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# A DYNAMIC OLIGOPOLY STRUCTURAL MODEL FOR THE PRESCRIPTION DRUG MARKET AFTER PATENT EXPIRATION*

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This article incorporates consumer learning and heterogeneity into a dynamic oligopoly model for the prescription drug market. In the model, both firms and patients need to learn the generic qualities via patients' experiences, generic firms' entry decisions are endogenous, but their entry timings depend on a random approval process. I apply the model to examine the impact of shortening the expected generic approval time. Although this policy experiment brings generics to the market sooner, it increases a potential entrant's likelihood of entering a crowded market and hence could reduce the total number of generic entrants and consumer welfare.

## 1. INTRODUCTION

In 1984, Congress passed legislation (the Hatch-Waxman Act) to eliminate the clinical trial study requirements for approving generic drugs. Prior to 1984 there were few generic entrants. By making generic entry easier, this policy change has made low cost generics much more accessible to the public. However, many patients, physicians and pharmacists are reluctant to prescribe or use generic as they are uncertain about generic quality. This type of concern was particularly serious during the 1980s when generics were relatively new (Mason and Bearden, 1980; Carroll and Wolfgang, 1991; Strutton et al., 1992). The prevalence of generic entry in the post-1984 period therefore creates an ideal situation for studying firm's entry and pricing behavior and market evolution when there is uncertainty about the product quality.

Past research has documented two stylized facts that characterize the market evolution of this industry (e.g., Grabowski and Vernon, 1986, 1992; Caves et al., 1991; Griliches and Cockburn, 1994; Frank and Salkever, 1997; Cook, 1998; Suh et al., 1998; Ching, 2004): (i) many brand-name originators increase their prices after generic entry[2] and (ii) there has been a slow diffusion of generic drugs into the market even after controlling for price differences between brand-name and generic drugs. A few studies (e.g., Frank and Salkever, 1992, 1997; Grabowski and Vernon, 1992) have conjectured that consumer heterogeneity in price sensitivity is needed to capture the pricing pattern;[3] in Ching (2010), I have argued that consumer learning is needed to explain the slow diffusion of generics. However, none of the existing empirical oligopoly models have these two features. In this article I incorporate consumer learning and heterogeneity into

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[2] Anti-infective drugs are an exception. Wiggins and Maness (2004) show that generic entry has been effective in reducing the brand-name price in this class of drugs.

[3] Their intuition is that when generics become available, price-sensitive patients switch to generics. This makes the demand faced by the brand-name firm become more inelastic and, consequently, they are able to raise prices.

a stochastic dynamic oligopoly model. The first goal of this research is to use this model to study the strategic interaction between brand-name originators and their generic counterparts. In particular, I use the model to empirically examine to what extent consumer heterogeneity can explain the brand-name pricing pattern.

My model also provides a coherent framework for evaluating the welfare impacts of public policies in this industry. Due to the increase in prescription drug expenditures, the postpatent prescription drug market has been the focus of public policy debates. Despite the greatly simplified approval procedures for generics after the passage of 1984 Hatch-Waxman Act, the FDA approval process still serves as a hurdle that delays generic entry. In fact, less than half of the drugs whose patents expired between 1984 and 1987 have generics available immediately after patent expiration (Office of Technology Assessment, 1993). This has led several interest groups to advocate various policy proposals to speed up the generic approval time (e.g., Meadows, 2003). Another goal of this research is to use this model to evaluate the welfare consequence of a hypothetical policy, in which the government shortens the expected approval time for generics. Such a policy could be achieved by giving more resources to the FDA.

The spirit of this research is similar to the work by Grabowski and Vernon (1987), who developed a computer simulation model to study the effect of extending the patent life on R&D incentive in the pharmaceutical industry. However, due to the constraint of computational power in the 1980s, they made many simplifying assumptions in the model. In particular, they assumed that firms made their decisions according to rules, instead of profit maximizing problems. Moreover, they chose their parameter values quite arbitrarily. This research is also related to an empirical work by Scott Morton (1999), which shows what factors influence the entry decision of generic firms. However, Scott Morton (1999) uses a reduced form approach to model profit functions, and therefore cannot evaluate new policies that change the postpatent environment, such as shortening the expected approval time.

To address the shortcoming of the previous researches, I model the postpatent competition using a dynamic oligopoly structural model. As I will explain in the next section, the time it takes the FDA to approve generic drugs is quite random. To study the effect of the expected approval time, I model the FDA random approval process, and the entry decision of generic firms. The parameter values of the model are estimated and calibrated from the real world data. As a result, the model can predict how the equilibrium number of generic entrants change with policy parameters, which may affect the expected return from entering the market.

Reiffen and Ward (2005) also model the random approval process explicitly. However, they do not incorporate consumer learning in the postpatent environment. Therefore, unlike the model developed here, their model cannot account for the effect of shortening approval time on the rate of learning, and this could affect the expected return of submitting a generic drug application to the FDA. Two other notable researches that are related to generic drug industry are Scott Morton (2000) and Ellison and Ellison (2007). They study the strategic entry deterrence behavior of brand-name incumbents. Although this article does not focus on this issue, my model can be extended to study them as well.

The theoretical literature on strategic learning and experimentation is also closely related to the model analyzed here. Rothschild (1974), McLennan (1984) and Aghion et al. (1991) consider a monopolist facing a fixed demand curve with unknown parameters. Aghion et al. (1993), Harrington (1995), and Keller and Rady (1998) analyze a duopoly market where firms are uncertain about the substitutability between their products. The models considered in Bergemann and Välimäki (1997, 2002) are most similar to the one developed here. In our models, both consumers and firms are uncertain about the quality of the products. They update their prior beliefs using past consumption experiences. Therefore, unlike other models, current demand depends on past sales.

The theoretical literature has provided many insights about firm's optimal strategies and potential market evolution outcomes. However, these models are stylized and hence cannot be estimated on real world data without significant modifications. The empirical model developed in this article is tailored for the prescription drug market. Although the model does not have a

closed form solution because of its complexity, I will provide an algorithm to solve it computationally.

Despite the recent advances in the structural empirical literature of learning (e.g., Erdem and Keane, 1996; Ackerberg, 2003; Crawford and Shum, 2005), most of the existing works have exclusively focused on modeling individual consumer behavior.[4] As far as I know, this is the first empirical article that explicitly models dynamic oligopoly behavior when there is uncertainty about product quality. My model is related to the class of dynamic oligopoly models introduced by Ericson and Pakes (1995) and Pakes and McGuire (1994, 2001). Due to the computational burden of solving this class of models, it is difficult to implement them in real-world industries. This article is one of a few empirical applications of fully dynamic oligopoly models (e.g., Gowrisankaran and Town, 1997; Benkard, 2004). Other works on dynamic oligopoly models typically do not apply directly to real-world data (e.g., Gowrisankaran, 1999; Cheong and Judd, 2000; Fershtman and Pakes, 2000). It should be emphasized that most of the previous papers model dynamics through investment and assume firms only make static price or quantity decisions. As an exception, Benkard (2004) models dynamic quantity decisions by introducing learning-by-doing on the supply side. In this article I model dynamic pricing decisions by introducing consumer learning on the demand side.

The main features of my model can be summarized as follows. In the model, all generic firms make their entry decisions in the period right before patent expiration. If a generic firm decides to enter, it pays the sunk cost of preparing an application for marketing the drug. However, it cannot enter until the FDA approves its application. The entry time is random from firms' point of view due to the idiosyncratic nature of the technology adoption process and the FDA approval process. Firms and physicians/patients are uncertain about the quality of generics. In each period, some patients reveal their experiences to the public, which will be used to update their prior in a Bayesian manner. Firms choose price to maximize the expected discounted net future profits. The equilibrium concept used here is Markov-Perfect Nash Equilibrium (MPNE).

The demand side parameters are estimated using the sales data on four chemicals that treat heart diseases; the supply side parameters are calibrated using institutional details and the number of generic firms decided to enter. Due to the computational burden of solving a MPNE, I only calibrate the supply side parameters for one chemical, clonidine. I find that the model explains the pricing pattern and slow diffusion of generics in the market of clonidine fairly well. In particular, I confirm that consumer heterogeneity plays a crucial role in generating the brand-name pricing pattern. In conducting the policy experiment that shortens the expected approval time, I find that generic drugs become available in the market sooner. However, surprisingly, the total number of generic firms deciding to enter drops. Notice that for any given number of firms that decide to enter, the likelihood for each of them to enter a market crowded with competitors in the early periods increases as the expected approval time reduces. Given the change in magnitude of the policy parameter, this "crowding" effect outweighs the "early-entry" effect. Consequently, the number of generic firms that are willing to pay the sunk cost of entry drops. Finally, I also find that the experiment improves the rate of learning and lower the equilibrium generic prices, but its impacts on consumer welfare are quite small.

The rest of the article is organized as follows. Section 2 provides an overview of the generic approval process. Section 3 presents the dynamic oligopoly model and the computational method I use to solve for a MPNE. Section 4 describes the data set and explains how to estimate and calibrate the parameters of the model. Section 5 presents the results. The last section is the conclusion.

## 2. BACKGROUND

To enter a market, a generic firm needs to submit an application for marketing the drug to the FDA. This application is called the Abbreviated New Drug Application (ANDA). In order

[4] See Dube et al. (2005) for a recent survey of this literature.

to obtain approval, a generic firm needs to prove that its product contains the same active ingredients, strength, dosage form, and route and is bioequivalent.[5] The time it takes to adopt the manufacturing technology and obtain approval from the FDA is quite uncertain. Depending on the formulation of the drug, the resource constraint and the experience of the firm, and the availability of raw materials, it could take several months to a few years for a generic firm to adopt the technology for manufacturing the durg. The approval process includes bioequivalence review, chemistry/microbiology/labeling review, plant inspection, and independent laboratory tests of preliminary batches of the product. It is not uncommon that the FDA needs an ANDA applicant to revise its application by clarifying their documents, repeating some tests, and submitting additional data. The factory could also fail in an inspection. As the FDA reports (Meadows, 2003), "(after the initial ANDA application is submitted) it takes more than 20 months on average for a new generic drug to be approved by the FDA, and it usually involves multiple review cycles. Only about 7% of applications are approved on the first cycle and about a third are approved on the second cycle." All the factors stated above should contribute to the uncertainty about the entry timing for generic firms. The model will build in this feature, as it plays an important role in the entry decision for generic firms.

There are no formal estimates of the costs of preparing an ANDA, but informal discussion with industry people suggests that it is typically several million dollars. It is common to see markets experience excess generic entry ex post. Some generic firms that receive FDA approval late make negative net profits (Scott Morton, 1999). This is consistent with the hypothesis that firms are forward-looking, and they make their entry decisions based on discounted expected profits. Since the entry time is random from firms' point of view, some generic firms may make negative net profits ex post if they receive the FDA approval late, even though the expected net profits from submitting an application to the FDA is positive.

In addition, if generic firms are forward-looking, they will have an incentive to reduce their prices in order to attract patients to try their products and hence reduce the uncertainty associated with generic drugs. At the same time, the brand-name firm may react by lowering its prices to keep patients from switching. The model developed here will capture this type of strategic behavior.

## 3. THE MODEL

In this section, I present a dynamic oligopoly structural model. The model is specifically designed to study the competition between a brand-name firm and generic firms after patent expiration. It describes a finite-horizon discrete-time industry starting from the period right before the patent expires. Firms choose price to maximize the expected discounted value of their net future profits given their information set. The industry structures are represented by states that summarize all currently available information relevant to current and future payoffs. There are four types of agents: patients, physicians, a brand-name firm, and generic firms. There are two types of products: a brand-name drug that is produced by the brand-name firm and has patent protection and generic drugs that are produced by the generic firms.

Product characteristics can be distinguished as $p_j$, $A_j$, and $\xi_j$, where $p_j$ is the price of product $j$, $A_j$ is the mean attribute level of product $j$, and $\xi_j$ represents some unobserved product characteristics (e.g., promotion effort). All agents in the model are perfectly informed about $p_j$ and $\xi_j$, but are imperfectly informed about each product's mean attribute levels, $A_j$.

At the beginning of each period, patients and firms make their purchase and pricing decisions, respectively, based on their perceptions of each product quality. After taking the drugs, some patients reveal their experience signals to the public when revisiting their physicians. Physicians, who act as an information aggregator,[6] update the public information on each product in a Bayesian fashion.

[5] Before 1984, generic firms also needed to repeat costly clinical and animal testing on active ingredients.

[6] This is motivated by the aspect of learning from others in the prescription drug market.

The equilibrium used here is MPNE, as defined by Maskin and Tirole (1988). The strategy space includes entry and pricing decisions. MPNE restricts the subgame perfect equilibria to those where actions only depend on payoff relevant state variables. This eliminates a large subset of subgame perfect equilibria that would normally exist in this type of model. Firms maximize their expected discounted profits conditional on their expectations about the evolution of the number of generic entrants, the perceived mean attribute levels and the perceived variances. Equilibrium occurs when all firms' expectations are consistent with the process generated by the optimal policies of their rivals.

The model can be broken up into three components: (1) learning about product attributes, (2) demand, and (3) supply. I now describe them in turn.

