GENERIC DRUG INDUSTRY DYNAMICS

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ABSTRACT

Because of its unique institutional and regulatory features, the generic drug industry provides a useful laboratory for understanding how competition evolves within a market. We exploit these features to estimate certain structural relationships in this industry, including the relationship between price and the number of competitors, and between drug characteristics and the entry process. Our methodology yields a number of findings regarding industry dynamic effects. We find that generic drug prices fall with the number of competitors, but remain above long-run marginal cost until there are 8 or more competitors. We also find that more firms enter, and enter more quickly in markets with greater expected rents. The size and time paths of generic revenues, rents and the number of firms are greatly affected by measures reflecting the expected market size. Finally, we demonstrate how these structural estimates can be used to evaluate recent policy changes toward the pharmaceutical industry.

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I. Introduction

Both the economics literature and the business press suggest that a typical pattern for a "new" industry (or what Jovanovic and MacDonald, 1994, call an *invention*) is to have an initial phase in which a small number of firms each earn significant profits, followed by a phase in which rapid entry of new firms leads to increased competition and dissipation of some of those profits. If costs are relatively stable, a "permanent" zero-profit equilibrium emerges. Alternatively, subsequent developments (e.g., innovations that increase optimal scale), may lead to a "shake out", whereby only a few large firms remain.

While this pattern seems to characterize many industries, the length of time during which early movers retain their profits, how prices adjust during the entry process, and the degree of shake out vary widely across industries (Gort and Klepper ,1982). Because the factors that influence the timing of entry and exit are idiosyncratic to each industry, empirical studies of this dynamic process tend to focus on a single industry (e.g., Gisser ,1999, Klepper and Simons, 2000), and in some sense, constitute a single data point.

The generic drug industry provides a useful laboratory for understanding how competition evolves within a market. One can conceptualize the output produced by generic manufacturers of each drug as constituting a market.[1] These markets have a number of attractive features. First and foremost, there are a large number of individual markets within the same industry, so we have multiple observations on similar dynamic processes.[2] Second, the market begins when the drug's patent expires, and hence the date at which the "invention" occurs is known in advance and the size of the potential revenue in each market can be projected with some accuracy. Third, entry occurs at discrete and observable points in time, so that the

[1] For this reason, we use the term *market* interchangeably with *generic drug* or *chemical*. In this study, the three terms simply refer to a prescription drug whose patent has expired. In particular, the use of the term market does not correspond to its antitrust meaning. Note that we study competition among generic producers of a chemical and not between generic producers and the branded producer.

[2] Bresnahan and Reiss (1991) also look at industries in which there are multiple (in their case, geographic) markets in each industry. The focus of their work is characterizing how the static equilibrium varies across markets, rather than the dynamics within markets.

researcher can measure changes in the number of producers and the consequence of those changes on pricing. Moreover, because entry requires FDA approval, firms must sink significant cost to apply for approval prior to knowing when, or how many, rivals will enter the market. Hence, firms must determine if their expected post-entry rents are sufficient to justify the costs associated with FDA application.

These factors enable us to impose restrictions on the functional forms that enable us to identify the parameters in certain relationships of interest. The first of these relationships is the effect of changes in available rents on the pattern of entry over time. The second relationship of interest is the effect of changes in structure (i.e., entry) on rents. Because structure and rents are simultaneously determined, these relationships need to be estimated jointly. In addition, because rents are not observable, estimating these relationships require a calculation based on several additional relationships, such as the relationship between generic revenue and market structure, and between price-cost margins and market structure.

While estimating the relationship between market structure and prices is a necessary component of estimating the relationship of interest, the estimated effect of structural changes on price is also of independent interest, since this relationship has been an area of on-going interest in the industrial organization literature.[3] This industry provides a good opportunity for estimating this relationship because of its unusual institutional features. Specifically, in these markets, the number of producers who apply for FDA approval to sell a drug depends on the expected rents in the market, and not on the price of the generic drug at any specific time. Hence, for any drug, the number of FDA-approved firms at any point in time likewise can reasonably be viewed as unaffected by the contemporaneous price. Of course, the reverse is probably not true; one would expect generic prices to be influenced by the number of generic producers in

[3] See Bresnahan (1988) for a discussion and analysis of this literature.

the market. Consequently, in this industry, the estimated relationship between the number of firms and the price can be viewed as a structural one.[4]

Taking advantage of the pooled time series/cross section (across 32 different chemicals) nature of the data, we can use an iterative procedure to compute the relationships of interest. This procedure yields a number of findings regarding industry dynamic effects. First, more firms enter, and enter more quickly in markets with greater expected rents. The size and time paths of generic revenues, profits and the number of firms are greatly affected by measures reflecting the expected market size. Second, consistent with previous work, we find that generic drug prices fall with the number of competitors. Specifically, we calculate that prices for the initial generic monopolist are 35% - 50% (or perhaps even more) above long-run marginal costs. Generic prices decline with the number of producers and begin to approach long-run marginal cost when there are 8 or more competitors. Finally, we find that the flow of generic industry profits increase as revenues grow but begin falling after five to eight months, as more entrants compete away price-cost margins.

Not only does the generic drug industry have features that make it a useful case study of industry dynamics, our structural estimates also provide a basis for evaluating some policy-relevant questions. In particular, we use our estimates to shed some light on the effects of two changes in government policy towards the generic drug industry that took place in the 1990s. First, as detailed below, the FDA increased their scrutiny of generic drug applications in mid 1989. While the policy may have allowed the FDA to discover, and therefore reject, more sub-standard applications, it also raised the cost of obtaining an ANDA for a qualified entrant. Our estimates provide a means of determining the effect of that higher cost on generic prices. Second, during the mid 1990s, the FDA appears to have adopted a policy of simultaneously

[4] Because of these unique features of this industry, the relationship between generic price and the number of producers has been studied previously (e.g., Caves, Whinston and Hurwicz, 1991). These studies are discussed in detail below.

approving several firms (shortly after the initial patent expired) for certain drugs.[5] Our estimates suggest that there are two consequences of this action. The first consequence is that prices will be lower for any given number of initial applicants, since competition among generics emerges earlier. At the same time, this change in policy reduces expected rents. Hence, if this change is anticipated by potential entrants, fewer firms will apply for FDA approval, leading to higher prices over some longer time period. Our structural estimates can be used to quantify the effects of this change, and thereby provide guidance to policy makers.

II. Background

Before it is able to begin manufacture and sale of a new chemical entity, a prospective manufacturer must obtain FDA approval. The process of obtaining a New Drug Approval (NDA) from the FDA is both expensive and time consuming. The manufacturer must demonstrate, through a series of clinical trials, that the drug is safe and efficacious. It has been estimated that for the average drug which was first tested in humans in the 1970s and early 1980s, its producer had spent over $65 million (in 1987 dollars) on development, and an additional $48 million on clinical and other testing.[6] In addition, the clinical trial process took upwards of 7 years. These drugs typically reached the market in the 1980s.

Prior to 1984, producing a generic version of most existing drugs involved a similar application process. Although the generic producer did not face the cost of determining which drugs were technically feasible and economically viable, it still faced the hurdle of demonstrating the safety and effectiveness of its version before it could obtain FDA approval. The 1984 passage of the Waxman-Hatch Act reduced the regulatory burden for firms to gain FDA approval to produce and sell generic versions of existing drugs. To gain FDA approval under the Act, a producer of a generic drug need only demonstrate bioequivalence to a

[5]For example, the FDA approved nine generic entrants simultaneously for naproxen in December, 1993 and three generic entrants simultaneously for alprazolam in October, 1993.

[6] See J. DiMasi, R. Hansen, H. Grabowski and L. Lasagna (1991). This figure represents the expected cost of a successful drug, in the sense that it includes the cost of drugs which do not obtain an NDA.

drug which already has been approved by the FDA. Under the Waxman-Hatch process, a manufacturer applies for an Abbreviated New Drug Approval (ANDA) from the FDA. The ability to obtain an ANDA, rather than an NDA, has reduced the cost of obtaining FDA approval considerably. As discussed below, we estimate that the cost of applying for an ANDA (including the cost of the requisite testing) was about $1.3 million in the early 1990s (and somewhat lower in the period immediately following passage of the Act).

Not surprisingly, this expedited approval process has increased the number of firms producing generic versions of previously-patented drugs. Cook (1998) reports that for 13 major drugs with patents expiring between 1990 and 1993, 11 had generic entry within two months of patent expiration. In contrast, she notes that in Caves, Whinston and Hurwicz's (1991) study of pre-Waxman-Hatch entry (between 1976 and 1982), only 2 of the top 13 drugs had generic entry within one year of patent expiration.

While the Waxman-Hatch Act lowered the time and expense required to enter production of a drug, one element of the decision confronting a firm interested in generic production did not change. Entry still requires a significant up-front expenditure, with a payoff that depends on the FDA's decisions with respect to that firm's application, as well as the timing of FDA approval of rivals' ANDA applications for that drug. Moreover, the time it takes the FDA to process applications can be both considerable and variable. In the vast majority of cases, the initial ANDA application is found deficient by the FDA, and the applicant is required to conduct additional tests, or submit additional material. In fact, the typical approved applicant has gone through 2 or 3 resubmissions before it obtains its approval. Hence, from the applicants perspective, the time between the initial submission and FDA approval is quite variable. Scott Morton (1999) calculates that between 1984 and 1994 the time between the initial application and approval of ANDAs has averaged about 19 months, with considerable year-to-year variation.

In addition to the time it takes to obtain an ANDA, entering a generic market requires a period of time to begin the production process, since an approved source of materials and adequate production

facilities are required at the time of the application. In total, the applicant has to anticipate two to three years elapsing from the time it begins preparing to enter until it can begin selling a generic drug.

III. Modeling Industry Dynamics

In this section, we discuss how certain institutional features of generic drug markets permit estimation of the structural relationships describing the evolution of the markets for generic versions of individual drugs. Two features of the entry process in this industry are important to understanding industry dynamics. First, as discussed above, for a firm unaffiliated with the initial patent holder, the timing of its entry into the market is not fully under the entrant's control. Not only is the date of its approval by the FDA uncertain, but in addition, each applicant does not know when, or how many, other ANDAs for that drug will be approved. In this sense, potential entrants are simultaneously making their entry decisions (although actual entry will be sequential).

A second feature of the industry that becomes important because of this uncertainty regarding timing is that an individual generic entrant's share of the aggregate generic profits is likely to be highly dependent on when it gains approval relative to other generic producers of that drug. By definition, firms that gain approval before rival generic firms are able to sell their product sooner, and will face fewer initial competitors. In addition, there is some evidence that such firms earn greater profits even after their rivals have entered.[7]

Together these two features create a kind of "lottery" for prospective entrants into producing a generic version of a drug. If a firm obtains early approval, it is likely to earn a positive return on its application-related costs, while firms obtaining approval later in the process are likely to lose money. Thus,

[7] Although we do not have any direct evidence on this point, information from a variety of sources points to such a relationship. In addition to anecdotal material from industry participants, Cook (1998) shows that sales are highly concentrated among a few firms in each market; even in markets with more than ten competitors, on average the top two generic producers sell more than 60% of the units. In addition, Bond and Lean (1977) and Berndt et al. (1995) provide several examples of drugs for which the first entrant had a substantial advantage.

in contrast to markets in which entry decisions are sequential and competition results in the last entrant earning zero profit, here the number of firms adjusts until the average firm earns zero profit.[8] Specifically (assuming *n* applicants of equal ability), the expected profit for each firm from applying for an ANDA is

$$Expected\ Profit = \frac{1}{E[n]} \sum_{t=1}^{\infty} \beta^t \left(\sum_{i=1}^{n} \rho_{it} \Pi_{it} \right) - A = \frac{V}{E[n]} - A \quad (1)$$

Where Π_{it} is total generic rent at time *t* with *i* firms in the market, ρ_{it} is the probability that *i* firms are in the market at time *t*, *A* is the cost of applying for an ANDA, and β is the discount factor. *V* is defined as the present value of the stream of total expected rents for all generic producers of a drug. Setting equation (1) equal to zero yields the zero-profit equilibrium condition that determines entry. Specifically, if the universe of potential entrants is large, then *n* adjusts until (1) is equal to zero (ignoring indivisibilities in the number of firms). This equilibrium condition is a useful tool for examining how changes in the competitive environment affect the market for generic drugs. The goal of this study is to estimate the relationships that form the basis of equation (1). This in turn allows us to study industry dynamics. Three specific relationships need to be estimated in order to make these determinations.

a. What are the generic profits at different times and with different numbers of competitors?

b. How many generic firms will enter a given market?

c. What is the probability that a specific number of firms will compete at a point in time?

Because the number of entrants depends in part on per-firm profits, and per-firm profits depend in part on price-cost margins, understanding the relationship between prices and the number of firms is relevant to all three questions. For this reason, we first discuss this relationship. Questions b and c both turn on the

[8] Consequently, in contrast to the markets examined here, in a market with sequential entry, changes in the profits earned by the first entrant will not change subsequent firms' incentive to enter. Another important difference between generic drug markets (where entry decisions can be viewed as simultaneous) and other markets is that an exogenous change in the number of competitors (e.g, due to a merger several years after patent expiration) can lead to higher prices without inducing entry, even if firms outside the market have the same entry costs as the incumbent.

interrelationship between the number of entrants and the rents to these entrants. That is, both the number of applicants and the speed of approval can be affected by the profitability of becoming a generic producer of a drug, while at the same time, profitability is affected by the number of entrants. Hence, as depicted in sub-section B, our approach is to jointly estimate entry decisions and profitability, given the relationship between generic price and the number of firms estimated in sub-section A.

A. Generic Price and the Number of Competitors.

As noted, our interest in understanding this relationship is first as an input in estimating the relationship between generic profitability and the number of entrants, and second, in the general question of the relationship between structure and pricing. While the latter question has been dealt with in other studies, we are interested in a specific aspect of this relationship, not explicitly examined elsewhere: How does the marginal effect of an additional competitor on a drug's prices change with the number of firms who already have an ANDA for that drug. To address this question, we estimate a regression of the form

$$\frac{P_{ik}}{P_{bk}} = \alpha_0 + \sum_{i=1}^{N-1} \alpha_i D_i + \sum_j \gamma_j X_j \qquad (2)$$

where P_{ik} is the price in the post-patent expiration period when there are i generic firms producing chemical k, and P_{bk} is the price of the branded version of product k in the month prior to patent expiration.[9] D_i is a dummy variable that equals one when there are i generic producers of chemical k and zero otherwise, and the X_{kj} are variables representing demand or cost shifters for drug k.

