A Dynamic Oligopoly Structural Model for the Prescription Drug Market After Patent Expiration

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Abstract

Motivated by the slow diffusion of generic drugs and the increase in prices of brand-name drugs after generic entry, I incorporate consumer learning and consumer heterogeneity into an empirical dynamic oligopoly model. In the model, firms choose prices to maximize their expected total discounted profits. Moreover, generic firms make their entry decisions before patent expiration. The entry time of generics depends on the FDA random approval process. I apply this model to the market of clonidine. The demand side parameters are estimated in a previous paper (Ching[16]). The supply side parameters are estimated and calibrated here. The model replicates the stylized facts fairly well. I confirm that consumer heterogeneity in price sensitivity plays an important role in explaining the brand-name pricing pattern. I also apply the model to examine the impact of a policy experiment, which shortens the expected approval time for generics. Although this experiment brings generics to the market sooner, it also reduces the number of generic entrants as the likelihood of entering a crowded market in the early periods increases. Given the change in magnitude of the policy parameter, the experiment improves the rate of learning, and lowers the equilibrium generic prices throughout the period. However, it hardly raises the overall 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 generics as they are uncertain about the generic quality. This type of concern was particularly serious during the 80s when generics were relatively new (Strutton et al.[48], Carroll and Wolfgang[12], and Mason and Bearden[39]). The prevalence of generic entry in the post-84 period therefore creates an ideal situation for studying firm's entry and pricing behavior, and market evolution when there are uncertainty about the product quality.

Past research have documented two stylized facts that characterize the market evolution of this industry (e.g., Caves et al.[13], Grabowski and Vernon[31][32], Suh et al.[49], Frank and Salkever[27], Griliches and Cockburn[33], Cook[18], and Ching[15]): (i) many brand-name originators increase their prices after generic entry[1]; (ii) there has been a slow diffusion of generic drugs into the market even after controlling for price differences between brand-names and generics. A few studies (e.g., Grabowski and Vernon[31] and Frank and Salkever[26][27]) have conjectured that consumer heterogeneity in price-sensitivity is needed to capture the pricing pattern[2]; in Ching[16], 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 paper I incorporate consumer learning and consumer heterogeneity into 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.

Since the demand side of my model is obtained by aggregating individual consumer choices, which based on utility maximization; and the supply side behavior is generated by profit maximization, the model provides a coherent framework for evaluating the welfare impacts of public

[1] Anti-infective drugs is an exception. Wiggins and Maness[51] show that generic entry has been effective in reducing the brand-name price in this class of drugs.

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

policies in this industry. Due to the increase in prescription drug expenditures, the post-patent 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 patent expired between 1984 and 1987 have generics available immediately after patent expiration (Office of Technology Assessment[50]). This has led several interest groups to advocate various policy proposals to speed up the generic approval time (e.g., Middleton[41]). 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. This could be achieved by giving more resources to the FDA.

The spirit of this research is similar to the work by Grabowski and Vernon[30], 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 80s, they made many simplifying assumptions in their model. In particular, they assumed that firms made their decisions according to rules, instead of profit maximizing problem. Moreover, they chose their parameter values quite arbitrarily. This research is also related to an empirical work by Scott Morton[46], which summarizes the factors that influence the entry decision of generic firms. However, Scott Morton[46] uses a reduced form approach to model profit functions, and therefore cannot evaluate new policies that change the post-patent environment, such as shortening the expected approval time.

To address the shortcoming of the previous researches, I model the postpatent competition using a Markov-perfect Nash equilibrium, where firms choose price to maximize their expected discounted profits. 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 changes with policy parameters, which may affect the expected return from entering the market.

There is another independent work-in-progress by Reiffen and Ward [44], which also model the random approval process explicitly. However, unlike the model developed here, they do not

incorporate consumer learning in the post-patent environment. Therefore, their model does not account for the effect of shortening approval time on the rate of learning, which in turn affects 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[47], and Ellison and Ellison[21], which study the strategic entry deterrence behavior of brand-name incumbents. Although this paper does not focus on these issues, the model developed here 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 [45], McLennan [40] and Aghion, Bolton, Harris and Jullien [3] consider a monopolist facing a fixed demand curve with unknown parameters. Aghion, Espinosa and Jullien [4], Harrington [34] and Keller and Rady [36] analyze a duopoly market where firms are uncertain about the substitutability between their products. The models considered in Bergemann and Välimäki[7] [8] 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 paper is tailored for the prescription drug market. Although the model does not have a closed form solution, 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[23], Ackerberg[1], and Crawford and Shum[19]), all the existing works have exclusively focused on modeling the individual consumer behavior. In terms of methodological contribution, this is the first empirical paper that explicitly models oligopoly behavior when there are uncertainty about product quality. My model also belongs to the class of dynamic oligopoly models introduced by Ericson and Pakes[24], and Pakes and McGuire[42][43]. Due to the computational burden of solving this class of models, it is difficult to implement them on real world industries. This paper is one of a few empirical applications of fully dynamic oligopoly models (e.g., Gowrisankaran and Town[29], and Benkard[6]). Other works on dynamic oligopoly models, which do not directly apply to real world data, include Fershtman and Pakes[25], Gowrisankaran[28], and Cheong and Judd[14]. It should be emphasized that most of the previous papers model dynamics through investment,

and assume firms only make static price or quantity decision. As an exception, Benkard[6] models dynamic quantity decisions by introducing learning-by-doing on the supply side. In this paper I model dynamic pricing decisions by introducing consumer learning on the demand side. In addition, I explicitly model consumers as Bayesian learners, as in Erdem and Keane[23].

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 the firm's point of view due to the idiosyncratic nature of the technology adoption process and the FDA approval process. Firms choose price to maximize the expected discounted net future profits. 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.

The model is applied to the market for clonidine, which is an anti-hypertension drug. The demand side parameters are estimated in another paper (Ching[16]), the supply side parameters are estimated and calibrated here. I find that the model explains the pricing pattern and the slow diffusion 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, the "crowding" effect outweighs the "early-entry" effect. Consequently, the number of generic firms that are willing to pay the sunk cost of entry drops. I also find that the experiment improves the rate of learning and lower the equilibrium generic prices. However, it hardly raises the overall welfare.

The rest of the paper is organized as follows. Section 2 provides an overview of the generic approval process and the market characteristics for clonidine. Section 3 presents the dynamic oligopoly model and the computational method I use to solve for a markov-perfect nash equilib-

rium. Section 4 describes the data set and explains how to estimate and calibrate the supply side parameters. Section 5 presents the results. The last section is the conclusion.

2 Background

2.1 Generic Drug Approval Process

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 Applications (ANDA). In order to obtain approval, a generic firm needs to prove that its product contains the same active ingredients, strength, dosage form, route and is bioequivalent.[3] 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 drug. 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. All these factors 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[46]). 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 the firm's 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.

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

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.

2.2 Clonidine

The dynamic oligopoly structural model is applied to the market for clonidine. Clonidine, an anti-hypertension drug, can also be used to treat migraine headaches. Its patent expired in July, 1986. The revenue for the quarter right before patent expiration is 25 million dollars. After patent expiration, the clonidine market behaved according to the stylized facts described above. Its market potential has attracted 12 generic firms to enter. Largely due to the random approval process, the entry time distribution is fairly spread out. As shown in Figure 1, the first generic enters in the quarter immediately after the patent expires, while the last one enters nine quarters later. In the 18 quarters after patent expiration, the brand-name price goes up from 59 to 87 cents per patient day, the generic price goes down from 23 to 8 cents per patient day, and the brand-generic sales ratio decreases from 5.1 to 0.3. Moreover, the number of generic entrants becomes stable at 12 from the 10th to 18th quarter, but the generic prices keep decreasing from 12 cents to 8 cents. The minimum and maximum quarterly total sales (including both the brand-name and generics) are 43.3 and 51.6 million patient days, respectively. Now I turn to discuss the model in detail.

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 which is produced by the brand-name firm and has patent protection, and generic drugs which are produced by the generic firms.

Product characteristics can be distinguished as p_j, A_j, and ξ_j, where p_j is the price of product j, A_j is the mean attribute level of product j, and ξ_j represents some unobserved product characteristics (e.g., promotion effort). All agents in the model are perfectly informed about p_j and ξ_j, but they may be imperfectly informed about each product's mean attribute level, 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's 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,[4] update the public information on each product in a Bayesian fashion.

The equilibrium used here is Markov-Perfect Nash Equilibrium (MPNE), as defined by Maskin and Tirole[38]. The strategy space includes entry and pricing decisions. MPNE restricts the subgame perfect equilibria to those where actions depend only 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 down into three components: (1) learning about product attributes, (2) demand, and (3) supply. I now describe these in turn. Since (1) and (2) are mainly drawn from Ching[16], I only discuss them briefly here.

3.1 Learning about Product Attributes

Prior to 1984, generics were relatively uncommon due to the high entry costs. As a result, the public felt unsure about the generic qualities when there were suddenly many generic alternatives available right after 1984. Although the FDA claims that their standard for approving generic

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

drugs is the same as for brand-name drugs, many physicians and pharmacists did not entirely trust the FDA in the 80s (Strutton et al.[48], Carroll and Wolfgang[11], Mason and Bearden[39]).[5]

I therefore assume the public is uncertain about the mean attribute of generic drugs (A_j). A drug is an experience good. Consumption of a drug provides 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 $j = 1, \cdots, n_g$ denote generic drugs. The experience variability may be expressed as:

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

where t indexes time ($t = 1, \cdots, T$); and i indexes the patients ($i = 1, \cdots, M$). The error term associated with experience variability (δ_{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, $A_j = A_k =: A_g, \forall j, k = 1, \cdots, n_g$, and the experience variability for generic drugs can be rewritten as:

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

for $j = 1, \cdots, n_g$. 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. Therefore, there is only uncertainty about A_g.

