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Health insurance and diversity of treatment

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ABSTRACT

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1. Introduction

A controversial issue has long been whether or not costly incremental innovation leading to "me-too" or "follow-on" drugs (as opposed to major innovation leading to breakthrough products) has some value for society as a whole. As argued by Wertheimer et al. (2001), "me-too" drugs have several advantages, among which "differing dose delivery systems and dosage forms that enable extended uses with a variety of patient population; availability of choice when patient response to and tolerance of a particular agent is subject to great variation; [and] the ability to tailor therapy to the needs and preferences of patients (pp 78)". In line with these comments, Di Masi and Paquette (2004) show that among 72 therapeutic classes, one third of the "me-too" drugs received a priority rating from the US FDA.¹ Moreover, 57% of these classes include a "me-too" drug that received such a priority rating. As such, diversity of treatment itself has an insurance role in that it increases the probability that a patient finds the best (or the least bad) treatment.

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We determine the optimal health policy mix when the average utility of patients increases with the supply of drugs available in a therapeutic class. Health risk coverage relies on two instruments, copayment and reference pricing, both of which affect the risk associated with health expenses and diversity of treatment. For a fixed supply of drugs, the reference pricing policy aims at minimizing expenses, in which case the equilibrium price of drugs is independent of the copayment rate. However, with an endogenous supply of drugs, diversity of treatment may substitute for insurance so that the reference pricing may depart from maximal cost-containment in order to promote entry. We next analyze the determinants of the optimal policy. While an increase in risk aversion, or in the side effect loss, increases diversity and decreases the copayment rate, an increase in entry cost decreases both diversity and the copayment rate.

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In terms of budgetary concerns, the key question that a health system faces is not only how much insurance coverage to provide but also what level of diversity of treatments to offer for a given pathology. In line with the literature on horizontal differentiation with Bertrand competition (e.g. see Anderson et al., 1995), one may object that the number of products at equilibrium in a unregulated market is excessive from a social welfare point of view. This argument would be reinforced in the pharmaceutical market as entry is subsidized via generous insurance coverage. This would ultimately plead in favour of a strong price control in order to discourage entry of "me-too" drugs (and possibly encourage major innovation). Our contribution is to challenge this view, namely that strong price control should limit the entry of "me too" drugs. We show that in a model where individuals are sufficiently risk averse with respect to poor health conditions, entry of "me too" drugs should be encouraged via soft price controls even when there is an (optimal or non optimal) insurance plan in place.

We analyze this issue in a context where health services are supplied in an imperfectly competitive market, as is the case for drugs' markets. In order to analyze the issue of the diversity of treatments offered to policyholders, we focus on two policy instruments that are used to maximize individuals' expected utility. The first is a standard linear copayment rate, while the second is a therapeutic reference pricing regulation. We use the latter instrument as it provides a simple characterization of the degree of the price







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¹ Drugs receiving *priority review* (as opposed to *standard review*) by FDA benefit from an accelerated procedure for approval (6 months as compared to 10 months under *standard review*).

control. Moreover, therapeutic reference pricing is used more and more frequently in developed countries² and its effectiveness has been demonstrated (*e.g.* see Brekke et al., 2009, 2011). While terms vary across countries, internal or therapeutic reference pricing (as opposed to external reference pricing) consists of determining a reference price as a weighted sum of drugs' prices adopted in the same therapeutic class. If the price of a drug is higher than this reference price, patients pay the full difference between the price of the drug and the reference price. This regulatory scheme can be perceived as a complement to copayment rates in order to encourage patients to consume low price drugs.

We build a model where there are several pharmaceutical firms selling horizontally differentiated drugs that belong to the same therapeutic class.³ All patients value the drugs differently because of their different side effects.⁴ Risk averse consumers benefit from an insurance plan consisting of a premium and a linear copayment rate subject to internal reference pricing. We consider a reference price that is a linear combination of extreme value prices in the market. By choosing the weight attached to the lowest price in the reference pricing formula, the regulator determines the pressure on the equilibrium price of drugs and thus on total health expenses.⁵ Our results show that in the short run, the reference pricing scheme aims at minimizing the price of drugs. Indeed, as long as the number of drugs in the therapeutic class is fixed, the health insurer is only willing to lower drugs prices since he cannot improve the drugs' diversity. However, in the long run, there may be room for a more lenient reference pricing policy accommodating some increase in health expenses in order to improve the diversity of treatments. The desirable level of the reference price is the result of a trade-off between a diversity effect (where a new drug decreases average side effects) and the fixed cost generated by additional drugs' entries. We particularly emphasize the role of policyholders' risk aversion by showing that the higher the level of risk aversion, the more likely it is that the regulator chooses a more lenient reference pricing policy. While an increase in risk aversion leads to a lower copayment rate and a higher diversity of treatments, an increase in innovation costs implies a lower copayment and a lower diversity of treatments.

