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ABSTRACT

In this paper I use data on all generic drug approvals granted from 1984-1994 to examine whether heterogeneity among potential generic entrants can be used to predict which firms will choose to enter a particular market. The findings suggest that a firm's portfolio characteristics, namely, its previous experience with a drug or therapy reduces the cost of preparing an ANDA and increases the probability of entry. A subsidiary's *parent's* experience is not generally significant in predicting entry of the subsidiary. Firms also prefer entering markets that are similar, in terms of revenue and sales to hospitals, to markets already in their portfolios. On both scientific and marketing dimensions, the evidence shows that firms are specializing. I explore several different ways of constructing the set of potential entrants and find that the results are not affected by methodological variation. Standard IO theory suggests that profits per entrant will decline in the number of entrants. Previous research has found that generic prices depend on the number of generic entrants, and the results presented here show that the total number of entrants increases with the size of the market (revenue). These findings imply that generic firms face a negative competition externality which makes their expectations about who else might be planning to enter any given market important in the entry decision. The limited evidence on entrant beliefs supports this conjecture as do several features of a regulatory upheaval when firms began entering different markets than they had in the past.

Fiona M. Scott Morton
Graduate School of Business
University of Chicago
1101 East 58th Street
Chicago, IL 60637
and NBER
fionasm@gsb.uchicago.edu

I. Introduction

A firm's decision to enter a particular market is one of the most important economic actions in a market economy. The number of firms in a market and distribution of market share have long been known to affect price levels and consumer welfare. Most research in this area uses the convenient assumption of symmetric firms, although this is of course not a good representation of reality. In contrast, this paper takes explicit account of heterogeneity among potential entrants to predict *which* firms are likely to enter which markets. In particular, it examines the entry choices of heterogeneous generic pharmaceutical firms and finds that they specialize along both scientific and marketing dimensions. The history and experience of a firm that lead it to enter particular markets can be thought of as firm 'capabilities,' in the sense that word is used in the business press. This industry provides a setting where a firm's capabilities can be explicitly measured and the result of using existing capabilities or developing new ones can be observed.

The entry decision is complex because the number of firms in a market affects the payoff to any one of them from entering that market; each entrant creates a negative externality for the others that can be severe. Profits earned by an entrant firm therefore depend on entry decisions of other firms. Entrants sink entry costs simultaneously because firms do not typically announce their entry plans and the FDA does not reveal whose application it has received. The timing of the game, combined with research showing generic prices (and presumably profits) depend on the number of generic entrants, implies that generic firms face the difficult problem of how to form expectations about where others will enter. Those expectations will affect its own entry decisions.

The question of which firms are expected to enter -- as well as do enter -- which markets in a simultaneous game is important. For a generic pharmaceutical manager making entry decisions for his or her firm, it is clearly a crucial problem. I discuss and examine how a generic pharmaceutical firm might form expectations of rivals' actions and what firm equilibrium strategies might be. I argue that repeat players may use an entry strategy that provides stability of expectations: specialization. Specialization based on both scientific and marketing characteristics is natural because it reflects lower costs and provides a well-understood way to form conjectures about where competitors will enter.

It is possible to conduct an empirical study of firm decision-making in the generic pharmaceutical industry because entry regulations create relatively good experiments and the regulatory agency, the Food and Drug Administration (FDA), generates data that are available to researchers. In this paper I use data on all generic drug entries from 1984 to 1994 to examine entry patterns and

specialization. In particular, I explore whether generic entrants are choosing markets based on past experience as measured by characteristics of their portfolios. I find that a firm's previous experience with a drug or therapy increases the probability of entry into a similar market. The experience of a firm's parent on various dimensions is generally not helpful in predicting entry, above and beyond the firm's (subsidiary) experience. Marketing similarities between the entry opportunity and characteristics of the firm's portfolio such as market revenue and hospital share are also important in explaining entry. Additionally, I show that larger markets, those that attract more entry, are markets with more sales to hospitals and those where the drug treats a chronic condition.

In 1989 a major scandal erupted when various illegal practices were uncovered in the generic drug industry. I present results showing that the subsequent regulatory upheaval re-weighted the components of entry cost and disrupted established industry practices, including the pattern of specialization. Firms began to enter markets that looked different, rather than similar, to markets they were already in.

II. Institutional Framework and Timing

A firm that invents a new drug must get approval from the FDA by showing the drug is safe and effective. A New Drug Application (NDA) reports tests showing safety and efficacy and is typically expensive to construct and takes many years to be approved. A firm taking this route is called an innovator and the product is typically promoted under a proprietary brand name. In 1984 the pharmaceutical regulatory regime was significantly altered by the Waxman-Hatch Act. This legislation, among other things, allowed generic firms to submit Abbreviated New Drug Applications (ANDAs) for drugs approved since 1962. A flood of new ANDAs was filed in response to the law. The advantages of the ANDA process are summarized in the quotation below.

> "The benefit of the ANDA process to generic manufacturers is that it does not require these companies to repeat costly clinical and animal research on active ingredients or finished dosage forms already found to be safe and effective. A generic drug must contain the same active ingredients; be identical in strength, dosage form, and route; be bioequivalent; and be manufactured under the same strict standards as the brand-name drug to gain FDA approval." (Frost and Sullivan report (1994))

Some firms submit both NDAs and ANDAs, but the vast majority specialize in one or the other. The other main type of firm in the industry is a "generic firm" that sells generic products. Figuring out how to manufacture the drug and performing the bioequivalency studies required for the ANDA can take from several months to a couple of years depending on the formulation of the drug, the effort and skill of the firm, and the availability of good suppliers. The application process requires factory inspections from the FDA and independent laboratory tests of several preliminary batches of the product. A firm must therefore be ready to make the product -- new equipment must be purchased and operational, for example -- months before the firm is legally permitted to begin selling it.

