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Do cost-sharing and entry deregulation curb pharmaceutical innovation?

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ABSTRACT

This paper examines the role of both cost-sharing schemes in health insurance systems and the regulation of entry into the pharmaceutical sector for pharmaceutical R&D expenditure and drug prices. The analysis suggests that both an increase in the coinsurance rate and stricter price regulations adversely affect R&D spending in the pharmaceutical sector. In contrast, entry deregulation may lead to higher R&D spending of pharmaceutical companies. The relationship between R&D spending per firm and the number of firms may be hump-shaped. In this case, the number of rivals which maximizes R&D expenditure per firm is decreasing in the coinsurance rate and increasing in labor productivity.

1. Introduction

Dramatically rising health expenditure costs in the last decades, in particular for prescription pharmaceuticals, have triggered ongoing debates about cost-sharing between health insurers and beneficiaries.[1] For instance, in the US, a reform of Medicare (a federal program which provides health insurance for the elderly) which went into effect in 2006 (Medicare Part D) introduced coverage of prescription drug expenditure for Medicare beneficiaries. There is, however, a coinsurance rate (the fraction of expenditure on medical services paid by the insured patient) of 25 percent.[2]

It is typically argued that, compared to full coverage, cost-sharing schemes help to keep health insurance premiums in check. There is a large empirical literature on the effects of prescription drug cost-sharing on health costs and health care utilization. Empirical estimates suggest that a 10 percent increase in patients' prescription drug charge (through higher coinsurance or higher copayment) reduces prescription drug spending by 1–6 percent (see, e.g., Goldman et al., 2007; Gemmill et al., 2008).

In contrast to such short-run demand effects of prescription drugs cost-sharing, long-run supply effects on pharmaceutical innovation are underresearched. Generally, a major concern in designing health insurance systems and regulating the pharmaceutical sector is the tension between keeping prices of pharmaceuticals low and ensuring that they treat illnesses effectively. The main issue therefore is the joint impact of cost-sharing schemes and regulation measures on price-setting behavior and the incentives of pharmaceutical companies to conduct R&D. As pointed out by Berndt (2002, p.45): "The resolution of this static

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[1] In the EU, the average annual real growth rate of spending for pharmaceuticals was 4.7 percent (3.8 percent in Germany) between 1998 and 2008 (OECD, 2010). In the US, there was a more than fivefold increase in spending for prescription drugs between 1990 and 2008 from 40.3 to 234.1 billion USD (see "The Kaiser Family Foundation, Prescription drug trends, May 2010", available at http://kaiserfamilyfoundation.files.wordpress.com/2013/01/3057-08.pdf).

[2] The rate applies after some deductible, up to an initial coverage limit. After a "catastrophic" coverage limit is reached, the coinsurance rate drops to 5 percent. In Switzerland basically all health insurance contracts have a coinsurance rate of 20 percent for branded prescription drugs and 10 percent for generic drugs.

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versus dynamic efficiency conflict is likely the single most important issue facing the pharmaceutical industry".

This paper attempts to shed light on the nature of the price-quality relationship in pharmaceutical markets. It examines the role of cost-sharing in health insurance systems, price regulations and deregulation of entry for both pharmaceutical R&D and drug prices.

The proposed theoretical model builds on the "ideal variety" framework, originated by Lancaster (1979). Although the framework has never been applied to the context of pharmaceutical markets and R&D (to the best of my knowledge),[3] it captures well the notion that patients seek the ideal drug for their type of illness.[4] The horizontal location of a pharmaceutical firm is interpreted as the type of illness to which the drug that the firm produces is targeted to, represented as a point on the circumference of a circle. That is, pharmaceuticals are imperfect substitutes to each other.[5] Firms choose their horizontal location along with prices and R&D spending.

We show that introducing insurance coverage of prescription drug expenditure (like Medicare Part D) raises both drug prices and pharmaceutical R&D spending, whereas an increase in the coinsurance rate within an existing cost-sharing scheme has the opposite effect. Intuitively, a lower coinsurance rate makes demand for pharmaceuticals less price-sensitive and therefore allows firms to charge higher price-cost margins. This, in turn, boosts the return to R&D. In fact, recent empirical evidence by Blume-Kohout and Sood (2013) suggests that Medicare Part D has raised R&D spending of pharmaceutical companies for prescription drugs used by the elderly. They find that the number of drugs entering early-phase clinical testing in a given therapeutic class and given year is higher, the larger the Medicare market share after the year 2004.