3.1. *Learning about Product Attributes.* Prior to 1984, generics were relatively uncommon due to the high entry costs. Although the FDA claims that their standard for approving generic drugs is the same as for brand-name drugs, many physicians and pharmacies did not entirely trust the FDA in the 1980s. As a result, the public felt unsure about the generic qualities when there were suddenly many generic alternatives available right after 1984 (Mason and Bearden, 1980; Carroll et al., 1986; Strutton et al., 1992).[7]

I therefore assume the public is uncertain about the mean attribute of generic drugs ($A_j$). Moreover, I assume that a drug is an experience good, and consumption of a drug provides the patients with information. But each patient $i$'s experience of the attribute of product $j$ at time $t(\tilde{A}_{ijt})$ may differ from its mean attribute level $A_j$, where $j = b$ denotes the brand-name drug, and $j = 1, \ldots, n_g$ indexes generics. The experience variability may be expressed as

$$\tilde{A}_{ijt} = A_j + \delta_{ijt}, \tag{1}$$

where $t$ indexes time ($t = 1, \ldots, T$) and $i$ indexes the patients ($i = 1, \ldots, M$). The error term associated with experience variability ($\delta_{ijt}$) is treated as an i.i.d. random variable, with zero mean and a variance that is constant over time. Since I only observe total generic sales and average generic prices, I assume all generic drugs share the same mean product attribute level. Hence, $A_j = A_k =: A_g, \forall j, k = 1, \ldots, n_g$, and the experience variability for generic drugs can be rewritten as

$$\tilde{A}_{ijt} = A_g + \delta_{ijt}, \tag{2}$$

for $j = 1, \ldots, n_g$. This feature implies that there is a free-rider's problem in learning among firms. When a generic firm lowers its price to attract more patients to try its product, it reduces the uncertainty about generics as a whole. However, each individual generic firm does not take this positive externality into account. As a result, generic prices may be set higher than the socially optimal level.

The initial period of the model ($t = 0$) is the period before the patent expires. I assume that the public has learned the true $A_b$ by the time a patent expires because it is quite common that brand-name products have already been on the market for around 6 to 10 years. Therefore, the public is only uncertain about $A_g$.

Let $\mathcal{A}_t$ be the set of experience signals that are revealed to physicians at time $t$. Since not every patient revisits his/her physician, the cardinality of $\mathcal{A}_t(card(\mathcal{A}_t))$ is generally smaller than the quantity of generics consumed at time $t(q_{gt})$, which is the total number of experience signals

[7] It should be noted that there was a generic scandal in the late 1980s. A few generic firms bribed the FDA officials to approve their applications quicker. During the investigation, the FDA found that some generic drugs produced by these firms were actually below the standard.

revealed to patients. Let $\kappa$ be the fraction of experience signals revealed to physicians in each period. Then $card(\mathcal{A}_t) = \kappa q_{gt}$.[8]

Physicians as a whole act like an information aggregator for the public. They use information revealed to them over time (i.e., $\mathcal{A}_t$) to update their prior expectation of $A_g$. Assuming that the distributions of the signal noise $\delta_{ijt}$ and the initial prior on $A_g$ are $N(0, \sigma_\delta^2)$ and $N(A, \sigma_{A_g}^2(0))$, respectively, the Bayesian updating rule (DeGroot, 1970) implies

$$E[A_g|I(t+1)] = E[A_g|I(t)] + \beta_g(t)(\bar{A}_{gt} - E[A_g|I(t)]), \tag{3}$$

where $\beta_g(t) = \frac{\sigma_{A_g}^2(t)}{\sigma_{A_g}^2(t) + \frac{\sigma_\delta^2}{\kappa q_{gt}}}$. $\bar{A}_{gt}$ is the sample mean of all the experience signals for generic drugs that are realized in period $t$.[9]

The perception variance at the beginning of time $t+1$ is given by (DeGroot, 1970)

$$\sigma_{A_g}^2(t+1) = \frac{1}{\frac{1}{\sigma_{A_g}^2(t)} + \frac{\kappa q_{gt}}{\sigma_\delta^2}}. \tag{4}$$

Equation (4) suggest that the perceived variance associated with $A_g$ (and consequently the perceived variance of $A_{ij}$) will be lower, ceteris paribus (a) the more precise the information gained via consumption experiences (i.e., the lower the experience variability of the product) and (b) the more experiences the public has about generic drugs.

3.2. *Demand.* To model the demand side, I modify the model presented by Ching (2010) who extends the individual level learning model of Erdem and Keane (1996) to allow for learning from others.[10] To keep the industry equilibrium model tractable when combining the demand side and supply side, I abstract away the principal–agent relationship among patients, pharmacists, physicians and hospitals when modeling the demand. In the model, each patient $i$ decides among $J$ possible alternatives in each of $T$ discrete periods of time, where $T$ is finite.[11] Alternatives are defined to be mutually exclusive. The choice set $J$ includes the generic drugs $(1, \ldots, n_g)$, the brand-name drug $(b)$, and an "outside" alternative (0). The outside alternative includes receiving no treatment and other nonbioequivalence drugs that could treat the same disease.

Let $I(t)$ denote the public information set at the beginning of time $t$. The expected utility of purchasing a generic drug $j$ is given by the following expression:

$$\begin{aligned} E[U_{ijt}|I(t)] = {} & -\alpha_i p_{jt} + \omega E[A_g|I(t)] - \omega r E[A_g|I(t)]^2 - \omega r\left(\sigma_\delta^2 + \sigma_{A_g}^2(t)\right) \\ & + \xi_{gt} + \zeta_{igt} + e_{ijt}, \end{aligned} \tag{5}$$

where $E[U_{ijt}|I(t)]$ is the expected utility for patient $i$ conditional on choice of product $j$ at time $t$, $p_{jt}$ is the price for product $j$ at time $t$, $\omega$ is the utility weight on the perceived attribute, $r$ is the risk coefficient, $\alpha_i$ is the utility weight that patient $i$ attaches to price, $\xi_{gt}$ represents the mean valuation of generic unobserved product characteristic at time $t$, and $(\zeta_{igt} + e_{ijt})$ represents the

[8] One can interpret $\kappa$ as the probability that a patient revisits a physician and discusses his/her experiences with generics. Since $q_{gt}$ is typically very large (in the order of several hundred thousands), I assume sampling errors can be ignored and hence $card(\mathcal{A}_t) = \kappa q_{gt}$.

[9] Let $A_g$ be the true mean attribute level of generic drugs. Then, $\bar{A}_{gt}|(\kappa q_{gt}, I(t)) \sim N(A_g, \frac{\sigma_\delta^2}{\kappa q_{gt}})$.

[10] This model has also been extended to study the interaction between informative detailing and learning from others in the prescription drug market (Ching and Ishihara, 2010a,b).

[11] Alternatively, one can interpret a decision-making unit as a patient–pharmacist pair, who jointly decide which alternative to choose.

distribution of consumer preferences about this mean. $\alpha_i$, $\xi_{gt}$, $\zeta_{igt}$, and $e_{ijt}$ are unobserved to the econometrician but observed by the patients in the model when they make purchase decisions. Each patient's objective is to maximize current period expected utility.[12]

The actual price paid by patients may vary because of variation in health insurance coverage. Since I do not have the distribution of actual prices paid by the patients, I allow $\alpha_i$ to be heterogeneous in order to capture this institutional feature. Moreover, the heterogeneity of $\alpha_i$ could be crucial in explaining why brand-name prices increase in response to generic entry.[13]

For each patient $i$, $\zeta_{igt}$ is common to all generic drugs. This introduces group correlation of utility levels. I use the nested logit framework in which $e_{ijt}$ is distributed Extreme Value with variance $(\pi\mu_2)^2/3$ and $(\zeta_{ilt} + e_{ijt})$ is distributed Extreme Value with variance $(\pi\mu_1)^2/3$. One interpretation is that conditioning on choosing generics, $e_{ijt}$ is an error term associated with generic drug $j$.

The expected utility of choosing the brand-name drug is similar to (5). However, since I assume that the patients have already learned perfectly about $A_b$, it follows that $\sigma_{A_b}(t) = 0$ and $E[A_b|I(t)] = A_b, \forall t = 0, \ldots, T$.

It is common that the value of the outside alternative increases over time because brand-name firms usually reduce their detailing efforts dramatically after patent expiration (Caves et al., 1991). The reduction in detailing efforts usually causes the outside alternative to become more attractive over time. To capture this possibility, I allow for a time trend in the expected utility of choosing the outside alternative plus a stochastic error component,

$$E[U_{i0ts}|I(t)] = \phi_{0i} + \phi_{ti}t + \tilde{e}_{i0t}, \tag{6}$$

where $\tilde{e}_{i0t} = \zeta_{i0t} + e_{i0t}$. My data set does not have information on differences in the value of the outside alternative. Thus, to account for the possibility that there is more unobserved variation in its valuation, I allow the outside good coefficients $(\phi_{0i}, \phi_{ti})$ to be heterogeneous.

To account for unobserved heterogeneity for $(\alpha_i, \phi_{0i}, \phi_{ti})$, I assume that they follow a discrete multinomial distribution with $K$ different "types" (Heckman and Singer, 1984). Each type $k$ is characterized by a different triple $(\alpha^k, \phi_0^k, \phi_t^k)$, and its population proportions of each type is given by $\pi_k$. The demand for each product is obtained by aggregating individual patient choices. When estimating the model, I consider two types. Therefore, the demand for product $j$ is $q_j = M.(\pi_0.Pr(j|k=0) + \pi_1.Pr(j|k=1))$, where $M$ is the potential size of the market and $Pr(j|k)$ is the probability that type $k$ patients choose product $j$.

As pointed out in Berry and Pakes (2007) and Ackerberg and Rysman (2005), the i.i.d. extreme value error terms ($e_{ijt}$'s) represent unobserved product differentiation that is symmetric across products. The unobserved product differentiation could be due to the uncertainty about quality differences among individual generics, which I do not model explicitly. This feature of the model has caused the price–cost margin to be strictly bounded away from zero even when the number of generics increases to infinity. The reason for this result is that each additional generic entrant creates one more dimension to the symmetric unobserved product differentiation (SUPD). Moreover, the higher the variance of $e_{ijt}$, the larger the bound, because it increases the market power of each product. Intuitively, $\mu_2$, which measures the variance of $e_{ijt}$, represents the degree of SUPD. One stylized fact in the generic drug industry is that the price of generics consistently decreases over time even when the number of generic entrants becomes fixed (Ching, 2004). This suggests that the degree of SUPD may decrease over time. This could happen if the uncertainty

[12] Allowing patients to maximize their lifetime utility will dramatically complicate the state space. Moreover, as Ching (2010) argues, there is an externality problem in the learning process. An individual patient does not take into account the spillover benefits of his/her experience signal to other patients. Therefore, the incentive of an individual patient/physician to experiment would likely be small, and the assumption that patients are myopic could be a good proxy.

[13] It should be noted that $\omega$ and $r$ are assumed to be homogeneous. I make this assumption because it is very difficult, if not impossible, to identify the parameters of the model if I allow all three coefficients, $(\alpha, \omega, r)$, to be heterogeneous given the market level data I have.

about qualities of individual generic drugs is resolved over time. To capture this, I model $\mu_2$ as a function of time since the first generic entry, $g_t$,

$$\mu_2(g_t) = \bar{\mu}_2 \exp(\iota g_t), \tag{7}$$

where $\bar{\mu}_2$ is a constant. In this parameterization, I allow the possibility that $\mu_2$ may decrease over time.

This approach is similar to Ackerberg and Rysman (2005). Alternatively, one could explicitly model the reason behind the decline of generic prices. However, the computational burden of the model developed here has already reached the limit given the current speed of computers. Moreover, the focus of this article is to understand the brand-name pricing pattern and to investigate the role of random approval time in generic entry decisions. I therefore decide to adopt this simpler approach to generate the decline of generic prices over time.

It should be emphasized that this feature of the model is not in Ching (2010). Moreover, in this article I allow $\phi_{0i}$ and $\phi_{ti}$ in the utility of the outside alternative to be heterogeneous, whereas Ching (2010) restricts them to be homogeneous. I find that these two modifications significantly improve the flexibility of the supply side model in generating the pricing patterns that mimic the data.

3.3. *Supply.* The supply side of the prescription drug market is modeled as a dynamic oligopoly problem. As mentioned above, the equilibrium concept is MPNE. The supply side of the model can be usefully divided into two parts: (1) the initial entry decision before patent expiration and (2) dynamic competition after patent expiration. I now detail them in reverse order.

3.3.1. *Dynamic competition after patent expiration.* In this section I discuss how firms compete after patent expiration. I make several simplifying assumptions: (1) Firms do not have an option of exiting the market, (2) generic firms cannot submit applications to the FDA after patent expiration, and (3) it is always profitable for a potential generic entrant to enter the market when its application is approved. Certainly, firms' behavior may violate these assumptions. However, such violations are fairly rare (see Scott Morton, 1999, 2000), and to include them would drastically complicate the model.

The model can be thought of as containing two stages every period, with entry and price setting in order. In the first stage, each potential generic entrant receives a notice from the FDA regarding the status of its application. In the second stage, having observed the FDA's decision, firms (including the ones that have just entered the market) choose their strategies to maximize the expected discounted value of their net future profits. I assume that the brand-name firm acts as a leader and set its price first. Then, taking the brand-name price as given, generic firms simultaneously set their prices. This leader–follower setup seems reasonable given that the brand-name firm is significantly larger than generic firms. Moreover, the leader–follower model is also easier to solve computationally compared with a model that assumes all firms choose their prices simultaneously.