In principle, N is the maximum number of entrants observed in the data. In practice, we take N to be the number of entrants such that the price effect of going from N-1 to N is negligible. Following this procedure, our empirical results allow us to set N equal to 11. That is, in the data, increasing the number of

[9] We use the branded price before patent expiration, rather than the contemporaneous branded price because the latter is likely to be determined jointly with the generic price. In contrast, the branded price before there is any generic entry is likely to be independent of the number of generic producers in future periods.

generic entrants from 10 to 11 never changes prices by an economically or statistically large amount. The interpretation of α_0 is the ratio of the generic price when there are 11 or more generic producers to the branded price that prevailed before patent expiration, if all other independent variables were equal to zero. The other α_i, such as α_5, are the increments in the ratio over α_0 when there are five firms in the market, rather than 11. Because α_0 reflects the ratio below which additional entry does not lead to lower prices, we view $(\alpha_0 + \Sigma\gamma_j X_{kj})P_{b,k}$ as the long-run marginal production cost of the drugs (where X_{kj} is the mean value of each X_j for that k). Under this assumption, $(\alpha_i /(\alpha_0 + \alpha_i + \Sigma\gamma_j X_{kj}))$ is a measure of the price-cost margin with i generic producers.

Since other factors in addition to the number of generic producers might affect prices, we include the X_j to adjust for some of these effects. The specific variables we include are:

– *Multiple*: A dummy variable which equals 1 if there were multiple branded products in the market prior to patent expiration.[10] To the extent these firms compete, pre-patent expiration prices would be lower for any given level of demand, which in turn implies the ratio of marginal cost to pre-expiration branded price would be higher, other things equal. Conversely, if the branded products were not competing with one another (e.g., because a licensing fee allowed for the monopoly profit to be shared between the branded firms), *Multiple* would have no effect.

- *Uses:* The number of ailments or *indications* for which each drug is used.

- *Subs*: The number of drugs that are therapeutic substitutes for the drug in any of its indications.

An increase in the number of substitutes (holding *Uses* constant) should reduce the pre-patent expiration branded price, and hence lead to a higher ratio of marginal cost to pre-expiration branded price. Conversely, holding the number of *Subs* fixed, we would expect that a drug with more *Uses* would have a

[10] Multiple brands might exist before patent expiration if the patent holder licensed the patent to another producer during the patent-protected period. This might occur if the two parties had some disagreement regarding which firm held the patent rights and reached a licensing agreement in lieu of litigation, or if two firms held complementary patents. In our sample, 7 of the 33 drugs had multiple brands prior to expiration.

higher pre-patent expiration branded price (all else equal), and hence a lower ratio of marginal cost to pre-expiration branded price.

– *Time*: Number of months since patent expiration. Reflects any effect due to the passage of time, rather than generic entry per se. For example, if there were costs savings associated with learning-by-doing, the sign on *Time* would be negative.

– *RGrowth*: The average monthly change in revenue during the year prior to patent expiration. We include this as a proxy for post-expiration demand growth, which may influence generic prices. It is plausible that higher revenue growth is associated with higher generic prices.

This specification has several noteworthy features. Using dummy variables for the number of generic producers imposes no constraints on the structure of the relationship between price and the number of competitors. Hence, we allow the marginal effect of an additional firm to change in an unconstrained manner with the number of competitors. This contrasts with some previous work, in which a specific structure on the relationship is assumed (e.g., where the number of firms, and/or some explicit function of the number of firms appear as explanatory variables).[11] Each such specification makes implicit assumptions about the pattern of price effects that can result from entry. For example, the implicit assumption made when the number of firms is used as an explanatory variable is that the effect of an increase of one in the number of firms is the same regardless of the initial number of firms. By allowing the marginal effect of an additional firm to vary with the number of firms, we can examine questions such as how many firms are necessary to lead to approximately marginal cost pricing. Allowing the marginal effect to vary is also important to our goal of accurately measuring the rents associated with any specific number of generic competitors.

[11] In other studies of generic drug competition, it has been assumed that the generic price decreases with the number of firms (Frank and Salkever, 1997), the number of firms and the number of firms squared (Caves, et al., 1991), or the number of firms and 1 divided by number of firms (Wiggins and Maness, 1996). These papers are discussed at greater length in Section V.

As noted above, this relationship can be viewed as a structural one if one views the number of firms at any time as exogenous. However, one standard criticism of empirical studies of the relationship between market structure and prices is that structure is not exogenous, but rather is determined by the profitability of entering the market.[12] Hence, an observed negative relationship between prices and the number of firms in the market might be due to the influence of concentration on prices (which is the maintained hypothesis of much of the early work on this topic), but might also be due to some other factor that influences both prices and structure. For example, if costs are higher in some markets, then the competitive prices (i.e., those that yield normal rates of return) will be higher and the number of firms lower than in lower-cost markets.

As equation (1) illustrates, this issue also arises in generic drug markets, as the number of firms applying for ANDAs adjusts in response to the available rents. However, the markets for generic versions of drugs have several features which ameliorate this problem. First, because we have a time series of generic prices for each drug, and demand and production cost probably do not change much over the three-year post-patent period, it is unlikely that prices and the number of firms in a market will be influenced by unobserved shocks. Second, because a time-series/cross-section panel exists, one can control for drug-specific effects. We do this by scaling the generic price by the pre-patent expiration branded price. This removes a significant portion of the between-drug variation, allowing for a large number of observations.[13] Finally, holding the number of ANDAs constant, the number of competitors in each market at any point in time is, in part, a function of the FDA review process, so that one might reasonably view the number of firms in each market

[12] This criticism dates back at least to Demsetz (1973). For more formal analysis, see Bresnahan (1986).

[13] That is, the panel structure allows us to control for price effects that are specific to each drug. Other studies have controlled for drug-specific effects by including market-specific dummy variables. Either assumption allows calculation of the average effect of increasing the number of competitors in a market. In addition, Frank and Salkever (1997) and Caves, et al. (1991) use instruments for the number of generic firms.

at any point in time as exogenous (i.e., not a function of the contemporaneous price).[14] Subsection B explicitly models the entry process.

B. The Relationship between Structure and Profitability

Equation (1) implies that in equilibrium, the number of generic producers of the drug will be a function of the rents associated with that drug, and the difficulty of producing an application that is acceptable to the FDA . This suggests that for the drugs in our sample, the number of firms that gain an ANDA will be increasing in measures that are positively correlated with rents, such as branded revenues prior to patent expiration, and decreasing in the cost of applying. We model this relationship between the total number of firms applying for ANDAs to sell a drug and the characteristics of that drug using a Poisson model. The use of the Poisson model implies that the number of applications corresponding to any specific set of drug characteristics is stochastic, where the density of potential outcomes for the number of approved firms, n, is given by

$$f(n) = \exp(-\mu)\mu^{n} / n! \quad (3)$$

and μ is the expected number of occurrences (i.e., applications for ANDAs) for a given set of values for the exogenous variables. The value of μ is estimated from a cross-sectional regression of the number of firms that obtain ANDAs within 3 years of patent expiration (our measure of the number of applications) against total rents and a measure of application costs. There is reason to believe that application costs varied over time in our sample period. In particular, as discussed in Scott Morton (1999), it was discovered in 1989 that some ANDAs had been fraudulently obtained. One result of this "generic drug scandal" was an increase in

[14]The fact that most applications require one or more resubmissions suggests that the lag between initial submission of an application and its eventually approval is stochastic. This implies that while the number of approvals is related to the aggregate rents, the actual number of FDA-approved firms at any point in time may plausibly be independent of contemporaneous price.

the FDA's efforts in investigating applications. This appears to have slowed down the approval process. Following Scott Morton, we assume that application costs may have been higher after July 1989. This is reflected in a dummy variable, which we denote *Stringent*, that equals 1 for the period after mid 1989. Consequently, we estimate the relationship between μ and the cost and benefit of applying as

$$\mu = V \exp(\phi_1 + \phi_1 Stringent). \quad (4)$$

where V is called the "exposure" and the exponential term reflect the rate at which the exposure leads to entry. This structural relationship provides us a means to determine how the number of entrants adjusts to changes in the costs and benefits of approval. It also provides us with a means of estimating the time-series of entry within each market, since the expected number of producers at each point in time depends on the total number of applications, as detailed below.

To represent the FDA approval process described in Section II, we assume that once a firm applies for an ANDA, it faces an uncertain period of time before it gains approval. Specifically, we model the time-series relationship between rents and entry by positing that there is a probability λ of any firm j obtaining an ANDA during month t. We assume λ is constant over time (i.e., follows a *hazard function* with a constant hazard rate). Since λ is assumed constant over time, $1/\lambda$ is the expected length of time between application and FDA approval. We estimate the following relationship for λ as

$$\ln \lambda_{it} = \theta_1 + \theta_2 V + \theta_3 Stringent \times V. \quad (5)$$

We postulate that λ may be increasing in V (which means that $\theta_2 > 0$), either because firms apply earlier in high V markets and/or have a greater incentive to file accurately. Since the value of λ may also depend on the regulatory environment; in equation (5), we portray this with by interacting the *Stringent* variable with

V. As discussed above, the FDA review process became more stringent in the period following the generic drug scandal, so that we would expect a lower hazard rate for any given *V* during that period (i.e., $\theta_3 < 0$).

Given λ, the total number of applicants for ANDAs in a market influences the number of firms with ANDAs at each moment of time through the binomial formula. Specifically, define $S = \exp(-\lambda t)$, as the *Survivorship* function, where "surviving" means the applicant has not yet been approved (i.e., S_t is the probability that a firm will not obtain FDA approval by month *t*). Then, using equation (3) along with the binomial formula, the probability that *i* firms have ANDAs in period *t* is

$$\rho_{it} = \sum_n f(n) \frac{n!}{(n-i)!i!} (1 - S_t)^i S_t^{n-i}. \tag{6}$$

Equation (3) and (4) characterize the effect of *V* on the expected number of firms applying for ANDAs. At the same time, μ has an effect on *V* through the impact of μ (via equation (3)), and therefore on the path of entry over time, as depicted in equation (6). To see the effect of the number of generic producers at any *t* on *V*, recall the definition of *V*,

$$V = \sum_{t=1}^{\infty} \beta^t \left(\sum_{i=1}^{n} \rho_{it} \Pi_{it} \right) = \sum_{t=1}^{\infty} \beta^t \left(\sum_{i=1}^{n} \rho_{it} \frac{P_{it} - C}{P_{it}} P_{it} Q_{it} \right). \tag{1'}$$

An implication of this characterization of equation (1') is that the effect of *i* on *V* is mediated through the effects of *i* on expected margins and revenue. Changes in ρ_{it} change the probability weights associated with each *i*. To the extent that margins and revenue change with the number of firms, the available rents will likewise be a function of *i*. The estimate of the parameters in equation (2) therefore provide one necessary component for determining rents. The other component required for estimating our system of equations is a relationship between total revenues to generic producers and *i*. Our estimation of this relationship are of the form

$$P_{it}Q_{it} = \tau_0 + \tau_1 P_{bt}Q_{bt} + \sum_{j-2}^{J} \tau_j X_{jk} \quad (7)$$

where $P_{i,k}Q_{i,k}$ is total monthly generic revenue in market k with i producers, $P_{b,k}Q_{b,k}$ is the branded firm's total monthly revenue prior to patent expiration, and the X_{jk} are other variables that might affect generic revenue.

Given this relationship, we have a system of three structural equations (1, 3 and 5) in three unknowns (V, μ and λ). Because these equations are non-linear, we estimate them equations iteratively. Specifically, our procedure starts with some initial values for λ and μ for each drug (we refer to these values as λ^0 and μ^0). These are used to calculate $f(n)$, the density of n_j, and the ρ_{it} according to equations (4) and (6). We then calculate V using the calculated ρ_{it} and $f(n)$ and the estimated coefficients from equations (2) and (7). Given this V, we can estimate equations (3) and (5). The resulting estimates are a predicted μ, $\hat{\mu}$ and a predicted λ $\hat{\lambda}$. If $\hat{\mu}$ and $\hat{\lambda}$ are sufficient close to μ^0 and λ^0, we view the process as convergent; that is, we view these values as the appropriate estimates. If the predicted μ and λ are sufficiently different than the initial values, we then go through the same process again, calculating a new V based on λ^1 and μ^1 (where μ^1 and λ^1 are set equal to $\hat{\mu}$ and $\hat{\lambda}$ from the first iteration). The process continues until iteration z where μ^z and λ^z are sufficiently close to μ^{z-1} and λ^{z-1}.

IV. Data

The previous section discussed the method we use to estimate the structural equations of interest. As discussed there, the information required for these estimates includes data on prices, quantities, dates of entry, and measures of market-specific variables that affect demand for each drug in our sample.

Our primary source for price and quantity data is IMS Inc., a proprietary vendor of information to the pharmaceutical industry. The specific IMS data we used was their *Generic Spectra* data set.[15] The IMS data provided us with up to 6 years of monthly price and quantity data for the patent holder (3 years before patent expiration, 3 years after) for a group of 32 drugs that went off patent in the late 1980s and early 1990s, and subsequently faced competition from generic producers. The data on the generic entrants contains monthly price and quantity data for each of the first three generic entrants, and similar data combining all generic entrants, for the 3 years following patent expiration. A list of the drugs examined in the study and the month and year they first faced generic competitors is provided in Table 1.

The Generic Spectra data includes prices derived from two different sources; one based on product shipments, the other based on price surveys. The product shipment source contains data on quantities purchased (in kilograms of active ingredient) and expenditures made by pharmacies and hospitals for each drug in our sample. The data are provided separately for each strength (e.g., 50 mg.) and form (e.g., oral solid) of the drug. Our measure of price per kilogram is the average revenue derived by dividing total revenue by quantity.

The shipment-based data are derived primarily from purchases by pharmacies and hospitals, who purchase from distributors, who in turn purchase from manufacturers. A small proportion, perhaps 5%, of purchases are made directly from manufacturers. IMS captures these two types of sales differently. The purchases from distributors are captured by IMS directly monitoring shipment data of a high percentage of distributors (98% of all such shipments are contained in their sample). Direct purchases from manufacturers are estimated from a sample of invoices. IMS then combines these two kinds of sales information.

