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Pharmaceutical followers ☆

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ABSTRACT

We estimate a model of drug demand and supply that incorporates insurance, advertising, and competition between branded and generic drugs within and across therapeutic classes. We use data on antiulcer drugs from 1991 to 2010. Our simulations show that generics and "me-too" drugs each increased consumer welfare more than $100 million in 2010, holding insurance premiums constant. However, insurance payments in 2010 fell by nearly $1 billion due to generics and rose by over $7 billion due to me-too antiulcer drugs.

1. Introduction

Prescription drug spending as a share of U.S. national income more than tripled between 1984 and 2010.[1] This occurred despite the generic share of prescriptions quadrupling over the same period.[2] The increased use of generic drugs was facilitated by the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) which exempted generic manufacturers from costly clinical trials. However, some branded manufacturers responded by launching "me-too" drugs, meaning patented drugs that require clinical testing for regulatory approval, but are little differentiated from drugs already on the market. The quintessential me-too drug is Nexium (esomeprazole) which became one of the highest-selling drugs of all time, despite being the fifth branded drug in its class and facing competition from generic versions of other drugs in its class. We formulate a demand and supply model to examine how pharmaceutical followers – both generic and me-too drugs – affect competition and welfare.

Some contend me-too drugs waste resources, perceiving that the gains in therapeutic value are small given that their molecular structure is similar to existing drugs and, unlike generics, me-too drugs require costly clinical trials to gain approval. In 2000, the editor of the *New England Journal of Medicine* recommended that regulators reject drugs that are too similar to existing options: "requiring manufacturers to demonstrate that a new drug is substantially better than anything available would help to stem the rising tide of me-too drugs" (Angell, 2000). Me-too drugs may also drain regulatory resources, because they require approval by the U.S. Food and Drug Administration (FDA), which has a backlog of drugs to review.[3]

A key challenge in quantifying the impact of new product entries in the U.S. drug market is the pervasive role of health insurance.[4] Insured patients only pay a fraction (copayment) of the full price of pharmaceutical products, so the relevant price that the decision-maker faces is typically much lower than the posted price recorded in national datasets. Moreover, insurers often receive substantial rebates from manufacturers, creating an additional disconnect between the

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[1] Prescription drug expenditures as a share of national income rose from 0.5% in 1984 to 1.7% in 2010, according to National Health Expenditure data.

[2] The generic share of prescriptions rose from 19% in 1984 to 78% in 2010 (Berndt and Aitken, 2011).

[3] While faster review for potential blockbuster drugs can be worth hundreds of millions of dollars to some manufacturers (Ridley et al., 2006), faster review for other drugs might be inefficient. For example, the fifth branded drug in a class might not provide much variety or competition. Likewise, the same might be true for the fifth generic version of the same drug.

[4] While insurance is an important feature of health care markets in developed countries, in developing countries like India there is little health insurance, so estimation of pharmaceutical demand does not need to account for the role of insurance. See, for example, Chaudhuri et al. (2006).

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price observed in the data and the actual payoff to the producer. Accounting for both distortions is critical to performing meaningful counterfactuals: ignoring the first risks incorrectly concluding that patients are insensitive to price, while ignoring the second distorts the implied costs faced by suppliers.

Ours is the first study to tackle the distortions from both insurance copayments and rebates. To account for copayments, we estimate the relationship between price and copayment using insurance plan data, imputing copayments at the national level. The copayment–price relationship is then used to link the supply-side modeling of pricing decisions to copayments. To account for rebates paid by manufacturers to insurers, we exploit a government policy that constrains optimal rebates prior to generic entry. For rebates after generic entry, we identify implied rebate levels from changes in estimated marginal costs over time under the assumption that rebates are constrained prior to generic entry. After generic entry, fixed-rebate marginal costs jump, indicating a change in rebates consistent with the aforementioned cost distortion. We exploit this discrete jump to estimate the new rebate level.

Our demand model also allows for rich substitution patterns among drugs, which is important for obtaining accurate counterfactual predictions. To do so, we extend the work of Ellison et al. (1997), Stern (1996), Branstetter et al. (2011), and Bokhari and Fournier (2013) by modeling pharmaceutical demand using a discrete choice framework developed by Bresnahan et al. (1997). The framework allows for correlations across multiple nests, or clusters, of products. In particular, we allow for preferences to be correlated among products of the same class, same brand status (branded or generic), same form (tablet or capsule), and same molecule. Our framework allows the data to inform whether (and quantify the extent to which) drugs that vary across one or more of these dimensions are substitutes. Alternatively, drugs that vary across a dimension could be treated as perfect substitutes, or as non-substitutes that exist in separate markets altogether. On the supply side, we follow Bresnahan (1987) and others in modeling firms as playing a static pricing game. Incorporating the supply side allows us to recover marginal costs as well as simulate how prices would change under counterfactual scenarios.