The noise term δ_{ijt}, and the initial priors on A_g are assumed to be normally distributed. Letting $t = 0$ be the initial period of the model, I have that

$$\delta_{ijt} \sim N(0, \sigma_\delta^2), \tag{3}$$

[5]It should be noted that there was a generic scandal in the late 80s. 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.

$$A_g \sim N(A, \sigma^2_{A_g}(0)), \tag{4}$$

where $\sigma^2_{A_g}(0)$ is the initial prior variance (at $t = 0$) of 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 revealed to patients. Let κ be the fraction of experience signals revealed to physicians in each period. Then $card(\mathcal{A}_t) = \kappa q_{gt}$.[6]

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. According to the Bayesian rule (DeGroot[20]),

$$E[A_g|I(t+1)] = E[A_g|I(t)] + \beta_g(t)(\bar{A}_{gt} - E[A_g|I(t)]), \tag{5}$$

where $\bar{A}_{gt}$ is the sample mean of all the experience signals for generic drugs that are realized in period t.[7] $\beta_g(t)$ is a Kalman gain coefficient, which is a function of experience variability (σ^2_δ), perceived variance ($\sigma^2_{A_g}(t)$), total quantity of generic drugs consumed at time t (q_{gt}) and the fraction of experience signals revealed to the public (κ). It can be expressed as:

$$\beta_g(t) = \frac{\sigma^2_{A_g}(t)}{\sigma^2_{A_g}(t) + \frac{\sigma^2_\delta}{\kappa q_{gt}}}. \tag{6}$$

The perception variance at the beginning of time $t+1$ is given by (DeGroot[20]):

$$\sigma^2_{A_g}(t+1) = \frac{1}{\frac{1}{\sigma^2_{A_g}(0)} + \frac{\kappa Q_{gt}}{\sigma^2_\delta}}, \tag{7}$$

where $Q_{gt}(= \sum_{\tau=1}^{t} q_{g\tau})$ is the cumulative consumption of generics, or,

$$\sigma^2_{A_g}(t+1) = \frac{1}{\frac{1}{\sigma^2_{A_g}(t)} + \frac{\kappa q_{gt}}{\sigma^2_\delta}}. \tag{8}$$

Equations (7) and (8) 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

[6] One can interpret κ as the probability that a patient revisits a phsyician 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 $card(\mathcal{A}_t) = \kappa q_{gt}$.

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

gained via consumption experience (i.e., the lower the experience variability of the product); (b) the more experiences the public has about generic drugs.[8]

3.2 Demand

Since the focus here is to develop a tractable industry equilibrium model and I only have product level data, I abstract away from the principal-agent relationship among patients, pharmacists, physicians and hospitals when modeling demand. In the model each patient i[9] decides among J possible alternatives in each of T discrete periods of time, where T is finite. Alternatives are defined to be mutually exclusive, so that if $d_{ij}(t) = 1$ indicates that alternative j is chosen by patient i at time t and $d_{ij}(t) = 0$ indicates otherwise, then $\sum_{j \in J} d_{ij}(t) = 1$. The choice set J includes the brand-name drug (b), the generic drugs $(1, ..., n_g)$, and an "outside" alternative (0). The outside alternative includes receiving no treatment and other non-bioequivalence drugs, which could treat the same disease.

Let $I(t)$ denote the public information set at the beginning of time t. I assume that the utility of consuming a drug can be approximated by an additive compensatory multi-attribute utility model (Lancaster[37]). As in Erdem and Keane[23], I assume further that consumers are risk averse with regard to perceived variability in product attributes. The expected utility of purchasing a generic drug j is given by the following expression:

$$\begin{aligned} E[U_{ijt}|I(t)] &= -\alpha_i p_{jt} + \omega E[A_g|I(t)] - \omega r E[A_g|I(t)]^2 - \omega r(\sigma_\delta^2 + \sigma_{A_g}^2(t)) + \xi_{gt} \\ &\quad + \zeta_{igt} + e_{ijt}, \end{aligned} \tag{9}$$

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; ω is the utility weight on the perceived attribute; r is the risk coefficient; α_i is the utility weight that patient i attaches to price; ξ_{gt} represents the mean valuation of generic unobserved product characteristic at time t; $(\zeta_{igt} + e_{ijt})$ represents the distribution of consumer preferences about this mean. α_i, ξ_{gt}, ζ_{igt} and e_{ijt} are unobserved to the econometrician

[8] Note that κ and σ_δ^2 cannot be separately identified. In Ching[16], I estimate σ_δ^2 by fixing κ at some value.

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

but observed by the patients in the model when they make purchase decisions. Each patient's objective is to maximize current period expected utility.[10]

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 α_i to be heterogeneous in order to capture this institutional feature. Moreover, the heterogeneity of α_i could be crucial in explaining why brand-name prices increase in response to generic entry.[11]

For each patient i, ζ_{igt} is common to all generic drugs. This introduces group correlation of utility levels. In the nested logit framework, e_{ijt} is distributed Extreme Value with variance $(\pi\mu_2)^2/3$, and $(\zeta_{igt}+e_{ijt})$ is distributed Extreme Value with variance $(\pi\mu_1)^2/3$.[12] One interpretation is that conditioning on choosing generics, e_{ijt} is an Extreme Value error term associated with generic drug j.

The expected utility of choosing the brand-name drug is similar to (9). However, since I assume that the patients have already learned perfectly about A_b, we have that $\sigma_{A_b}(t) = 0$ and $E[A_b|I(t)] = A_b, \forall t = 0, \cdots, T$.

The expected utility associated with the outside alternative depends on an intercept, a time trend and a stochastic error component,

$$E[U_{i0ts}|I(t)] = \phi_{0i} + \phi_{0ti}t + \tilde{e}_{i0t}, \tag{10}$$

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 the valuation of the outside alternative, I allow the outside good coefficients (ϕ_{0i}, ϕ_{0ti}) to be heterogeneous.

As in Heckman and Singer[35], I specify the heterogeneity of the price response coefficient (α_i) and the coefficients for the outside alternative (ϕ_{0i}, ϕ_{0ti}) as discrete multinomial. Accordingly, we distinguish between two different "types" of individuals, where each type k is characterized by a

[10] Allowing patients to maximize their lifetime expected utility will dramatically complicate the state space. Ching[16] provides several justifications for modeling patients to be myopic.

[11] It should be noted that ω 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, (α, ω, r), to be heterogeneous given the market level data I have.

[12] The exposition of the nested logit model framework follows from Cardell[10].

different triple $(\alpha^k, \phi_0^k, \phi_{0t}^k)$. The population proportions of each type are given by π_k. The demand for each product is obtained by aggregating individual patient choices.

As pointed out in Berry and Pakes[9] and Ackerberg and Rysman[2], the *i.i.d.* extreme value error terms (e_{ijt}'s) represent unobserved product differentiation that is symmetric across products.[13] This unobserved product differentiation could be due to differences in promotion efforts, sales networks across geographic regions, or incomplete information about product characteristics. This feature of the model causes 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 generic entering the market adds one more dimension to the symmetric unobserved product differentiation (SUPD) space. Moreover, the higher the variance of e_{ijt} the larger the bound, as it increases the monopoly power of each firm. Intuitively, the variance of e_{ijt}, which is measured by μ_2, represents the degree of SUPD for generics. In the data, the price of generics consistently decreases over time even when the number of generic entrants becomes fixed (Ching[15]). This suggests that the degree of SUPD decreases over time. To capture this, I model μ_2 as a function of time since the first generic entry (t_e),

$$\mu_2(t_e) = \bar{\mu}_2 exp(-\iota t_e), \tag{11}$$

where $\bar{\mu}_2$ is a constant. In this parameterization, I allow the possibility that μ_2 may decrease over time.[14] This could happen, for example, if pharmacists, who initially have heterogeneous prior belief about individual generic qualities, learn that they are actually very similar over time.

This feature has significantly improved the flexibility of the supply side model in generating the pricing patterns that are observed in the data. 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 computer. Moreover, the focus of this paper 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 the simpler approach to generate the decline of generic prices over time.

[13] Note that $E[A_g|I(t)]$ is also an unobserved product characteristic but it enters the model in a structural way.

[14] This approach is similar to Ackerberg and Rysman[2] Note also that Elrod and Keane[22] called terms like e_{ijt} "unique" factors and terms like A_g the loadings on a "common factor", and showed how the relative importance of each other could be identified from switching patterns in individual level panel data.

3.3 Supply

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 generic firm to enter the market when its application is approved. Certainly, firm's behavior may violate these assumptions. However, such violations are fairly rare (see Scott Morton[47], Scott Morton[46]), 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 that 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 which 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 $S_t = \{E[A_g|I(t)], \sigma_{A_g}(t), n_{gt}, n_{pt}, \xi_t\}$, where $\xi_t = (\xi_{bt}, \xi_{gt})$, as the set of state variables that are relevant to the decisions of firms. Let $P_e(k; n_{pt-1}, t)$ be the probability that k potential generic entrants are allowed to enter the market in period t, conditional on

n_{pt-1}.[15] Let p_{bt} be the brand-name price, $\tilde{p}_{gt} = (p_{1t}, \cdots, p_{n_g t})$ be a vector of generic prices, n_{et} be the number of potential generic entrants that receive approval to enter in period t, and β be the discount factor. 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., $\sigma_{A_g}(T) = 0$, $E[A_g|I(T)] = A_g$).[16]

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 $t < T$ and for $j = 1, \cdots, n_{gt}$, the generic entrant's value function is:

$$\begin{aligned} V_g(S_t) &= \sup_{p_{jt} \geq 0} [\pi(S_t, p_{bt}, \tilde{p}_{g-jt}, p_{jt}) \\ &\quad + \beta \{ \sum_{k=0}^{n_{pt}} P_e(k; n_{pt}, t+1) E[V_g(S_{t+1}) | S_t, q_{gt}(p_{bt}, \tilde{p}_{g-jt}, p_{jt}), n_{et+1} = k] \}], \\ V_g(S_T) &= \sup_{p_{jT} \geq 0} [\pi(S_T, p_{bT}, \tilde{p}_{g-jT}, p_{jT})]. \end{aligned} \tag{12}$$

It should be noted that each generic firm j 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 ($\sigma_{A_g}(t+1)$) through the total demand for generics (q_{gt}).