A generic firm that has already entered the market is referred to a *generic entrant*. A generic firm that is still waiting for the FDA to approve its application is referred to a *potential generic entrant*. Let $n_{gt}$ be the number of generic entrants (after the disclosure of the FDA approval decision) in period $t$ and $n_{pt}$ be the number of potential generic entrants in period $t$ (after the disclosure of the FDA's decision). I denote $S_t = \{E[A_g|I(t)], \sigma_{A_g}(t), n_{gt}, n_{pt}, \xi_t\}$, as the set of state variables that are relevant to the decision of firms. Let $P_e(k; n_{pt-1}, t)$ be the probability that there are $k$ potential generic entrants that are allowed to enter the market in period $t$, conditional on $n_{pt-1}$.[14] Let $p_{bt}$ be the brand-name price, $\tilde{p}_{gt} = (p_{1t}, \ldots, p_{n_g t})$ be a vector of

[14] Notice that $P_e(k; n_{pt-1}, t)$ does not depend on $(E[A_g|I(t)], \xi_t)$. Hence, endogenous entry does not create a selection biased problem in this model.

generic prices, $n_{et}$ be the number of potential generic entrants that receive approval to enter in period $t$ (i.e., $n_{et} = n_{gt} - n_{gt-1}$), and $\beta$ be the discount factor. The per period profit for firm $j$ is $\pi_j = (p_j - mc) * q_j(p_b, \tilde{p}_g)$, where $q_j(p_b, \tilde{p}_g)$ is determined by the demand model described above. To ease the computational burden of solving the dynamic optimization problem, I assume the uncertainty about the generic attribute is completely resolved in the terminal period $T$, i.e., $\sigma^2_{A_g}(T) = 0$, $E[A_g|I(T)] = A_g$.[15]

Recall that $q_{gt}$ is the total demand for generics. Let $\tilde{p}_{g-jt}$ denote a vector of generic prices for all generic entrants but firm $j$. Then for $t < T$, for $j = 1, \ldots, n_{gt}$, the generic entrant's value function is

$$(8)\quad V_g(S_t) = \sup_{p_{jt}\geq 0}\Bigg[\pi(S_t, p_{bt}, \tilde{p}_{g-jt}, p_{jt}) + \beta\left\{\sum_{k=0}^{n_{pt}} P_e(k; n_{pt}, t+1)E[V_g(S_{t+1})|S_t, q_{gt}(p_{bt}, \tilde{p}_{g-jt}, p_{jt}), n_{et+1} = k]\right\}\Bigg],$$

$$V_g(S_T) = \sup_{p_{jT}\geq 0}[\pi(S_T, p_{bT}, \tilde{p}_{g-jT}, p_{jT})].$$

It should be noted that each generic firm explicitly takes into account the effect of its pricing decision ($p_{jt}$) on the next period expected mean attribute ($E[A_g|I(t+1)]$) and perceived variance ($\sigma^2_{A_g}(t+1)$) through the total demand for generics ($q_{gt}$).

Let $\tilde{p}^*_{gt}(p_{bt}) = (p^*_{1t}(p_{bt}), \ldots, p^*_{n_g t}(p_{bt}))$ be the optimal prices for generic entrants conditional on $p_{bt}$. Since all generic entrants are identical with respect to $(E[A_{gt}|I(t)], \sigma^2_{A_g}(t), \xi_{gt})$, I will only consider equilibria that are symmetric across generic entrants, that is, $p^*_{jt}(p_{bt}) = p^*_{kt}(p_{bt}), \forall j, k = 1, \ldots, n_{gt}$. This implies that all generic firms have equal market shares and make equal profits in the equilibrium.

Now I consider the brand-name firm's problem. The difference between the brand-name firm's problem and the generic firm's problem is that the brand-name firm recognizes how the generic prices will react to its pricing decision. The brand-name firm's Bellman equation is similar to the generic firm's except that the $\tilde{p}_{gt}$ is replaced with $\tilde{p}^*_{gt}(p_{bt})$.

$$(9)\quad V_b(S_t) = \sup_{p_{bt}\geq 0}\Bigg[\pi(S_t, p_{bt}, \tilde{p}^*_{gt}(p_{bt})) + \beta\left\{\sum_{k=0}^{n_{pt}} P_e(k; n_{pt}, t+1)E[V_b(S_{t+1})|S_t, q_{gt}(p_{bt}, \tilde{p}^*_{gt}(p_{bt})), n_{et+1} = k]\right\}\Bigg],$$

$$V_b(S_T) = \sup_{p_{bT}\geq 0}[\pi(S_T, p_{bT}, \tilde{p}^*_{gt}(p_{bT}))].$$

Similarly, the brand-name firm explicitly takes into account the dynamic effect of its current pricing decision on future demand.

The expectations in (8) and (9) are taken over the distribution of the random components of $S_{t+1}$ conditional on $(S_t, q_{gt}, n_{et+1})$ (i.e., $E[A_g|I(t+1)]$ and $\xi_{t+1}$). The number of entrants and the number of potential generic entrants evolve stochastically in a Markovian manner. The perception variance, conditional on $q_{gt}$, evolves deterministically. More specifically, $n_{gt+1} = n_{gt} + n_{et+1}$ in the case of number of generic entrants, $n_{pt+1} = n_{pt} - n_{et+1}$ in the case of number

[15] Having a terminal period allows one to solve the dynamic programming problem by using backward induction. Otherwise, one needs to solve for a fixed point using reiteration method, which would be more computationally burdensome. As long as $T$ is chosen to be large enough, the finite horizon dynamic programming problem described in this section would be close to the infinite horizon dynamic programming problem.

of potential generic entrants and $\sigma^2_{A_g}(t+1) = \frac{1}{\frac{1}{\sigma^2_{A_g}(t)} + \frac{\kappa q_{gt}}{\sigma^2_\delta}}$ in the case of perception variance. Conditional on the true mean attribute, $A_g$, the distribution of the expected mean generic attribute is implied by Equation (3). Let's denote this conditional distribution as $\phi(E[A_g|I(t+1)]|I(t), A_g)$. The generic firms' expectation of the value function conditional on $A_g$ can be written as

$$E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1} = k; A_g] = \int \left\{ \int V_g(S_{t+1}|S_t, q_{gt}, A_g) d\phi(E[A_g|I(t+1)]|I(t), A_g) \right\} df_\xi(\xi_{t+1}), \tag{10}$$

where $f_\xi$ is the distribution for $\xi$.

Since generic firms do not know the true $A_g$, they have to integrate it out to form the expectation of the value function. Let $f^a_t$ be the prior distribution of $A_g$ at time $t$. Then

$$E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1} = k] = \int E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1} = k; A_g] df^a_t(A_g). \tag{11}$$

The expectation of the value function for the brand-name firm is similar. It should be highlighted that the computational burden of solving this model is mainly due to the integrations in (10) and (11). Since there is no closed form expression for $E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1} = k]$, numerical methods will be used. I will discuss the computational issue in Section 3.4.

3.3.2. *Initial entry decision before patent expiration.* Now I discuss the initial period of the model (i.e., the period before patent expiration). The initial period can be divided into two stages. In the first stage, the nature draws a true mean attribute level for generic drugs ($A_g$) from $N(A, \sigma^2_{A_g}(0))$, which is the public initial prior for $A_g$. In the second stage, a large number of generic firms decide sequentially whether to enter, where the order is chosen randomly. I assume generic firms are identical ex ante and they face the same sunk cost of entry ($c_e$).[16] After paying this sunk entry cost, a generic firm obtains a lottery that determines when it can start selling its products.

Denote the state vector excluding the number of potential generic entrants by $\tilde{S}_t = S_t \backslash n_{pt}$. If there are $m$ generic firms that pay the sunk entry cost in the initial period, then the value of being a potential generic entrant is

$$V_{pe}(\tilde{S}_0, n_{p0} = m) = \beta \left\{ \sum_{k=0}^{m} P^*_e(k, m, t = 1) E[V_g(S_1)|S_0, q_{g0} = 0, n_{e1} = k] \right\}, \tag{12}$$

where $P^*_e(k, m, t)$ is the probability that the FDA approves $k$ potential entrants in period $t$ including the one in question. Then in equilibrium, the initial number of potential generic entrants ($n^*_{p0}$) is

$$n^*_{p0}(\tilde{S}_0) = \begin{cases} 0 \text{ if } V_{pe}(\tilde{S}_0, n^*_{p0} = 1) \le c_e, \text{ else} \\ \min\{m \in \Im_+ : c_e \le V_{pe}(\tilde{S}_0, n^*_{p0} = m), V_{pe}(\tilde{S}_0, n^*_{p0} = m+1) < c_e\}. \end{cases} \tag{13}$$

[16] $c_e$ includes the cost of adopting the manufacturing technology and preparing an application for marketing the drug. Although firms may actually face asymmetric costs of entry as their prior manufacturing experiences may vary, allowing asymmetric entrants is beyond the scope of this research. See Gallant et al. (2009) for a new structural approach to address this issue.

Note that each firm's decision is deterministic, and $n^*_{p0}(\tilde{S}_0)$ is the cutoff such that $V_{pe}$ falls below $c_e$ when $n_{p0} > n^*_{p0}(\tilde{S}_0)$.

3.4. *Model Parameterization and Computation Issues.* In this section, I discuss the numerical methods that I used to solve the equilibrium model. Readers who are not interested in the details may skip to the next section.

One way to solve this type of dynamic multi-agent model is to transform it to a stochastic discrete version (e.g., Benkard, 2004). To illustrate the model parameterization of a stochastic discrete version of this model, suppose that I discretize $E[A_g|I(t)]$ and $\sigma_{A_g}(t)$ into $n_a$ and $n_\sigma$ points, respectively:

$$E[A_g|I(t)] = \{A_1, A_2, \ldots, A_{n_a}\}, \tag{14}$$

$$\sigma_{A_g}(t) = \{\sigma_1, \sigma_2, \ldots, \sigma_{n_\sigma}\}, \tag{15}$$

where

$$A_1 < A_2 < \cdots < A_{n_a}, \tag{16}$$

$$0 = \sigma_1 < \sigma_2 < \cdots < \sigma_{n_\sigma}. \tag{17}$$

Recall that $\sigma^2_{A_g}(t)$ evolves according to Equation (4). This equation describes a continuous process. For the purpose of the discrete version of the model, I therefore transform it into a stochastic discrete process, which I denote $\tilde{\sigma}^2_A(t)$.[17] To accomplish this, I define $\tilde{\sigma}^2_{A_g}(0) = \sigma^2_{A_g}(0)$, then calculate $\sigma^2_{A_g}(t+1)$ from $\tilde{\sigma}^2_{A_g}(t)$ and $q_{gt}$ using (4). Now I compare $\sigma^2_{A_g}(t+1)$ to the set of discretized values $\{\sigma_1, \sigma_2, \ldots, \sigma_{n_\sigma}\}$ and find the closest two points to $\sigma^2_{A_g}(t+1)$. Let $\sigma^2_d$ and $\sigma^2_u$ be the two closest discretized points such that $\sigma^2_d \le \sigma^2_{A_g}(t+1) \le \sigma^2_u$. Then the distribution of $\tilde{\sigma}^2_{A_g}(t+1)$ given $\tilde{\sigma}^2_{A_g}(t)$ and $q_{gt}$ is defined as follows:

$$\tilde{\sigma}^2_{A_g}(t+1) = \begin{cases} \sigma^2_u \ \text{ with prob } \dfrac{\sigma^2_{A_g}(t+1) - \sigma^2_d}{\sigma^2_u - \sigma^2_d}, \\ \sigma^2_d \ \text{ with prob } 1 - \dfrac{\sigma^2_{A_g}(t+1) - \sigma^2_d}{\sigma^2_u - \sigma^2_d}. \end{cases} \tag{18}$$

Now let's consider how to obtain the expected value function, $E[V_j(S_{t+1})|S_t, q_{gt}(p_{bt}, \tilde{p}^*_{gt}(p_{bt})), n_{et+1} = k; A_g]$, $j \in \{b, g\}$ (see Equation 10). Conditional on $E[A_g|I(t)]$ and $A_g$, $E[A_g|I(t+1)]$ is normally distributed according to (3). Its mean and variance are given by

$$E\{E[A_g|I(t+1)]|A_g\} = (1 - \beta_g(t))E[A_g|I(t)] + \beta_g(t)A_g, \tag{19}$$

$$\text{Var}\{E[A_g|I(t+1)]|A_g\} = \beta_g(t)^2 \frac{\sigma^2_\delta}{\kappa q_{gt}}. \tag{20}$$

Next, I need to transform the normally distributed $E[A_g|I(t+1)]$ to a discrete random variable, $\tilde{E}[A_g|I(t+1)]$, with support $\{A_1, A_2, \ldots, A_{n_a}\}$. I first define a set of points

[17] The process needs to be stochastic to ensure the value function is continuous in $q_{gt}$ (or $\tilde{p}_{gt}$).

$\{A_{1,2}, A_{2,3}, \ldots, A_{n_a-1,n_a}\}$ such that $A_{i,i+1} = \frac{A_i + A_{i+1}}{2}$. Then I assign the probability to each discretized points $A_1, A_2, \ldots, A_{n_a}$ as follows:

$$Prob(A_i) = \Phi(A_{i,i+1}) - \Phi(A_{i-1,i}), \text{ for } i \neq 1 \text{ or } n_a, \tag{21}$$

$$Prob(A_1) = \Phi(A_{1,2}), \tag{22}$$

$$Prob(A_{n_a}) = 1 - \Phi(A_{n_a-1,n_a}), \tag{23}$$

where $\Phi(.)$ is the cdf of $E[A_g|I(t+1)]$ conditional on $E[A_g|I(t)]$ and $A_g$. For simplicity, let's assume that there is no demand shock ($\xi_j$) for the moment. Then, given the discrete distribution of $\tilde{E}[A_g|I(t+1)]$, the expected value function is simply

$$\begin{aligned} &E[V_j(S_{t+1})|S_t, q_{gt}, n_{et+1}; A_g] \\ &\quad = \sum_{l=1}^{n_a} Prob(E[A_g|I(t+1)] = A_l)\bar{V}_j(E[A_g|I(t+1)]|S_t, q_{gt}, n_{et+1}; A_g), \end{aligned} \tag{24}$$

where

$$\begin{aligned} &\bar{V}_j(E[A_g|I(t+1)]|S_t, q_{gt}, n_{et+1}; A_g) \\ &\quad = \sum_{l\in\{u,d\}} Prob(\tilde{\sigma}_{A_g}(t+1) = \sigma_l)V_j(S_{t+1}|S_t, q_{gt}, n_{et+1}; A_g), \end{aligned} \tag{25}$$

for $j \in \{b, g\}$.