The time between submission of the ANDA and granting of approval from the FDA averaged about seventeen months over the 1984-94 period, although annual averages have varied greatly over the last decade (Scott Morton (1996)). Therefore, a firm must start applying for permission to manufacture a specific drug two to three years before its patent expires if the entrant wishes to be active in the market immediately following patent expiration. Historically, many firms have not applied in a timely fashion despite the well-known fact that a firm that is first into a market and the only generic for even a few months earns large profits. A useful rule of thumb is that generic markets for most drugs do not last very long compared to the product life of a patented and branded drug. By the time all the patents on a drug have expired, it is relatively old technology and superior therapeutic substitutes are very likely to have been invented. Demand for the drug in patient days and revenue begins to fall after patent expiration; not many drugs remain major markets five years after patent expiration. (See Caves et al. (1991) and Stern (1995).) Thus, we should not see profit-maximizing generic firms wasting any time in entering a market -- once the relevant patents expire -- and the model will not build in an option for delay.[1]

The FDA does not reveal what applications it has received from which firms; *no one can receive information on pending applications from the FDA*. However, firms may announce their own intentions or actions. An (admittedly incomplete) examination of annual reports and interviews suggests that announcing is rare. Industry participants claim they do not want to reveal that they think a particular market is a good one to enter. Since all firms have access to essentially the same information, this claim does not seem to be very convincing. However, another firm's opinion could function as an additional signal of value for what could be an unknown, but common, value. Additionally, although a firm might announce it has applied for a particular drug, there is no guarantee approval will be granted in the time frame anticipated by the applicant. The announcement is not credible. The firm could still be missing some tests or have a sloppy application. At the last minute, the FDA could decide a trial did not meet

[1] Bolton and Farrell (1990) model an option for delay in their entry game.

FDA standards and must be redone; or the factory might fail a late inspection. A year's delay (which could easily happen due to regulatory uncertainty) can cause an application that was submitted and announced to be approved *after* that of a competitor responding to the announcement. A firm therefore cannot precommit to a market with an application announcement. The result of this lack of announcing is that generic firms are effectively sinking entry costs simultaneously.

The pharmaceutical industry is characterized by high fixed costs (invention) and low marginal costs (production). Although an ANDA and the research involved are much less costly than basic research and NDAs, entry cost is nevertheless significant for a generic drug project where there is likely to be vigorous price competition. The average size of brand markets in the sample that later attract one generic entrant is $22 million. Generic products usually capture about half of molecule volume, although at prices 30-50% lower than the brand price. Thus per firm generic revenues are likely to be less than $10 million per year, perhaps as low as $5 million for a product (perhaps with multiple concentrations). In interviews I have been told that filing an ANDA costs one quarter of a million dollars, twenty million dollars and various figures in between. This order of magnitude matches a one-entrant market size, although ANDA costs clearly must vary across drugs and firms. Generic drug industry participants exhibit great concern over excess entry, falling prices, and the effect on profits. Stories of unexpected failures due to the appearance of extra entrants are common. If fixed and sunk costs were zero, marginal cost pricing would provide an acceptable rate of return, no one would be willing to charge less than marginal cost, and manufacturers would not worry about making a drug on which they are losing money overall. I therefore make the assumption that fixed sunk costs are an important component in the project's budget.

The FDA imposes no requirement to produce once an ANDA is granted. Thus an unused but approved ANDA is an option, available to be used if prices rise, rivals exit, or the market becomes more attractive for any reason. Exit -- formal withdrawal of the ANDA -- is not an attractive alternative unless price is expected to be below marginal cost for the life of the drug (where marginal cost includes the opportunity cost of using equipment to make other drugs). There are several categories of ANDA withdrawal: the firm may discontinue the product, the product can be withdrawn by mutual consent, the firm might violate an FDA standard so that the FDA withdraws the ANDA, or the product may be found not to be efficacious (all NDA and ANDAs for that product are withdrawn). The last two (and maybe three) reasons are cases where the FDA is forcing the firm to exit, rather than situations where the firm chooses to leave the market because it is unsatisfactory. An ANDA can be sold or transferred easily with the physical production site, or if the original manufacturer becomes a contract manufacturer for the new owner. Buying an ANDA without its factory means new tests and inspections must be carried out to the

FDA's satisfaction; this is not necessarily faster or cheaper than starting from scratch. Thus entry by a particular firm is a fairly irreversible decision; the costs that can be recovered upon exit from one drug (and not a factory) are close to zero.

In 1989 what became known as the "generic scandal" broke out. Investigations by the US Attorney's office in Baltimore began in 1988, and by the end of 1989 had uncovered several cases of bribery in the generic drug approval process. Four reviewers at the FDA were found to have been taking bribes in return for speeding approval of the bribing firms' ANDAs.[2] Additionally, some firms were found to have submitted the original branded product as their own in tests designed to compare a potential generic to the brand. The "generic" drug would pass the test with flying colors.[3] In one case a generic firm was actually selling the recoated branded product.[4] Later in the investigation, violations of manufacturing rules were also uncovered. The fallout from these discoveries greatly affected approvals and manufacturing in the following several years. The FDA's Generic Drug Division fired many reviewers and the remaining reviewers proceeded very cautiously and slowly. New reviewers were hired, ethics standards promulgated, and the division was reorganized. ANDAs granted from 1989-1993 took years longer than usual to be approved.