Let $\tilde{p}^*_{gt}(p_{bt}) = (p^*_{1t}(p_{bt}), \cdots, p^*_{n_g t}(p_{bt}))$ be the vector of optimal prices for generic entrants conditional on p_{bt}. Since all generic entrants are identical with respect to $(E[A_{gt}|I(t)], \sigma_{A_g}(t), \xi_{gt})$, I will only consider equilibria which are symmetric across generics, that is, $p^*_{jt}(p_{bt}) = p^*_{kt}(p_{bt}), \forall j, k = 1, \cdots, n_{gt}$.

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

[15] 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 bias problem in this model.

[16] 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 solution, 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.

generic firm's except that the $\tilde{p}_{gt}$ is replaced with $\tilde{p}^*_{gt}(p_{bt})$.

$$\begin{aligned} V_b(S_t) &= \sup_{p_{bt}\geq 0}[\pi(S_t, p_{bt}, \tilde{p}^*_{gt}(p_{bt})) \\ &\quad +\beta\{\sum_{k=0}^{n_{pt}} P_e(k; n_{pt}, t+1)E[V_b(S_{t+1})|S_t, q_{gt}(p_{bt}, \tilde{p}^*_{gt}(p_{bt})), n_{et+1}=k]\}], \\ V_b(S_T) &= \sup_{p_{bT}\geq 0}[\pi(S_T, p_{bT}, \tilde{p}^*_{gt}(p_{bT}))]. \end{aligned} \tag{13}$$

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

The expectations in (12) and (13) 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 ξ_{t+1}). The number of entrants, the number of potential generic entrants, and the perception variance evolve stochastically in a Markovian manner. I have the law of motion $n_{gt+1} = n_{gt} + n_{et+1}$ for the number of generic entrants, $n_{pt+1} = n_{pt} - n_{et+1}$ for the number of potential generic entrants, and $\sigma^2_{A_g}(t+1) = \frac{1}{\frac{1}{\sigma^2_{A_g}(t)} + \frac{\kappa q_{gt}}{\sigma^2_\delta}}$ for the perception variance (Equation (8)). Recall that the expected mean level of the generic attribute evolves stochastically according to Equation (5):

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

This equation gives the distribution of the expected mean generic attribute, conditioning on the true mean attribute, A_g. Denoting 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,

$$\begin{aligned} &E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1}=k; A_g] = \\ &\quad \int\{\int V_g(S_{t+1}|S_t, q_{gt}, A_g) d\phi(E[A_g|I(t+1)]|I(t), A_g)\} df_\xi(\xi_{t+1}), \end{aligned} \tag{14}$$

where f_ξ is the distribution for ξ.

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

$$E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1}=k] = \int E[V_g(S_{t+1})|S_t, q_{gt}, n_{et+1}=k; A_g] df^a_t(A_g). \tag{15}$$

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 (14) and

(15). 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 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, 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).[17] After paying this sunk entry cost, a generic firm obtains a lottery which 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 which pay the sunk entry cost in the initial period, then the value of being a potential generic entrant is:

$$V_{pe}(\tilde{S}_0, n_{p0} = m) = \beta\{\sum_{k=0}^{m} P_e^*(k, m, t = 1) E[V_g(S_1)|S_0, q_{g0} = 0, n_{e1} = k]\}, \tag{16}$$

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 the equilibrium number of generic firms that decide to enter in the initial period (n^*_{p0}) is:

$$n^*_{p0}(\tilde{S}_0) = \begin{cases} 0 \text{ if } V_{pe}(\tilde{S}_0, n^*_{p0} = 1) \leq c_e, \text{ else} \\ \min\{m \in \Im_+ : c_e \leq V_{pe}(\tilde{S}_0, n^*_{p0} = m), V_{pe}(\tilde{S}_0, n^*_{p0} = m + 1) < c_e\}. \end{cases} \tag{17}$$

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.

[17] 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.

One way to solve this type of dynamic multi-agent model is to discretize the state variables (e.g., Benkard[6]). To illustrate the parameterization of a stochastic discrete version of this model, suppose that I discretize $E[A_g|I(t)]$ and $\sigma^2_{A_g}(t)$ into n_a and n_σ points, respectively.

$$E[A_g|I(t)] = \{A_1, A_2, \cdots, A_{n_a}\}, \tag{18}$$

$$\sigma^2_{A_g}(t) = \{\sigma_1, \sigma_2, \cdots, \sigma_{n_\sigma}\}, \tag{19}$$

where

$$A_1 < A_2 < \cdots < A_{n_a}, \tag{20}$$

$$0 = \sigma_1 < \sigma_2 < \cdots < \sigma_{n_\sigma}. \tag{21}$$

Recall that $\sigma^2_{A_g}(t)$ evolves according to Equation (8). This equation describes a continuous process. For the purpose of the discrete version of the model, I need to transform it into a stochastic discrete process, which I denote by $\tilde{\sigma}^2_A(t)$.[18] 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 (8). Now I compare $\sigma^2_{A_g}(t+1)$ to the set of discretized values $\{\sigma_1, \sigma_2, \cdots, \sigma_{n_\sigma}\}$ and find the closest two points to $\sigma^2_{A_g}(t+1)$. Let σ^2_d and σ^2_u be the two closest discretized points such that $\sigma^2_d \leq \sigma^2_{A_g}(t+1) \leq \sigma^2_u$. 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:

$$\tilde{\sigma}^2_{A_g}(t+1) = \begin{cases} \sigma^2_u & \text{with prob } \frac{\sigma^2_{A_g}(t+1)-\sigma^2_d}{\sigma^2_u-\sigma^2_d}, \\ \sigma^2_d & \text{with prob } 1-\frac{\sigma^2_{A_g}(t+1)-\sigma^2_d}{\sigma^2_u-\sigma^2_d}. \end{cases} \tag{22}$$

Now let's consider how to obtain the expected value function, $E[V_j(S_{t+1})|S_t, q_{gt}(p_{bt}, \tilde{p}^*_{gt}(p_{bt})), n_{et+1} = k; A_g], j \in \{b, g\}$ as shown in Equation (14). Conditional on $E[A_g|I(t)]$ and A_g, $E[A_g|I(t+1)]$ is normally distributed according to (5). Its mean and variance are given by:

$$E\{E[A_g|I(t+1)]|A_g\} = (1-\beta_g(t))E[A_g|I(t)] + \beta_g(t)A_g, \tag{23}$$

$$Var\{E[A_g|I(t+1)]|A_g\} = \beta_g(t)^2 \frac{\sigma^2_\delta}{\kappa q_{gt}}. \tag{24}$$

Next, I need to transform the normally distributed $E[A_g|I(t+1)]$ into a discrete random variable, $\tilde{E}[A_g|I(t+1)]$, with support $\{A_1, A_2, \cdots, A_{n_a}\}$. I first define a set of points $\{A_{1,2}, A_{2,3}, \cdots, A_{n_a-1,n_a}\}$

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

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

$$Prob(A_i) = \Phi(A_{i,i+1}) - \Phi(A_{i-1,i}), \text{for } i \neq 1 \text{ or } n_a, \tag{25}$$

$$Prob(A_1) = \Phi(A_{1,2}), \tag{26}$$

$$Prob(A_{n_a}) = 1 - \Phi(A_{n_a-1,n_a}), \tag{27}$$

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 (ξ_j) for the moment. Then, given the discrete distribution of $\tilde{E}[A_g|I(t+1)]$, the expected value function is simply,

$$E[V_j(S_{t+1})|S_t, q_{gt}, n_{et+1}; A_g] = \sum_{l=1}^{n_a} Prob(E[A_g|I(t+1)] = A_l)\bar{V}_j(E[A_g|I(t+1)]|S_t, q_{gt}, n_{et+1}; A_g), \tag{28}$$

where

$$\bar{V}_j(E[A_g|I(t+1)]|S_t, q_{gt}, n_{et+1}; A_g] = \sum_{l \in \{u,d\}} Prob(\tilde{\sigma}_{A_g}(t+1) = \sigma_l)V_j(S_{t+1}|S_t, q_{gt}, n_{et+1}; A_g), \tag{29}$$

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

The numerical integration method described in (25) - (27) 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 given by this method will deteriorate. But as long as I locate the true A_g far from the end points,[19] the probability that the model will reach the end points will be small. Hence, I do not expect this will significantly affect the results. Similarly, I integrate the demand shocks by transforming them into discrete random variables.

Finally, 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 (15)).

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

4 Data, Estimation and Calibration

4.1 Data

The data for this study include: quarterly observations on revenue and quantity sold from Intercontinental Marketing Services (IMS),[20] patent expiration dates from the pharmaceutical Manufacturers Association (PMA), ANDA approval dates from the Food and Drug Administration (FDA), daily defined doses from Medi-Span, and the number of potential patients from the National Ambulatory Medical Care Survey and the National Hospital Discharge Survey. The units for quantity are transformed into number of patient days using daily defined dose. I divide revenue by quantity sold to obtain price.

To estimate the entry probabilities for generics, I use entry data on 25 drugs.[21] The sample selection criterion are explained in Ching[16]. This sample covers five therapeutic classes: heart disease drug, depressant, anti-depressant, anti-psychotic drug, and antibiotic.

In Ching[16], I estimate the demand model by therapeutic class. Clonidine belongs to the class of heart disease drugs, which consists of seven drugs in the sample. Treating product/quarter as one observation, the number of observations are 300 for this class.