The numerical integration method described in (21)–(23) is similar to the classical quadrature methods (e.g., extended midpoint rule). Notice that as the mean of the distribution moves toward the end points (i.e., $(A_1, A_{n_a})$), the approximation of this method will deteriorate. But in principle, if one locates the true $A_g$ far from the end points, the probability that the model will reach the end points will be small.[18] Then I use Gauss–Hermite quadrature to integrate $E[V_j(S_{t+1})|S_t, q_{gt}, n_{et+1} = k; A_g]$ over $A_g$ to obtain $E[V_j(S_{t+1})|S_t, q_{gt}, n_{et+1} = k]$ (Equation 11). Finally, I integrate the demand shocks by transforming them into discrete random variables.

I should note that the profit maximization problem does not have a closed form solution. I therefore need to conduct a numerical nonlinear search for the optimum in each period, as I use backward induction to solve the model. As a result, for every trial set of price, I need to solve for the multiple integration problems discussed above numerically. This explains the high computational burden of solving a MPNE for this model.

## 4. DATA, ESTIMATION, AND CALIBRATION

4.1. *Data.* Data sources for this study include IMS America, the Pharmaceutical Manufacturer Association (PMA), the Food and Drug Adminstration the National Ambulatory Medical Survey, and National Hospital Discharge Survey.[19]

The patent expiration dates are obtained from the PMA, and ANDA approval dates are from the FDA. I use the ANDA approval dates as a proxy for entry dates. To estimate the entry probabilities for generics, I use entry data on 25 drugs (including the four drugs used in the

[18] This can be done once we obtain estimates of $A_g$'s.

[19] IMS America is a marketing research company that specializes in collecting sales data for the U.S. pharmaceutical industry.

TABLE 1
THE NUMBER OF GENERIC ENTRANT OVER TIME

| | Time Since Patent Expired (Quarter) | | | | |
|---|---|---|---|---|---|
| Chemical | 0th | 4th | 8th | 12th | Max |
| Amiloride | 0 | 1 | 1 | 1 | 1 |
| Clonidine | 3 | 8 | 12 | 12 | 12 |
| Disopyramide | 0 | 3 | 7 | 10 | 11 |
| Methyldopa | 1 | 4 | 14 | 16 | 17 |
| Hydrochlorothiazie Methyldopa | 0 | 0 | 4 | 6 | 12 |
| Propranolol | 0 | 5 | 14 | 17 | 21 |
| Verapamil | 0 | 0 | 10 | 15 | 15 |
| Baclofen | 0 | 3 | 3 | 3 | 3 |
| Carbamazepine | 0 | 0 | 3 | 5 | 7 |
| Clorazepate | 4 | 11 | 12 | 12 | 12 |
| Diazepam | 0 | 10 | 16 | 16 | 18 |
| Flurazepam | 0 | 0 | 3 | 7 | 11 |
| Lorazepam | 0 | 1 | 4 | 11 | 13 |
| Oxazepam | 0 | 0 | 0 | 5 | 10 |
| Temazepam | 0 | 3 | 4 | 7 | 9 |
| Desipramine | 0 | 1 | 4 | 4 | 4 |
| Doxepin | 0 | 2 | 8 | 11 | 11 |
| Haloperidol | 0 | 10 | 11 | 12 | 13 |
| Maprotiline | 0 | 0 | 0 | 4 | 4 |
| Perphenazine | 0 | 0 | 0 | 2 | 3 |
| Thiothixene | 0 | 0 | 0 | 5 | 5 |
| Trazodone | 0 | 0 | 7 | 9 | 11 |
| Cephalexin | 4 | 9 | 12 | 13 | 13 |
| Cephradine | 1 | 2 | 4 | 4 | 4 |
| Clindamycin | 0 | 2 | 2 | 2 | 2 |

demand estimation). This set of drugs are selected because their patents expired during the first four-year period from 1984 through 1987. This period is chosen because the 1984 Hatch-Waxman Act lowered entry barriers for generic drugs. This sample covers five therapeutic classes: heart disease drugs (7), depressants (8), antidepressants (4), antipsychotic drugs (3), and antibiotics (3). Since most of the firms enter the market immediately after they have received an ANDA approval, I use ANDA approval dates as a proxy for entry dates.

Table 1 shows the number of generic entrants over time for 25 drugs whose patents expired between 1984 and 1987. An interesting fact is that many generic firms did not enter the market immediately after patents expired; instead their entry times spread out over the course of up to 20 quarters. This, together with the fact that most of generic firms submitted their applications before patent expired (Scott Morton, 1999), is consistent with the main assumption made here: Firms cannot fully control their entry times.

I use the sales data of four high blood pressure drugs obtained from IMS America to estimate the demand side parameters. These four drugs are amiloride, clonidine, methyldopa, and hydrochlorothiazide methyldopa.[20] For each drug, I observe quarterly revenue and quantity sold for both the brand-name original and the total sales of its generic counterparts from the quarter right after patent expiration to the fourth quarter of 1990. Prices used in this study are obtained by dividing revenue by quantity sold. Treating a quantity and price pair for each product as

[20] In selecting data to estimate the demand side parameters, I have tried pooling data from different combinations of heart disease drugs for estimation (I have access to data for seven drugs). The four drugs used here allow me to obtain parameter estimates, at which the dynamic equilibrium model is able to generate predicted demand and pricing patterns that are reasonably close to the data. This probably reflects that there is heterogeneity across drugs. In order to apply the dynamic oligopoly model developed here to other heart disease drugs or other classes of drugs, one probably needs to change the exact functional form and reestimate the parameters. I leave this for future research.

an observation, the total number of observations is 171. I also obtain the daily defined doses (DDD) and average treatment duration (ATD) from Medi-Span. DDD is used to standardize the quantity unit to the number of patient days. ATD is used to obtain the number of patient days that on average each purchase decision would amount to. The number of patients who have been diagnosed with a particular condition is obtained from National Ambulatory Medical Care Survey and National Hospital Discharge Survey. These estimates together with ATD are used to create the potential size of the market for each drug.

Figure 1 shows the average prices and quantities of brand-name drugs and their generic counterparts for four markets that I used to estimate the demand model. In particular, it shows that (i) the brand-name prices increase over time whereas their sales decline over time and (ii) it takes time for the sales of generics to penetrate the market. Moreover, in three out of these four markets, the entry times of generic firms are quite spread out (see Table 1). Note that amiloride is an exception because it only has one generic entrant. Overall the market characteristics of the data are consistent with the stylized facts used to motivate this study.

### 4.2. *Estimation and Calibration*

4.2.1. *Demand parameters.* There is a potential endogeneity problem that arises when estimating the demand model $E[A_g|I(t)]$ and $\xi_t$ are unobserved to the econometrician but potentially observed to firms. Consequently, these unobserved characteristics could be correlated with price, making price endogenous. It should be emphasized that because there are two unobserved product characteristics (i.e., $E[A_g|I(t)]$ and $\xi_t$), it is difficult to use the nonlinear GMM estimation approach proposed by Berry et al. (1995) to estimate the demand side parameters. I therefore use the method that I developed in Ching (2000, 2010) to estimate this model. This method involves approximating the pricing policy function by expressing it as a function of both observed and unobserved state variables and potential instrumental variables. To control the endogeneity problem, I jointly estimate this pseudo-pricing policy function with the demand side model.

The specification of the pricing policy function follows Ching (2010). More specifically, for $j \in \{b, g\}$, I assume

$$\log(p_{jt}) = \gamma_{j0} + \gamma_{j1}t + \gamma_{j2}n_{gt} + \gamma_{j3}\sigma^2_{A_g}(t) + \gamma_{j4}E[A_g|I(t)] + \gamma_{j5}(\xi_{jt} - \xi_{-jt}) + \tilde{v}_{jt}. \tag{26}$$

Although this functional form might seem restrictive, it is able to capture the observed pricing pattern fairly well, as shown in Ching (2010).

It should be highlighted that I assume $n_{gt}$ plays the role of an instrumental variable. As I argued above, although the entry decisions of generic firms are endogenous, they often cannot control the exact timing of approval date. As a result, $n_{gt}$ should be largely uncorrelated with the structural error terms of the model.

The details of the estimation procedure are outlined in Appendix A.1. When estimating the model, I assume that $\xi_j$ is drawn from an i.i.d. $N(0, \sigma^2_\xi)$. As mentioned before, the demand model estimated in Ching (2010) is similar to the one here with two main differences emphasized at the end of Section 3.2. For identification purposes, I need to fix $(\kappa_l, \mu_{1,l})$ for one chemical, where $l$ indexes chemical. I choose to the fix the ones for amiloride. To reduce the number of parameters to be estimated, I assume that $\frac{\mu_{1,l}}{\mu_{2,l}}$'s are the same across chemicals, and $\mu_{k,l} = \tilde{\mu}_l * \mu_{k,amiloride}$, where $k$ indexes nest. For identification reason, I also need to fix $\tilde{\mu}_l$ for one chemical, so I again choose amiloride. As a result, I need to estimate $(\mu_{2,amiloride}, \tilde{\mu}_2)$ for clonidine, methyldopa, and hydrochlorothiazide methyldopa (in addition to other utility parameters). Since the number of entrants is fixed over time for the market of amiloride, $\iota$ for amiloride is not identified.[21] I therefore set it to zero. The total number of demand side parameters that I estimate is 39.

[21] The nonidentification of $\iota$ can be seen by writing down the nested logit formula.

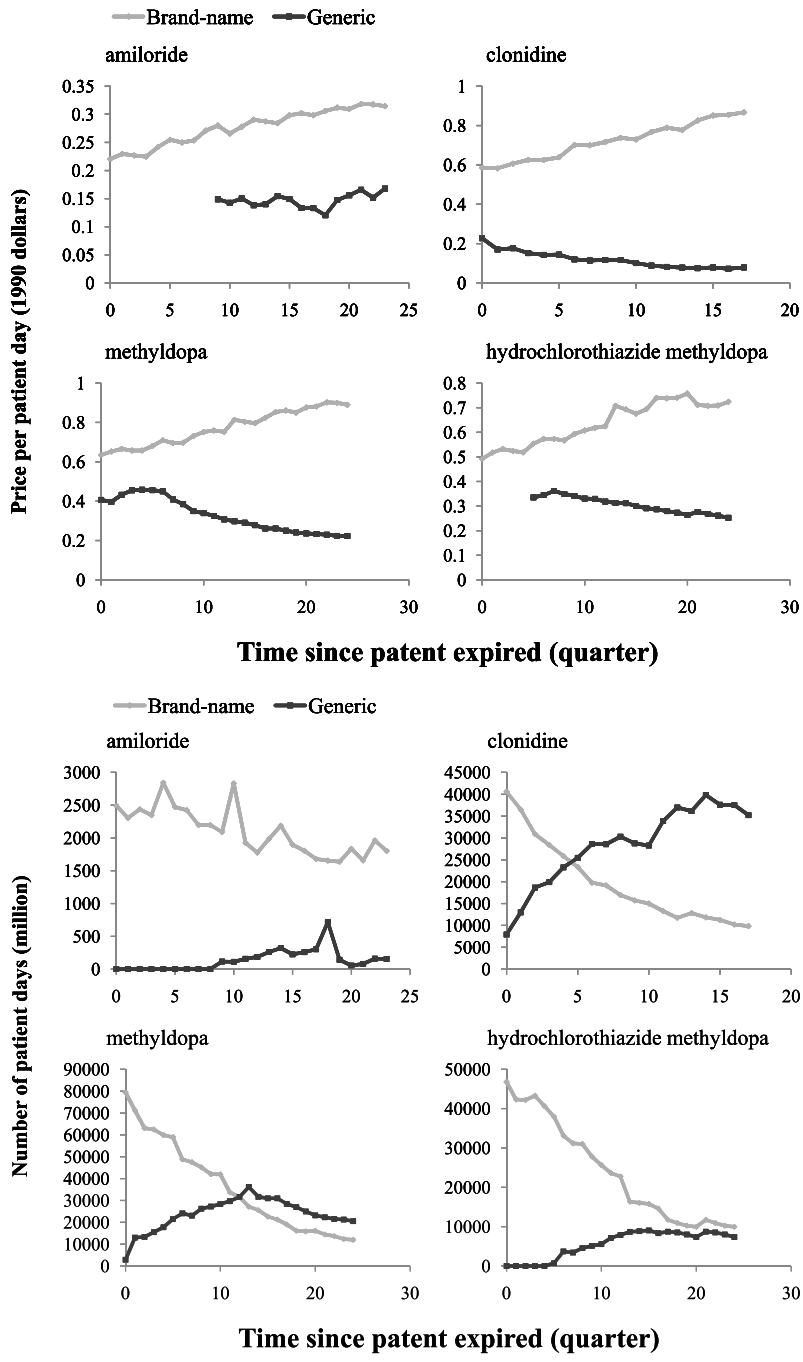


FIGURE 1

PRICES AND QUANTITIES DEMANDED OVER TIME

The results of the structural demand parameters are reported in Tables 2 and 3. Overall, the qualitative results are very similar to Ching (2010). All of the preference parameters are significant. Consumers are risk averse ($r$ is positive) and have pessimistic initial prior ($A$ is lower than $A_{g_j}$); around 22% of the population is price sensitive ($\pi_0 = 0.22$); the estimate of

TABLE 2
ESTIMATED PARAMETERS FOR THE UTILITY FUNCTION

| | Estimates (S.E.) |
|---|---|
| Risk coefficient ($r$) | 0.631* |
| | (0.010) |
| Utility weight for attribute ($\omega$) | 0.012* |
| | (2.8e-4) |
| Experience variability ($\sigma_\delta^2$) | 0.249* |
| | (0.036) |
| Type 0 price coefficient ($\alpha^0$) | 0.032* |
| | (0.004) |
| Type 1 price coefficient ($\alpha^1$) | 0.010* |
| | (0.001) |
| Proportion of type 0 ($\pi_0$) | 0.219* |
| | (0.007) |
| Standard deviation of unobserved product characteristic ($\sigma_\xi$) | 0.194* |
| | (0.008) |
| Initial prior variance ($\sigma^2_{A_g}(0)$) | 33.48* |
| | (1.987) |
| Initial prior means ($A$) | −17.96* |
| | (0.392) |
| Variance parameter of the first nest for amiloride ($\mu_1$) | 0.5 |
| | n.a. |
| Variance parameter of the second nest for amiloride ($\mu_2$) | 0.308* |
| | (0.005) |
| Log-Likelihood | −854.60 |

NOTES:
Standard errors are reported in parentheses.
Number of draws for demand shocks = 100.
Number of draws for $E[A_g|I(t)] = 100$.
*$t$-statistic $> 1.96$.