Additionally, although this was not a concern of the FDA investigation, it became known that industry participants had been bribing employees of rival firms for information on approval activity. Many firms were engaging in gossip and inquiry into the entry plans of rival generic firms. The people in the industry included in my informal poll claim much of this activity came to a halt at the time of the FDA scandal and investigation because managers were worried that their behavior would be interpreted as unethical or illegal. This left firms with much less information on the entry plans of competitors.

The discovery of irregularities in the approval process led to a review of what are known as "good manufacturing practices." Many more, and stricter, inspections of manufacturing facilities were carried out than had gone on previously. Many firms were forced to withdraw products from the market for a period of months -- years, in some cases -- until their manufacturing satisfied the FDA. During the time the products were off the market the firms were upgrading their manufacturing process, suppliers, or procedures and training. The regulatory changes took place over several years and involved political actors from Congress, Health and Human Services, the FDA, and law enforcement. The criminal

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[2] The investigation was launched because Mylan became suspicious that its drugs were not getting approval as quickly as competitors and found incriminating evidence in the garbage can of their FDA reviewer. (Chicago Tribune, Nov. 22, 1992)

[3] The independent labs doing the testing noticed when the coating chipped off, the brand logo was visible!

[4] This hardly seems like a profit-maximizing strategy.

investigation was still going strong in 1992, although most convictions had been secured by then.[5] Overall, the period from 1988 to at least 1992 was a time of great upheaval and uncertainty in the generic drug industry.

III. Model

The entry game and the role of competition and fixed costs has been addressed by a number of researchers (Bresnahan and Reiss (1988, 1991b), for example). These models predict the total number of entrants in a market, partly because this piece of information is of great interest to I.O. economists and policy makers. However, the issue of exactly which potential entrant ends up entering is undetermined in many game theoretic models of entry. Typically, entrants are modeled as drawn from a limitless pool of identical potential entrants, probably an unrealistic assumption for most markets. Often it is difficult to measure and model heterogeneity among potential entrants; additionally, heterogeneity has a strong impact on form of the entry game. Berry (1992) addresses the question of which entrants enter which markets, as well as how many entrants enter a market, in his study of the airline industry. However, the generic pharmaceutical industry is characterized by simultaneous entry, rather than sequential, as in the Berry model. The following simple model illustrates its main features.

The game has two periods. In the first period firms choose whether or not to enter specific markets by sinking their fixed costs. In the second period production and sales determine net profits. Profits will depend on the number of entrants in two ways. First, equilibrium price will decline in the number of entrants. (Price will hereafter mean generic price.) Despite the fact that the product is very homogeneous and the industry looks like it should exhibit Bertrand pricing, several studies have documented that generic prices fall steadily with the number of generic firms (Caves et al. (1991), Frank and Salkever (1995), Wiggins and Maness (1995)).

Secondly, an increasing number of firms means smaller quantity sold for each, all else equal. I assume a molecule's market size is fixed because products are relatively old by the time their patents expire; the brand has expanded the market as much as it can. The drop in price due to the introduction of generics does not increase total quantity sold of the molecule, probably due to the price-insensitivity of doctors (see CWH (1991)).[6] However, lower generic prices will increase generic quantity at the expense of brand quantity. If total generic quantity sold is Q, and n is the number of generic firms, I assume Q/n falls with n, despite the expansion in Q due to lower prices. The important feature of the model is that

[5] Chicago Tribune, Nov. 22, 1992 p 13A

profits decline with an additional entrant. This will hold, and the coordination problem will be particularly important, when both price and quantity sold per firm decline with additional entry. The expression below represents total profits for firm i earned in market j.

$$\Pi_{ij} = (p_j(n) - c_{ij})q_{ij}(n) \; - \; F_{ij}$$

where price (p) and quantity (q) depend on the number of firms (n) in the manner described. c_{ij} and F_{ij} denote the marginal cost and fixed entry cost respectively that are specific to firm i and market j.

The idea here is that there is heterogeneity across firms and it shows up in firm costs. The model will produce the same entry rule whether firms differ in marginal cost, fixed cost, or both.[7] For the purposes of discussion, for the rest of the paper I will assume that it is the fixed cost of entry that differs across firms and markets, while marginal costs are constant across firms.[8] Firms differ in the skills of their research group, suppliers, equipment, etc. which will affect ANDA cost. Drug markets also vary in how difficult a drug is to formulate and test, and therefore how much an entrant will spend to enter. The basic implications of this sort of model are that in larger markets more firms will find it profitable to enter, each additional entrant will lower the net profit of all other entrants, and lower cost firms should enter where higher cost firms should not. The analysis in the paper will test these implications.

In equilibrium firms choose markets to enter based on differences in past experience. Each firm has a fixed cost F_i that is observable and common knowledge. Strategies are enter if $F_i<F^*$ and stay out if $F_i>F^*$. F^* is defined such that firms with costs higher in the distribution than F^* earn negative profit when all firms with $F_i<F^*$ enter. No mistakes occur under this scheme because each firm knows where it lies in the realized distribution of fixed costs for the market and will not enter if there is not "room" for it. The postulated strategies form a Nash equilibrium because the low cost entrants will earn non-negative profit when the high cost firms stay out and therefore prefer to enter, while the high cost firms

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[6] The elasticity of demand is clearly not zero at all price levels. However, in the observed price range, elasticity of demand for a molecule is very low.