4.2 Estimation and Calibration

4.2.1 Demand Parameters

There is an endogeneity problem that arises when estimating the demand model: $E[A_g|I(t)]$ and ξ_t are unobserved to the econometrician but potentially observed to the consumers and firms. These unobserved characteristics will in general be correlated with price, making price endogenous. To handle this problem, I have developed an estimation technique that involves approximating the pricing policy function. Ching[16] explains the method and applies it to estimate the demand model. The estimated demand parameters for clonidine (or more generally for heart disease drugs) from Ching[16] are reproduced in the first two columns of Table 1. It is found that patients are

[20] IMS is a company that specializes in collecting sales data for the pharmaceutical industry. IMS data represent combined sales from drugstores and hospitals.

[21] Since most generic firms enter the market immediately after they receive approval from the FDA, I use ANDA approval date as a proxy for generic entry date.

heterogeneous in terms of price-sensitivity. They are also risk-averse, uncertain about the generic quality and have pessimistic initial priors (i.e., the initial prior mean attribute (A) is lower than the true mean attribute (A_g)).

It should be noted that the parameters that determine the variance of the extreme value error terms (i.e., $\mu_1, \bar{\mu}_2, \iota$) are calibrated. I have tried to estimate them along with other demand parameters but find that they are not well-identified. I first normalize $\mu_1 = 1.0$. Then I calibrate the initial guess of all the demand parameters by informally matching predicted equilibrium market shares and pricing patterns with the observed ones. In particular, $\bar{\mu}_2$ is chosen such that the equilibrium predicted initial generic price matches with the actual initial generic price. ι is chosen such that the equilibrium generic price declines at the same rate as I observe in the data. Then I fix $\mu_1, \bar{\mu}_2$ and ι at the calibrated values when estimating other parameters.

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. Let $\lambda(t)$ be the probability that a potential generic entrant receives an approval from the FDA in period t. Then the probability that there are k potential generic entrants which are allowed to enter the market in period t, conditional on n_{pt-1}, is:

$$P_e(k, n_{pt-1} = m, t) = \left(\begin{array}{c} m \\ k \end{array} \right) \lambda(t)^k (1 - \lambda(t))^{m-k}. \quad (30)$$

I use equation (30) as the likelihood function for estimation. $\lambda(t)$ is determined by a logit model with an intercept, therapeutic class dummies, time since the patent expired and its square, as regressors. The results are reported in Table 2. I also use this equation to set up the value function for the generic entrants and the brand-name firm (see Equation (12) and (13)).

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

$$P_e^*(k, n_{pt-1} = m, t) = \lambda(t) \left(\begin{array}{c} m-1 \\ k-1 \end{array} \right) \lambda(t)^{k-1} (1 - \lambda(t))^{(m-1)-(k-1)}$$

$$= \begin{pmatrix} m-1 \\ k-1 \end{pmatrix} \lambda(t)^k (1-\lambda(t))^{m-k}. \quad (31)$$

I use this equation to calculate a generic firm's expected return from submitting an application to the FDA (see Equation (16)).

4.2.3 Sunk Cost of Entry, Marginal Cost of Production and Discount Factor

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 equal to 12, which is the observed number in the data. The calibrated value is 1.2 million (1990) dollars for clonidine. From my informal conversations with people in the industry, this number is quite reasonable.

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 the marginal cost (mc) to be zero. In section 5.4, I study the robustness of the results by examining two alternatives: mc = 4 and 8 cents.

It is well-known that the discount factor, β, is difficult to estimate in applied dynamic programming research. I therefore set $\beta = 0.9$, which is in line with most of the existing applied works. Again, I will study the robustness of the results by resolving the model with $\beta = 0$ in section 5.4.

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, T, to be 30 when solving the model. The length of a period is a quarter. When computing the solution of the model, $E[A_g|I(t)]$, $\sigma_{A_g}(t)$ and ξ_{jt} are all discretized into three values. $E[A_g|I(t)]$ takes the values {-18, -12, -6}, $\sigma_{A_g}(t)$ takes {0, 16, 33}, and ξ_{jt} takes {-1, 0, 1}.

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.[22] For each sequence, I simulate 100 sequences of price and quantity pairs for both the brand-name drug and the generic drugs, using the dynamic oligopoly model based on the estimated and calibrated parameter values. Using these 100X100=10,000 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, which is the period covered by the data. The average predicted prices and quantities demanded match reasonably well with the data. In particular, the model is able to accurately fit the pricing and demand pattern for the brand-name drug. However, it slightly overpredicts the generic prices (by less than 10 cents) for the first few quarters, and it underpredicts the demand for generics by about 20-30%. It should be emphasized that the estimation procedure for the demand parameters (detailed in Ching[16]) does not make use of the dynamic oligopolistic supply side. Hence, these parameters were not chosen to fit the firm's price and quantity decisions. Also, when calibrating the supply side model, I do not require the model to match the observed prices and quantities. Hence, I find that the overall goodness-of-fit results are reasonably satisfactory.

One important feature of the model is that there is consumer heterogeneity in price sensitivity. Interestingly, the equilibrium model is able to predict how demand patterns vary across consumer type, though I only observe aggregate demand behavior. Figures 3 and 4 show the predicted quantity demanded by consumer type. Since α^0 is much larger than α^1 (see Table 1), I refer to type 0 consumers as price-sensitive consumers, and type 1 consumers as price-insensitive consumers. The model predicts that both the price-sensitive consumer demand and the price-insensitive consumer demand for generics increase over time initially. 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.

Note that the estimates of the demand model imply that price-sensitive consumer demand for generics decreases after it reaches a peak in the 10th quarter. The reason for this is twofold: first, the price-sensitive consumers' valuation of the outside good increases over time, as captured by the

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

positive sign of the time coefficient associated with it (see ϕ_t^0 in Table 1); second, the variance of the idiosyncratic taste associated with the generic nest (i.e., $\mu_2(t_e)$) is decreasing over time (see Equation (11) and Table 1), which tends to drive down the utility of choosing the generic nest. The decline in price-sensitive consumer demand for generics has lead to the aggregate generic demand to drop after the 11th quarter, as shown in Figure 2. Notice that I calibrate the parameters for $\mu_2(t_e)$ to only match the decline in generic prices. Conceivably, one can calibrate or estimate $\bar{\mu}_2$ and ι to match both the demand and pricing patterns, using maximum likelihood or GMM. Unfortunately, due to the complexity of the dynamic oligopoly model, these estimation procedures, which involve using the supply side explicitly, are computationally too burdensome to implement at this point.

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 fairly stable over time – overall it declines by only about 20% throughout the period. When the patent has just expired, about 50% of the brand-name drugs consumers are the price-insensitive type. In the 18th quarter, about 94% 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[31], Frank and Salkever[27] and Ching[16], this may be the main explanation for why the brand-name firm raises its prices over time after patent expiration.

I should note that the price-insensitive consumer demand for generic drugs keeps increasing over time (see Figure 4). Since the price-insensitive consumer demand for the brand-name drug remains fairly 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[16], 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 3 shows the summary statistics for the three models, which are based on the simulation results for the first 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 smaller 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 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 similar surplus when there are only price-insensitive patients, but slightly higher surplus when there are only price-sensitive patients.

In terms of consumer surplus, patients are better off if they are all price-insensitive, and worse off if they are all price-sensitive. Even though both brand-name prices and generic prices are higher when all patients are price-insensitive, the impact of prices on the utility of choosing either the brand-name drug or generic drugs is very insignificant. Consequently, the consumer welfare is improved if all patients are price-insensitive (or they have more generous insurance coverage for prescription drugs) holding everything else the same. However, it should be noted that the model has not specified how a more generous insurance plan would be financed. In general, patients will need to pay higher insurance premiums or higher tax rates. Hence it is not clear if patients would necessarily be better off if a more generous universal insurance coverage were implemented.

Now I turn to discuss how the brand-name pricing pattern varies across models with only one type of consumers. When there are only price-sensitive patients, 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, the brand-name firm keeps its prices high and stable over time. Note that the increase in generic sales does not reduce the brand-name sales in the model with only price-insensitive patients. Generic firms gain the market share mainly at the expense of the outside good. Even though the generic price drops over time, patients are 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 unchanged. It should be emphasized that neither of these two extreme cases can generate increasing brand-name prices over time. 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. Figure 5 and 6 illustrate this relationship by plotting the brand-name prices of these three models and the composition of the consumer types, respectively. 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 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 accomplish this goal. In order to investigate the effect of this policy, I increase the intercept term (γ_0) in the logit model from -2.63 to -1.0. This increases the probability of entry for each generic at all periods after patent expiration. In particular, it raises 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 vs. 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 30% 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 lower compared with the original model.

The predicted generic demand pattern seems puzzling. The initial 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 demand in this experiment becomes lower in the later periods? Notice that the entry decision of generic firms is endogeneous, 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 as every applicant have better chances to enter early now. In other words, although generic firms on average start earning profits sooner, the profits that they receive in the early periods are likely to be significantly lower compared with the original model. The overall effect on the expected return of submitting an application, conditioning on the number of applicants, is therefore ambiguous. Consequently, the implication on the number of generic firms decided to submit an application is also ambiguous if the FDA shortens the expected approval time.

Nevertheless, one would expect 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. In Ching and Tan[17], we study the theoretical implications of this random entry feature in detail.

Assuming the sunk cost of entry remains at 1.2 million dollars, which is the calibrated value, the equilibrium number of generic firms that decide to enter declines from 12 to 6 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 six quarters, as shown in Figure 9. This explains why in the early periods, the predicted generic demands from the experiment are higher than those from the original model, and the predicted generic prices are lower, as shown in 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 for generics

is reduced by nearly 10% throughout the 18 quarters after patent expiration. Consequently, even though the average number of generic entrants in the original model is higher after the 7th quarter, its predicted generic demand does not surpass those predicted by the experiment immediately.

It is worth pointing out that the generic prices in the original model remain higher than those in the experiment throughout the period (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 8th quarter on. The 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 the first generic entry (t_e) is on average shorter for the original model. Since the unobserved product differentiation among generics decreases as t_e increases (Equation (11)), this leads to higher average generic prices for the original model in the long run as well.