The second set of price data in Generic Spectra is obtained from a sample of pharmacies. It includes data on the average transaction prices paid by pharmacies, and the average realized selling prices received

[15] IMS Health, Generic Spectra™

by pharmacies by drug strength and form. These selling prices are based on the actual transactions prices per package (e.g., 100 pills) received by the pharmacies in the sample. According to IMS, the measured acquisition price would reflect all relevant discounts, with the exception of year-end quantity discounts provided by some manufacturers. We refer to these two series as pharmacy transaction prices. Some summary statistics on the drugs in the Generic Spectra data set are provided in Table 2.

For drugs with multiple strength/form combinations, we faced the question of how to construct a price series from these data. Our method was to use price data only on the strength/form of the drug that generated the most revenue in the year prior to patent expiration, as long as that strength/form was available as a generic.[16] For all but two of the drugs the generic form of this strength/type was available; in most cases it was the best-selling strength/type for both the innovator and the generic firms. For the two exceptions (Metaproterenol and Albuterol), there was no generic version of the most popular form, so that the price data recorded are for the best selling generic strength/form.[17]

The reason we chose the price for the best selling strength/form as the basis of our price analysis, rather than the average price for all strengths is that with the latter, one observes changes in the price variable whenever there are changes in the relative sales of different strengths of the drug, even if prices are unchanged. The advantage of our approach is that it measures a change only if a price charged by the manufacturer or pharmacy changes. The disadvantage is that we do not use information on price changes for other strengths. The trade-off seems to favor our approach if the manufacturer does not anticipate changes in relative sales volume, so that the forces changing relative shares are uncorrelated with those

[16] Since the price data covered retail pharmacies, forms of the drugs which are not typically sold by pharmacies (e.g., injectables) are excluded from the price analysis.

[17] For these two drugs, the most popular form of the branded production was an aerosol inhalant. Entry into the generic production of this form came several years after generic entry into the drug forms reflected in our data. We believe that the delay in developing a generic aerosol was due to an unexpired patent on the aerosol delivery system, even after the patent on the chemical had expired. There also were unresolved issues related to demonstrating bioequivalence of aerosol products to the branded versions.

changing prices. On the other hand, if changes in relative demand are anticipated, then prices will move for the same reasons as relative demand, and price changes for one strength may understate or overstate the "average" change in prices. We thought that changes in relative sales of different strengths/forms of a drug are likely to be unanticipated, and hence we choose to look at a representative price, rather than the average price across strengths and forms.

Another issue we faced was what time period constitutes an observation. Specifically, should each month constitute an observation, or should we take an average over all months in which the number of generic producers did not change? The first approach implicitly treats each month as an independent observation, which seems to be unlikely, and we instead chose to use the average price for all of the months with the same number of generic producers as a single observation.[18] This approach reduces the number of observations substantially, which tends to reduce the statistical significance of our results, but as Tables 4-6 indicate, we are still able to find significant pricing effects.

Data on the timing of entry were collected from the FDA publication *Approved Drug Products*, commonly referred to as the *Orange Book*. The Orange Book lists the date each firm received its NDA or ANDA from the FDA. The Orange Book also enables us to determine if there were multiple branded products prior to patent expiration. Because the Generic Spectra data is limited to 3 years of post-patent expiration data, we limit our analysis of entry to ANDAs awarded within three years of patent expiration.[19]

Finally, we constructed two demand-side variables - *Uses* and *Subs* - to capture demand differences across drugs. *Uses* measures the number of ailments or *indications* for which each drug is used. *Subs*

[18]As Mouton (1986) observes, using multiple observations with essentially unchanged exogenous variables leads to an downward bias in estimated standard errors. For this reason, we chose the conservative approach of taking only one data point for each number of competitors in each market.

[19]A useful feature of the 3-year time frame is that the process of entering generally takes at least three years. Hence, any firm that receives an ANDA in this time frame will have commenced the process prior to observing the ANDAs that were awarded to other firms.

measures the number of alternative drugs that are generally used to treat these same indications.[20]

The basic method used to create these variables was to first determine the indications for which each drug is used. If a drug was available in both an oral and an intravenous (IV) or intramuscular (IM) version, we confined the analysis to the oral version only. The primary source in determining indications was the *American Hospital Formulary Service (AHFS) Drug Information*, 1996, augmented by AMA *Guide to Prescription and Over-the-Counter Drugs*, and *The People's Pharmacy*. To the extent possible, we included not only the FDA-approved (or *labeled*) indication, but significant unlabeled uses as well. This constitutes our *uses* variable.

For each indication, we determined the other drugs which are also used for that indication. We defined substitutes fairly narrowly, so that two patients with similar symptoms might reasonably be prescribed either the drug in our sample or the substitute. One source of these data was the AHFS book. It was developed as a formulary; its specific purpose is to provide the information hospitals need to determine which drugs to buy, and which drugs primarily serve indications for which lower price alternatives are available. This source was augmented by the *AMA Guide to Prescription and Over the Counter Drugs.* The Guide has several dozen discussions of classes of drugs, and describes which drugs have similar mechanisms of action. Finally, for two classes of drugs (hypotensives and antibiotics), we consulted a practicing internist.

Based on this, we constructed a variable called *Subs* by summing the number of substitutes in each use over all of its *Uses* for each drug in our sample (counting each substitute only once, regardless of how many uses it can be a substitute in). We then used the Orange Book to determine the date when each substitute for the drugs in our sample came on the market. This enabled us to determine the number of

[20] While the IMS provides information on the "therapeutic class" (e.g, *cephalosporin antibiotics*) to which each drug belongs, these categories tend to be over-inclusive in that all drugs in the therapeutic class would not actually be used for the same ailment, as Caves, Whinston and Hurwitz (1991) and Lu and Comanor (1998) have noted. Caves, Whinston and Hurwitz (1991) further note that a suitable measure of substitution would have been helpful to their analysis, but found such a measure difficult to construct. Scott Morton finds that the *therapeutic class* variable has little predictive power in her regressions. Lu and Comanor (1994) follow a similar procedure to that used here and find that their measure does have explanatory power.

substitutes on the market on the day the first generic version of the product was available, and also whether any new substitutes subsequently became available.

V. Results

A. OVERVIEW

Figure 1 depicts the basic empirical method used to estimate the structural parameters of interest. The presentation of our results in this section follows this blueprint. Subsection B presents our estimates of the relationship between the number of producers and generic prices, as characterized in equation (2). Because price effects both play a part in other results, and are of interest in of themselves, we examine the robustness of those results by using several alternative price series. This subsection also includes a discussion of relationships between generic prices and the number of competitors that have been found in other studies. Subsection C presents the revenue regression depicted in equation (6). By combining the estimates from equations (2) and (6), we can calculate the aggregate generic profits associated with any specific number of generic producers.

As the diagram in Figure 1 indicates, V, μ and λ are jointly determined, so that equations (3) and (5) were estimated using an iterative procedure. This procedure searches for a combination of V, μ and λ that constitutes an equilibrium (i.e., so that the V calculated in iteration z results in the same μ and λ in iteration $z+1$ as the μ and λ used to determine V in iteration z). We find that convergence occurs in the 28th iteration. The resulting estimates relating to the time path of entry are presented in subsection D. Subsection E presents our estimates of the equilibrium values of V for the 32 drugs we study.

B. PRICES AND STRUCTURE

1.Findings - The pricing equations we estimate are of the form

$$\frac{P_{ik}}{P_{ok}} = \alpha_0 + \sum_{i=1}^{n-1} \alpha_i D_i + \gamma_1 Subs + \gamma_2 Uses + \gamma_3 time + \gamma_4 Rgrowth + \gamma_5 Multiple + e_{it} \qquad (2')$$

Where $P_{i,k}/P_{b,k}$ is the ratio of the price in the post-patent expiration period when there are i generic producers of drug k, to the price charged by the branded firm prior to patent expiration. D_i is a dummy variable which equals 1 when there are i producers of drug k.

We estimate equation (2') for 8 different price series. The first four regressions, which are reported in Table 4, use the data derived from the sample of pharmacy prices. The first two regressions are based on the transaction prices paid by pharmacies (which we call wholesale price), while the last two regressions are based on the prices charged by pharmacies (retail prices). For both wholesale and retail prices, we estimate equation (2') for both the average generic price and the price of the first generic entrant's product. Table 5 is based on shipments by distributors and manufacturers. The prices used in these regressions are derived by dividing total revenue by quantity shipped. We estimated these regressions separately for drug stores and hospitals, and for both types of buyers we analyze both the average generic price and the first generic entrant's price.

To interpret these results, first note that the intercept represents the ratio of generic price to the branded price when the number of competitors is large, and all other independent variables are equal to 0. For example, the estimate of 0.429 for the coefficient on the intercept in column (1) of Table 4 implies that on average, the generic price would be about 43% of the pre-patent expiration price of the branded product when there are 11 or more competitors, if all other variables were equal to zero. As discussed above, adding the other variables (evaluated at their mean values) times the relevant coefficients to the intercept can reasonably be viewed as an estimate of the ratio of marginal cost to the branded price, which here equals .533. The interpretation of the other firm number coefficients, such as the coefficient on one firm (α_1 from equation 2') is the increase in this ratio due to having fewer than 11 generic competitors. For example, the coefficient of 0.287 on one-firm in column (1) of Table 4 implies that ratio of generic price to pre-patent expiration branded price will be 0.820 (= 0.287 + 0.533) when there is a single generic firm.

Note that, as one would anticipate, the α_i generally decline with the number of competitors. Again, using the example of the coefficient estimates from the first column of Table 4, the ratio of generic price to pre-patent expiration branded price falls from .820 with one generic competitor to .762 with two generic competitors, and continues to decline toward .533 as the number of competitors rises. However, given the size of the α_is' standard errors, one cannot draw conclusions about the incremental effect of an additional competitor on equilibrium prices.

The implied marginal costs tend to be lower, and the firm coefficients higher in Table 5 as compared to Table 4. For example, in the first column of Table 5, we find that the implied ratio of marginal cost to pre-patent expiration branded price when there are 11 or more firms is about 21% of the pre-patent expiration branded price (compared with an estimated ratio of about 53% in the first column of Table 4). However, the estimate of the premium over the intercept associated with any specific number of firms (i.e., any specific α_i) is higher than in the first column of Table 4. For example, α_1 = 0.536 in the first column of Table 5, yielding an estimate of the ratio when there is one generic producer of 0.745 (=0.536 +0.209), similar to that in the first column of Table 4 (0.820 = .287 + .533).

While there are some differences across the eight regressions in regard to the magnitudes of the pricing effects, the general picture is quite similar across equations. In every case, there is an economically and statistically significant difference between the price when there is a single generic competitor, and the price when there is a large number of generic competitors in the market. A price cost margin remains when there are relatively few generic producers, but eventually the premium shrinks and disappears. In Table 4, the coefficients for 7-10 firms are not statistically significant in any regression, and are typically less than 0.1. In Table 5, the coefficients sometimes remain statistically significant with up to 9 generic firms (and in one case, up to 10), although the magnitude of the coefficients continue to decline as the number of firms rises, and is generally in the positive 0.15-0.25 range for more than 6 firms.

Figure 2 presents a graphical representation of the estimated relationship between the average wholesale generic price and the number of firms in the market from the first columns of Tables 4 and 5. The results suggest a negative relationship between price and the number of firms. They also suggest that the marginal effect of an additional firm tends to decline with the number of firms.

Of the other variables, only *Multiple* seems to have an effect that is consistent across specifications. *Multiple* has the anticipated positive sign in all of the regressions reported in Tables 4 and 5. Moreover, it is statistically significant at the 5% level in 5 of the 8 regressions, and economically meaningful. For example, the coefficient of 0.069 in column 1 of Table 5 implies that having multiple branded products pre-patent expiration increases the ratio of generic price to branded price by 0.069.

The signs of both the *Subs* and *Uses* variables tend to vary across equations. *Subs* has the predicted positive sign in 4 of the 8 regressions, and is statistically significant at the 5% level in 4 regressions; however, in 2 of these 4, the sign is negative. *Uses* has the predicted negative sign in only 2 of the 8 regressions. Moreover, in 4 of the 6 cases in which the sign is positive, it is statistically significant at the 5% level. Neither *Time* nor *RGrowth* is statistically significant in any regression, although both are positive more often than they are negative.

2. Comparison to Other Results

Estimating the relationship between price and industry structure has a long history in industrial organization economics. One general criticism of the approach is that is implicitly assumes that structure is exogenous, whereas in most industries it should be viewed as endogenous. As discussed in Section III, the markets for generic versions of drugs have several features which ameliorate the endogeneity problem, and hence make measuring the relationship between the number of firms and prices more meaningful.

Perhaps due to these features, the relationship between the price of a generic drug and the number of firms producing that drug has been examined in at least three previous studies. All three studies of which

we are aware use annual price and quantity data from IMS, and find a negative relationship between the generic price and the number of generic competitors.[21]

All three studies impose a specific functional form (e.g., in Frank and Salkever,1997, price is assumed to be related to the number of firms), and consequently, the coefficient estimates cannot be directly compared to ours. What we can compare is the predicted change in price resulting from a specific increase in the number of generic producers. For example, our results from the first two columns of Table 4 imply that an increase in the number of generic producers from 1 to 10 will reduce wholesale generic prices by 35 to 40%. The estimates in Table 5 are larger; the predicted price declines range from 50 to 70%. Previous studies yield predicted values that fall between these sets of estimates. The estimates in Caves et al. (1991) imply that when there is only one generic producer, price is about 40% below the pre-patent expiration branded price, and declines by about 50% (to 70% below the pre-patent expiration branded price), when there are 10 such producers. Using the estimates from Frank and Salkever (1997), one would estimate that an increase in the number of generic producers from one to 10 would lead to a 45% reduction in price. Finally, Wiggins and Maness' (1996) estimate that an increase in the number of sellers (which includes both generic distributors and manufacturers) from 1 to 10 would lead to a 48% decrease in average generic price (based on Table 5 in their study).