[7] Later in the paper, I use drug experience variables to proxy for fixed cost differences across firms. Experience variables will also pick up any experience-based differences in marginal cost. Other marginal cost differences come from the batch production nature of pharmaceutical manufacturing. The marginal cost of a batch (rather than a pill) includes the opportunity cost of capital. A firm with strong demand for more drugs than it can produce at one time has an attractive outside option, production of one of its other drugs, for any given piece of capital. Since the quality of the outside option will vary across firms and over time, the marginal cost of a batch will also vary. The problem of opportunity cost of a batch is an important factor in the firm's decision to enter a market, and it is impossible to measure without detailed plant-level data. Finally, there will be some marginal cost differences are due to characteristics of the production process that I cannot measure or control for. These final two sources of marginal cost differences are unaccounted for in this study.

will only lose money if they enter and the low cost firms also enter, so they prefer to stay out. A firm's fixed cost level will help predict entry in this game, as will the cutoff level for the market, F*.

All firms can work out the cutoff point in the fixed cost distribution. The firm enters if its own fixed cost falls below that cutoff level.

$$pr(entry_{ij}) = pr(F_{ij} < F_j^*)$$

where F_j^* represents the cutoff fixed cost level for market j.

The model most closely related to this problem is that of Dixit and Shapiro (1986). They describe a case of N identical potential entrants vying for spots in a market that "holds" only M firms, and build a model based on mixed strategies.[9] There is a probability of entry from which each firm can calculate its expected profits from entering or not (using a binomial probability density). The equilibrium probability of entry is derived from the indifference of a firm to choosing enter or not enter.[10] Dixit and Shapiro point out that choosing a pure strategy equilibrium in which only M firms play "enter" is artificial unless the reason for choosing those M firms is incorporated into the game. The model and the empirics below do incorporate reasons for particular firms to enter, allowing the firms to do better than just flipping a coin, and allowing the researcher (and presumably competitors) to predict entry, although not perfectly.

Firms bear considerable risk due to simultaneous entry in the standard model of competition described above. "Over-entry" results in a lower than expected market price, volume, and profits, and the *ex post* desire not to have entered the market in the first place. Price might stay above marginal cost, and yet below a level that yields zero profit on the project, without firms having the incentive to exit the industry. "Under-entry" of course, produces economic profits until additional firms are approved to make the drug (which normally would occur within two to three years). At any moment, each firm is trying to enter only "good" markets. Each is trying to be in a market with the equilibrium, or fewer than equilibrium, number of firms.

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[8] The correct assumption undoubtedly varies by market.

[9] Large markets cannot be served by only one firm because each firm has an upward sloping supply curve due to the opportunity cost of capital (using all its machines to increase output of one drug) and the risk associated with dedicating a large part of the firm's capital to one drug.

[10] The probability of entry times the number of potential entrants can be greater or less than the number of firms which can earn positive profits; which direction the inequality goes depends on the shape of the profit function. Dixit and Shapiro show that for convex profit functions (Cournot, for example) on average there will be over-entry.

This raises the difficult problem of how generic firms make entry decisions in conjunction with other firms when they cannot explicitly coordinate. Bolton and Farrell (1990) examine the classic problem of two firms deciding whether or not to enter a natural monopoly market. They are primarily interested in when a central planner can do better than the decentralized case of each firm deciding based on its own private information. The randomness inherent in not coordinating will result in "mistakes." If firms could avoid those mistakes by using the services of a central planner, welfare would be increased. The increase in social welfare in their model comes from the reduction in "duplication" (both firms enter) and "delay" (both firms wait for the other to enter). These are analogous to the generic pharmaceutical industry where producer surplus is saved if the fixed cost of entry is not paid twice and consumer surplus is increased if the entry occurs quickly so that prices fall. However, Bolton and Farrell show that if private information, perhaps about the entry costs of the two firms, is sufficiently important, central planning will result in lower total surplus.

It is difficult to isolate evidence of the negative externality problem from the 'low-cost firms should enter' story. If it is the case that an entrant's profits depend on the number of other entrants in the market, then an entry decision cannot depend on a firm's own characteristics alone. Because of oligopoly or competitive interaction, the entrant's beliefs about the actions of other entrants will affect its entry decision.[11] Each firm has an interest in not entering if it believes too many other firms will enter. Beliefs about other players' strategies determines which equilibrium (of many) is selected. Any set of beliefs that coordinated firms' actions would work: geographic, alphabetic, phases of the moon, etc.. However, beliefs are difficult to measure and I will be unable to use them in the empirical analysis.

The cost story, on the other hand, reflects a situation where there are firms with sufficiently high fixed costs that they cannot earn positive profit even if given an entry slot; beliefs about who else will enter do not affect entry decisions. However, if any firm with costs below a certain threshold can earn positive profits in the market, then market size should not be a helpful predictor of entry. The reason more firms enter larger markets is because they can fit - despite the business stealing efforts of their rivals. Thus the significance of market size measures in predicting entry will provide some evidence for the existence of negative competitive externalities in the industry. I use observable characteristics of the firm and its portfolio to proxy for firm fixed costs of entry. Estimation relies on those firm characteristics as well as knowledge of actual and potential entry events and measures of market size such as revenue.

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[11] Notice that beliefs matter only among firms that could make a profit if they were given an entry slot. For example, it is easy to construct an example of a natural monopoly where any firm in the cost distribution could earn non-negative profits as a monopolist, but none could earn non-negative profits in a duopoly.

IV. Data

The data I use to examine entry behavior are ANDA approvals granted from 1984-1994. A firm becomes part of the dataset if it is granted an ANDA in the time period; a particular drug becomes part of the dataset if it is applied for in an ANDA approved during this time period. Each approved ANDA is an observation. The FDA provides the submission date, the approval date, the applicant name as well as characteristics of the drug such as ingredients, form, route (into the body), and strength. I recode the FDA's detailed form and route descriptions into five basic categories according to the type of machinery needed to manufacture a drug with certain characteristics and the cleanliness standards required in the manufacturing facility. The first category is oral solid, which forms the bulk of the observations in the data. The second group is injectable drugs, third is topical preparations, followed by oral liquids, and then ocular drugs.[12] Note that the ANDAs making up the dataset are not a sample, but the complete universe of ANDAs approved in the United States during the time period 1984-94.