Another interesting result is that generic prices for the experiment and the original calibrated model become very close after the 10th quarter. It appears that 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 μ_2, declines over time. When the number of generic firms is large, the equilibrium generic price becomes mainly determined by μ_2 (Anderson et al.[5]). It turns out that given the parameter values, six generic entrants is already large enough for μ_2 to dictate the equilibrium generic prices.

As shown in Table 4, the overall welfare implications from the experiment (the second column) are very similar to those from the original model (the first column). In particular, the consumer welfare has only improved by about 0.7% in the experiment, which seems to be much smaller than what the supporters of this policy expects. It appears that a narrower choice of generic products has counteracted most of the benefits of having generics available sooner.

5.4 Robustness

In this subsection, I check the robustness of the results. Forward-looking behavior clearly plays an important role in generic firm's entry decisions as demonstrated in the policy experiment. 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 decided to apply for ANDA unchanged (i.e., remains at 12). The results are summarized in the last column of Table 4.

Compared with the original model, the model with myopic firms predicts that the average generic price is about 17 percent higher in the first quarter, and that the average generic sales are about 10 percent lower. The generic price gap and sales gap between these two models diminish over time and they converge to almost the same values from the 10th quarter on. 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 particularly strong at the beginning as the public has a very 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 declines. 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.

As discussed before, the predicted generic demand does not fit the actual demand well because the price-sensitive patients' utility of choosing the outside option increases over time, and the variance of the idiosyncratic taste associated with the generic nest decreases over time. Recall that these parameters are fixed at the initial calibrated values during the estimation. If these parameters are allowed to change during the estimation, the goodness-of-fit of the model could potentially be improved. Based on the discrepancies between the simulated data and the actual data, I slightly modify the parameter of the outside good time trend associated with the price-sensitive patients, and the parameters that determine the variance of the idiosyncratic taste for generics in order to see if that improves the goodness-of-fit. The modified parameters are shown in the third column of Table 1. Essentially, I lower the values of the time trend for the outside good and that for the variance of the logit errors. I also lower the value of $\bar{\mu}_2$. The goodness-of-fit results from the modified parameters are shown in Figure 11 and the second column of Table 5. Overall, the model with modified parameters performs better than the original model in fitting the generic

price and the generic demand. The overprediction of generic price disappears. In addition, it only underpredicts the demand for generics by about 10-20% (instead of 20-30% in the original model). In terms of other dimensions, the predictions from the model with modified parameters performs very similar to the original model. The message from this exercise is that the model is able to explain the data quite well. Moreover, the welfare implications from the original model is robust with respect to the minor modifications of these three parameters.

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 third and the fourth column in Table 5. 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 also 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 shown that brand-name price is essentially a function of the proportion of brand-name sales accounted for by price-insensitive patients.

In this paper 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, which reduces the expected approval time for generic drugs. The interest groups who propose this policy expects that the policy could significantly improve the 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 the policy. Given the change in magnitude of the policy parameter in this paper, I find that the number of generic firms decided to enter reduces by a half, though on average generic drugs become available sooner. The early entry of generics has lead 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. It turns out that this policy experiment hardly improves the consumer welfare.

The key message of this policy experiment is that even if the government spend 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, which would help the government to direct its resources more efficiently.

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.

Table 1: Estimated Preference parameters for clonidine

	Estimate	Standard Error	Modified value
ESTIMATED PARAMETERS			
Learning parameters:			
risk coefficient (r)	0.731*	0.036	
utility weight for attribute (ω)	0.014*	0.001	
experience variability (σ_δ^2)	0.18*	0.02	
initial prior variance ($\sigma_{A_g}^2(0)$)	33.31*	0.88	
initial prior mean (A)	-17.77*	0.05	
True mean attributes (A_g)	-5.77*	0.10	
Fraction of experience signals revealed (κ)	7.1e-11*	7.7e-13	
Consumer heterogeneity parameters:			
type 0 price coefficient (α^0)	0.029*	3.0e-4	
type 1 price coefficient (α^1)	0.010*	1.0e-4	
proportion of type 0 (π_0)	0.367*	0.005	
standard deviation of unobserved product characteristic (σ_ξ)	0.237*	0.008	
Time trend for the outside good:			
type 0 (ϕ_t^0)	0.146*	0.001	0.12
type 1 (ϕ_t^1)	-0.008	0.016	
CALIBRATED PARAMETERS**			
Parameters for the variance of logit errors:			
first stage:(μ_1)	1.0		
second stage:			
constant term ($\bar{\mu}_2$)	0.7		0.5
coefficient for time trend (ι)	0.1		0.07
Other supply side parameters:			
Sunk cost of entry (million, 1990 dollar)	1.2		
Marginal cost of production (mc)	0.0		
Discount factor (β)	0.9		

Standard errors are reported in parenthesis
Notes:
* t-statistic > 1.96
** Standard errors for calibrated parameters are not reported.

Table 2: Estimated parameters for Entry Probability

	estimate	standard error
intercept (γ_0)	-2.636*	0.201
time since patent expired (γ_1)	0.051	0.049
time since patent expired^2 (γ_2)	0.006*	0.003

Probability that a potential generic entrant receives approval, $\lambda = \frac{exp(X\gamma)}{1+exp(X\gamma)}$.
Notes:
* significant at 5% level
** significant at 10% level

Table 3: 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 (M**$):*				
Brand-name	n.a.	13.9	12.7	17.4
Generic	n.a.	0.46	0.52	0.46
Combined	n.a.	14.36	13.22	17.86
Average quarterly consumer surplus (M$):				
Price-sensitive patient	n.a.	5.7	24.6	n.a.
Price-insensitive patient	n.a.	109.4	n.a.	160.7
Combined	n.a.	115.1	24.6	160.7
Average total quarterly surplus (M$):	n.a.	129.5	37.8	160.7
Market Characteristics:				
Average brand-name prices ($ per patient day):				
1st quarter	0.59	0.57	0.47	0.95
9th quarter	0.72	0.64	0.35	0.94
18th quarter	0.87	0.84	0.31	0.94
Average generic price ($ per patient day):				
1st quarter	0.23	0.30	0.24	0.71
9th quarter	0.12	0.15	0.10	0.28
18th quarter	0.08	0.08	0.04	0.12
Average quarterly brand-name sales (M no. of patient days):				
1st quarter	40.6	35.8	64.7	18.5
9th quarter	15.7	19.7	28.8	18.3
18th quarter	9.8	13.3	12.5	18.3
Average quarterly generic sales (M no. of patient days):				
1st quarter	7.9	2.0	4.0	0.7
9th quarter	28.8	25.7	44.0	12.0
18th quarter	35.2	23.7	21.0	22.0

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

Table 4: Welfare and Market Characteristics: Experiment with Reducing the Expected Approval Time and Myopic Firms

	Original Model ($\beta = 0.9$)	Reducing Approval Time	Myopic ($\beta = 0$)
Welfare Statistics:			
Average quarterly producer surplus (M$):*			
Brand-name	13.9	13.8	14.0
Generic	0.46	0.49	0.46
Combined	14.36	14.29	14.46
Average quarterly consumer surplus (M$):			
Price-sensitive patient	5.7	6.0	5.6
Price-insensitive patient	109.4	109.9	109.3
Combined	115.1	115.9	114.9
Average total quarterly surplus (M$):	129.5	130.2	129.3
Market Characteristics:			
Average brand-name prices ($ per patient day):			
1st quarter	0.57	0.57	0.57
9th quarter	0.64	0.65	0.65
18th quarter	0.84	0.84	0.84
Average generic price ($ per patient day):			
1st quarter	0.30	0.28	0.35
9th quarter	0.15	0.14	0.15
18th quarter	0.08	0.07	0.08
Average quarterly brand-name sales (M no. of patient days):			
1st quarter	35.8	35.6	35.8
9th quarter	19.7	19.5	19.7
18th quarter	13.3	13.4	13.3
Average quarterly generic sales (M no. of patient days):			
1st quarter	2.0	2.7	1.8
9th quarter	25.7	27.3	25.5
18th quarter	23.7	22.7	23.6

*M stands for million.

Table 5: Welfare and Market Characteristics: Sensitivity Analysis

	Original Model (mc=0)	Modified Parameters	mc=4	mc=8
Welfare Statistics:				
Average quarterly producer surplus (M$):*				
Brand-name	13.9	14.3	14.1	14.1
Generic	0.5	0.4	0.5	0.6
Combined	14.4	14.7	14.6	14.7
Average quarterly consumer surplus (M$):				
Price-sensitive patient	5.7	3.1	5.1	4.5
Price-insensitive patient	109.4	109.9	108.2	106.9
Combined	115.1	113.0	113.3	111.4
Average total quarterly surplus (M$):	129.5	127.7	127.9	126.1
Market Characteristics:				
Average brand-name prices ($ per patient day):				
1st quarter	0.57	0.57	0.60	0.63
9th quarter	0.64	0.62	0.68	0.73
18th quarter	0.84	0.79	0.88	0.92
Average generic price ($ per patient day):				
1st quarter	0.30	0.28	0.33	0.37
9th quarter	0.15	0.12	0.18	0.22
18th quarter	0.08	0.08	0.11	0.15
Average quarterly brand-name sales (M no. of patient days):				
1st quarter	35.8	35.8	34.2	32.6
9th quarter	19.7	21.2	18.8	17.9
18th quarter	13.3	14.4	12.8	12.4
Average quarterly generic sales (M no. of patient days):				
1st quarter	2.0	2.1	1.9	1.8
9th quarter	25.7	27.2	23.5	21.3
18th quarter	23.7	28.0	22.0	20.4
Sunk costs of entry (M$):	1.2	1.04	1.14	1.09

*M stands for million.