C. REVENUE AND STRUCTURE

Equation (7) relates the total revenue derived from generic sales to other observable characteristics of the market. In contrast to equations (2) - (5), we are not primarily interesting in testing any hypotheses about the individual parameters of equation (6). Rather, the main use of these results is in estimating *V*. The specification we estimate is the following:

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[21] In contrast, the relationship between the number of generic producers and the branded price is less clear. Caves et al. (1991), Grabowski and Vernon (1992) and Frank and Salkever (1997), find that generic entry has a relatively small negative effect on branded price. However, Wiggins and Maness (1996) find a rather large effect of generic entry on branded prices.

$$\ln(GenericRev) = \tau_0 + \tau_1 \ln(BrandRev) + \tau_2 Subs + \tau_3 Uses + \tau_4 FrDrug + \tau_5 Multiple + \tau_6 (Stringent) + \tau_7 (\%Conv.\ Insurance) + t_8 (1/time) + \tau_9 \left(\ln(BrandRev)/time\right) + \tau_{10}(1/i) + \tau_{11}\left(\ln(BrandRev)/i\right). \quad (7')$$

The dependent variable is the natural logarithm of generic revenue. The explanatory variables include

Ln(BrandRev) - the natural logarithm of total revenue for the branded product(s) six months before patent expiration,

FrDrug - the percentage of branded revenue obtained through drug stores sales and other outpatient outlets (as opposed to hospital sales) prior to patent expiration,

i - the number of generic producers

% of Conv Insurance - The percentage of all insureds that are covered by a fee-for-service structure, as opposed to some kind of managed care organization (MCO), and

Subs, Uses, Multiple, *Stringent*, and *Time* are the same variables used in equation (2).

We expect τ_1 to be positive and close to one; a given percentage increase in pre-patent expiration revenue should lead to a similar percentage increase in generic revenue. Both τ_2 and τ_3 are proxies for demand elasticity; an increase in the number of substitutes means that more alternatives are available (i.e., higher elasticity), while holding the number of substitutes constant, more uses will reduce elasticity. However, because the effect of elasticity on generic revenue is ambiguous,[22] the only prediction we can make is that an increase in *Subs* has an opposite effect on elasticity of an increase in *Uses*, so that τ_2 and τ_3 should have opposite signs. Similarly, the sign of τ_4 is ambiguous. On the one hand, hospitals are more likely to switch away from the branded product to the generic version of that product (especially during the sample period) than the individual consumers who purchase at drug stores, which suggests higher generic revenue for drugs with higher hospital sales. On the other hand, competition between generic producers is likely to

[22] The reason is that there are two offsetting effects of elasticity on generic revenue, holding pre-expiration revenue constant. For any given price discount relative to the branded product, higher elasticity implies lower initial margins (making discounts less profitable), but likely means that any given price discount will result in larger generic revenues.

be more intense for drugs with a high hospital share, since hospitals are likely to be more willing to switch between generic suppliers.[23] This suggests that generic prices and revenues will be lower for drug which more of their sales are made by hospitals.

We hypothesize that the sign on τ_5 will be negative, since in markets which had two firms prior to patent expiration, generic producers will have to face two competing branded producers, and all else equal, will find it more difficult to make sales. It seems likely that the generic drug scandal would reduce consumers' perception of the quality of generic drugs. Hence, we would expect lower demand and revenue for generic drugs in the post-scandal period, so that τ_6 would be negative. MCOs tend to have policies that encourage the use of generic drugs. We would therefore anticipate that as the percentage of patients covered by conventional insurance falls, generic revenue would increase, so that τ_7 would be negative. We expect τ_8 to be negative; total generic revenue should increase over time (and so decrease with the reciprocal of *Time*), as purchasers become more familiar with the generic product.[24] The effect of the number of competitors (i.e., the sign of τ_{10}) is less clear; an increase in the number of generic producers reduces price and increases quantity of generics sold, so that the net effect on total generic revenue of more competitors depends on whether the (post-entry) demand elasticity is less than unity. We also include two interactive terms; the ratio of *Ln(BrandRev)* to *Time* and the ratio of *Ln(BrandRev)* to the number of generic producers.

Table 5 presents the results of our estimation of equation (7). We estimated four alternative specifications; column 1 shows estimates of the unconstrained equation, while the estimates in columns 2-4 set (respectively) $\tau_9 = 0$, $\tau_{11} = 0$, and $\tau_9 = \tau_{11} = 0$. These constraints test whether allowing the effects of *Time* and the number of producer to differ across markets of different sizes affects our results. Allowing these

[23] The pricing evidence supports this conjecture; as Table 5 shows, the average hospital price approaches the competitive level with fewer firms than the average drug store price.

[24] We use reciprocals of the number of firms and time since patent expiration to better reflect the expected relationship. The functional form chosen implies that the marginal effect of both time and the number of firms remains positive, but decreases as both increase.

effects to differ across markets does not seems to affect the estimates of the effects of any of variables on rents, as the results are consistent across specifications. In all specifications, τ_1 is between 1.06 and 1.1, indicating the elasticity of generic revenue with respect to branded revenue is fairly close to unity. In fact, in no case can the null hypothesis that $\tau_1 = 1$ be rejected at the 5% level. The sign of τ_2 is negative, and the sign of τ_3 is positive, suggesting that generic producers received less revenue in markets with more elastic demand. As expected, the existence of competing brands before patent expiration also led to a statistically significant reduction in generic revenue. As anticipated, generic revenues are lower in the post-scandal period ($\tau_6 < 0$), and rises as the percentage of patients covered by traditional insurance falls ($\tau_7 < 0$). As anticipated, generic revenue increases over time, and therefore, the sign of τ_8 is negative. Finally, τ_{10} is positive, which suggests that demand elasticity is greater than 1.

The relationship between expected monthly revenue and time is depicted for three hypothetical drugs in Figure 3. These drugs were chosen by dividing our sample of markets into three size categories on the basis of pre-patent expiration sales, and analyzing the average drug in each category. These correspond to monthly branded revenues prior to patent expiration of $2.77 million, $7.35 million and $19.46 million respectively. The middle line shows the relationship for the average *medium*-sized market, and the upper and lower lines depict the relationship for the average *large* and *small* markets, respectively. These depicted relationships reflect the predicted increase in the number of generic producers over time (using equations 5 and 6), which in turn influences the total revenue. For all three hypothetical markets, monthly revenue increases monotonically with time. In addition, in all three cases, the monthly revenue increases relatively rapidly with time in the early portion of the sample, and tends to flatten out after about one year.

D. ENTRY

As noted in Section III, we are interested in explaining entry in two senses. First, we are interested in the cross-sectional relationship between the total number of firms applying for ANDAs for each drug in our sample and the available rents. Second, given the total number of applicants in each market, we are

interested in explaining the time series of entry; that is, how entry occurs over time for each drug.

Equation (3) relates the number of generic producers that ultimately enter each market to the available rents to generic entrants. The causality between available rents and the number of generic producers runs in both directions, so that equations (4) and (5) must be estimated using an iterative procedure where V adjusts to changes in μ and λ. Using the *Generic Spectra* data, the structural form estimates that result from this procedure are

$$\mu = V \exp(\underset{(0.12)}{0.59} - \underset{(0.19)}{0.66}\ Stringent) \tag{4'}$$

where the standard errors are in parentheses.

The model implies that during the non-scandal period the expected number of firms applying for ANDAs increases by about 1.8 (= exp(0.59)) with every $1 million increase in the rents available in generic production of the drug. The standard error of the estimate on the coefficient on the constant is 0.12, so that we can be highly confident that the effect of a $1 million increase in V is to increase the number of ANDAs by between 1.4 and 2.3 during the non-scandal period. The model also implies that the relationship was weaker during the period following the generic drug scandal. This is consistent with newspaper accounts, which describe the post-scandal period as one of greater FDA scrutiny of applications. Equation (4) implies that the expected number of ANDAs increased by only about 0.94 (=exp(-.07)) with every $1 million increase in V during this period. This suggests that the effect of increased scrutiny was substantial.

Using these estimated coefficients, the model implies that for a market with a V of $5.9 million (approximately the average market in our sample), μ would be 7. 7 (evaluated at the mean value for stringent). This in turn implies that the probability of exactly one application for an ANDA in this market is about .5% (i.e., $f(1) \approx .005$, $f(2) \approx .02$, $f(3) \approx .05$, etc.).

The first two columns of Table 7 compare the expected number of approved ANDAs within three

years of patent expiration to the actual number of approvals for each drug. For most of these drugs, this procedure seems to yield an accurate prediction of the number of ANDAs. One conclusion from the analysis is that incentive effects (as measured by the available rents) are important in determining the number of applicants for ANDAs. It follows that factors that reduce the available rents can have a significant effect on the number of applicants.

We can also use this equation to estimate the costs of applying for an ANDA (including the necessary testing). Specifically, the reciprocal on the coefficient on V from equation (4) gives the average cost for an ANDA application. This implies that the average cost was slightly over $550,000 (= 1/1.8) during the period prior to the scandal (the late 1980s), and was about $1.07 million (=1/0.94) million in the period following the scandal.[25]

The other sense in which we are interested in entry is explaining the time series of entry for each drug. We model the probability of FDA approval in any given month with a hazard function, with the probability of approval (λ) related to the rents and regulatory environment, as

$$\ln(\lambda) = -2.48 + 0.026\ V - 0.034\ V \times Stringent. \qquad (5')$$
$$\qquad\qquad (0.170)\quad (0.025)\qquad (0.017)$$

The positive coefficient on the size of the rents (V) indicates that V not only has an influence on the total number of ANDAs (via equation (4)), but also suggests that higher V increases the probability that a given firm gains FDA approval in a given month; each firm's efforts to gain approval is apparently greater in markets with higher available rents. Consistent with the premise of greater scrutiny during the post-scandal period, the coefficient on the interactive *Stringent* term suggests that the probability of approval fell during that period.

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[25]Scott Morton (2000) also examines the cross-sectional relationship between the number of entrants and market characteristics. Her results are not directly comparable to ours because 65% of the drugs in her sample were low-revenue drugs which had zero entry. Methodologically, her study differs from ours in that she estimates the reduced form relationship between the number of entrants and characteristics, rather than jointly estimating the structural relationships between rents and entry.

Given our estimates of λ and μ from equations (4') and (5'), we calculate the probability of *i* firms having gained approval by time *t* using the binomial formula (as shown in equation (6)). For example, this implies that for a market with V = $5.9 million, the probabilities of *i* firms gaining approval in the first six month following patent expiration are:

Months Since Patent Expiration	Number of Generic Entrants					
	0	1	2	3	4	5+
1	51.1%	34.3%	11.5%	2.6%	0.4%	0.1%
2	27.7%	35.6%	22.8%	9.8%	3.1%	1.0%
3	15.8%	29.2%	26.9%	16.5%	7.6%	4.0%
4	9.5%	22.4%	26.3%	20.6%	12.1%	9.0%
5	6.0%	16.8%	23.7%	22.3%	15.7%	15.5%
6	3.9%	12.7%	20.5%	22.2%	18.0%	22.7%

These probabilities change over time, and by 24 months after expiration, the likelihood that 5 or more applicants are approved in such a market is about 65%. Figure 4 depicts how the expected number of approved firms varies over time for three different sized markets.

A graphical illustration of the reliability of this technique is presented in Figure 5. Figure 5 shows the distribution of the predicted number of firms with ANDAs associated with each actual number of such firms. For example, the display of points vertically above the "8" in Figure 5 is the set of values predicted by our model for every observation in which the actual number of firms with ANDAs is eight. The predicted values in this case tend to cluster around 8, although predictions range from approximately six to around eleven. The squares in the figure reflect the actual and predicted number of total applications. Generally, the distributions of predicted values follow the actual number fairly closely (i.e., the points tend to follow the 45 degree line).

Another way of evaluating our estimates is to construct a "pseudo R^2," which we create by taking the difference between the actual and the expected number of entrants. For example, for each predicted value associated with eight actual entrants, we take the residual (i.e., the difference between our estimate and eight). We calculate the variance of this residual and of the actual number of entrants. These variances are

akin to the unexplained sum of squares and the total sum of squares and their difference represents the explained sum of the squares. The ratio of the explained sum to the total sum is similar to the usual R^2 calculation. The ratio is 0.387 in this case. Given the large number of observations (over 1,000) and the fact that our predictions use only five parameters, we view this as a reasonably accurate representation for such a parsimonious model. As such, it suggests that the Poisson/hazard rate analysis is a useful way of modeling the dynamic entry process.

Given this path of expected entry, our estimates of the coefficients of equation (2) allow us to calculate the expected margins at each point in time. The time paths of expected margins for typical large-revenue, medium-revenue and small-revenue drugs are depicted in Figure 6. As shown there, margins decline faster for drugs with larger revenue, reflecting the fact that the predicted number of firms is larger for those drug, and margins are inversely related to the number of firms.

E. CALCULATION OF RENTS

Equations 2, 6 and 7 relate the margins, expected number of generic producers and total revenue at each point in time to observable characteristics of the drug markets. Observable characteristics include *Subs*, *Uses*, *Time*, *Frdrg* and *Branded Revenue.* From these estimates, we can derive a relationship between the expected total and per-firm rents in each market and these observable characteristics.

The final 2 columns of Table 8 show the monthly pre-patent expiration revenues and the total rents (V) to generic producers for each drug. The underlying calculation incorporates the estimates from equations (2) - (7).[26] As noted in Section III, while the calculations in Table 8 are made using the estimated relationships from equations (4) and (5), the procedure used to derive these estimates was iterative so that rents are treated as endogenous (i.e., in each iteration, the predicted value of rents from the previous iteration is used to estimate the coefficients of equations (4) and (5)).

[26] The calculation uses the coefficient estimates from the second column of Table 4 for the price effects of entry, and the first column of Table 7 for the revenue effects.

The relationship between expected monthly industry rents and time is depicted for three different size markets in Figure 7. As in Figures 3, 4 and 6, the middle line shows the relationship for the average *medium*-sized market (as measured in pre-expiration revenue) and the upper and lower lines depict the average *large* and *small* market, respectively. Again, these relationships are drawn so that the time-varying parameters are allowed to change. In particular, we allow the expected number of firms to increase over time (using equation 6), which in turn influences both the total revenue and the margins. One interesting feature of Figure 7 is that for all three hypothetical markets, the monthly rent increases with time in the early portion of the sample period, but eventually reaches a maximum and then declines. The non-monotonicity of the relationship reflects two offsetting effects. While total generic revenue increases over time, the margin continues to fall with the increased competition. Since the increase in revenue is fairly slow after the first year (see Figure 3), the effect of increased competition eventually dominates.