By contrast, deregulation of entry may foster pharmaceutical innovation. The result suggests that the repeated claim by pharma lobbyists – that anything which raises profits in the pharmaceutical sector would be conducive to R&D – is potentially erroneous. Appropriate policy measures to foster entry include encouraging entry of foreign firms, restricting marketing practices, and reducing patent breadth with respect to the design of a pharmaceutical product. In fact, patent breadth with respect to product design has a natural representation in the proposed model, as a segment on the circumference of the circle of illnesses which includes the point targeted by a pharmaceutical firm. Patent protection means that potential rivals are prohibited to locate on this segment. Our analysis suggests that the relationship between pharmaceutical innovation and the number of firms may be hump-shaped, i.e., is positive (negative) if the intensity of competition is low (high). In this case, the R&D-maximizing number of firms decreases in the coinsurance rate and increases in the stage of development, captured by the productivity of labor.

We also examine the role of two kinds of price regulations for pharmaceuticals.[6] First, we suppose that prices are directly be set by the government, as practiced in France and Italy. We focus on the simple case where such price controls ignore R&D costs and show that stricter direct price regulation unambiguously reduces R&D expenditure. Second, we study the effects of a price cap – a limit amount of a patients' expenses for a drug which is reimbursed by an insurer. Such cost-sharing device is common in the public health insurance system of Germany and Japan. We show that a stricter price cap reduces both R&D spending on pharmaceuticals and drug prices. The results on the effects of price regulations on R&D expenditure are consistent with a large body of empirical evidence (e.g., Scherer, 1993; Vernon, 2005; Giaccotto et al., 2005).

The paper is organized as follows. Section 2 discusses the relation of our analysis to the literature. Section 3 sets up and analyzes the basic model which focusses on coinsurance policy and restricted entry, where the number of pharmaceutical firms is given. It also discusses the relationship of competition and innovation, first, by allowing for a competitive fringe which can imitate pharmaceuticals and, second, by endogenizing the number of firms which enter at some fixed costs as long profits are non-negative (ruling out imitation). Section 4 examines the effects of price regulations for pharmaceuticals. Section 5 analyzes how the "optimal" number of firms, defined as maximizing R&D expenditure per firm, depends on the coinsurance rate and the (exogenous) productivity of labor. The last section concludes.

2. Related literature

This paper is not the first one to study the relationship between health policy and innovation incentives of pharmaceutical firms. At the theoretical level, Garber et al. (2006) analyze the case of a single-product monopoly firm which sells a pharmaceutical product. The drug is assumed to have heterogeneous effects on the utility of ill consumers. It is shown that, at a coinsurance rate which ensures efficient drug utilization, profits of the monopoly firm may exceed consumer surplus. Thus, R&D incentives may be excessive. Lakdawalla and Sood (2013) analyze a similar framework and argue that a health insurance contract which sets copayment at marginal costs and where innovators are paid an ex-ante fee equal to consumer surplus may at the same time achieve two goals: it may lead to efficient drug utilization and provide efficient incentives for introducing the drug into the market. Lakdawalla and Sood (2009) argue that a public health insurance system with some price-negotiation by the government is welfare-improving, particularly when coupled with an increase in patent length.

The framework proposed in this paper is different to this literature in several respects. First, it captures both horizontal and vertical differentiation of pharmaceuticals. Second, it analyzes product market competition among pharmaceutical companies rather than a monopoly firm. While monopoly situations may exist in some pharmaceutical markets, the exclusive focus on these situations may be less appropriate to capture markets like those for cancer medication, hypertension medication, pain killers, and antibiotics. In such markets there is some substitutability within product groups and pharmaceutical companies engage in price competition. Third, and related, the main contribution of this paper is to examine the price-quality relationship in pharmaceutical markets by contrasting health insurance policy and competition policy like the patent breadth. The salient feature to analyze competition policy is to depart from the monopoly assumption.

At the empirical level, Acemoglu et al. (2006) examine whether the first Medicare program (the "Social Security Act of 1965") had an impact on pharmaceutical innovation. They find no evidence that drug spending of the elderly (aged 65–74) relative to that of the non-elderly (55–64) went up. Similarly, there was no significant

[3] The ideal variety model is sometimes used in the international trade literature (e.g. Helpman, 1981; Wong, 1995; Hummels and Lugovsky, 2009).

[4] Besides realism in this respect, the ideal variety framework also has the attractive feature that the price elasticity of demand depends on the competitive environment of firms. Notably the standard version of the alternative (and far more often applied) "love of variety" model of monopolistic competition by Dixit and Stiglitz (1977) and Ethier (1982) predicts that the price elasticity of demand for a good – and thus the price mark-up – is constant. However, the empirical support for this prediction is generally weak. Under a constant price elasticity, the health insurance system could not have any effect on prices for pharmaceuticals.

[5] Examples are pain killers, antibiotics, hypertension medication, and pharmaceutical cancer therapy.

[6] For an overview on price regulations in the market for pharmaceuticals, see Sood et al. (2009).