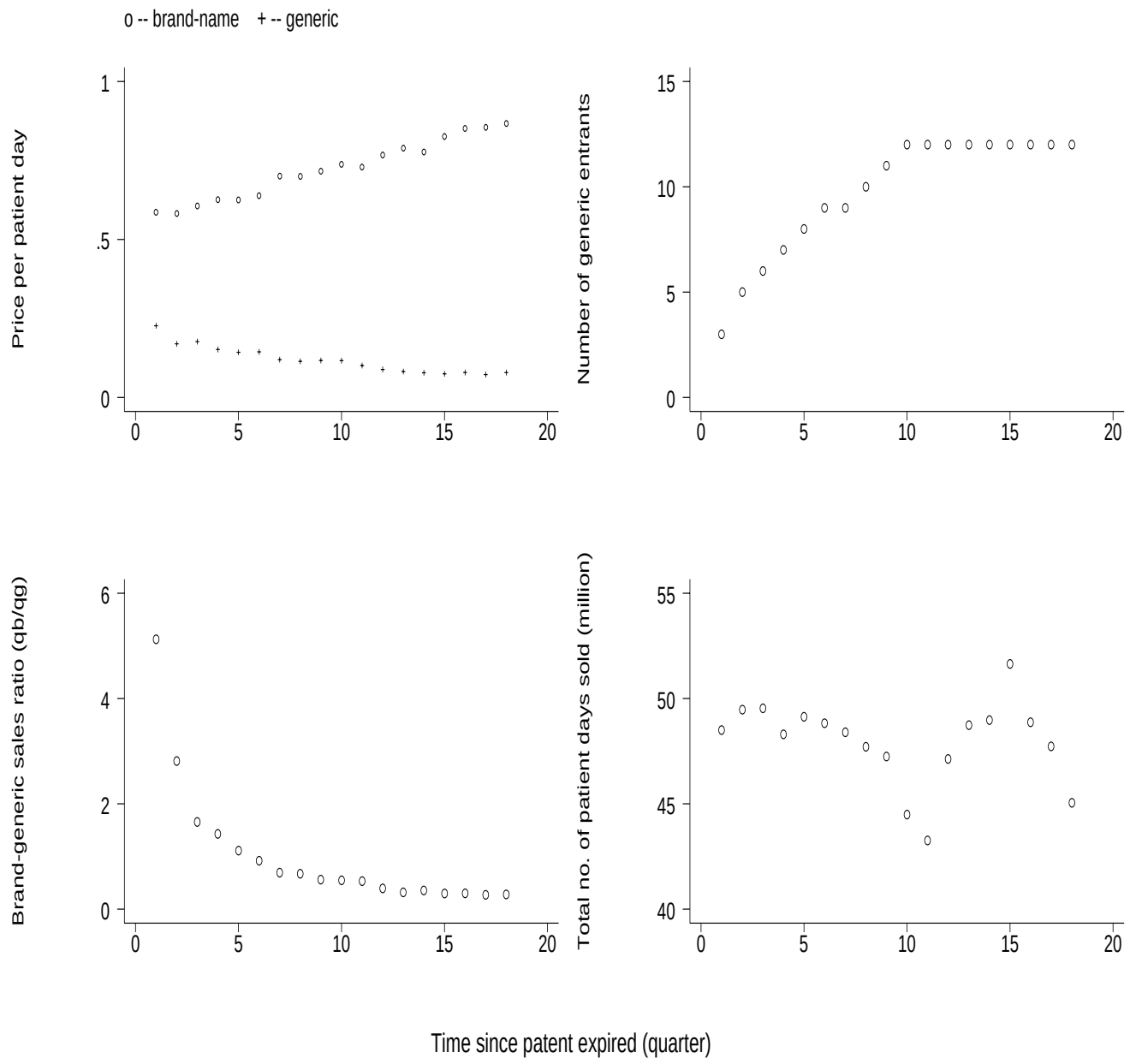

Figure 1: Market characteristics for clonidine

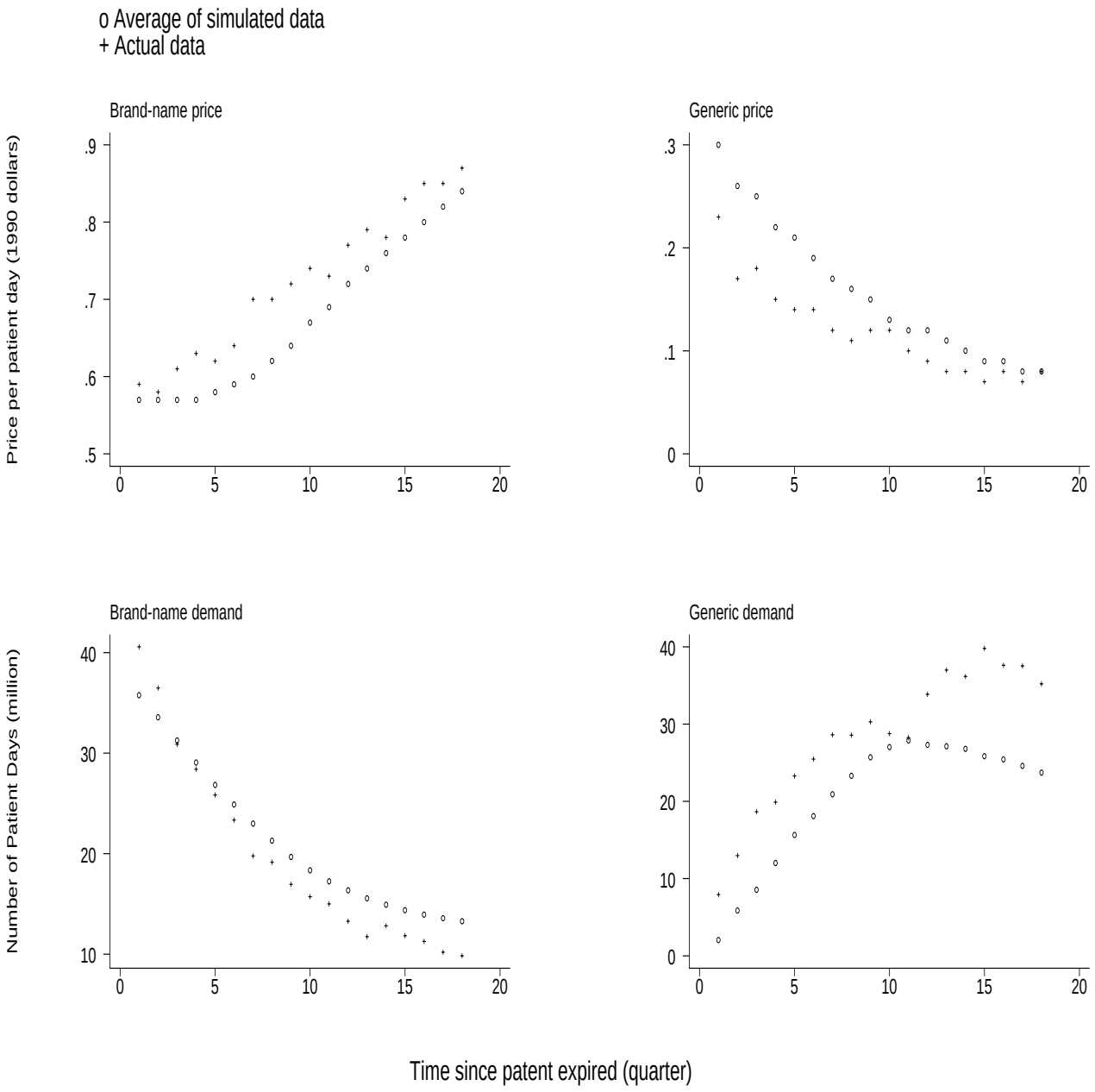

Figure 2: Original calibrated model: price and quantity demanded

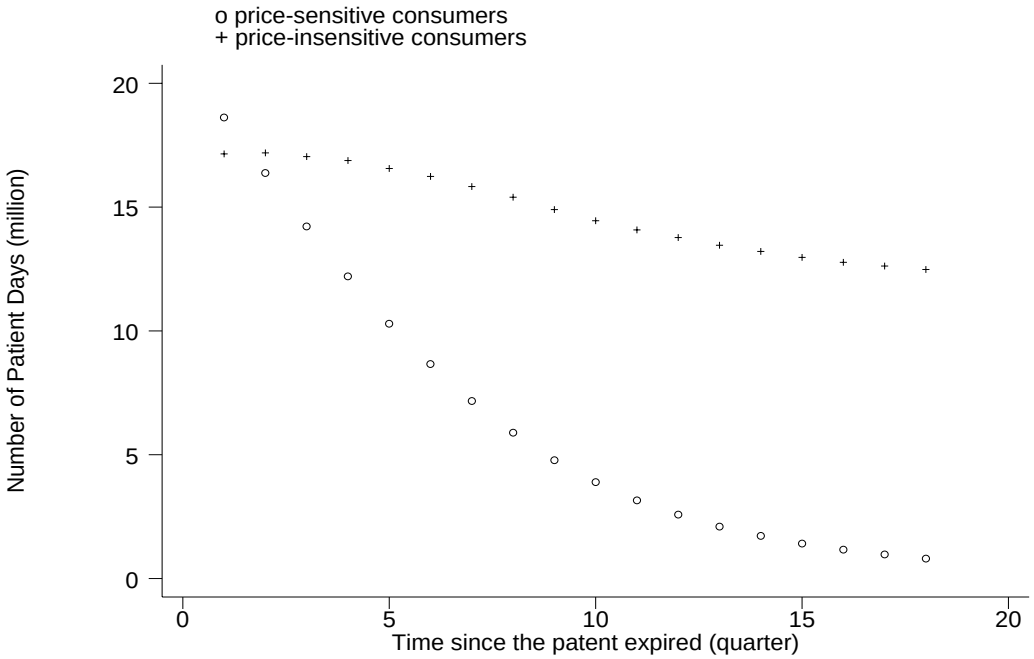

Figure 3: Brand-name demand by consumer type

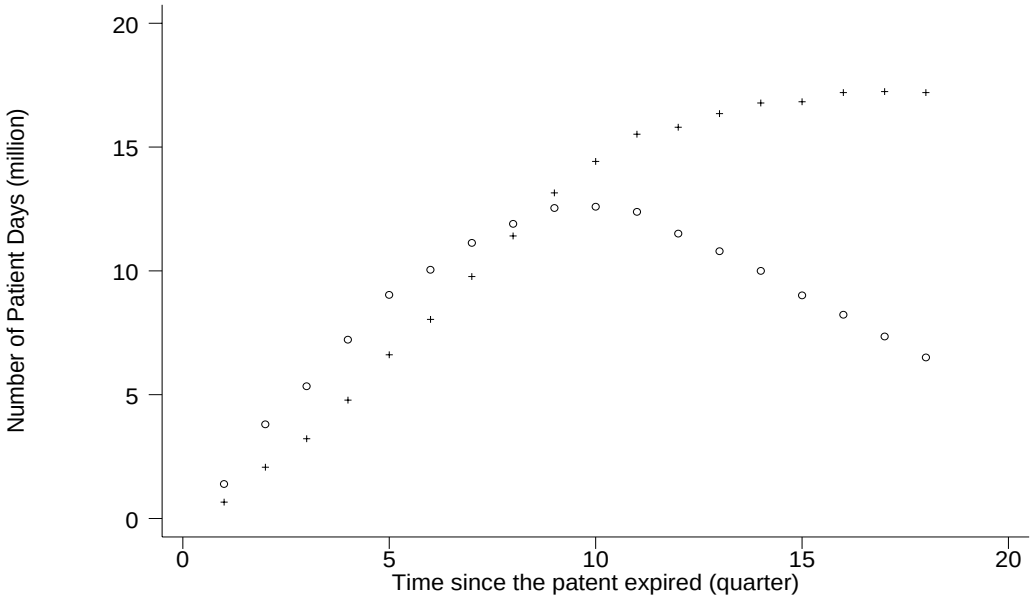