VI. Using the Structural Estimates

The structural estimates detailed in Section V indicate how individual drug markets develop over time. As discussed above, in the typical market in our sample our model predicts that the expected number of firms applying for ANDAs in such a market would be 7.7, and given the predicted hazard rate, we obtain the predicted path of entry illustrated in Figure 4. Using the estimates from Table 4, this in turn implies the path of expected price illustrated in Figure 7. Given these relationships, we anticipate that the total expected generic rents would be about $5.9 million. The structural equations can also be used to evaluate how the number of firms will vary with the size of the market (as measured by pre-expiration revenues). Specifically, if pre-expiration monthly revenues were $19.5 million, V would increase to about $9.2 million, and we would expect about 11 firms would enter in equilibrium.

One interesting use of the structural estimates is simulating the effect of an exogenous change that affects rents. Specifically, as discussed above, for several drugs whose patents expired in the mid 1990s, the

FDA approved multiple initial ANDAs. To the extent that this reflects a new policy, it will have effects in both the short-run and the long-run. To see how such a policy can change the equilibrium, consider a drug with $7.35 million in pre-patent expiration monthly revenues, and suppose the FDA announced that in the future, they will approve the first four ANDAs on the same day (shortly after patent expiration), rather than use the traditional path approval, which we modeled in equations (5) and (6). The direct effect of this is to reduce the path of expected prices in the months following patent expiration. Holding the total number of entrants constant, based on our estimates from equation (2) and our estimates of ρ_{ip}, the expected price will be 19% lower due to the new policy.

There is also an indirect effect from this policy, which is to reduce the rents to gaining an ANDA. Aggregate rents fall because the per-firm rents with 4 competing firms are less than 1/4 of the rents with a single firm (and less than ½ the per-firm rents with two firms, etc). Hence, the most profitable outcomes are precluded when this policy is in place. We calculate that if, in expectation, 7.7 firms continued to apply, aggregate rents would decline to $4.5 million, so that if application costs are about $800,000 (as suggested by the initial equilibrium), the 11 firms would, on average, lose money. In order for all entrants to earn non-negative profits, the number of entrants would have to decline. We estimate that, conditional on four (randomly-chosen) firms gaining ANDAs shortly after patent expiration, the resultant expected number of entrants in equilibrium is slightly under six. Figure 8 shows the path of expected prices under the initial equilibrium and this alternative equilibrium. Expected prices are much lower for the first 14 months under the new policy (32% lower in the first month), but the effect of a smaller number of entrants eventually dominates, and by the 15th month price is actually higher with the new policy. On average, the effect of the policy is to reduce price by about 1% over the first 3 years.

Another question that can be addressed by these estimates is the effect of the more stringent review process that was instituted in the wake of the generic drug scandal. While the approach potentially screened out some fraudulent drug applications, the change in the review process reduced the number of non-

fraudulent products approved as well. We can use our structural estimates to calculate the effect of the more stringent standards on prices. In the median-sized market, our estimates indicate that the more stringent review process reduced the expected number of applicants from 8.2 to 6.7, resulting in a reduction in expected consumer surplus by about $2.5 million per market, or about 8.4% of revenue in that market.

VII. Conclusion

This paper develops a methodology for estimating the structural relationships that describe generic drug industry dynamics. These estimates enable us to describe how a market in this industry evolves from monopoly pricing towards competitive pricing. Two elements of the methodology are noteworthy. First, because the exact nature of the relationship between price and the number of competitors is critical to our estimation, the structural assumptions made about this relationship will have a large influence on our results. To minimize the possibility of misspecification, we allowed the data to determine the nature of the pricing relationship by using a general functional form. Our interesting finding from this functional form is that the negative effect of increased competition on prices continues until at least the fifth, and perhaps even the sixth or seventh firm enters.

The second noteworthy element of our estimation procedure is that we use a system of simultaneous equations to estimate the relationship between entry and profitability. We do this because it is likely that the causality between the number of entrants and the available rents runs in both directions. We estimate these relationships simultaneously using functional form restrictions that follow from the economic model to identify the system, which is then estimated using an iterative process.

Our estimates indicate that the flow of generic industry rents increases for the initial five to ten months after patent expiration but then fall as more entrants compete away price-cost margins. We find that more firms enter, and enter more quickly, in markets with greater expected rents. Finally, the size and time paths of generic revenues, rents and the number of firms are greatly affected by measures reflecting the

expected market size. A consequence of these relationships is that the extent to which prices approach competitive levels in a market depends upon, among other things, the potential revenues in the market. We estimate that for markets of sufficient size (as measured by pre-patent expiration revenue), entry will ultimately lead to near competitive pricing. In contrast, in small markets, prices will remain above marginal cost without inducing additional entry. Finally, this analysis suggests that even in relatively large markets, mergers between competitors can lead to higher prices. Moreover, such price increases may not induce entry, even if potential entrants have the same entry costs as the incumbents, and entry would restore pre-merger prices.

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Table 1
Drugs and Dates of Generic Entry in the IMS Generic Spectra Data Set

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Blocadren	Timolol Maleate	May, 1989
Calan/Isoptin	Verapamil	April, 1986
Catapres	Clonidine	July, 1986
Cleocin	Clindamycin	October, 1987
Clinoril	Sulindac	April, 1990
Depakene	Valproic Acid	May, 1986
Desyrel	Trazodone	October, 1986
Duficef/Ultracef	Cefadroxil	March, 1989
Dyazide/Maxzide	Triamterene	September, 1987
Feldene	Piroxicam	April, 1992
Flexeril	Cyclobenzaprine	May, 1989
Haldol	Haloperidol	May, 1986
Inderal	Propranolol	July, 1985
Keflex	Cephalexin	April, 1987
Loniten	Minoxidil	March, 1987
Ludiomil	Maprotiline	January, 1988
Minipress	Prazosin	May, 1989
Minocin	Minocycline	August, 1990
Moduretic	Amilioride w/ HCTZ	July, 1989
Nalfon	Fenoprofen	August, 1988
Procardia/Adalat	Nifedipine	September, 1990
Sinequan/Adapin	Doxepin	Apri, 1986
Tegretol	Carbamezepine	June, 1986
Tenormin	Atenolol	July, 1991
Tolectin	Tolmetin	December, 1991
Valium	Diazepam	August, 1985
Vancocin	Vancomycin	August, 1986
Ventolin	Albuterol	December, 1989

source: IMS Health, Generic SpectraTM

Table 2
Summary Statistics for IMS Generic Spectra Data

Variable	Mean	Standard Deviation
Monthly Total Generic Revenue ($ millions)	2.28	2.82
Monthly Total Generic Quantity (million Kg)	0.85	1.88
Monthly Branded Revenue Prior to Patent Expiration ($ million)	11.18	10.34
Number of Substitutes Chemicals	9.70	5.77
Number of Uses	2.97	2.10
Multiple Brand Dummy	0.23	0.42
Fraction of Sales to Drugstores	0.89	0.17
Time trend	17.85	10.34
Number of ANDAs	5.82	4.30
Average Generic Wholesale Price relative to Pre-patent Branded Value	0.690	0.184
First ANDA Wholesale Price relative to Pre-patent Branded Value	0.710	0.198
Average Generic Retail Price relative to Pre-patent Branded Value	0.755	0.162
First ANDA Retail Price relative to Pre-patent Branded Value	0.779	0.165
Average ANDA Drugstore Revenue/Quantity relative to Pre-patent Branded Value	0.561	0.294
First ANDA Drugstore Revenue/Quantity relative to Pre-patent Branded Value	0.592	1.176
Average ANDA Hospital Revenue/Quantity relative to Pre-patent Branded Value	0.505	0.302
First ANDA Hospital Revenue/Quantity relative to Pre-patent Branded Value	0.568	0.351

source: IMS Health, Generic SpectraTM

Table 3
Summary Statistics for Data used in Price Regressions

Variable	Mean	Standard Deviation
Pre-patent Revenue Growth Rate (% per month)	1.596	0.609
Time Trend	16.018	10.166
Number of Uses	3.715	2.396
Number of Substitute Chemicals	12.071	5.575
Multiple Brand Dummy	0.201	0.402
Dummy for 1 ANDA	0.055	0.228
Dummy for 2 ANDAs	0.091	0.289
Dummy for 3 ANDAs	0.098	0.298
Dummy for 4 ANDAs	0.116	0.321
Dummy for 5 ANDAs	0.098	0.298
Dummy for 6 ANDAs	0.091	0.289
Dummy for 7 ANDAs	0.067	0.251
Dummy for 8 ANDAs	0.067	0.251
Dummy for 9 ANDAs	0.061	0.240
Dummy for 10 ANDAs	0.043	0.203
Average Generic Wholesale Price relative to Pre-patent Branded Value	0.659	0.165
First ANDA Wholesale Price relative to Pre-patent Branded Value	0.686	0.182
Average Generic Retail Price relative to Pre-patent Branded Value	0.733	0.140
First ANDA Retail Price relative to Pre-patent Branded Value	0.762	0.137
Average ANDA Drugstore Revenue/Quantity relative to Pre-patent Branded Value	0.483	0.244
First ANDA Drugstore Revenue/Quantity relative to Pre-patent Branded Value	0.498	0.265
Average ANDA Hospital Revenue/Quantity relative to Pre-patent Branded Value	0.505	0.251
First ANDA Hospital Revenue/Quantity relative to Pre-patent Branded Value	0.525	0.285

source: IMS Health, Generic SpectraTM

Table 4
Price Regression Results Using Sample of Pharmacy Prices: Dependent Variable is the Ratio of the Generic Price to Pre-Patent Expiration Branded Price

	Average Wholesale Price	First Wholesale Price	Average Retail Price	First Retail Price
Intercept	0.429*	0.296*	0.528*	0.531*
	(0.088)	(0.102)	(0.078)	(0.080)
Time (times 10)	0.016	0.024	0.013	0.004
	(0.014)	(0.016)	(0.012)	(0.010)
Number of Substitutes	-0.003	0.005	-0.000	0.005
	(0.003)	(0.004)	(0.003)	(0.003)
Number of Uses	0.016+	0.024+	0.010	0.004
	(.007)	(.008)	(0.006)	(.007)
Multiple	0.061	0.014	0.076*	0.076*
	(0.033)	(0.035)	(0.027)	(0.028)
RGrowth	0.031	0.046	0.026	0.029
	(0.022)	(0.025)	(0.019)	(0.020)
One Firm	0.287*	0.343*	0.225*	0.205*
	(0.066)	(0.077)	(0.059)	(0.061)
Two Firms	0.229*	0.282*	0.166*	0.169*
	(0.056)	(0.063)	(0.049)	(0.050)
Three Firms	0.257*	0.262*	0.205*	0.175*
	(0.052)	(0.060)	(0.046)	(0.047)
Four Firms	0.195*	0.193*	0.150*	0.128*
	(0.047)	(0.054)	(0.042)	(0.043)
Five Firms	0.180*	0.150*	0.138*	0.110*
	(0.049)	(0.057)	(0.044)	(0.045)
Six Firms	0.113+	0.118+	0.079	0.065
	(0.048)	(0.056)	(0.043)	(0.044)
Seven Firms	0.066	0.112	0.033	0.061
	(0.056)	(0.065)	(0.050)	(0.051)
Eight Firms	0.063	0.087	0.035	0.065
	(0.053)	(0.062)	(0.047)	(0.049)
Nine Firms	0.075	0.073	0.084	0.073
	(0.053)	(0.062)	(0.047)	(0.049)
Ten Firms	-0.002	-0.035	-0.007	-0.017
	(0.061)	(0.070)	(0.054)	(0.056)
Adjusted R^2	.242	.160	.178	.104
Number of Obs.	164	164	164	164

Asterisks denote significance at the 1% level and plus signs denote significance at the 5% level. Standard errors in parentheses.

source: IMS Health, Generic SpectraTM

Table 5
Price Regression Results Using Shipment Data: Dependent Variable is the Ratio of Generic Price to Pre-Patent Expiration Branded Price

	Average Drugstore price	First Drugstore Price	Average Hospital Price	First Hospital Price
Intercept	0.048 (0.106)	-0.046 (0.121)	0.354* (0.130)	0.195* (0.131)
Time (times 10)	0.029 (0.017)	0.036 (0.019)	-0.035 (0.020)	-0.023 (0.022)
Number of Substitutes	0.008+ (0.004)	0.009+ (0.004)	-0.012+ (0.005)	-0.015* (0.005)
Number of Uses	-0.000 (0.010)	-0.000 (0.010)	0.030* (0.011)	0.055* (0.011)
Multiple	0.069+ (0.034)	0.080+ (0.040)	0.025* (0.045)	0.055 (0.045)
RGrowth	-0.001 (0.026)	-0.001 (0.029)	0.011 (0.033)	0.048 (0.032)
One Firm	0.506* (0.080)	0.582* (0.090)	0.365* (0.101)	0.464* (0.104)
Two Firms	0.563* (0.067)	0.645* (0.076)	0.408* (0.085)	0.491* (0.085)
Three Firms	0.485* (0.062)	0.555* (0.072)	0.427* (0.077)	0.490* (0.078)
Four Firms	0.430* (0.057)	0.507* (0.065)	0.342* (0.069)	0.420* (0.070)
Five Firms	0.339* (0.059)	0.448* (0.070)	0.327* (0.072)	0.391* (0.076)
Six Firms	0.258* (0.058)	0.328* (0.066)	0.228* (0.071)	0.312* (0.073)
Seven Firms	0.225* (0.067)	0.310* (0.076)	0.150* (0.081)	0.193+ (0.082)
Eight Firms	0.154+ (0.063)	0.225* (0.063)	0.127* (0.078)	0.184+ (0.078)
Nine Firms	0.141+ (0.064)	0.204* (0.074)	0.155* (0.077)	0.162+ (0.077)
Ten Firms	0.069 (0.073)	0.083 (0.088)	-0.031* (0.089)	0.030 (0.092
Adjusted R^2	.475	.459	.429	.507
Number of Obs.	164	156	158	140

Asterisks denote significance at the 1% level and plus signs denote significance at the 5% level. Standard errors in parentheses.

source: IMS Health, Generic SpectraTM

Table 6
Regressions Results: Dependent Variable is the Natural Logarithm of Total Generic Revenue

