacher, Neil Imus, Peter Thomas, Michelle Burtis, Michael Keeley, and Michael Topper for helpful comments.

[1] This is not to suggest that there may not be occasions when market definition analysis is a straightforward affair. As pointed out in the Spring 2007 edition of this newsletter, "a patented pharmaceutical that is the clear treatment of choice for a well-defined medical problem would generate a clear relevant market analysis." Malcolm B. Coate & Jeffrey H. Fischer, *Insights on Market Definition at the Federal Trade Commission*, ABA SECTION OF ANTITRUST LAW, ECONOMICS COMMITTEE NEWSLETTER, Vol. 7, No. 1 at 17 n.6.

[2] Direct-to-consumer advertising has become more prevalent in recent years and may prompt consumers to take a more proactive role in the choice of their treatment.

[3] PBMs contract with health insurance companies to manage their formularies and negotiate prices with drug manufacturers and pharmacies.

[4] Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998), *available at* http://www.cbo.gov/ftpdoc.cfm?index=655&type=0&sequence=0.

[5] Advertisements in medical journals also provide information to physicians.

[6] Free samples distributed to physicians can also provide important non-monetary benefits to patients. For example, free samples can improve patient compliance with the prescribed drug regimen and offer added convenience to patients by, for instance, saving a trip to the pharmacy. Promotions in general can improve patient education by increasing the information patients and physicians have on the available treatment options, potentially resulting in improved medical care.

[7] D. Reiffen & M.R. Ward, *Generic Drug Industry Dynamics*, 87 REV. OF ECON. AND STAT. 37 (2005).

[8] Insurers and PBMs also encourage generic substitution by paying higher dispensing fees to pharmacies for prescriptions filled with generic drugs than for prescriptions filled with branded drugs. In addition pharmacies often earn higher margins on generic drugs than they earn on branded drugs, which further encourages them to substitute generic drugs for branded drugs.

[9] An insurer may also require that patients first try generic drugs to determine their effectiveness before the insurer is willing to cover branded drugs within the same therapeutic category.

[10] In recent years, both Verispan and IMS Health have begun to offer data on patient co-payments These data are often incomplete, do not go back far historically, and provide information on the number of prescriptions that fall within certain co-payment ranges, instead of the average co-payment.

[11] The wholesale price may not reflect all discounts offered by drug manufacturers to pharmacies. For example, volume discounts and prompt payment discounts may not be reflected in these prices. Generally, these discounts are thought to be a fairly small percentage of the total price.

[12] The retail price is the sum of the patient co-pay and the amount insurers reimburse pharmacies for the drug. Thus, rebates from drug manufacturers to insurers and PBMs will not be included in this price.

[13] For this reason, cross price elasticity estimates based on retail or wholesale prices from IMS or Verispan are unlikely to be reliable.

[14] Studies of the effect of generic entry on the price of branded drugs have focused on wholesale and retail prices, and thus ignore the effect of generic entry on rebates to insurers and PBMs and free samples to physicians. (See, for example, A. Saha et al., *Generic Competition in the US Pharmaceutical Industry*, 13 INT'L J. OF ECON. OF BUS. 15 (2006).)