Figure 4: Generic demand by consumer type

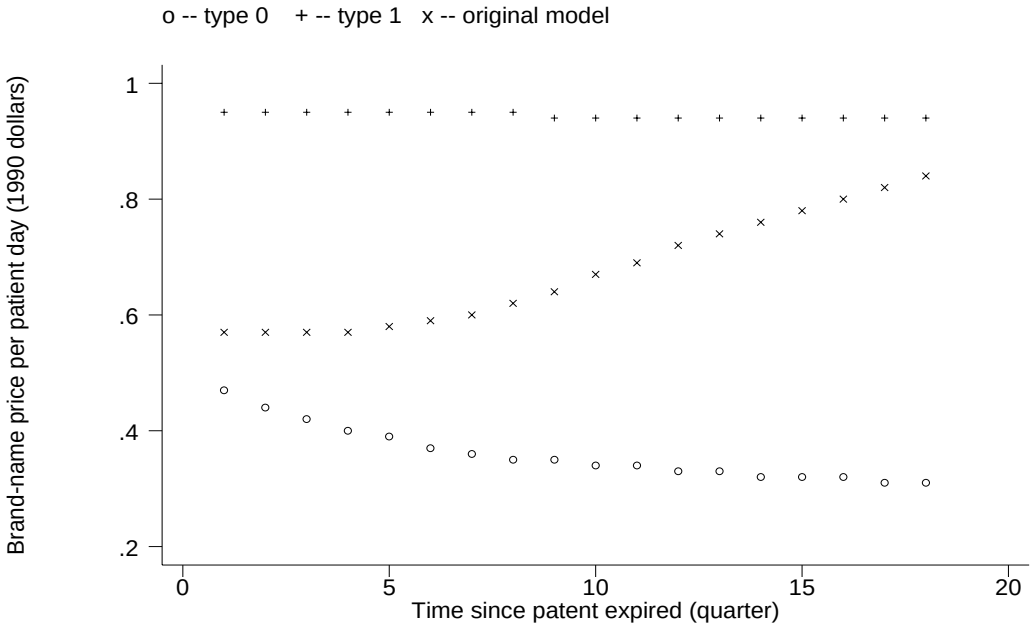

Figure 5: Brand-name prices from the original model, and models with only one patient type

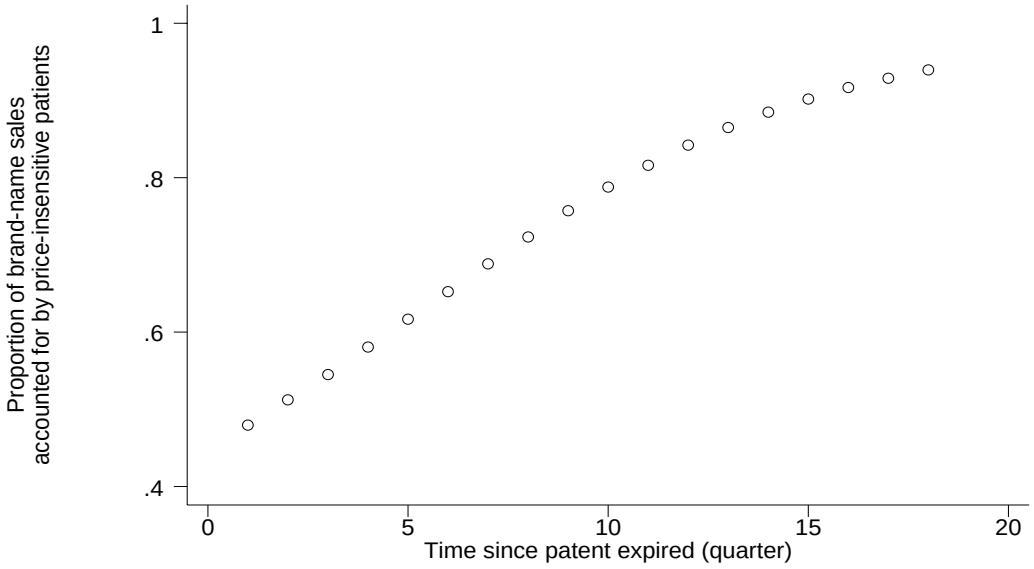

Figure 6: Proportion of brand-name sales accounted for by price-insensitive patients