	Model 1	Model 2	Model 3	Model 4
Intercept (τ_0)	-1.359$^+$ (0.548)	-1.354$^+$ (0.549)	-1.327$^+$ (0.549)	-1.313$^+$ (0.550)
Log Pre-Expiration Branded Revenues (τ_1)	1.087* (0.039)	1.098* (0.054)	1.062* (0.044)	1.080* (0.055)
Number of Substitutes (τ_2)	-0.069* (0.009)	-0.069* (0.009)	-0.069* (0.009)	-0.068* (0.009)
Number of Uses (τ_3)	0.186* (0.022)	0.186* (0.022)	0.185* (0.022)	0.185* (0.022)
Fraction of Sales in Drug Stores (τ_4)	0.568* (.218)	0.559* (.220)	0.567* (.218)	0.548* (.220)
Multiple brands (τ_5)	-0.627* (0.088)	-0.627* (0.088)	-0.627* (0.088)	-0.625* (0.088)
Post-Scandal (τ_6)	-0.569* (0.140)	-0.571* (0.140)	-0.568* (0.140)	-0.573* (0.140)
Fraction Conventional Insurance (τ_7)	-1.113 (0.777)	-1.115 (0.785)	-1.082 (0.777)	-1.142 (0.778)
Inverse of Time (τ_8)	-3.211* (0.212)	-3.204* (0.214)	-3.649* (0.447)	-3.682* (0.451)
Log Pre-Patent Revenues/Time (τ_9)			0.227 (0.205)	0.253 (0.210)
Inverse of the Number of Firms (τ_{10})	0.644* (0.141)	0.702* (0.253)	0.640* (0.141)	0.756* (0.256)
Log Pre-Patent Revenues/Firms (τ_{11})		-0.033 (0.119)		-0.066 (0.122)
Adjusted R^2	.550	.550	.551	.550
Number of Obs.	1019	1019	1019	1019

Asterisks denote significance at the 1% level and plus signs denote significance at the 5% level. Standard errors are in parentheses.

source: IMS Health, Generic SpectraTM

Table 7
Predicted Number of Generic Producers and Generic Rents

Brand Name	Generic Name	Actual Number of ANDAs	Predicted Number of ANDAs	Brand Sales Prior to Patent Expiration ($ millions)	Predicted Total Generic Rents ($ millions)
Alupent/Metaprel	Metaproterenol	9	5.82	8.56	4.84
Asendin	Amoxapine	2	1.31	2.00	1.40
Ativan	Lorazepam	13	11.61	11.37	6.44
Atromid-S	Clofibrate	3	4.44	1.31	2.51
Blocadren	Timolol	6	0.60	1.10	0.62
Calan/Isoptin	Verapamil	10	9.68	8.06	5.37
Catapres	Clonidine	13	9.52	5.33	5.28
Cleocin	Clindamycin	1	2.72	1.10	1.97
Clinoril	Sulindac	6	8.73	16.46	9.36
Depakene	Valproic Acid	4	5.69	2.92	3.16
Desyrel	Trazodone	9	7.82	5.56	4.58
Duricef/Ultracef	Cefadroxil	3	6.50	10.99	6.47
Dyazide/Maxzide	Triamterene/HCTZ	6	12.78	23.99	9.16
Feldene	Piroxicam	9	12.29	27.37	13.16
Flexeril	Cyclobenzaprine	4	7.48	10.97	7.72
Haldol	Haloperiodol	17	12.02	7.09	6.66
Inderal	Propranolol	18	17.69	24.66	9.80
Keflex	Cephalexin	11	19.13	23.32	12.50
Loniten	Minoxidil	5	5.93	2.77	3.80
Ludiomil	Maprotiline	4	2.32	1.71	1.79
Minipress	Prazosin	7	8.52	10.45	8.80
Minocin	Minocycline	3	7.03	7.47	7.53
Moduretic	Amiloride/HCTZ	6	5.07	4.70	5.43
Nalfon/Nalfon200	Fenoprofen	15	6.61	5.80	5.79
Procardia/Adalat	Nifedipine	5	8.46	25.93	9.06
Sinequan/Adapin	Doxepin	11	6.99	5.04	3.87
Tegretol	Carbamazepine	6	9.91	5.57	5.49
Tenormin	Atenolol	12	12.95	45.66	13.87
Tolectin	Tolmetin	7	4.87	4.87	5.22
Valium	Diazepam	16	14.81	28.07	8.21
Vancocin	Vancomycin	7	11.94	9.45	6.61
Ventolin/Proventil	Albuterol	14	9.22	36.59	9.87

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Name Brand	Generic Name	Date of First Generic Entry
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Dummy for 10 ANDAs	0.043	0.203
Average Generic Wholesale Price relative to Pre-patent Branded Value	0.659	0.165
First ANDA Wholesale Price relative to Pre-patent Branded Value	0.686	0.182
Average Generic Retail Price relative to Pre-patent Branded Value	0.733	0.140
First ANDA Retail Price relative to Pre-patent Branded Value	0.762	0.137
Average ANDA Drugstore Revenue/Quantity relative to Pre-patent Branded Value	0.483	0.244
First ANDA Drugstore Revenue/Quantity relative to Pre-patent Branded Value	0.498	0.265
Average ANDA Hospital Revenue/Quantity relative to Pre-patent Branded Value	0.505	0.251
First ANDA Hospital Revenue/Quantity relative to Pre-patent Branded Value	0.525	0.285

data source: IMS Health, Generic SpectraTM

Table 4
Price Regression Results Using Generic Spectra Pharmacy Data: Dependent Variable is the Ratio of the Generic Price to Pre-Patent Expiration Branded Price

	Average Wholesale Price	First Wholesale Price	Average Retail Price	First Retail Price
Intercept	0.429*	0.296*	0.528*	0.531*
	(0.088)	(0.102)	(0.078)	(0.080)
Time (times 10)	0.016	0.024	0.013	0.004
	(0.014)	(0.016)	(0.012)	(0.010)
Number of Substitutes	-0.003	0.005	-0.000	0.005
	(0.003)	(0.004)	(0.003)	(0.003)
Number of Uses	0.016+	0.024+	0.010	0.004
	(.007)	(.008)	(0.006)	(.007)
Multiple	0.061	0.014	0.076*	0.076*
	(0.033)	(0.035)	(0.027)	(0.028)
RGrowth	0.031	0.046	0.026	0.029
	(0.022)	(0.025)	(0.019)	(0.020)
One Firm	0.287*	0.343*	0.225*	0.205*
	(0.066)	(0.077)	(0.059)	(0.061)
Two Firms	0.229*	0.282*	0.166*	0.169*
	(0.056)	(0.063)	(0.049)	(0.050)
Three Firms	0.257*	0.262*	0.205*	0.175*
	(0.052)	(0.060)	(0.046)	(0.047)
Four Firms	0.195*	0.193*	0.150*	0.128*
	(0.047)	(0.054)	(0.042)	(0.043)
Five Firms	0.180*	0.150*	0.138*	0.110*
	(0.049)	(0.057)	(0.044)	(0.045)
Six Firms	0.113+	0.118+	0.079	0.065
	(0.048)	(0.056)	(0.043)	(0.044)
Seven Firms	0.066	0.112	0.033	0.061
	(0.056)	(0.065)	(0.050)	(0.051)
Eight Firms	0.063	0.087	0.035	0.065
	(0.053)	(0.062)	(0.047)	(0.049)
Nine Firms	0.075	0.073	0.084	0.073
	(0.053)	(0.062)	(0.047)	(0.049)
Ten Firms	-0.002	-0.035	-0.007	-0.017
	(0.061)	(0.070)	(0.054)	(0.056)
Adjusted R^2	.242	.160	.178	.104
Number of Obs.	164	164	164	164

Asterisks denote significance at the 1% level and plus signs denote significance at the 5% level. Standard errors in parentheses.

data source: IMS Health, Generic SpectraTM

Table 5
Price Regression Results Using Generic Spectra Pharmacy Data: Dependent Variable is the Ratio of Generic Price to Pre-Patent Expiration Branded Price

	Average Drugstore price	First Drugstore Price	Average Hospital Price	First Hospital Price
Intercept	0.048 (0.106)	-0.046 (0.121)	0.354* (0.130)	0.195* (0.131)
Time (times 10)	0.029 (0.017)	0.036 (0.019)	-0.035 (0.020)	-0.023 (0.022)
Number of Substitutes	0.008+ (0.004)	0.009+ (0.004)	-0.012+ (0.005)	-0.015* (0.005)
Number of Uses	-0.000 (0.010)	-0.000 (0.010)	0.030* (0.011)	0.055* (0.011)
Multiple	0.069+ (0.034)	0.080+ (0.040)	0.025* (0.045)	0.055 (0.045)
RGrowth	-0.001 (0.026)	-0.001 (0.029)	0.011 (0.033)	0.048 (0.032)
One Firm	0.506* (0.080)	0.582* (0.090)	0.365* (0.101)	0.464* (0.104)
Two Firms	0.563* (0.067)	0.645* (0.076)	0.408* (0.085)	0.491* (0.085)
Three Firms	0.485* (0.062)	0.555* (0.072)	0.427* (0.077)	0.490* (0.078)
Four Firms	0.430* (0.057)	0.507* (0.065)	0.342* (0.069)	0.420* (0.070)
Five Firms	0.339* (0.059)	0.448* (0.070)	0.327* (0.072)	0.391* (0.076)
Six Firms	0.258* (0.058)	0.328* (0.066)	0.228* (0.071)	0.312* (0.073)
Seven Firms	0.225* (0.067)	0.310* (0.076)	0.150* (0.081)	0.193+ (0.082)
Eight Firms	0.154+ (0.063)	0.225* (0.063)	0.127* (0.078)	0.184+ (0.078)
Nine Firms	0.141+ (0.064)	0.204* (0.074)	0.155* (0.077)	0.162+ (0.077)
Ten Firms	0.069 (0.073)	0.083 (0.088)	-0.031* (0.089)	0.030 (0.092
Adjusted R^2	.475	.459	.429	.507
Number of Obs.	164	156	158	140

Asterisks denote significance at the 1% level and plus signs denote significance at the 5% level. Standard errors in parentheses.

data source: IMS Health, Generic SpectraTM

Table 6
Regressions Results: Dependent Variable is the Natural Logarithm of Total Generic Revenue

	Model 1	Model 2	Model 3	Model 4
Intercept (τ_0)	-1.359$^+$ (0.548)	-1.354$^+$ (0.549)	-1.327$^+$ (0.549)	-1.313$^+$ (0.550)
Log Pre-Expiration Branded Revenues (τ_1)	1.087* (0.039)	1.098* (0.054)	1.062* (0.044)	1.080* (0.055)
Number of Substitutes (τ_2)	-0.069* (0.009)	-0.069* (0.009)	-0.069* (0.009)	-0.068* (0.009)
Number of Uses (τ_3)	0.186* (0.022)	0.186* (0.022)	0.185* (0.022)	0.185* (0.022)
Fraction of Sales in Drug Stores (τ_4)	0.568* (.218)	0.559* (.220)	0.567* (.218)	0.548* (.220)
Multiple brands (τ_5)	-0.627* (0.088)	-0.627* (0.088)	-0.627* (0.088)	-0.625* (0.088)
Post-Scandal (τ_6)	-0.569* (0.140)	-0.571* (0.140)	-0.568* (0.140)	-0.573* (0.140)
Fraction Conventional Insurance (τ_7)	-1.113 (0.777)	-1.115 (0.785)	-1.082 (0.777)	-1.142 (0.778)
Inverse of Time (τ_8)	-3.211* (0.212)	-3.204* (0.214)	-3.649* (0.447)	-3.682* (0.451)
Log Pre-Patent Revenues/Time (τ_9)			0.227 (0.205)	0.253 (0.210)
Inverse of the Number of Firms (τ_{10})	0.644* (0.141)	0.702* (0.253)	0.640* (0.141)	0.756* (0.256)
Log Pre-Patent Revenues/Firms (τ_{11})		-0.033 (0.119)		-0.066 (0.122)
Adjusted R^2	.550	.550	.551	.550
Number of Obs.	1019	1019	1019	1019

Asterisks denote significance at the 1% level and plus signs denote significance at the 5% level. Standard errors are in parentheses.

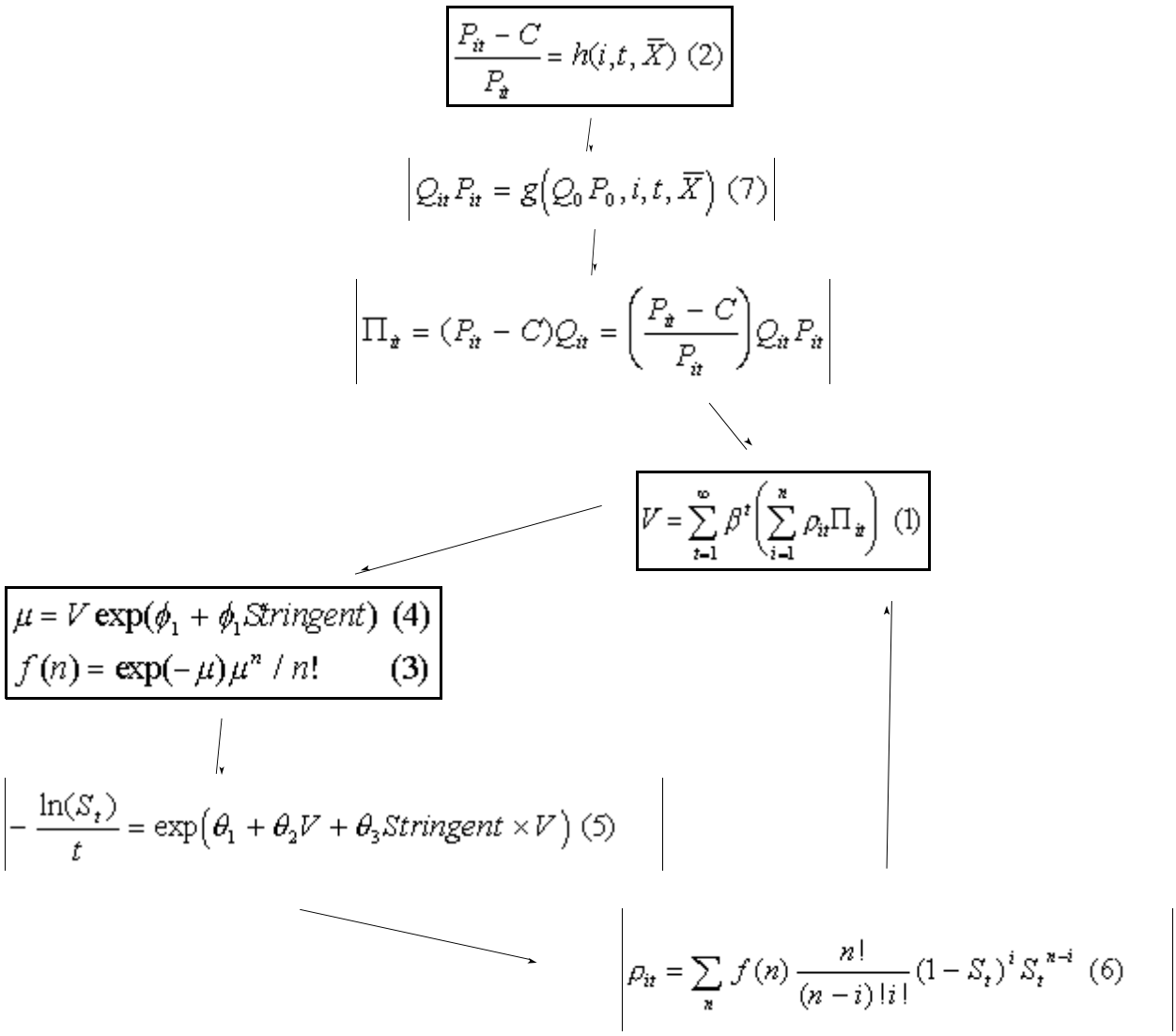
data source: IMS Health, Generic SpectraTM