TABLE 3
PARAMETERS THAT ARE CHEMICAL SPECIFIC

| | $A_{g_j}$ | $\kappa$ | $\phi_0^0$ | $\phi_0^1$ | $\phi_t^0$ | $\phi_t^1$ | $\iota$ | $\tilde{\mu}$ |
|---|---|---|---|---|---|---|---|---|
| Amiloride | −11.60* | 6.67e-6 | 0.966* | 1.881* | −0.002* | 0.011* | 0 | 1 |
| | (0.131) | n.a. | (0.073) | (0.072) | (0.004) | (0.003) | n.a. | n.a. |
| Clonidine | −5.36* | 8.20e-11* | −1.520* | 0.956* | 0.160* | 0.007* | −0.118* | 2.126* |
| | (0.709) | (3.35e-12) | (0.100) | (0.071) | (0.017) | (0.004) | (0.009) | (0.066) |
| Methyldopa | −13.83* | 2.52e-9* | −2.379* | −0.097* | 0.159* | 0.027* | −0.019* | 1.786* |
| | (0.224) | (5.23e-10) | (0.335) | (0.050) | (0.003) | (0.002) | (0.003) | (0.065) |
| Hydrochlorothiazide methyldopa | −12.86* | 6.70e-10* | −0.358* | 0.436* | 0.040* | 0.052* | −0.041* | 1.690* |
| | (0.266) | (2.44e-10) | (0.355) | (0.045) | (0.015) | (0.004) | (0.002) | (0.066) |

NOTE:
Standard errors are reported in parentheses.
*$t$-statistic $> 1.96$.

$\alpha_0$ is three times that of $\alpha_1$.[22] The parameter estimates for the utility of outside alternatives are also very different across types. It should be emphasized that $\iota$'s are negative and significant

[22] According to a publication by the U.S. Congress, Office of Technology Assessment (1993), about 30% of the nonelderly population did not have private health insurance coverage for prescription drugs in 1989. My estimates suggest that 22% of the population is price sensitive. The percentage is smaller than the percentage of the uninsured population. However, it is possible that some consumers do not have insurance coverage and yet they are price insensitive, perhaps because they are self-employed and have high income or wealth.

TABLE 4
PRICING POLICY FUNCTION

| Brand-name | | Generic | |
|---|---|---|---|
| *Time trend* ($\gamma_{b1}$): | | *Time trend* ($\gamma_{g1}$): | |
| All chemicals | 0.014* | Amiloride, | |
| | (0.002) | Hydrochlorothiazide methyldopa | −3.5e-4 |
| *No. of generics* ($\gamma_{b2}$): | | | (0.002) |
| Amiloride | 0.028 | Clonidine | −0.034* |
| | (0.041) | | (0.004) |
| Clonidine | 0.013* | Methyldopa | −0.034* |
| | (0.006) | | (0.003) |
| Methyldopa | 4.8e-4 | *No. of generics* ($\gamma_{g2}$): | |
| | (0.003) | Amiloride, clonidine, | |
| | | Hydrochlorothiazide methyldopa | −0.028* |
| Hydrochlorothiazide methyldopa | 0.009** | | (0.005) |
| | (0.005) | Methyldopa | −0.003 |
| | | | (0.004) |
| $\sigma_{A_g}(t)(\gamma_{b3})$ | 0.001 | $\sigma_{A_g}(t)(\gamma_{g3})$ | −0.003* |
| | (1.6e-3) | | (0.001) |
| $E[A_g \mid I(t)](\gamma_{b4})$ | 2.6e-5 | $E[A_g \mid I(t)](\gamma_{g4})$ | −0.028* |
| | (2.9e-3) | | (0.005) |
| $\Delta\xi_j(\gamma_{b5})$ | −9.6e-4 | $\Delta\xi_j(\gamma_{g5})$ | −2.8e-4 |
| | (7.7e-4) | | (6.5e-4) |

NOTE:
Standard errors are reported in parentheses.
*$t$-statistic >1.96; **$t$-statistic >1.65.

for clonidine, methyldopa, and hydrochlorothiazide methyldopa, indicating that the degree of product differentiation among different generic alternatives declines over time.

The results of the pricing policy functions are reported in Table 4.[23] The total number of parameters for pricing policy functions is 24. For the brand-name pricing policy function, I find that the time trend is positive and significant, the number of generics is positive and significant for clonidine and hydrochlorothiazide methyldopa, but none of the unobserved state variables are significant. For the generic pricing policy function, I find that the time trends are negative, but only significant for clonidine and methyldopa; the number of generics are negative for all chemicals, but only significant for clonidine and methyldopa; moreover, $\sigma^2_{A_g}(t)$ and $E[A_g \mid I(t)]$ are negative and significant.

Other than the demand parameters, I also need to obtain the parameters that determine the entry probabilities, the sunk cost of entry, the marginal costs of production, and the discount factor. In the following subsections, I discuss how to estimate and calibrate them.

4.2.2. *Entry probabilities.* I model entry probabilities as a binomial distribution. Recall that $n_{pt}$ is the number of potential generic entrants in period $t$ (after the disclosure of the FDA's approval decision in period $t$). Let $\lambda(t)$ be the probability that a potential generic entrant receives approval from the FDA in period $t$. Then the probability that there are $k$ potential generic entrants that are allowed to enter the market in period $t$, conditional on $n_{pt-1}$, is

$$P_e(k, n_{pt-1} = m, t) = \binom{m}{k} \lambda(t)^k (1 - \lambda(t))^{m-k}. \tag{27}$$

This random entry process does not depend on the state variables and the structural errors of the dynamic oligopoly model. Therefore, one can simply use Equation (27) as the likelihood

[23] To save space, the intercepts of the pricing policy functions are not reported here. They are available upon request.

TABLE 5
LOGIT MODEL OF ENTRY

| | Estimate | S.E. |
|---|---|---|
| Intercept for heart disease drugs | −2.636* | 0.201 |
| Intercept for depressants | −2.536* | 0.200 |
| Intercept for antidepressants and antipsychotic drugs | −2.803* | 0.208 |
| Intercept for antibiotics | 1.561* | 0.323 |
| Time since patent expired | 0.051 | 0.049 |
| Time since patent expired$^2$ | 0.006* | 0.003 |

NOTE:
Probability that a potential generic entrant receives approval,
$\lambda = \frac{\exp(X\gamma)}{1+\exp(X\gamma)}$.
*Significant at 5% level.

function to estimate the parameter of the entry process. $\lambda(t)$ is determined by a logit model with an intercept, therapeutic class dummies, and time since the patent expired and its square as regressors. In particular, I use four therapeutic class dummies for (1) heart diseases drugs, (2) depressants, (3) antidepressants and antipsychotic drugs, and (4) antibiotics to control for the heterogeneity of the approval uncertainty across different classes of drugs. The results are reported in Table 5. I also use this equation to set up the value function for the generic entrants and the brand-name firm (see Equations (8) and (9)).

The probability that the FDA approves $k$ potential entrants in period $t+1$ including the one in question is then

$$P_e^*(k, n_{pt-1} = m, t) = \lambda(t)\binom{m-1}{k-1}\lambda(t)^{k-1}(1-\lambda(t))^{(m-1)-(k-1)} = \binom{m-1}{k-1}\lambda(t)^k(1-\lambda(t))^{m-k}. \tag{28}$$

I use this equation to calculate a generic firm's expected return from submitting an application to the FDA (see Equation (12)).

4.2.3. *Sunk cost of entry, marginal cost of production, and discount factor.* It is well known that the discount factor, $\beta$, is difficult to estimate in applied dynamic programming research. Given that the length of a period is a quarter, I set $\beta = 0.98$, which roughly corresponds to an 8% annual interest rate. I will study the robustness of the results by resolving the model with $\beta = 0$ in Section 5.4.

The marginal cost of production for drugs is assumed to be fixed over time. It is believed that the marginal cost of production is typically very low for drugs. In fact, the average generic price for clonidine converges to almost zero. The lowest observed generic price is about 8 cents per patient day (the highest observed generic price is 23 cents). Hence, in the simulation exercise, I set marginal cost (mc) to be zero. In Section 5.4, I will study the robustness of the results by examining two alternatives: mc = 4 and 8 cents.

The sunk cost of entry, $c_e$, is difficult to obtain directly from industry data. Annual reports from companies do not break down R&D costs by product. Therefore I use the model's prediction to calibrate this parameter. I choose $c_e$ such that the predicted number of generic firms that decide to submit an application is equal to 12, which is the observed number in the data. The calibrated

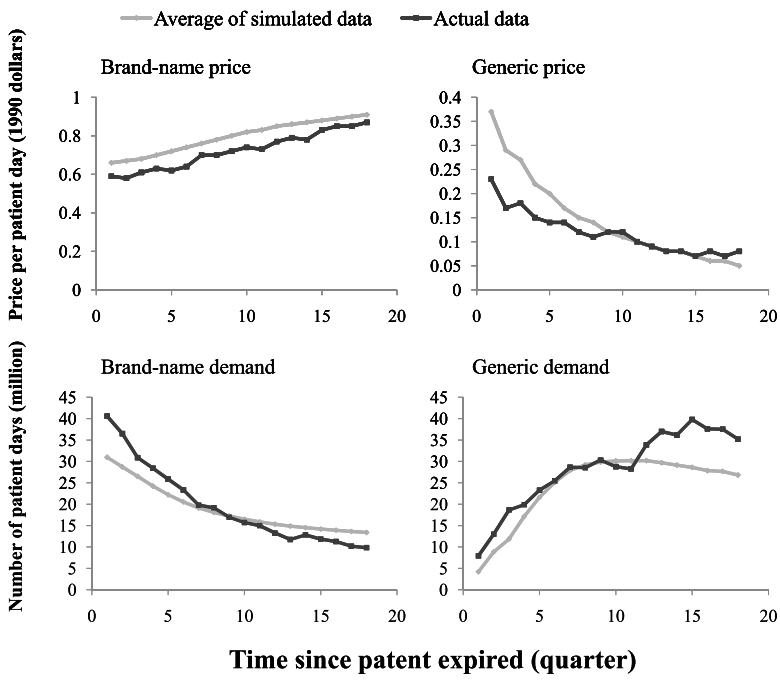


FIGURE 2

ORIGINAL CALIBRATED MODEL: PRICE AND QUANTITY DEMANDED

value is 1.64 million (1990) dollars for clonidine. From my informal conversations with people in the industry, this number is quite reasonable.

## 5. RESULTS

In this section, I discuss the goodness of fit, the role of consumer heterogeneity, and a policy experiment, which studies the effect of shortening the expected approval time for generic drugs.

5.1. *Goodness of Fit and Demand Patterns by Consumer Type.* I set the terminal period to $T = 30$ when solving the model. When computing the solution of the model, $E[A_g|I(t)]$, $\sigma^2_{A_g}(t)$ and $\xi_{jt}$ are discretized as follows: $E[A_g|I(t)]$ takes the values $\{-18, -15, -13, -9, -6\}$, $\sigma^2_{A_g}(t)$ takes $\{0, 4, 10, 23, 30\}$, and $\xi_{jt}$ takes $\{-1, 0, 1\}$. For the Gaussian Hermite quadrature, I use 20 points. Given the current parametrization of the model, it takes about 50 hours to solve this equilibrium model using a Core 2 Duo 2.4 GHz processor.[24] Setting the number of generic firms that decide to submit an application to be 12, which is the observed number in the data, I use the estimated random entry process to simulate 100 sequences for the number of generic entrants.[25] For each sequence, I simulate 100 sequences of price and quantity pairs for both the brand-name drug and generic drugs, using the dynamic oligopoly model based on the estimated and calibrated parameter values. Using these $100 \times 100$ simulated market histories, I then compute the average predicted number of generic entrants, prices, and quantities for each period.

Figure 2 plots the average predicted prices and sales, along with the observed prices and sales, up to the 18th quarter after the patent expired. This is the period covered by the data. The average predicted prices and quantities demanded match reasonably well with the data. In particular,

[24] Admittedly, the discretization is rough here. However, the CPU time of solving this model indicates that this specification has already reached the constraint of the current CPU technology.

[25] Each sequence consists of $\{n_{gt}, n_{pt}\}_{t=1}^{T}$, where $n_{gt} + n_{pt} = 12$.