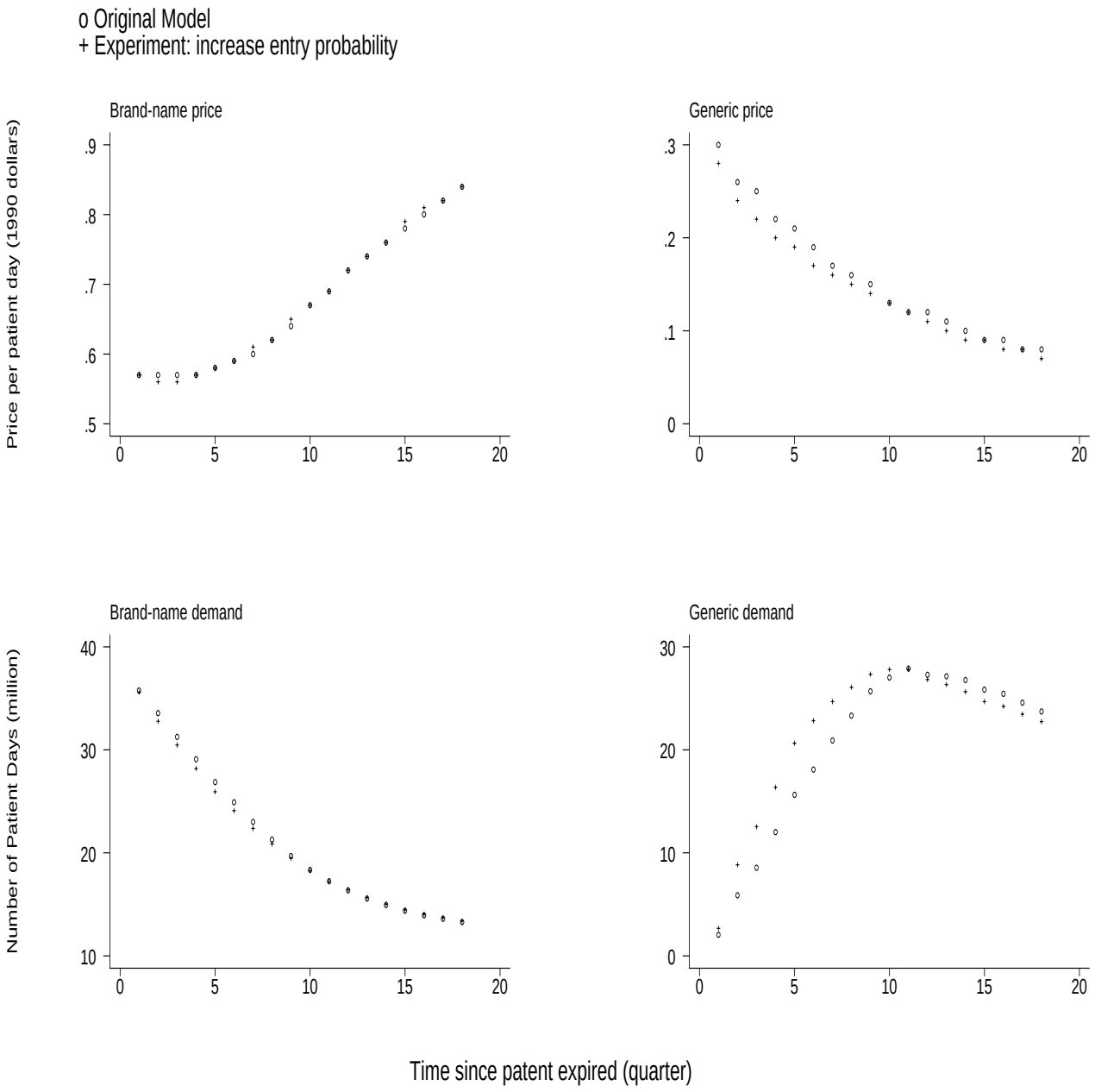

Figure 7: Increase probability of entry: price and quantity demanded

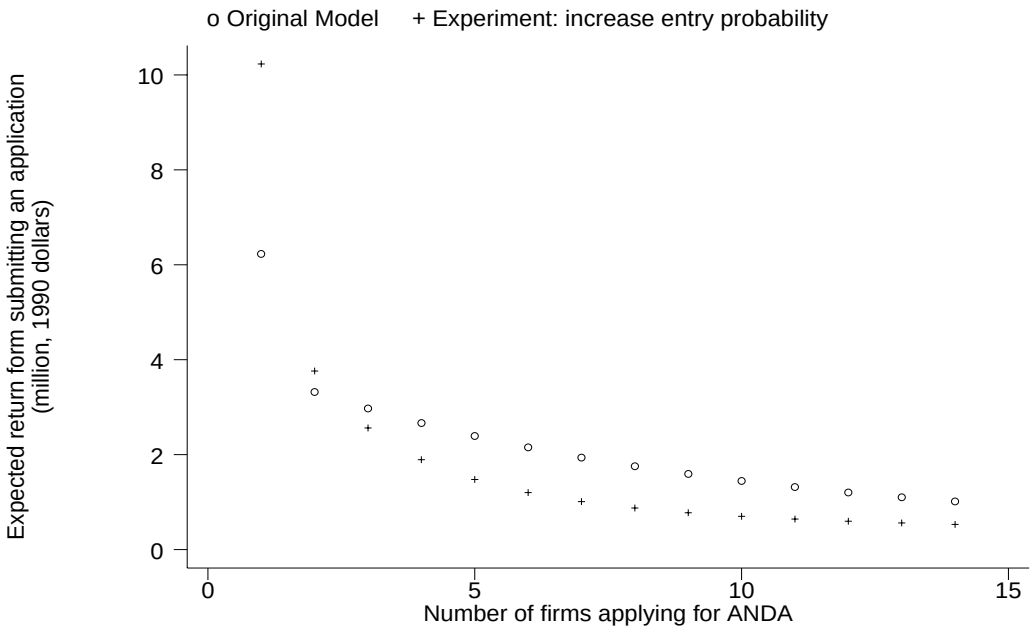

Figure 8: Expected return from submitting an ANDA application

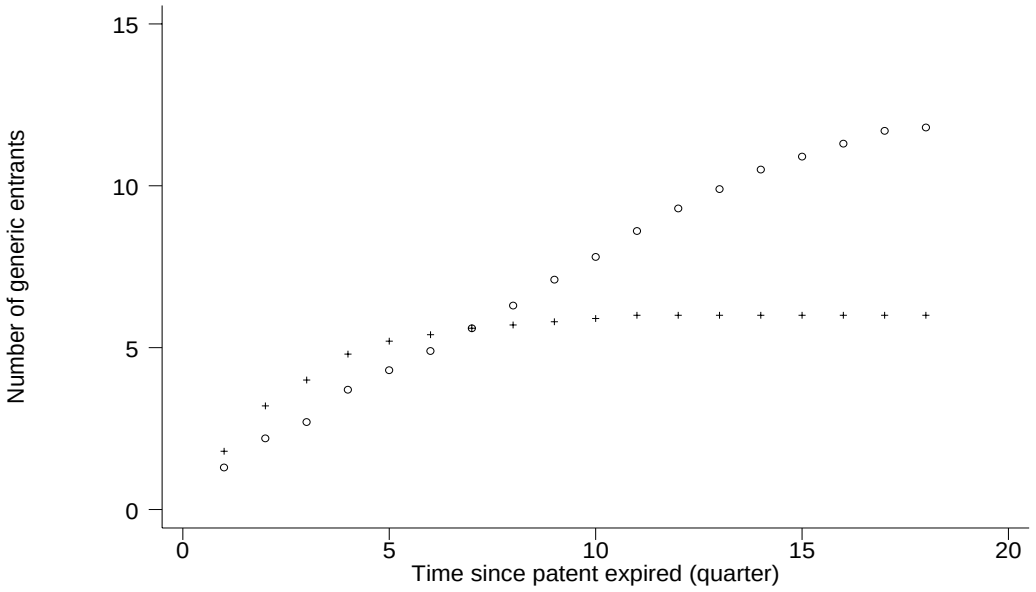

Figure 9: Average Number of generic entrants

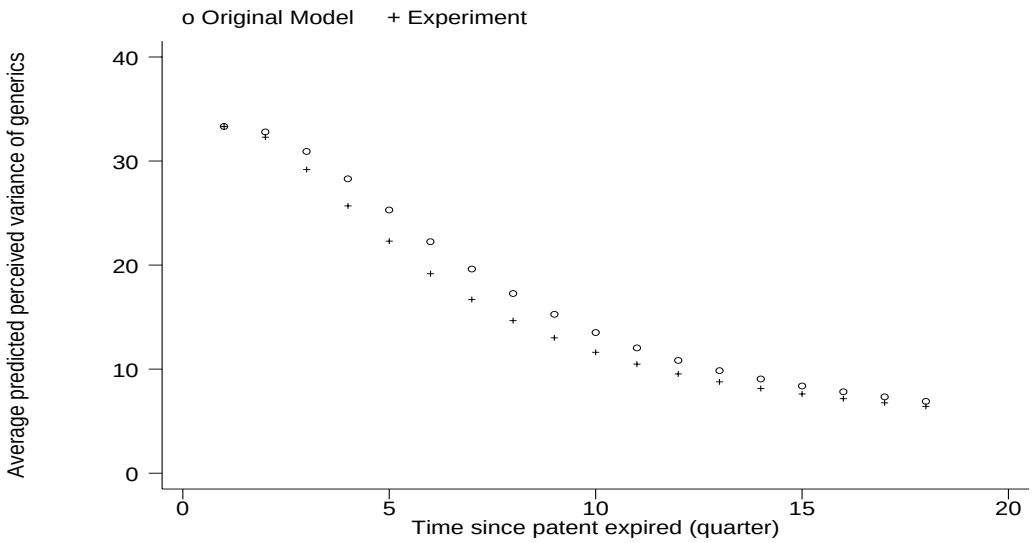

Figure 10: Average predicted perceived variance: Increase entry probability experiment

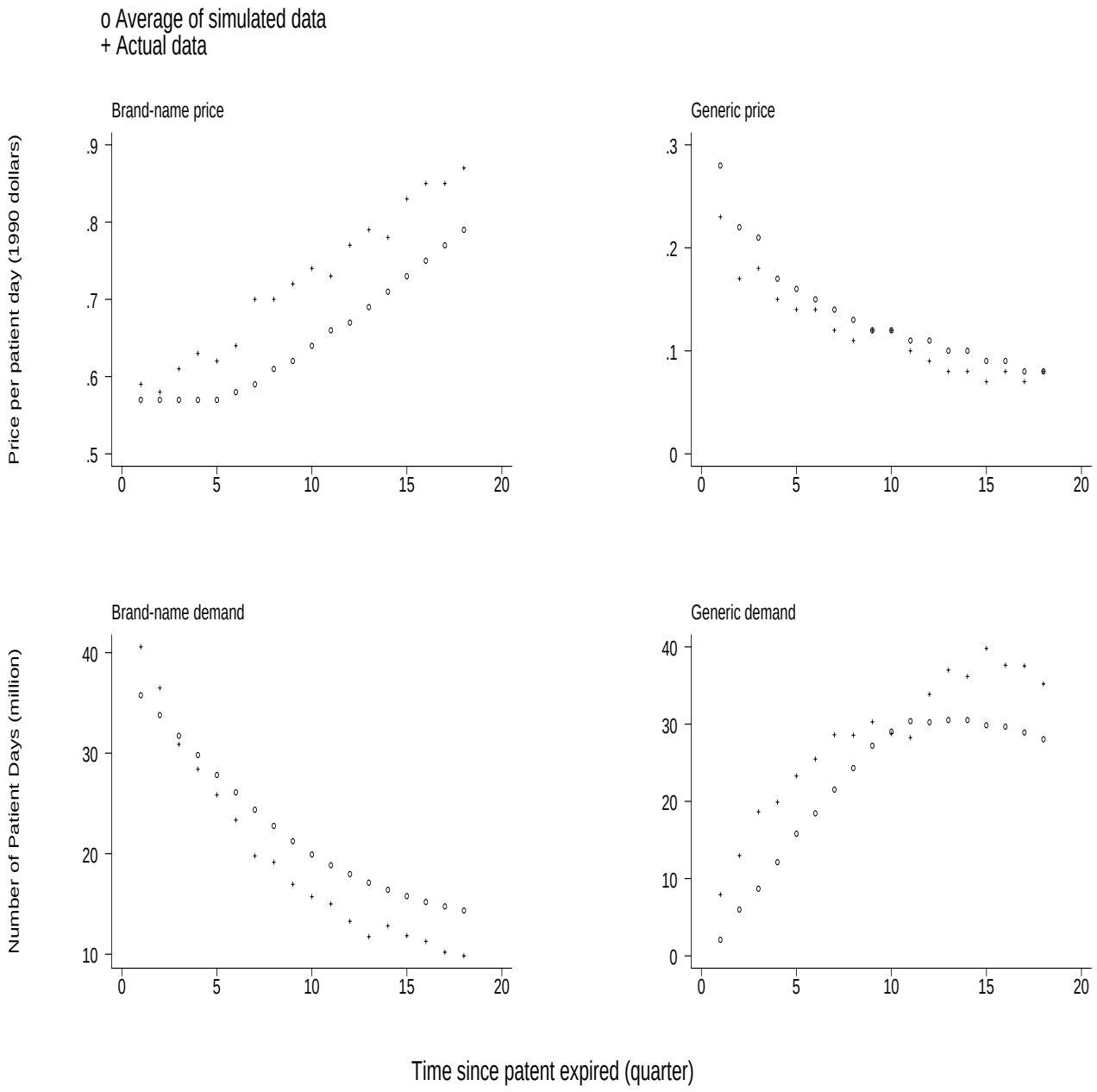

Figure 11: Original calibrated model with minor modifications: price and quantity demanded

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