I have calculated or collected information on additional variables such as the firm's primary type of product (brand or generic) and the parent of the applicant (if it exists). A drug's therapeutic class is assigned according to the description under "indications" in the 1993 volume of Physician's GenRx, a comprehensive pharmaceutical reference. There are approximately thirty therapeutic categories in the dataset. I also include the date legal restrictions on entry into the drug expire. Simply including the last patent expiration date is not a good method because, first of all, there are usually several patents in force and it is not obvious to the uninformed observer which one is the binding patent. Also, the FDA may have extended exclusivity rights due to excessive approval times, or may have granted an exclusivity period for a new route or dosage form, among other innovations. I resolved cases where the published dates for these restrictions did not match the entry pattern by telephoning patent lawyers at the firm in question. Although time-consuming, this method was quite successful; I was forced to exclude only a few drugs from the final estimation due to uncertainty about when generics could enter the market.

Additionally, I know the revenue of the brand in the year before restriction expiration (or 1984 if restriction expiration is pre-84). These data were collected from IMS (a pharmaceutical data collection firm) Drugstore and Hospital Audits of the appropriate year. Some approved ANDAs are for drugs that experienced their first generic entry pre-Waxman Hatch.[13] Pre-Waxman-Hatch entry will obviously affect the attractiveness of the market for later generic entrants, so I collect information on the number of

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[12] The sixth category is "other" which only contains an aerosol preparation.

[13] The timing and variation in the application and FDA approval processes are described in detail in Scott Morton (1996).

generic entrants in the market before the regulatory change. The IMS revenues include revenue of all producers in 1984, rather than just brand revenue, for those drugs that have generic entry before 1984.

The FDA will release information on all approved ANDAs, including the date the ANDA was submitted to the FDA. However, information on ANDAs that were never approved, or have not been approved yet, is not released to anybody. Therefore, markets that open up in later years may have entrants still waiting for approval that the dataset does not show. A firm whose application is unsuccessful after some time at the FDA might withdraw it rather than continue an unsuccessful process, and the researcher would never observe the attempt at entry. I do not have any information on how prevalent this type of outcome might be. It will affect my results only to the extent that "good" entrants give up and do not enter due to regulatory delay. If all low-fixed-cost entrants persevere, then the only effect on the estimation will be that the pool of potential entrants is missing a few true members.

I do not include ANDAs that are filed for a "bulk" product, an intermediate step *en route* to the final pharmaceutical product. Also, a separate ANDA is required for each concentration, for each packaging type in the case of injectables, and sometimes for different manufacturing plants. I compare observations to locate and remove the duplicate ANDAs in my dataset, keeping the application with the earliest submission date. These two steps reduce the number of observations in the dataset to 1233. Each remaining ANDA or NDA is a unique combination of drug, form, and restriction expiration. A few products have multiple concentrations with different patent expiration dates; those products appear more than once in the dataset because the concentrations are effectively separate markets.

The theory discussed above says that firms that could potentially enter, but do not, are important players in the entry game. Normally it is very difficult to find any information on the existence, number, or characteristics of potential entrants who do not end up entering. However, with the data described above, I am able make a start at constructing a set of potential entrants. The basic dataset contains the entry opportunities actually taken by firms. The unit of analysis for *potential* cases of entry will be the firm-opportunity, defined by a firm name and a patent expiration date. For all the methods described below, potential entrants are assumed to decide if they want to enter or not at the time of the first entrant's ANDA submission date. This is a strong assumption, but in the absence of firm-level scheduling information, it seems to be the best that can be done.[14] The first method for defining the set of potential entrants uses the product of all firms and all drug markets that are in the sample to make the complete set of firm-opportunities. All firms and drugs that show up in any ANDA approved from 1984-1994 are interacted (once each) to form a large dataset of all possible firm*drug combinations. Those

[14] Using the time of the second ANDA to be submitted does not affect the results.

combinations that did not see actual entry are assigned a zero as the value of the dependent variable, whereas those that did result in entry get a one. This approach obviously misses potential entrants that end up never entering the industry at all. I employ this methodology a second time by using the parent company as the firm unit rather than the subsidiary. The parent dataset is somewhat smaller than the subsidiary-based dataset.

The vast majority of observations in the dataset created by Method One do not experience entry (98%). The datasets created by the first methods include "firm-opportunities" in years when the firm has not yet come into existence. This might not be realistic, although a firm does have to make its first entry sometime and it probably has some choice over which market will be its first. The second potential entrant dataset I experiment with limits firms to considering entry into markets that open *after* they have submitted an ANDA for something else; a firm is not allowed to be a potential entrant until it has been a real entrant. The second method cuts down on the number of non-entries for each potential entrant. The final, and most restrictive, method of constructing potential entrants allows only firms with experience with the particular form in question to be potential entrants. The idea here is that there is a type, a "pill firm" for example, that is visible and known to the industry. Only these firms will enter pill markets. If a pill is about to lose patent protection, only those firms that have a pill in their portfolio or will have a pill in their portfolio by the end of 1994, can be considered potential entrants.

For all three methods of constructing potential entrants, information about firm products in existence before 1984 must be included. The pre-84 information is the stock of products already being made by the firms in the industry. I record here the portfolios of all generic firms in the dataset and the portfolios of all 'brand' firms in the same corporate entity as a generic firm in the dataset. These observations are added to the 84-94 actual entries and potential entries. The final dataset includes the 1984 stock of drugs produced by generic corporations and the flow for the following eleven years.