Table 7
Predicted Number of Generic Producers and Generic Rents

Brand Name	Generic Name	Actual Number of ANDAs	Predicted Number of ANDAs	Brand Sales Prior to Patent Expiration ($ millions)	Predicted Total Generic Rents ($ millions)
Alupent/Metaprel	Metaproterenol	9	5.82	8.56	4.84
Asendin	Amoxapine	2	1.31	2.00	1.40
Ativan	Lorazepam	13	11.61	11.37	6.44
Atromid-S	Clofibrate	3	4.44	1.31	2.51
Blocadren	Timolol	6	0.60	1.10	0.62
Calan/Isoptin	Verapamil	10	9.68	8.06	5.37
Catapres	Clonidine	13	9.52	5.33	5.28
Cleocin	Clindamycin	1	2.72	1.10	1.97
Clinoril	Sulindac	6	8.73	16.46	9.36
Depakene	Valproic Acid	4	5.69	2.92	3.16
Desyrel	Trazodone	9	7.82	5.56	4.58
Duricef/Ultracef	Cefadroxil	3	6.50	10.99	6.47
Dyazide/Maxzide	Triamterene/HCTZ	6	12.78	23.99	9.16
Feldene	Piroxicam	9	12.29	27.37	13.16
Flexeril	Cyclobenzaprine	4	7.48	10.97	7.72
Haldol	Haloperiodol	17	12.02	7.09	6.66
Inderal	Propranolol	18	17.69	24.66	9.80
Keflex	Cephalexin	11	19.13	23.32	12.50
Loniten	Minoxidil	5	5.93	2.77	3.80
Ludiomil	Maprotiline	4	2.32	1.71	1.79
Minipress	Prazosin	7	8.52	10.45	8.80
Minocin	Minocycline	3	7.03	7.47	7.53
Moduretic	Amiloride/HCTZ	6	5.07	4.70	5.43
Nalfon/Nalfon200	Fenoprofen	15	6.61	5.80	5.79
Procardia/Adalat	Nifedipine	5	8.46	25.93	9.06
Sinequan/Adapin	Doxepin	11	6.99	5.04	3.87
Tegretol	Carbamazepine	6	9.91	5.57	5.49
Tenormin	Atenolol	12	12.95	45.66	13.87
Tolectin	Tolmetin	7	4.87	4.87	5.22
Valium	Diazepam	16	14.81	28.07	8.21
Vancocin	Vancomycin	7	11.94	9.45	6.61
Ventolin/Proventil	Albuterol	14	9.22	36.59	9.87

data source: IMS Health, Generic SpectraTM

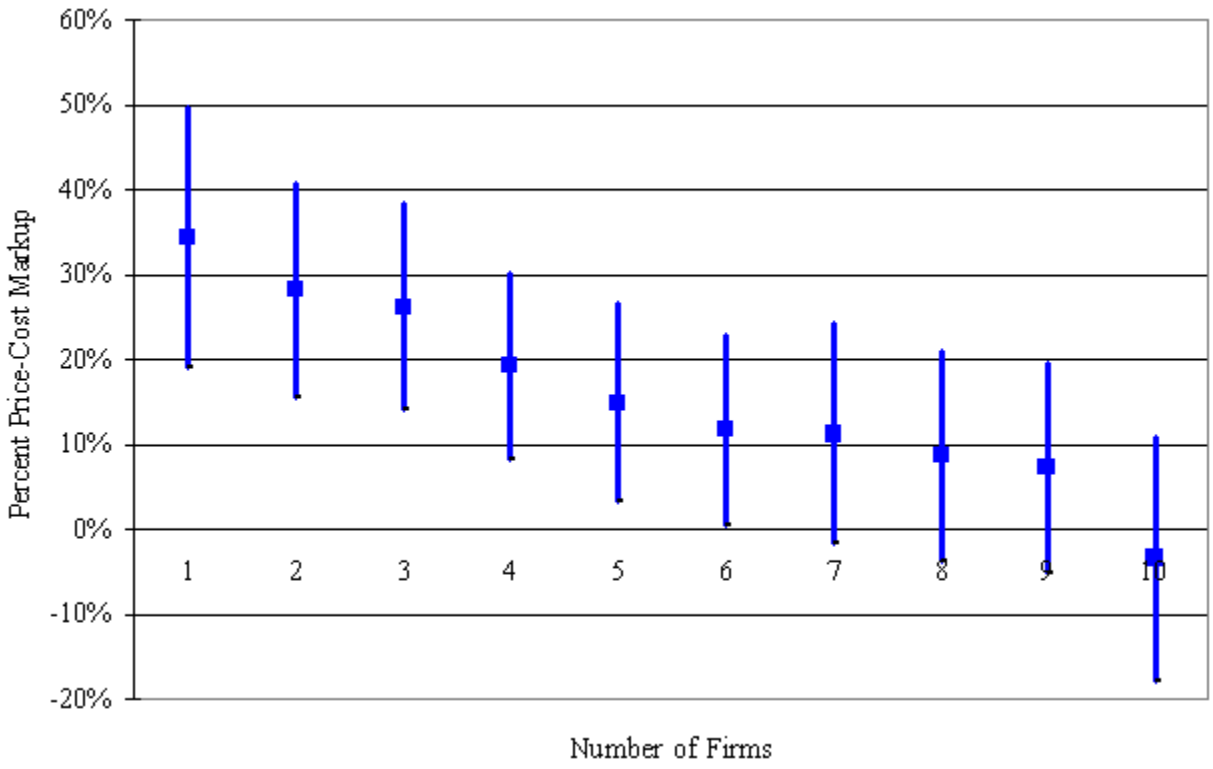
Figure 1
Estimating Structural Relationships



Definitions

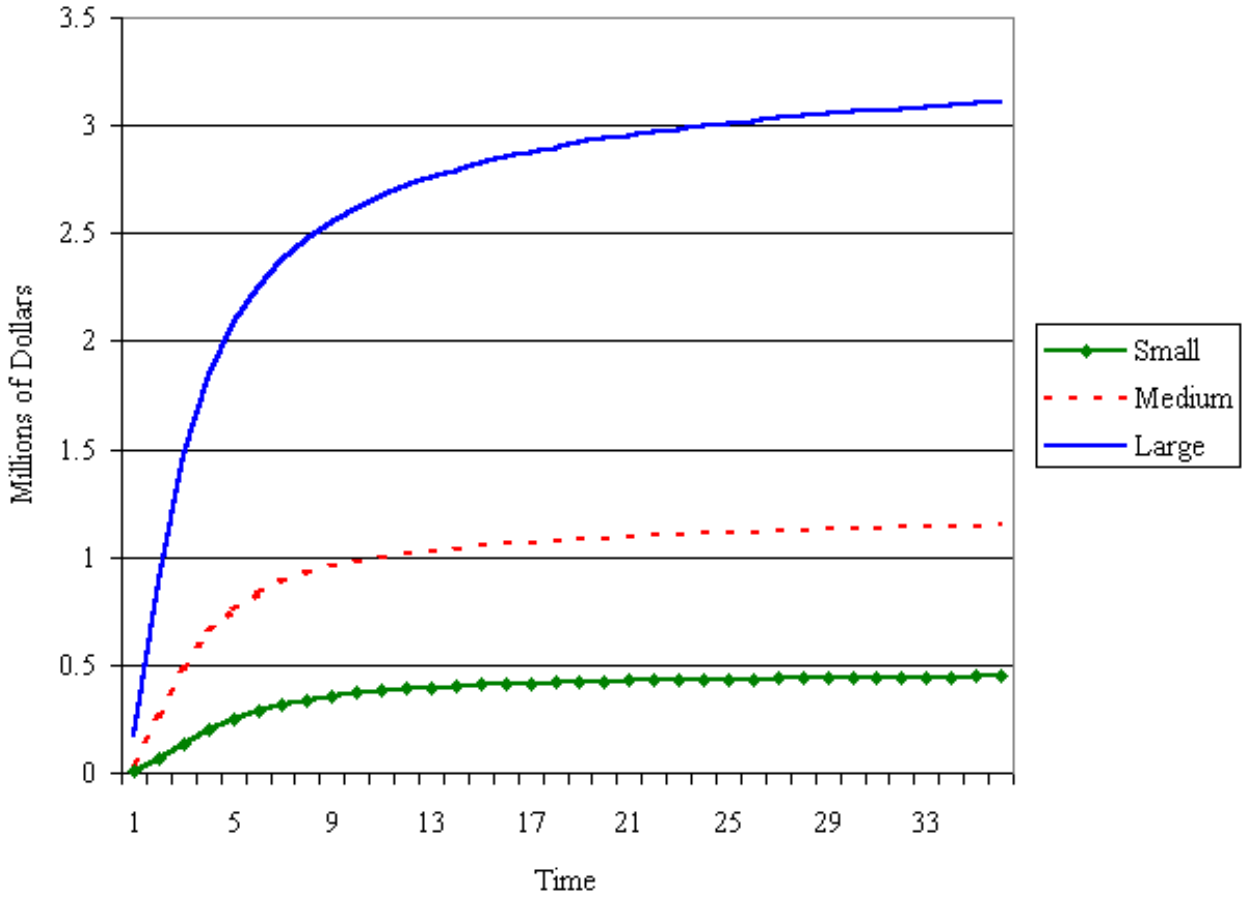
- V - present value of total expected generic rents
- n - total number of ANDAs (entrants)
- Π_{it} - total generic rents when there are i competing generic producers at time t
- P_{it} - generic price when there are i competing generic producers at time t
- Q_{it} - total generic quantity when there are i competing generic producers at time t
- ρ_{it} - probability of i competing generic producers at time t
- S_t - Survivorship probability at time t

Figure 2
Estimated Average Price-Cost Markup (and Twice the Standard Error)
As a Function of the Number of Firms



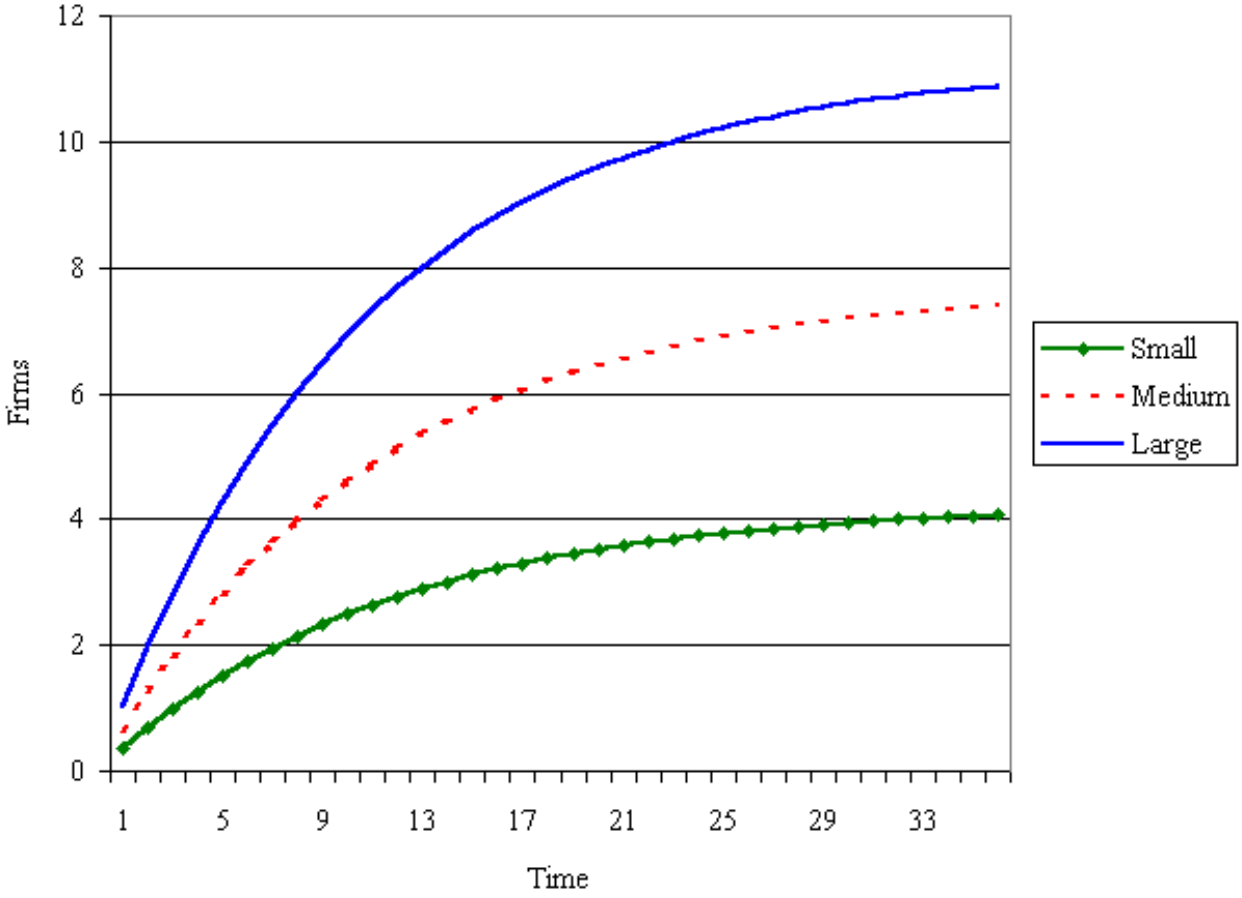
data source: IMS Health, Generic SpectraTM