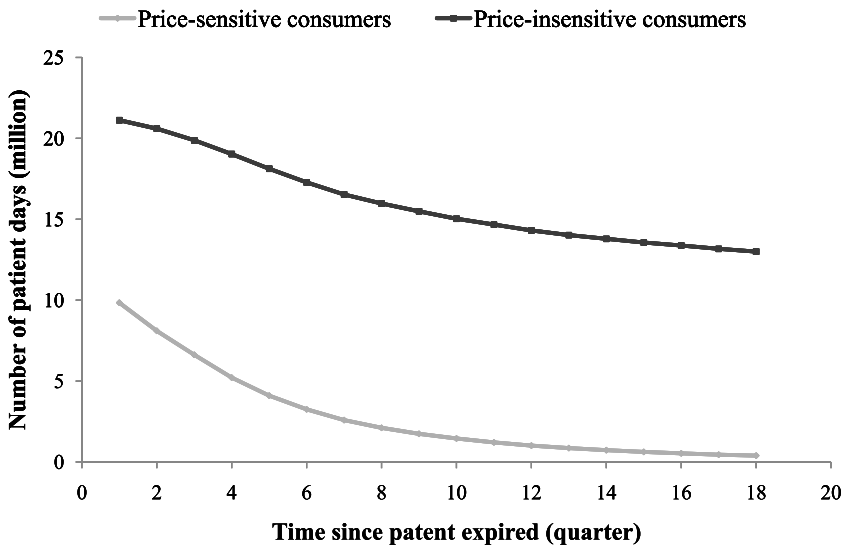


FIGURE 3

BRAND-NAME DEMAND BY CONSUMER TYPE

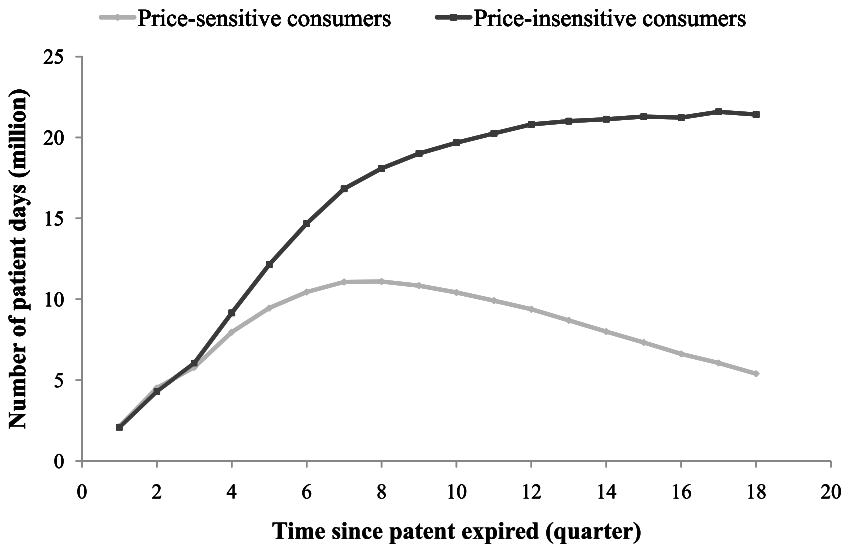


FIGURE 4

GENERIC DEMAND BY CONSUMER TYPE

the model is able to replicate the general pricing and demand pattern for the brand-name drug, although with some discrepancies. It should be emphasized that the estimation procedure for demand parameters (detailed in Ching, 2010) and the choice of marginal cost parameter do not make use of the dynamic oligopolistic supply side. In other words, these parameters were not chosen to match the firm's price and quantity decisions with the observed data. Hence, I find that the overall goodness-of-fit results, which are based on the equilibrium model, are reasonably satisfactory.

One important feature of the model is that there is consumer heterogeneity in price sensitivity. Interestingly, although I only observe aggregate demand behavior, the equilibrium model is able to predict how demand patterns vary across consumer type. Figures 3 and 4 show the predicted

quantity demanded by consumer type. Since $\alpha^0$ is much larger than $\alpha^1$ (see Table 2), I refer to type 0 consumers as price-sensitive consumers and type 1 consumers as price-insensitive consumers. Figure 3 shows that the evolution of the predicted brand-name demand patterns are very different across consumer type. For price-sensitive consumers, the demand drops very quickly by more than 90% from the first quarter to the 18th quarter. For price-insensitive consumers, it remains relatively high over time—overall it declines by less than 40% throughout the period. When the patent has just expired, about 63% of the brand-name drug consumers are the price-insensitive type. In the 18th quarter, about 97% of the brand-name drug consumers are price-insensitive. This suggests that the demand faced by the brand-name firm becomes more inelastic over time. As argued in Grabowski and Vernon (1986), Frank and Salkever (1992), and Ching (2010), this may be the main explanation for why the brand-name firm raises its prices over time after patent expiration.

The model predicts that both the price-sensitive consumer demand and the price-insensitive consumer demand for generics increase over time initially (see Figure 4). This is mainly due to the decrease in the perceived variance for generics and generic prices. Both factors raise the utility of choosing generic drugs.

I also find that the price-sensitive consumer demand for generic drugs decreases after it reaches a peak in the 7th quarter. The main reason for this is because the price-sensitive consumers' valuation of the outside good increases over time, as captured by the positive sign of the time coefficient associated with it (note that $\phi_t^0$ is much higher than $\phi_t^1$ for clonidine, as shown in Table 3). The decline in price-sensitive consumer demand for generics has led to the predicted aggregate generic demand to drop after the 11th quarter, as shown in Figure 2. Finally, the price-insensitive consumer demand for generic drugs keeps increasing over time. Since the price-insensitive consumer demand for the brand-name drug remains relatively stable over time, this implies that generic firms attract price-insensitive consumers mainly at the expense of the outside good.

5.2. *The Roles of Price-sensitive and Price-insensitive Consumers.* To illustrate the roles of consumer heterogeneity in the model further, I compare results of the original model with two separate models, where I allow only price-sensitive patients and price-insensitive patients, respectively. As argued in Ching (2010), one factor contributing to consumer heterogeneity is that insurance plans for prescription drugs are very diverse. One can think of the model with only price-insensitive patients as approximating an economy that has universal insurance coverage for prescription drugs, where the degree of price-sensitivity corresponds to the coinsurance rate of the plan. Table 6 shows the summary statistics for the three models, which are based on the simulation results for the 18 quarters since the patent expired. Compared with the original model, the brand-name firm charges higher prices and receives larger surplus when there are only price-insensitive patients, and it sets lower prices and receives lower surplus when there are only price-sensitive patients. The intuition behind the results is standard: Price-insensitive patients prefer the brand-name drug to generics, if everything else is the same. Therefore, if there are only price-insensitive patients in the market, the brand-name firm is in a position to raise its profits by charging higher prices. The results for generic firms are similar in terms of their pricing decisions. Compared with the original model, they receive a similar surplus when there are only price-insensitive patients, but a slightly higher surplus when there are only price-sensitive patients.

Now I discuss how the brand-name pricing pattern varies across models with only one type of consumer. As shown in Figure 5, when there are only price-sensitive patients (i.e., type 0), the brand-name firm behaves according to standard oligopoly models—it reduces prices over time when facing more generic competition. But when there are only price-insensitive patients (i.e., type 1), the brand-name firm keeps its prices high and only slightly increases them over time. Why does the model predicts this pattern? Note that the increase in generic sales does not reduce the brand-name sales much in the model with only price-insensitive patients, as shown in

TABLE 6

WELFARE AND MARKET CHARACTERISTICS: ORIGINAL MODEL, MODEL WITH ONLY PRICE-SENSITIVE PATIENTS, AND MODEL WITH ONLY PRICE-INSENSITIVE PATIENTS

| | Data | Original Model | Only Price-sensitive Patients | Only Price-insensitive Patients |
|---|---|---|---|---|
| Welfare statistics: | | | | |
| *Average quarterly producer surplus (million $):* | | | | |
| Brand-name | n.a. | 14.7 | 13.0 | 16.6 |
| Generic | n.a. | 0.50 | 0.62 | 0.49 |
| Combined | n.a. | 15.2 | 13.62 | 17.1 |
| *Average quarterly consumer surplus (million $):* | | | | |
| Price-sensitive patient | n.a. | 1.4 | 20.0 | n.a. |
| Price-insensitive patient | n.a. | 142.8 | n.a. | 167.1 |
| Combined | n.a. | 144.2 | 20.0 | 167.1 |
| *Average total quarterly surplus (million $):* | n.a. | 159.4 | 33.6 | 184.2 |
| Market characteristics: | | | | |
| *Average brand-name prices ($ per patient day)* | | | | |
| 1st quarter | 0.59 | 0.66 | 0.47 | 0.90 |
| 9th quarter | 0.72 | 0.80 | 0.33 | 0.95 |
| 18th quarter | 0.87 | 0.91 | 0.30 | 0.96 |
| *Average generic prices ($ per patient day)* | | | | |
| 1st quarter | 0.23 | 0.37 | 0.25 | 0.62 |
| 9th quarter | 0.12 | 0.12 | 0.07 | 0.19 |
| 18th quarter | 0.08 | 0.05 | 0.02 | 0.07 |
| *Average quarterly brand-name sales (million no. of patient days):* | | | | |
| 1st quarter | 40.6 | 31.0 | 70.3 | 21.6 |
| 9th quarter | 15.7 | 17.2 | 30.0 | 16.8 |
| 18th quarter | 9.8 | 13.4 | 14.2 | 15.4 |
| *Average quarterly generic sales (million no. of patient days):* | | | | |
| 1st quarter | 7.9 | 4.2 | 11.2 | 2.3 |
| 9th quarter | 28.8 | 29.9 | 60.2 | 19.9 |
| 18th quarter | 35.2 | 26.8 | 28.5 | 24.5 |

*Prices and sales in the "Data" column are the actual observed ones for clonidine.

Figures 3 and 4. Even though the generic price drops over time, many patients are still not willing to substitute generics for the brand-name drug due to their low price sensitivity. Consequently, the brand-name firm can keep its prices high. It should be emphasized that even though brand-name prices increase slightly over time when all patients are price-insensitive, the magnitude of the change is much smaller than what we observe in the data. The message from these results is quite clear: Without consumer heterogeneity in price sensitivity, it is difficult for an economic model to explain why the brand-name price rises after patent expiration.

In the original model with two types of consumers, the proportion of price-insensitive consumers who choose the brand-name drug increases over time as increasing number of price-sensitive consumers switch away from the brand-name drug. Roughly speaking, the brand-name firm raises its prices as the average price sensitivity of the consumers, who continue to purchase the brand-name drug, decreases over time. Figures 5 and 6 illustrate this relationship. Figure 5 plots the brand-name prices of these three models over time. Figure 6 plots the proportion of brand-name sales accounted by price-insensitive patients over time. It can be seen that the brand-name prices in the original model are approximately equal to the weighted average of the brand-name prices in the two models with homogeneous patients. I should note that the

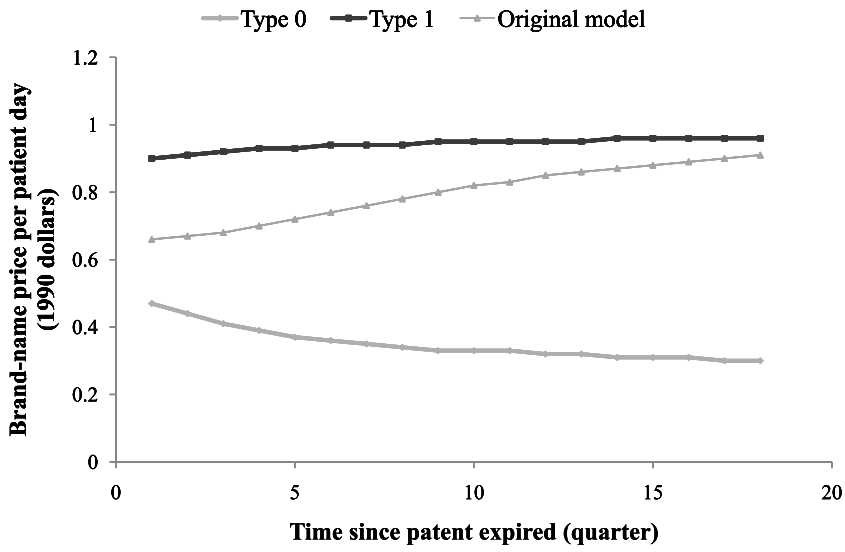


FIGURE 5

BRAND-NAME PRICES FROM THE ORIGINAL MODEL AND MODELS WITH ONLY ONE PATIENT TYPE

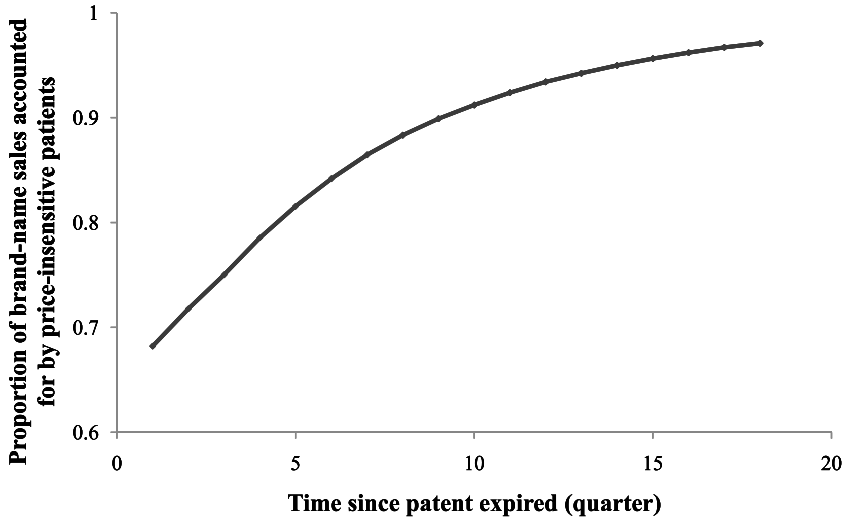


FIGURE 6

PROPORTION OF BRAND-NAME SALES ACCOUNTED FOR BY PRICE-INSENSITIVE PATIENTS

predicted brand-name firm pricing behavior is not due to price discrimination. Although the model here has consumer heterogeneity, I assume firms can only choose one price for all patients. The brand-name firm's pricing behavior in the model is mainly driven by the composition of consumers buying the brand-name drug in equilibrium.