Some observations cannot be used in the estimation, but are kept in the dataset so the portfolios are complete. These observations mostly have irregular regulatory or restriction information. For example, there are a few ANDAs that have a reported application date *later* in time than the approval date.[15] Other unused observations are those where the applicant primarily manufactures branded drugs, but has also applied for one or more ANDAs; such a manufacturer could have many reasons to enter a market that are beyond the scope of this paper. Applications received before November 1984 are not used for estimation since the new regulatory regime had not yet started. Means of the variables and counts in the different datasets are reported in Tables Ia and Ib.

The factors I use to measure the fixed cost of a generic manufacturer are indicators of whether the firm has previous experience with some aspect of the current entry opportunity. The main idea is that it is much cheaper to prepare an ANDA that requires equipment or procedures a firm already has in place. For example, a firm preparing an ANDA for its first topical drug has to purchase a "cream line," years before it can be used regularly, and the firm's chemists have to work with tests and FDA standards that are new and unfamiliar. A firm that already makes creams will have much lower costs of preparing the same ANDA. An application that includes an ingredient the firm has used before in another product lowers the cost of preparing the ANDA because the firm already has FDA-certified suppliers and its research team is familiar with the properties of that supplier's product. The cost of preparing the ANDA may also be lower if the research team has experience with the therapeutic class; FDA standards for absorption into the body vary according to the therapeutic goal of the drug. Additionally, a familiar therapy or a product that is part of a drug family may create distribution economies (in addition to lowering application costs) for the firm that already manufactures the related products. Retail establishments want to carry a complete selection and may prefer to purchase them all from one manufacturer. Distribution costs are probably not sunk, but can certainly be included in fixed costs.

I can observe past applications and check if an ingredient, family form, or therapeutic class is similar to the current entry opportunity. I define a drug "family" to be closely related drugs that cannot be classified as the same thing -- two iron compounds, for example, or the 5 or 6 different kinds of erythromycin. A family match is a slightly weaker version of an ingredient match. The components that make up the cost of preparing an ANDA are listed in the following table. Below each category is a description of its expected response to previous firm experience.

component of fixed cost	Ingredient	Recipe and Testing	Capital	Distribution
large effect?	Large	medium	large	large
reason	suppliers located and certified; compound properties known	experience with form, family & ingredient reduces research resource expenditure	experience with form reduces cost to opportunity cost of a few batches rather than purchase price for 1-2 years	if distributing therapy already, reduces effort to find customers

[15] According to the FDA this is because a firm had to withdraw an ANDA to meet a new standard and the official resubmission date then ended up being after approval had been granted to make the drug.

The number of matches between the current observation and the drugs in the firm's portfolio at the time of the current observation is calculated for each of the measures listed. The past experience of the firm is compared to the current application opportunity by matching values for the current opportunity's therapeutic class, specific ingredients, drug family, and manufacturing form with those same characteristics of drugs in the firm's portfolio.[16] The match variables measure the number of times a firm has had experience with the particular compound, therapeutic area, or form that represents the new entry opportunity.[17]

Sometimes a patent or exclusivity restriction applies only to one strength of a drug out of several -- usually a strength approved later than the initial products. The additional patent prevents a generic from entering that strength at the same time as the others of the same drug and form.[18] Because the second market causes additional entry cost and delayed sales, total drug revenue will not accurately reflect market size. I include the revenue from the second concentration as a separate variable; it will have a negative coefficient if the delayed revenues make the market less attractive.

A non-trivial question is whether the unit of analysis should be the subsidiary or the parent firm. Subsidiaries of a firm might have their own research labs and be fairly free-standing, or the firm might be centralized. In the centralized case, the corporation's research lab submits different ANDAs with the "applicant" (subsidiary) name that will be most attractive to the group of physicians or consumers the corporation is trying to target with the drug. An ANDA may be submitted legally in the name of any subsidiary and after approval it is easy to change the applicant name to that of a different subsidiary. To allow for either case, I create variables based on both the applicant name and the parent firm for use in the analysis. If the parent is outside the pharmaceutical industry, there is no relevant information to be included.

A parent match variable is clearly one each time the equivalent variable for the subsidiary is one; if subsidiary B has made a particular form before, then, in looking across all drugs belonging to parent B,

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[16] A particular problem in linking the two datasets is the changes in firm names and ownership of an ANDA over the 12 year sample period. Simple name changes were easy to account for. The portfolios of firms that merged were adjusted to create a combined portfolio. The remaining changes in ownership appear to be genuine transfers of an ANDA from one firm to another. There are about 50 of these observations in the dataset.

[17] One might think that firms have a strong incentive to enter several related markets at one time to spread the cost of learning about a new form or therapeutic area over several projects. For example, a firm purchasing a cream line might have decided creams were generally a good area to go into and might apply for two or three cream ANDAs in close succession. Seventeen out of fifty-two cases of firms entering a new form show signs of economies of scope; the firm enters a second market in the same form within six months of the first.

[18] In one case the additional strength was not approved until years after generic entry, so when applying, generic firms might not have known of its existence. In all other cases, the brand's version of the late concentration was approved before the first patent expired, so information was complete.

we will find a match on form also. Ideally, one wants the parent match variable to take the value one only if, for example, a particular form is *not* made at the firm level, but *is* made somewhere else in the corporate organization. I subtract the number of firm matches from the number of parent matches to find the net impact of parent organizations. (In the same way, family matches are corrected by subtracting ingredient matches, since the latter is a subset of the former.) The coefficients on the parent variables therefore represent the impact of parent experience above and beyond firm experience.