Figure 3
Predicted Market Revenue



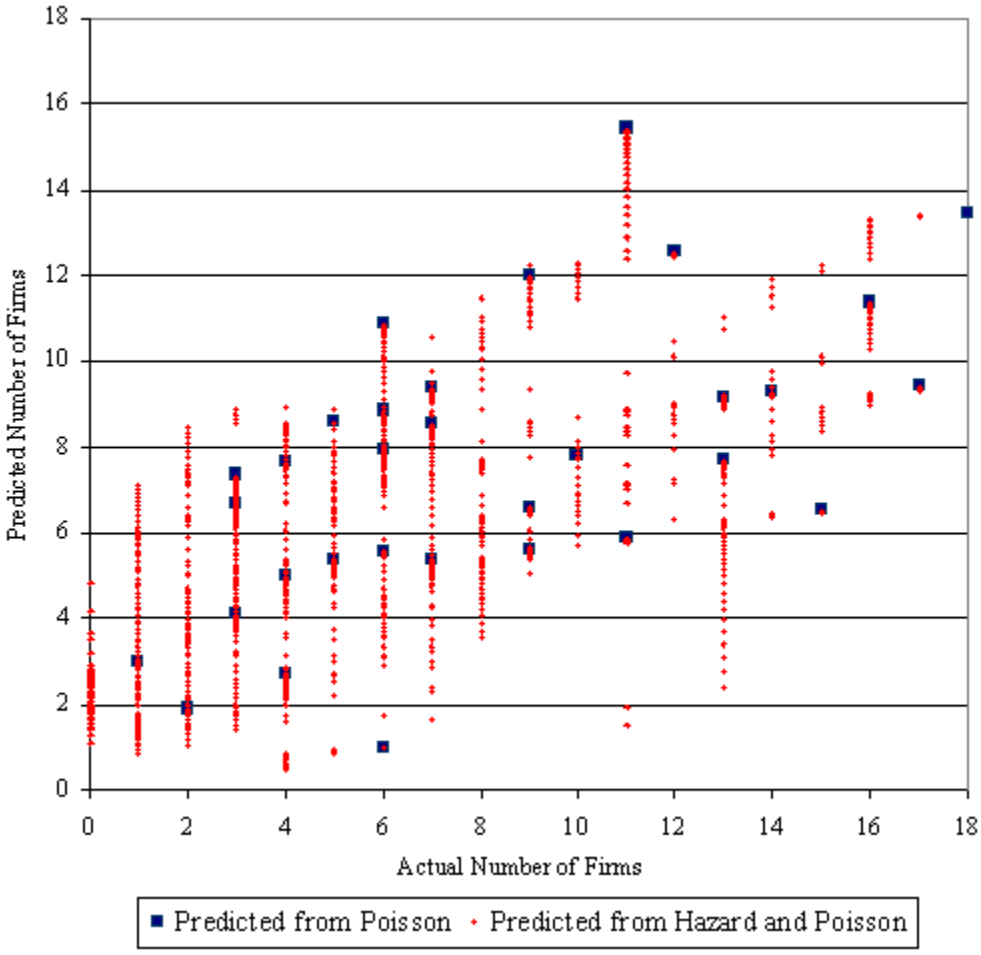
data source: IMS Health, Generic SpectraTM

Figure 4
Predicted Number of Firms



data source: IMS Health, Generic SpectraTM

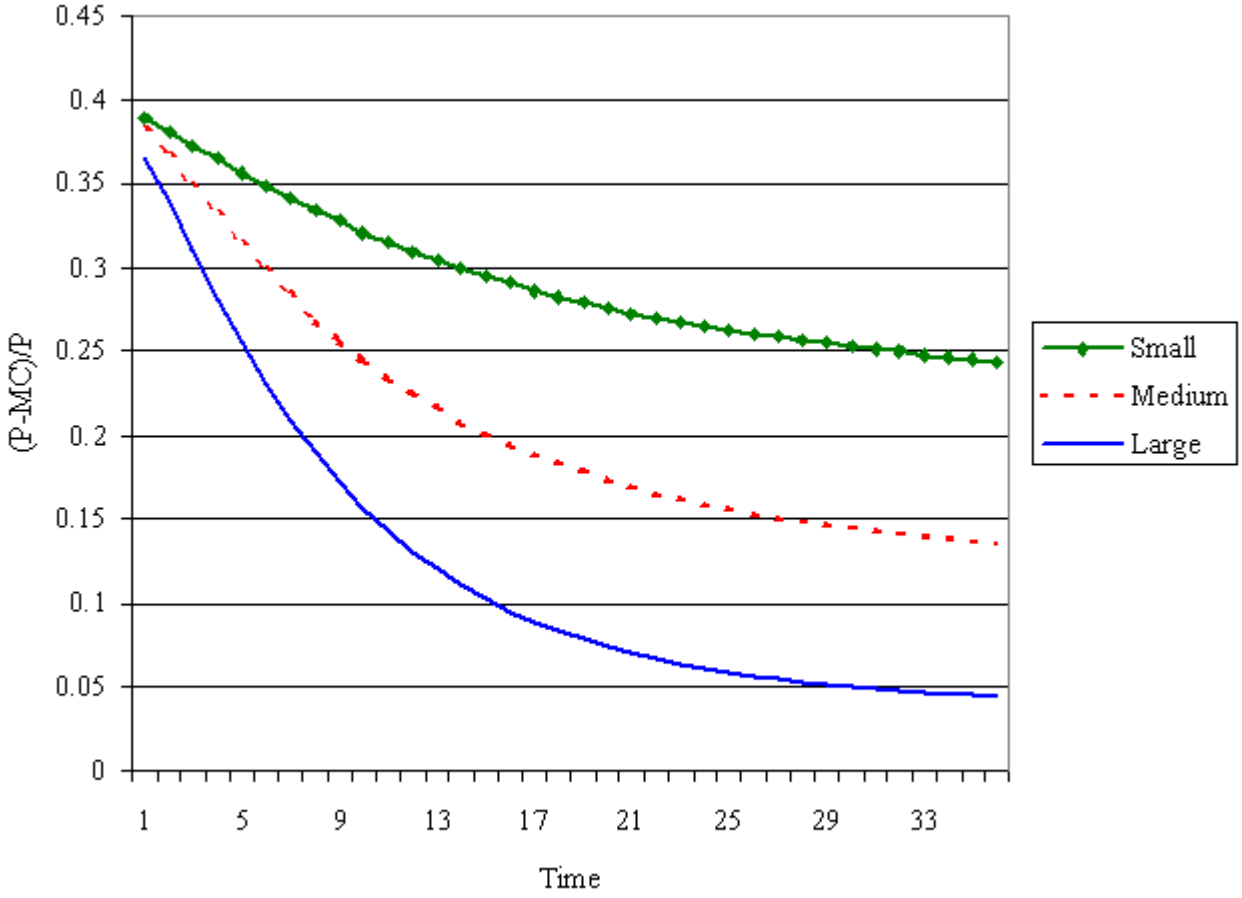
Figure 5
Generic Entry Goodness of Fit



data source: IMS Health, Generic SpectraTM

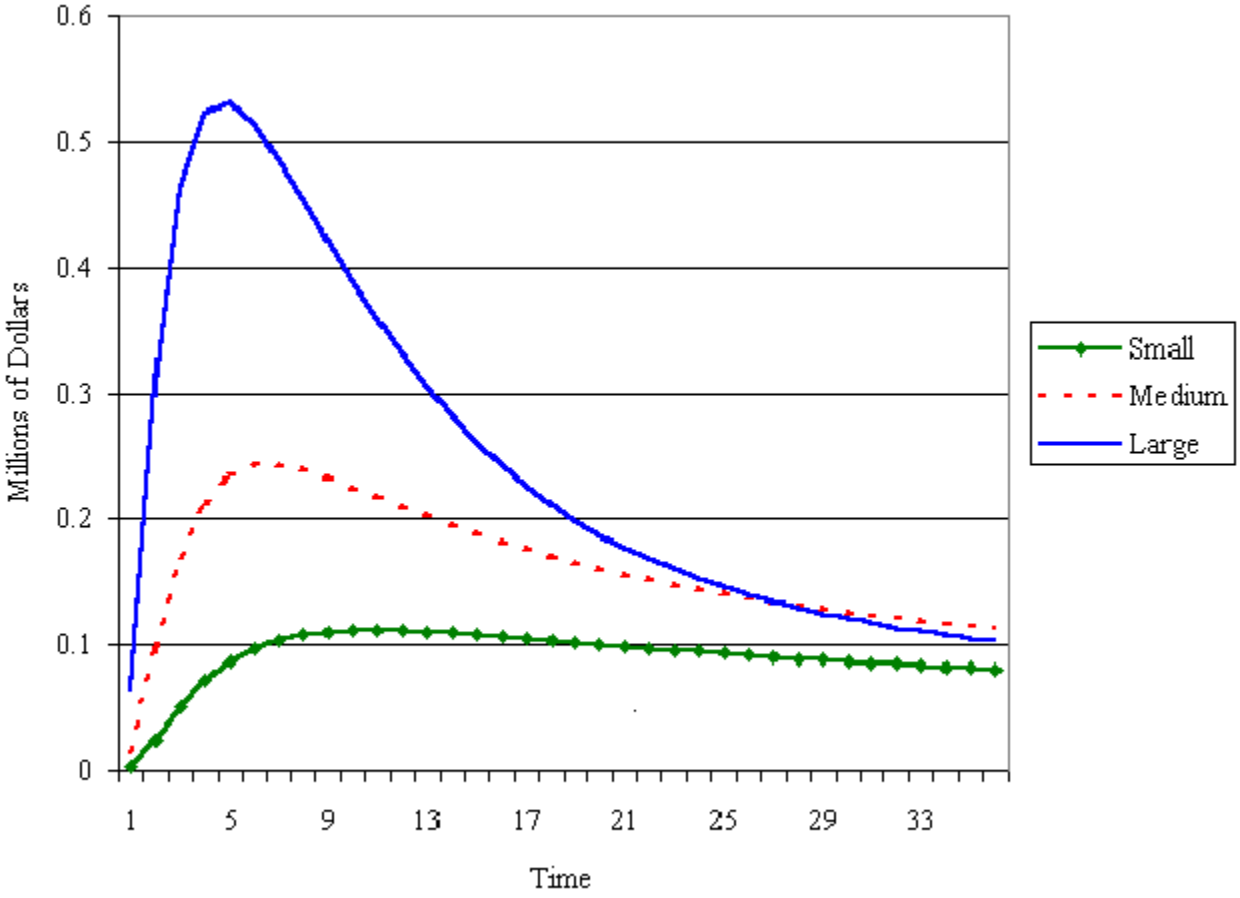
Boxes correspond to number of total applicants for ANDAs. Diamond shapes corresponds to the panel of observations on the number of firms are different points in time.

Figure 6
Expected Margins



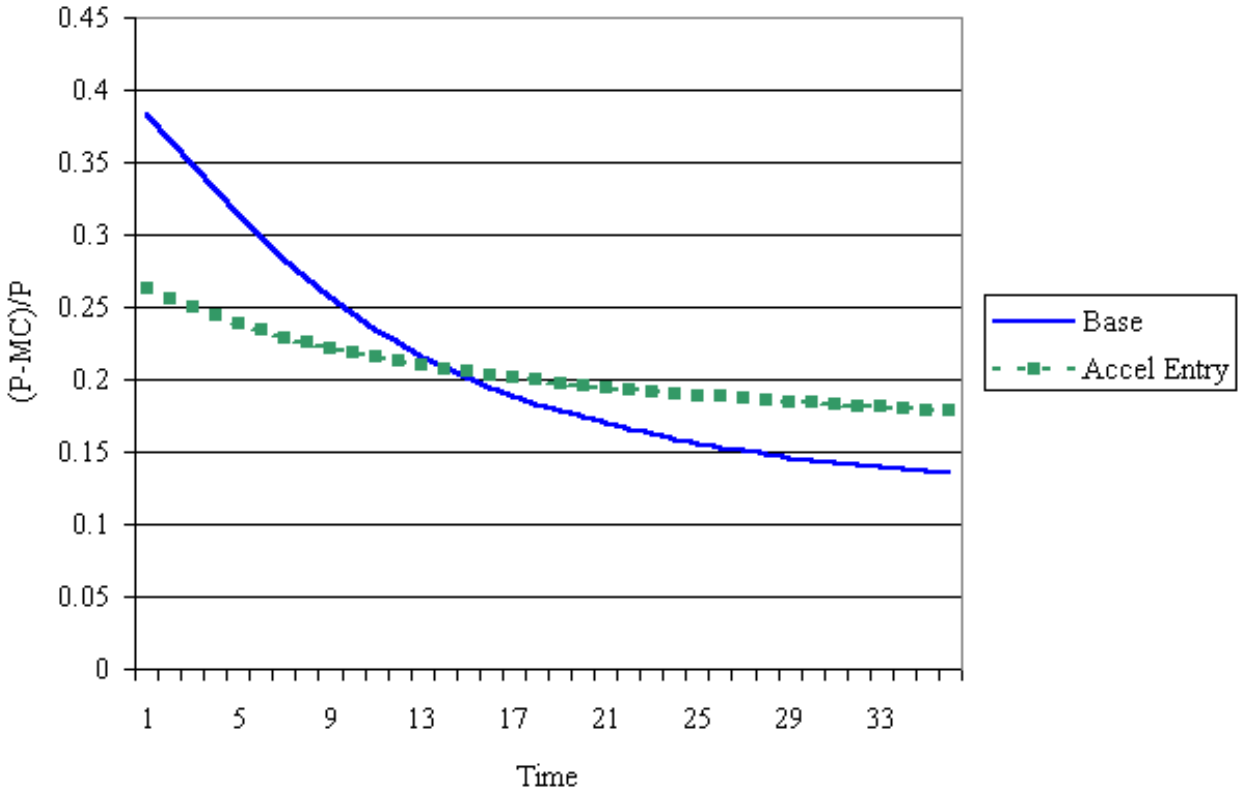
data source: IMS Health, Generic SpectraTM

Figure 7
Expected Industry Profits



data source: IMS Health, Generic SpectraTM

Figure 8
Margin Paths Over Time



data source: IMS Health, Generic SpectraTM