1.1. Related literature

While mainly normative, our article borrows from the positive literature dealing with drugs' price regulation. To the best of our knowledge, this is the first paper that endogenizes both the reference pricing regulation and insurance scheme in a fully-fledged equilibrium model. Brekke et al. (2007) develop a general set-up containing horizontal and vertical differentiations in drugs' markets. They consider two reference pricing rules, namely internal and external reference pricing as well as price cap regulation, with both regulatory schemes being associated with an exogenous copayment rate. Concerning the internal reference pricing, they consider the laboratories' best reply function, and provide comparative statics on the equilibrium allocation. They show that an increase in the weight attached to the lowest price leads to a reduction in prices and increases the market share of the cheapest drug (the generic drug in their context).

In a model that distinguishes breakthrough and follow-on drugs, Bardey et al. (2010) evaluate the long run impact of reference pricing on pharmaceutical innovation, delays of introduction, patients' health and expenditures. They show that reference pricing regulation yields lower prices and therefore delays pioneer drugs and "me-too" entries. Nevertheless, as "me-too" entries are more delayed, it may favor costly breakthroughs and may increase health expenditures in the long run. Miraldo (2007) compares the equilibrium allocations under various alternative regimes: copayment and reference pricing schemes.⁶ In contrast, our model is more narrow on the reference pricing, however the optimal copayment rate and the drugs' pricing regulations are jointly determined.

On the normative side, very few papers study health insurance in the context of pharmaceutical markets. Lakdawalla and Sood (2009) show that encouraging health insurance can be welfare improving as it lowers static deadweight loss (*i.e.* it implies more efficient utilization) without altering incentives for innovation. They also show in another paper (2013) that a competitive health insurance market can combine static and dynamic efficiency in the drugs' market: a premium-financed fixed fee is offered to drugs' monopolists which ensures second best utilization and extracts the full surplus so that incentives for innovation are optimal. Their model however, does not provide for the optimal diversity of treatment since individuals can only benefit from at most one innovation.

The next section presents the set-up. Section 3 is devoted to the short-term analysis assuming a fixed number of drugs. Section 4 characterizes the optimal regulation in the long run, with an endogenous number of drugs. Section 5 discusses some possible extensions. Lastly, Section 6 concludes.

2. The set-up

Consider a collection of policyholders $J \equiv (0, 1)$ who can be unwell with probability π and healthy with probability $1 - \pi$. We normalize the size of the population to 1. In case of illness, each patient chooses a drug among $N (\geq 2)$ treatments, denoted by a subscript $i \in I \equiv (1, N)$. We refer to N as the diversity of treatment. When choosing a drug *i* in case of illness, a patient's net income is $w_s^i = w - \rho - p_i^{7}$, where w is an exogenous income, ρ denotes the premium paid to the health insurer and p_i is the out-of-pocket price paid for consuming drug *i*. When healthy, the net income is $w_h =$ $w - \rho$. In the state of illness, policyholders are horizontally differentiated: when consuming drug *i*, a policyholder $j \in I$ is affected by a side effect which depends on an individual's stochastic variable $\tilde{x}_i^i \in X$, observed by the policyholders before consumption takes place. The shocks \tilde{x}_{i}^{i} are identically and independently distributed across policyholders and drugs over $\mathbb{R}+$, and follow an exponential distribution with distribution function $F(x) = 1 - \exp(-x)$. This assumption implies that the mass of individuals with large adverse effects is always lower than the mass of individuals with small adverse effects.⁸

² See Lopez-Casanovas and Puig-Junoy (2000), Danzon (2001) and Danzon and Ketchman (2004) for more details on reference pricing and its applications.

³ This horizontal differentiation set-up can capture two types of competition in drugs' market. It accomodates competition between brand-name drugs, i.e. pioneer drug and me-too drugs, which belong to the same therapeutic class. It also fits the competition between generic drugs which reproduce the same molecule (horizontal differentiation occurs because formulation, packaging as well as delivery systems are allowed to vary). Conversely, an horizontal differentiation framework is not well adapted to model competition between brand-name and generic drugs.

⁴ Side effects accommodate secondary effects per se, adverse drug reactions, drugdrug interactions, dosing schedules as well as delivery systems.

⁵ In some European markets, such as Germany, the weight also depends on supply conditions and market shares. We thank a referee for pointing that to us.

⁶ A recent work by <u>Brekke et al. (2015a)</u> analyses a similar issue in a set-up encompassing vertical and horizontal differentiation. The authors test the empirical validation of their model in a companion paper (<u>Brekke et al., 2015b</u>).

⁷ There is no lump sum monetary compensation for being sick. This may be ruled out by law or because the state of illness is not verifiable by the regulator.

⁸ Our main result can be shown to hold if the distribution is such that 1 - F(x) is log-log concave (see Bardey et al., 2013)

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