Three other variables measure firm characteristics. One is a simple dummy variable indicating the firm was later indicted in the generic scandal. I expect these firms to be submitting more applications since the probability of quick and smooth approval for these applications was higher than it would normally be if the bribery was effective. None of the indicted firms has an approval after the scandal breaks.[19] The final two variables measure how closely the market characteristics of the current entry opportunity match those of the firm's portfolio. *Difference from Hospital Share* is the absolute value of the difference between the current opportunity's share of revenues from hospitals and the equal-weighted average of that variable in the firm's recent portfolio. I do not have the hospital share information for older portfolio drugs, so they are not included in the measure. The earliest entry opportunity has no portfolio characteristic to be compared to; the variable is given a zero value for these observations. *Difference in Revenue* is defined analogously: the absolute value of the difference between the current entry opportunity's revenue and that of the firm's recent portfolio. Summary statistics for the firm characteristic variables are listed in Table Ib; simply by examining the means of these variables by outcome, one can see the strong correlation with the entry decision.

If a firm submits an application six months or more after the first approval for the drug has been granted, I define its entry decision to be "late," rather than a decision made simultaneously with other firms. Approximately 400 entries in the dataset are "late." A firm could have up to three types of reasons for submitting an ANDA after other firm(s) have already been approved. First, uncertainty about demand for the drug might have been realized between the time the first entrant submitted the ANDA and its approval. If the realization is more positive than the initial expectation, additional firms, with somewhat higher costs, will want to enter. Secondly, the firm might simply have experienced delays in preparing the application. Since the generic market was booming during the early part of my sample period, agents at these firms were busy, and might have had a high opportunity cost to being on time in any given market. However, since in equilibrium they are expected to enter, entry may be worth doing despite being late. Third, the firm could receive information indicating there has been a "mistake" in the entry

[19] Some firms dissolve, others are subject to very slow approval times for the next four years.

process; perhaps the firm notices the absence of an expected entrant. However, a spectator cannot be completely certain of lack of entry because existing entrants could always be delayed by the FDA.

Explanations one and two match the existing model; late observations could be added to the dataset and the pattern of results should not change. We can be relatively sure the late entrant is motivated by reasons one or two if its entry is not so late that it can have good information about approvals (or lack thereof). If the late entrant does not submit its application after more than three quarters of all final applicants enter and not more than two years after the first entrant, I assumed it is motivated by reasons one and two. Regressions including "acceptable" late observations produce results very similar to those without late observations, so the results use data excluding only very late observations.

V. Analysis and Results

The estimation technique used here is a simple probit: enter or not enter, using the decision rule discussed above.

$$\text{pr(entry)} = \text{pr}(F_i \leq F^*)$$

Both F_i and F^* are estimated with linear models. X_j is a matrix of characteristics of market *j* that determine market size, while Z_{ij} is a matrix of firm characteristics that predict the fixed cost of entry for firm *i* into market *j*. Assuming the sum of the errors is distributed normally leads to the following equation:

$$\text{pr(entry)} = \text{pr}(Z_{ij}\beta + \varepsilon_{ij} < X_j\gamma + \eta_j) = \Phi(X_j\gamma - Z_{ij}\beta)$$

that can be estimated using a probit technique.

The variables discussed above are used to form an estimate of entry cost for each firm opportunity. Each match variable is labeled with either "firm" or "parent" depending on how the match was calculated, and a variable name, e.g. "therapy," to indicate the variable matched over. The remaining problem is how to measure market size. The econometrician needs some way to predict the expected number of entrants that can earn positive profits in a market. In a Cournot setting, for example, profits are quadratic in *n* and the expression is fairly complex. For the purposes of this paper, I simplify

the situation and use a reduced-form linear model to predict the expected number of entrants. Since the revenue of the drug market before entry is the single most important predictor of the number of generic entrants, I use log revenue (*LnRevenue*), and *Revenue* as explanatory variables. I know from past work (Scott Morton (1994)) that if a drug treats a chronic condition, it attracts more generic entry. The dummy variable *chronic* and its interaction with *LnRevenue* are included. Lastly, the share of the drug's revenues coming from hospitals also might affect the penetration of generics relative to the incumbent brand, so the variable *HospLnRevenue* is included in the specification. As discussed above, a single strength market's revenue is the sum of the known revenues of both strengths with the delayed-strength revenue entering again to allow for a negative coefficient. Only first-strength markets are included in the estimation.

Basic Results

The results of the estimation are reported in Table II. The first column reports the basic specification. The cost variables perform exactly as predicted. *Firm form* has a precisely estimated and stable coefficient; previous experience with a particular form reduces the cost of entry and increase its likelihood. I include the squares of the firm form and firm therapy match variables to reflect non-linearity in their impact. As one might predict, the coefficient on the quadratic term is negative, indicating that an additional match increases the probability of entry *less* as the number of matches grows. The last line of Table II contains the standard normal pdf value of the mean of the estimated index, which, when multiplied by a coefficient, creates a marginal effect. For the first match in the firm's portfolio, the probability of entry increases by about 0.08%; a firm with one hundred form matches increases its probability of entry by 2.3%. *Parent form's* coefficient is negative and for the most part significantly different from zero. This coefficient reflects the specialization of subsidiaries by form. In a case of complete specialization, if the subsidiary has no experience with the form but the parent does, that subsidiary will certainly not enter the market but another part of the corporation might.[20] *Firm therapy* also has a significantly positive coefficient, slightly bigger, but less precisely estimated than the form coefficient. The coefficient on squared firm therapy is an order of magnitude larger than the squared form coefficient because therapy matches are rarer than form matches (mean value 1 instead of 6.7). The total effect of firm therapy matches is positive for all observations in the sample. This result is