We use monthly U.S. pharmaceutical price, advertising, and utilization data from 1991 to 2010. We focus on classes of drugs that contain quintessential me-too drugs: the H2 antagonists (H2s) and proton pump inhibitors (PPIs), including the aforementioned Nexium (esomeprazole), which treat ulcers and reflux. Our data include generic entry for every H2 and PPI molecule that has a generic version as of 2010.[5]

We estimate own-price (copayment) elasticities for branded drugs in the range of −1.5 to −5.1, with higher magnitudes corresponding to branded drugs that face generic competition. As expected, we find higher cross-price elasticities associated with the same classes, brand/generic statuses, forms, and molecules. Cross-price elasticities are also higher when a drug faces more competition from other sources. For example, an increase in the price of Nexium (esomeprazole), the market leader from 2005 to 2010, has a much larger effect on other PPIs that face generic competition than those that do not. This occurs because the primary market for PPIs faces generic competition from those who have preferences for branded drugs. Hence, these drugs are particularly sensitive to price movements by branded competitors.

Using our estimates of the supply-side and demand-side parameters, we perform two sets of counterfactuals. The first considers removing the pharmaceutical followers currently on the market. Removing me-too drugs (i.e. only keeping the first molecule in each class) or removing all generics leads to substantial drops in utilization which correspond to drops in consumer welfare of more than $100 million per year, holding insurance premiums fixed. However, the removal of these two groups has starkly different effects on insurance payments and manufacturer profits, effects that dwarf the consumer surplus changes. When generics are removed, profits gross of fixed costs rise by over $1 billion as the market becomes less competitive. Insurance payments rise nearly $1 billion. When me-too drugs are removed, insurance payments plummet, falling by over $7 billion annually, with manufacturer profits also falling by more than $4 billion.

Our second set of counterfactuals examines the effects of generic competition for the blockbuster me-too Nexium (esomeprazole). In the short run (a few months after generic entry) with one generic manufacturer, the branded drug reduces its price and competes, so consumer welfare rises. Adding additional generic competitors beyond the first has little effect on welfare because there is already significant price competition between the branded and generic manufacturers. However, adding generics does shift sales from the branded drug to the generics, effectively shutting the branded drug out of the market.

If only one generic version of Nexium (esomeprazole) were available, we find that consumer welfare would actually be higher in the short run than in the long run. In the long run, generic quality is sufficiently high and marginal costs sufficiently low that the branded manufacturer would raise its prices to compete only for consumers with strong preferences for branded drugs. This phenomenon – the branded manufacturer raising its price in the face of generic competition – is known as the "generic paradox" (Scherer, 1993).[6] When the branded manufacturer raises price, it is not only bad for consumers of the branded drug, but also for consumers of the generic drug, because the generic drug manufacturer can raise its price as well. In this example, there is only one generic manufacturer. However, in markets with high demand, many generic manufacturers enter. With a second generic manufacturer, prices fall and consumer welfare rises. We estimate that with two or more generic manufacturers of Nexium (esomeprazole), consumer welfare will rise by about $200 million per year.

Dubois and Lasio (2013) also examine pharmaceutical demand in the antiulcer market. However, in contrast to our study of the U.S. market, they consider the impact of price regulation, a key institutional feature of most high-income markets, excluding the U.S. Exploiting cross-sectional variation in the degree or existence of price regulation, they are able to identify the impact of regulation in the settings in which it binds. Using their demand and supply estimates, they then identify the impact of regulation and examine counterfactuals in which regulation is eliminated.

While several studies have examined the welfare implications of pharmaceutical competition (Bokhari and Fournier, 2013; Branstetter et al., 2011; Chaudhuri et al., 2006; Dutta, 2011; Granlund, 2010), our paper is alone in tackling the intervening role of insurance, a key institutional feature of the U.S. market.[7] Pharmaceutical studies using U.S. data frequently recover price elasticities that are inconsistent with profit maximization under standard models of supply, making it difficult if not impossible to solve for equilibrium prices in counterfactual

[5] The number of generic manufacturers that enter to compete with the branded manufacturer depends on market size (Grabowski et al., 2007; Reiffen and Ward, 2005), advertising by the branded manufacturer (Scott Morton, 2000), and the manufacturer's previous experience (Gallant et al., 2011; Scott Morton, 1999).

[6] When faced with generic competition, the price of the branded drug sometimes remains relatively high or even increases. This might be explained by a perception among consumers that the branded drug is higher quality (Frank and Salkever, 1997; Grabowski and Vernon, 1992; Regan, 2008). Alternatively, the branded manufacturer's optimal price path might be increasing, with entry by a generic causing a fall relative to trend but not relative to previous prices (Bhattacharya and Vogt, 2003). Finally, branded drug prices might increase slowly after generic entry due to consumer heterogeneity in price sensitivity and the resolution of consumer uncertainty about generic quality (Ching, 2010a).

[7] Bokhari and Fournier (2013) also solve for counterfactual prices using U.S. data, but their study differs from ours in two important ways. First, they use an Almost Ideal Demand System instead of a discrete choice framework. Second, like the aforementioned studies, they lack copayment data and must use price.