5.3. *Reducing the Expected Approval Time.* In this subsection, I conduct a policy experiment that increases the likelihood of approving generic drugs for entry into the market. The FDA inspection of generic drug quality is necessary to ensure safety for the general public. However, it is also widely believed that consumer welfare could be improved if the FDA reduced the approval time while keeping the standard of quality control unchanged. Giving more resources to the FDA, allowing them to hire more inspectors, or computerizing their procedures could

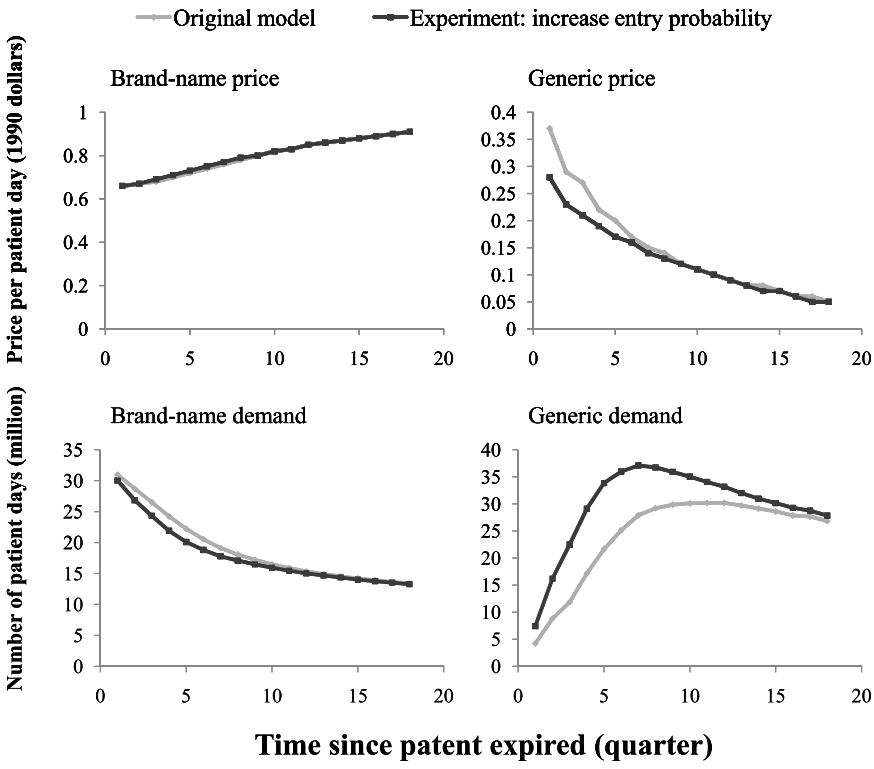


FIGURE 7

INCREASE PROBABILITY OF ENTRY: PRICE AND QUANTITY DEMANDED

accomplish this goal. In order to investigate the effect of this policy, I increase the intercept term ($\gamma_0$) in the logit model from $-2.64$ to $-1.0$. This increases the probability of entry in the period immediately after the patent expires from 0.07 to 0.27.

Figure 7 plots the average predicted price and demand under the experiment versus the original calibrated model. The average predicted demand for the brand-name drug in the experiment is very similar to that in the original model. The average predicted demand for generic drugs in the experiment is found to be higher than that in the original model by about 40% for the first six quarters. The gap then diminishes after the 6th quarter. After the 11th quarter, the average predicted demand for generics in the experiment becomes very close to those predicted by the original model.

The predicted generic demand pattern seems puzzling. The overall increase in generic demand seems to be too small. Given the magnitude of the increase in the entry probability, one might think that generics should become available much sooner and hence expect a much larger initial increase in generic demand, and the difference should be sustained. Moreover, why does the average predicted generic demand in this experiment drop in the later periods? It should be emphasized that the entry decision of generic firms is endogenous, and shortening the expected approval time has some subtle impacts on the expected return of submitting an application to the FDA in the first place. Other than allowing each generic firm to enter earlier, it also increases the likelihood that a generic firm enters a crowded market in the early periods compared with the original model. The overall effect on the expecting return of submitting an application, conditioning on the number of applicants, is therefore ambiguous. Consequently, the implication on the number of generic firms deciding to submit an application is also ambiguous if the FDA shortens the expected approval time. In Appendix A.2, I illustrate the intuition in a simple two-period model with two firms.

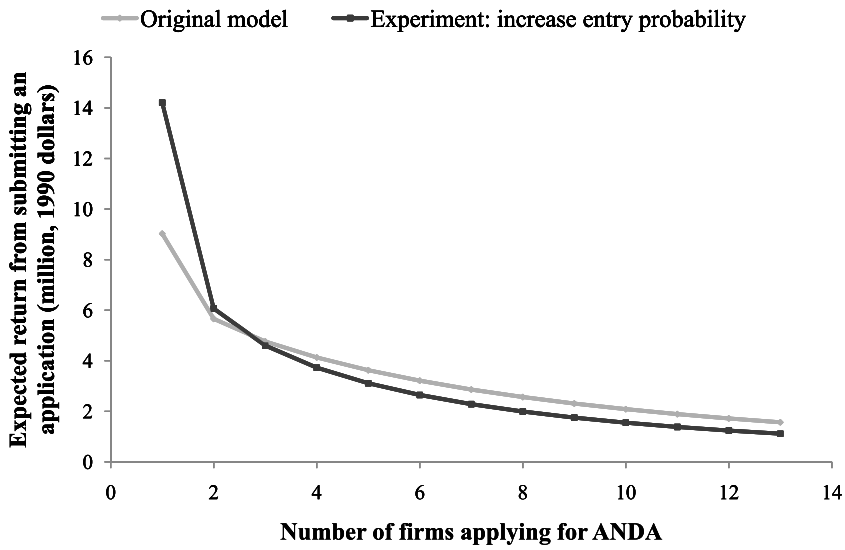


FIGURE 8

EXPECTED RETURN FROM SUBMITTING AN ANDA APPLICATION

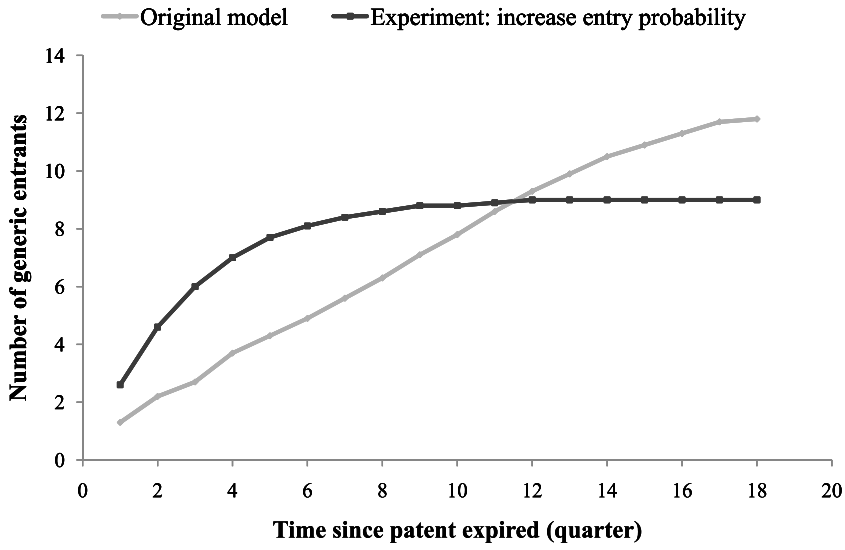


FIGURE 9

AVERAGE NUMBER OF GENERIC ENTRANTS

In general, one would expect that the "crowding" effect should dominate when the number of applicant is large. This is illustrated in Figure 8, which plots the generic expected return from submitting an application. Compared with the original model, the expected return in the experiment is lower when there are more than two applicants, but higher otherwise.

Assuming the sunk cost of entry remains at 1.64 million dollars, which is the calibrated value, the equilibrium number of generic firms that decide to enter declines from 12 to 9 in the experiment. Although the number of firms that decide to enter drops, the improved chances for each generic to receive an approval increases the average number of generic firms for the first 11 quarters, as shown in Figure 9. This explains why in the early periods, the predicted generic

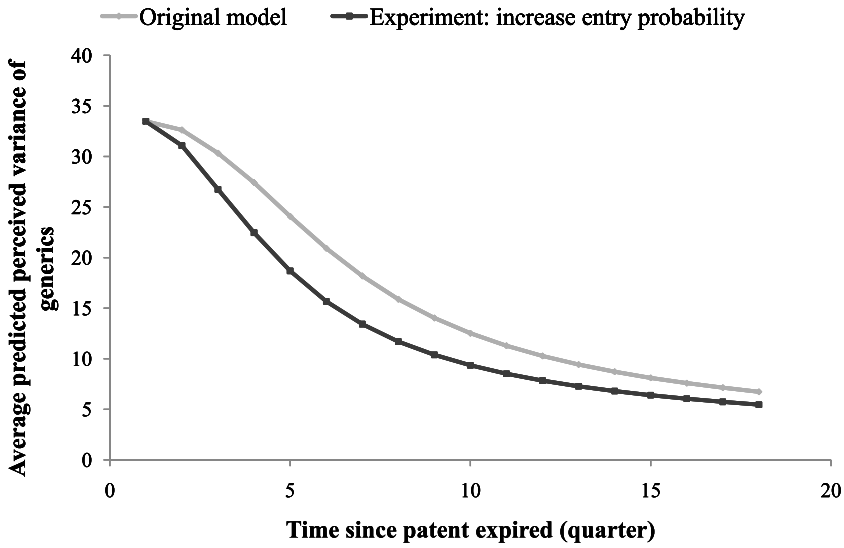


FIGURE 10

AVERAGE PREDICTED PERCEIVED VARIANCE

demands from the experiment are higher than those from the original model, and the predicted generic prices are lower (see Figure 7).

As displayed in Figure 10, the initial increase in the generic demand also allows the market to learn the generic quality quicker. The average perceived variance is smaller in the policy experiment: The difference ranges from 5% in the second quarter to nearly 26% in the ninth quarter, and then reduces to about 13% at the end of the period. Consequently, even though the average number of generic entrants in the original model is higher after the 11th quarter, its predicted generic demand does not surpass those predicted by the experiment throughout the rest of the period.

It is worth pointing out that the generic prices in the original model remain higher than those in the experiment throughout the period (see Figure 7). This may seem puzzling, as the mean number of generic firms and the level of uncertainty are both higher in the original model from the 12th quarter onwards. The main reason for this result is that generic entry usually occurs later in the original calibrated model, due to the smaller probability of approval. This implies that the time since first generic entry ($g_t$) is on average shorter for the original model. This leads to higher average generic prices for the original model in the long run because the unobserved product differentiation among generics decreases as $g_t$ increases, given that $\iota$ is estimated to be negative.

Another interesting result is that generic prices for the experiment and the original calibrated model become very close after the ninth quarter. It appears that the equilibrium generic prices are not too sensitive to the number of generic firms as time passes by. This is mainly because the degree of the product differentiation among generics, as measured by $\mu_2$, declines over time. When the number of generic firms is large, the equilibrium generic price becomes mainly determined by $\mu_2$ (Anderson et al., 1992). It turns out that, given the parameter values, nine generic entrants is already large enough for $\mu_2$ to dictate the equilibrium generic prices.

As shown in Table 7, the overall welfare implications from the experiment (the second column) are very similar to those from the original model (the first column). In particular, consumer welfare has only improved by about 2.5% in the experiment, amounting to only around \$4.5 million (=148.7 − 144.2 million). This seems to be much smaller than what the supporters of this policy expect. It appears that a narrower choice of generic products has counteracted most of the benefits of having generics available sooner.

TABLE 7

WELFARE AND MARKET CHARACTERISTICS: EXPERIMENT WITH REDUCING THE EXPECTED APPROVAL TIME, MYOPIC FIRMS, AND DIFFERENT MARGINAL COSTS

| | Original Model $\beta = 0.98$, $mc = 0$ | Reducing Approval Time | Myopic $\beta = 0$, $mc = 0$ | $\beta = 0.98$, $mc = 4$ | $\beta = 0.98$, $mc = 8$ |
|---|---|---|---|---|---|
| Welfare statistics: | | | | | |
| *Average quarterly producer surplus (million $):* | | | | | |
| Brand-name | 14.7 | 14.1 | 14.8 | 14.9 | 15.0 |
| Generic | 0.50 | 0.60 | 0.50 | 0.59 | 0.67 |
| Combined | 15.2 | 14.7 | 15.2 | | |
| *Average quarterly consumer surplus (million $):* | | | | | |
| Price-sensitive patient | 1.4 | 2.2 | 1.3 | 0.9 | 0.5 |
| Price-insensitive patient | 142.8 | 146.5 | 142.7 | 141.3 | 139.8 |
| Combined | 144.2 | 148.7 | 144.0 | 142.2 | 140.3 |
| *Average total quarterly surplus (million $):* | | | | | |
| | 159.4 | 163.4 | 159.2 | 157.7 | 156.0 |
| *Market characteristics:* | | | | | |
| *Average brand-name prices ($ per patient day)* | | | | | |
| 1st quarter | 0.66 | 0.66 | 0.66 | 0.69 | 0.73 |
| 9th quarter | 0.80 | 0.80 | 0.80 | 0.85 | 0.88 |
| 18th quarter | 0.91 | 0.91 | 0.91 | 0.94 | 0.98 |
| *Average generic prices ($ per patient day)* | | | | | |
| 1st quarter | 0.37 | 0.28 | 0.40 | 0.41 | 0.45 |
| 9th quarter | 0.12 | 0.12 | 0.12 | 0.16 | 0.19 |
| 18th quarter | 0.05 | 0.05 | 0.05 | 0.09 | 0.12 |
| *Average quarterly brand-name sales (million no. of patient days):* | | | | | |
| 1st quarter | 31.0 | 30.0 | 31.0 | 29.6 | 28.3 |
| 9th quarter | 17.2 | 16.5 | 17.2 | 16.6 | 16.0 |
| 18th quarter | 13.4 | 13.3 | 13.4 | 13.0 | 12.6 |
| *Average quarterly generic sales (million no. of patient days):* | | | | | |
| 1st quarter | 4.2 | 7.4 | 4.1 | 4.0 | 3.7 |
| 9th quarter | 29.9 | 35.9 | 29.7 | 27.8 | 25.7 |
| 18th quarter | 26.8 | 27.8 | 26.8 | 25.2 | 13.6 |
| *Sunk costs of entry (Million $)* | 1.64 | n.a. | n.a. | 2.45 | 2.35 |

5.4. *Robustness.* In this subsection, I check the robustness of the results. Forward-looking behavior certainly plays an important role in generic firm's entry decisions. But it is not clear how important this feature is in determining firm's pricing decisions. I investigate this issue by solving the model with $\beta = 0$, and keeping the number of generic firms deciding to apply for ANDA unchanged (i.e., remains at 12). The results are summarized in the third column of Table 7. Compared with the original model, the model with myopic firms predicts that the average generic price is about 8% higher in the first quarter (40 cents vs. 37 cents), and that the average generic sales are about 2–3% lower (4.1 million vs. 4.2 million). The generic price gap and sales gap between these two models diminish over time, and they converge to almost the same values from the fourth quarter onwards. This shows that if generic firms are forward-looking, they have an incentive to lower their prices in order to attract more consumers to try their products. Such an incentive is stronger at the beginning, as the public has a more diffuse prior about the quality of generics. As the public gains more information about generics over time, the return of having more patients experiment with generics diminishes. Therefore, the decision rule of myopic generic firms becomes very close to that of forward-looking firms after several quarters.

In terms of other dimensions, the predictions from the model of myopic firms are very similar to those from the original model. Although generic firms sell more by charging lower prices in the original model, the increase in generic sales is quite insignificant and mainly obtained from the outside good. The brand-name pricing decisions and demand are almost the same in the two models. This suggests that the discount factor is not very important in the brand-name pricing decisions, given the parameter values of the model. Instead, the consumer heterogeneity plays the key role in determining brand-name prices.

I also check the robustness of the results by varying the marginal costs. In particular, I consider two additional cases: mc = 4 and 8 cents. (Recall that the lowest observed generic price is 8 cents.) The results are reported in the fourth and the fifth column in Table 7. It appears that the average predicted brand-name and generic prices increase roughly by the amount of the marginal costs. The average predicted brand-name and generic sales decrease accordingly. In particular, the goodness of fit for generic prices and generic demand worsens in these two cases. It appears that the original model, where mc = 0, explains the data better than these two alternative cases.

## 6. CONCLUSION

This research is the first step toward structural modeling of a dynamic equilibrium in the prescription drug market. I have shown that the model is able to mimic the stylized facts regarding the evolution of market shares as well as pricing and entry behavior. I have demonstrated that neither a model with only price-sensitive patients nor one with only price-insensitive patients can cause the brand-name firm to raise its prices after generic entry. I have also shown that brand-name price is essentially a function of the proportion of brand-name sales accounted for by price-insensitive patients.

In this article I have explicitly solved the dynamic equilibrium and obtain the decision rules of agents. This approach allows me to quantify the effect of altering specific policy parameters. I have investigated the impact of a public policy that reduces the expected approval time for generic drugs. The interest groups who propose this policy expect that the policy could significantly improve consumer welfare by bringing generics to the market sooner. However, this research shows that when firms are forward-looking, shortening the expected approval time could lower generic firms' expected return from entering the market. This could significantly reduce the number of generic firms who decide to enter, counteracting the intended effect of a policy. Given the change in magnitude of the policy parameter in this article, I find that the number of generic firms deciding to enter reduces from 12 to 9, though on average generic drugs become available sooner. The early entry of generics has led the public to learn the generic attribute quicker. In addition, the degree of the product differentiation among generics, which determines the stiffness of the price competition, on average drops at a faster rate. As a result, the generic prices become lower in the experiment, in particular for the initial few periods. It turns out that this policy experiment hardly improves consumer welfare.

The key message of this policy experiment is that even if the government spends a large amount of resources to improve the efficiency of the FDA in approving generic drugs, it does not necessarily achieve the goal of enhancing welfare. The main obstacle of predicting the outcome of this policy is that it alters generic's expected return of entering a market. In order to quantify the welfare consequence of policies that have such implications, it is important to build and estimate an equilibrium model that incorporates the FDA random approval process, generic entry decisions, firms' pricing decisions, and consumer learning behavior. The model developed here has incorporated all these features. In principle, one could use this model to calibrate a socially optimal expected approval time that would help the government to direct its resources more efficiently. This model could also be extended to investigate how policies that influence generic firms' entry decisions may affect brand-name firms' incentives to develop a new drug in the first place.

It is implicitly assumed that the policy experiment is imposed on one market only. If such a policy were imposed on all markets simultaneously, the coefficients that determines the value

of the outside good, which captures the value of other close substitutes, could change. In order to predict how the coefficient for the outside good changes when imposing a new policy on all prescription drug markets, one has to model intermolecular competition. I leave this for future research.

## APPENDIX

A.1. *Estimation Approach.* In this appendix, I describe the procedures to estimate the demand side parameters. The description here will be concise, and more details can be found in Ching (2000, 2010). As explained in Ching (2010), the GMM procedure proposed by Berry et al. (1995) cannot be applied to estimate the aggregate learning model presented here because the model has two unobserved product characteristics: $E[A_g|I(t)]$ and $\xi_t$. My estimation approach is likelihood based. To explain my method, it would be useful to review the classical full information maximum likelihood approach (FIML). In FIML, the econometrician needs to model the oligopolistic supply side explicitly and derive a pricing policy rule as a function of observed and unobserved product characteristics and other state variables. The econometrician then forms the joint likelihood function of a sequence of prices and quantities, and consistent estimates of the parameters can be obtained by maximizing the likelihood function. However, as noted in the article numerically solving an equilibrium model can be very time-consuming. To avoid this computational problem, I propose to approximate the pricing policy function. What state variables should enter the pricing policy function? As explained in Ching (2000, 2010), $E[A_g|I(t)]$ and $\xi_t$ might be correlated with $p_t$, where $p_t = (p_{bt}, p_{gt})$. In addition, $p_{jt}$ might also depend on $(\sigma^2_{A_g}(t), n_{gt}, t)$ through the dynamic oligopolistic equilibrium (recall that $n_{gt}$ is the number of generic entrants at time $t$). The time trend, $t$, may affect equilibrium prices because it enters the utility function for the outside good. A time trend in the pricing policy function could also capture some systematic increase in production costs over time. Hence, the true pricing policy function, $\wp(.)$, should be a function of $(n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_{bt}, \xi_{gt})$. For $j \in \{b, g\}$,

$$p_{jt} = \wp_j\big(n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_{bt}, \xi_{gt}\big)\nu_{jt}, \tag{A.1}$$

where $\nu$ is an error term that captures productivity shocks or "optimization" errors that prevent the firm from correctly implementing the optimal pricing policy function, $\wp_j(.)$. Implicitly, I allow for the possibility that firms observe the random factors that lead to ex post discrepancies between intended and realized decisions. If this happens, $\wp_j(.)$ would take these uncertainties into account.

Taking logs on both sides of Equation (A.1), I obtain,

$$\log(p_{jt}) = \log\big(\wp_j(n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_{bt}, \xi_{gt})\big) + \log(\nu_{jt}). \tag{A.2}$$

To approximate $\log(\wp_j(.))$, I propose to use a polynomial series estimator in Ching (2000, 2010), i.e., projecting $\log(p_{jt})$ onto a polynomial of $(n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_{bt}, \xi_{gt})$. Assuming that the error term, $\nu_{jt}$, is distributed log normally, I obtain the conditional likelihood of observing $p_t$:

$$f_p\big(p_t\big|n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_t; \theta_l, \gamma\big), \tag{A.3}$$

where $\xi_t = (\xi_{bt}, \xi_{gt})$, $\gamma$ is the vector of parameters that are associated with the state variables in $\wp_j(.)$, and $\theta_l$ is a set of learning parameters that determines $\sigma^2_{A_g}(t)$ and $E[A_g|I(t)]$.[26]

[26] Note that since I approximate $\log(\wp_j(.))$, $\nu_{jt}$ will also contain an approximation error, which should be a function of the state variables by construction. I assume that a polynomial series estimator is able to approximate $\log(\wp_j(.))$ well, and hence the magnitude of the approximation error is very small and can be ignored.

The observed quantity demanded, $q_{jt}$, follows a multinomial distribution and therefore is subject to sampling errors. The conditional likelihood of quantity demanded given prices, $f_q(q_t|p_t,.)$, can therefore be formed straightforwardly (Ching, 2010). The joint likelihood of observing $(q_t, p_t)$ is simply the product of $f_q(q_t|p_t,.)$ and $f_p(p_t|.)$, i.e.,

$$\begin{aligned}(A.4)\quad & l\left(q_t, p_t\middle|n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_t; \theta_d, \gamma\right) \\ &= f_q\left(q_t\middle|p_t, n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_t; \theta_d\right) f_p\left(p_t\middle|n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_t; \theta_l, \gamma\right).\end{aligned}$$

Now note that $\sigma^2_{A_g}(t)$ is a function of $\{q_{g\tau}\}_{\tau=0}^{t-1}$ (see Equation (4)). Therefore, one can rewrite (A.4) as

$$\begin{aligned}(A.5)\qquad & l\left(q_t, p_t|n_{gt}, t, \sigma^2_{A_g}(t), E[A_g|I(t)], \xi_t; \theta_d, \gamma\right) \\ &= l(q_t, p_t|n_{gt}, t, \{q_{g\tau}\}_{\tau=0}^{t-1}, E[A_g|I(t)], \xi_t; \theta_d, \gamma).\end{aligned}$$

For each market, the likelihood of observing $q = \{q_t\}_{t=0}^T$ and $p = \{p_t\}_{t=0}^T$ is

$$\begin{aligned}(A.6)\qquad & L\left(q, p\middle|\{n_{g\tau}, \tau, E[A_g|I(\tau)], \xi_\tau\}_{\tau=0}^T; \theta_d, \gamma\right) \\ &= \prod_{t=0}^T l\left(q_t, p_t\middle|n_{gt}, t, \{q_{g\tau}\}_{\tau=0}^{t-1}, E[A_g|I(t)], \xi_t; \theta_d, \gamma\right).\end{aligned}$$

But $(\xi_t, E[A_g|I(t)])$ are unobserved by the analyst and therefore must be integrated over to form the unconditional sample likelihood for $(q_t, p_t)$, that is

$$\begin{aligned}(A.7)\quad & L\left(q, p\middle|\{n_{g\tau}\}_{\tau=0}^T, \{\tau\}_{\tau=0}^T; \theta_d, \gamma\right) \\ &= \int\int \prod_t^T l\left(q_t, p_t|n_{gt}, t, \{q_{g\tau}\}_{\tau=0}^{t-1}, E[A_g|I(t)], \xi_t; \theta_d, \gamma\right) dF\left(\{\xi_\tau\}_{\tau=0}^T\right) dF\left(\{E[A_g|I(\tau)]\}_{\tau=0}^T\right).\end{aligned}$$

If $\xi_t$ is i.i.d., the above integrals can be rewritten as

$$\begin{aligned}(A.8)\quad & L\left(q, p\middle|\{n_{g\tau}\}_{\tau=1}^T, \{\tau\}_{\tau=0}^T; \theta_d, \gamma\right) \\ &= \int \left\{\prod_t^T \left[\int l\left(q_t, p_t|n_{gt}, t, \{q_{g\tau}\}_{\tau=0}^{t-1}, E[A_g|I(t)], \xi_t; \theta_d, \gamma\right) dF(\xi_t)\right]\right\} dF\left(\{E[A_g|I(\tau)]\}_{\tau=0}^T\right).\end{aligned}$$

Evaluating (A.8) numerically is very difficult. It involves high order integrals because $E[A_g|I(t)]$ is autocorrelated. I resolve this problem by using the method of simulated maximum likelihood (Ching, 2010).

A.2. *A Simplified Entry Model.* To illustrate the argument that reducing the uncertainty of the approval decision could lower the expected total discounted profits of entering the market in the first place, I consider the following simple model. There are two potential entrants and two periods: $t = 1, 2$. If a potential entrant decides to enter, he needs to pay a sunk costs of entry, $c_e$, and will enter the market in $t = 1$ with probability $p$ and with certainty that he will enter in period $t = 2$. Let $\pi(n)$ be the per period profit if there are $n$ firms in the market. We assume that $\pi(1) > \pi(2)$. If only one potential entrant decides to pay $c_e$ to enter the market, the expected

return would be

$$V(1) = p\pi(1) + \beta\pi(1), \tag{A.9}$$
$$= (p + \beta)\pi(1).$$

If both potential entrants decide to enter, the expected return would be

$$V(2) = (p(1-p)\pi(1) + p^2\pi(2)) + \beta\pi(2), \tag{A.10}$$
$$= p\pi(1) - p^2\pi(1) + p^2\pi(2) + \beta\pi(2).$$

PROPOSITION 1. *As* $p \to 1$, $V(2) \to (\pi(2) + \beta\pi(2))$.

PROOF. It follows from Equation (A.10).

PROPOSITION 2. *The expected return,* $V(2)$, *first increases with p up until* $p^*$, *and then decreases.*

PROOF.

$$\frac{\partial V(2)}{\partial p} = \pi(1) - 2p\pi(1) + 2p\pi(2) \tag{A.11}$$
$$= \pi(1) - 2p(\pi(1) - \pi(2))$$

It is clear that $\frac{\partial V(2)}{\partial p}$ is positive for $p < p^*$ and then negative for $p > p^*$, where $p^* = \frac{\pi(1)}{2(\pi(1)-\pi(2))}$. ■

The following numerical example illustrates that when there is uncertainty about entry date, it is possible to encourage more firms to enter the market. I assume that $\pi(1) = 10$, $\pi(2) = 0$, $c_e = 2$, and $\beta = 0.9$. In this example, when $p = 1$, $V(1) = 10$ and $V(2) = 0$. Therefore, when $p = 1$, only one potential entrant will enter the market. However, when $p = 0.5$, $V(1) = 5$ and $V(2) = 2.5 > c_e$. As a result, when $p = 0.5$, both potential entrants will enter the market. This illustrates that having some uncertainty about entry could encourage more firms to enter the market.

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