[20] Subsidiaries might be given territories that remove the necessity for a corporate decision over every market; for example, subsidiaries might specialize by form or by therapeutic class. In such a case, the subsidiaries are really acting as one firm, since there is no chance that the pill subsidiary, for example, will enter the injectable market. This behavior is likely to be a negative force on the parent form coefficient. I identify the firms with subsidiaries specialized by form and change the ownership variables so that the subsidiaries no longer exist; the parent name

consistent with the hypothesis that a firm's R&D and distribution costs will be lower for familiar therapies and lead to a greater probability of entry. The smaller coefficient on *parent therapy* is insignificant in most specifications. The same opposing effects that affected the parent form result are operating here.

The ingredient variables both have positive coefficients as expected. The signs of the ingredient coefficients are consistent with the idea that established suppliers and R&D experience with a particular compound lower the cost of entry. The *parent ingredient* coefficient may be driven by the importance of transfers of branded products from parents to generic subsidiaries. The *firm family* coefficient is positive, large, and significant, in contrast to the *parent family* coefficient that is never significantly different from zero. A single additional *firm family* match increases the probability of entry by 0.5%. It may be that a parent actively chooses to transfer a particular drug or ingredient to its generic subsidiary, whereas knowledge of related drugs (family matches) is harder to transfer between subsidiaries without an active effort.

Firms are entering the types of markets, as well as products, with which they already have experience. Absolute differences between the current entry opportunity and the characteristics of the firm's portfolio negatively affect the probability of entry. A revenue difference of fifty million dollars (the mean), reduces the probability of entry by about 0.4%. The share of a drug's revenues coming from the hospital sector is also an important portfolio characteristic. A difference of 0.33 between a firm's portfolio hospital share and current opportunity reduces the probability of entry by 0.7% A simple dummy variable indicating whether the firm was later indicted in the generic scandal reveals, as expected, that these firms enter more markets -- submit more applications -- than their characteristics indicate.

The probability of entry increases as market size grows. The market size coefficients are the expected sign and significantly different from zero. *Revenue* has a positive coefficient, while *LnRevenue* has a negative one; the total effect of all the revenue variables is positive, increasing slightly as revenue increases. *LnHospitalRev* is positive and significant as predicted; for generic producers who sell to hospitals disproportionately, hospital revenue may be more informative than total revenue. The coefficient on the *Chronic*LnRev* variable and the *Chronic* variable reveal that chronic markets of the mean size or larger are more attractive than non-chronic markets. *Second Strength Revenue* has a negative coefficient, as expected, implying later-expiring strengths are worth less. The revenue

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applies to all observations. As expected, the results show a positive parent form match, but parent therapy becomes negative. The same transformation of the data for therapies produces analogous results.

coefficients show that there is more entry as the brand pre-expiration sales grow; more entrants 'can fit' in larger markets. This notion in turn implies that entrants cause negative externalities for each other.

Some specifications include markets with entry before 1984 in the sample. Thirty percent of markets already have entry by 1984 and also experience entry during the sample period. What is important to the entering firms is the net size of the market, which is clearly affected by the existence of previous entrants I include *LnRevenueWH*, an interaction between revenue and a dummy for pre-Waxman-Hatch entry, because the revenue variable includes revenue from any existing generic entrants and is thus not comparable to revenue in markets with only the brand producing. This variable has a negative and significant coefficient, indicating that markets with existing entrants are not as attractive as their revenue size suggests. I also tried using a variable that measures the number of entrants already in the market in by the end of 1984 (when Waxman-Hatch takes effect), but if *LnRevenueWH* is included in the regression, the count variable is never significant. Since markets with pre-WH entry may exhibit a different entry game, column two displays the basic regression without those observations.[21] The significant coefficients are very similar in magnitude and the normal pdf value of the average index hardly changes, so the marginal effects of the variables are almost the same between the two columns.

Robustness Checks

Due to its somewhat *ad hoc* nature, the market size specification may not be very good way of modeling the size of markets with different attributes. An alternative method of estimation uses market fixed effects. Each separate market gets its own dummy variable that controls for market size without relying on a specific functional form and market characteristics. In particular, this method will be an improvement over estimating market size and translating to fixed cost if the distribution function G(.) varies across drugs. In the model outlined above I force G(.) and the function estimating the expected number of entrants to be constant across all observations, which may not be a valid restriction. The results of the dummy variable specification, both with and without observations where there is entry before the Waxman-Hatch Act, are in the third and fourth columns of Table II. Model fit is improved somewhat and the cost variable coefficients follow the same pattern as in the first two columns. Most coefficients are slightly larger in magnitude, particularly the ingredient coefficients, which also increase in significance. The normal pdf value of the average index declines by one-third in these specifications so that overall, marginal effects of the variables have declined slightly in most cases. The pseudo R^2 values are lower in the specifications where market size is estimated than in the specifications with fixed effects, indicating more variation is explained there. However, the loss of explanatory power in

estimating market size does not appear to be affecting the estimation of the coefficients on firm characteristics. The market fixed effect coefficients are not reported in the table because there are several hundred of them.

A conceptual problem exists when several subsidiaries of the same parent have the option to enter the same market. The parent might let each subsidiary make its own decision. On the other hand, one of the duties we might expect of headquarters would be to avoid duplication within the firm by coordinating the entry decision across subsidiaries. In such a case entry is determined simultaneously for several observations. This situation can be addressed in the estimation by using variables and entry opportunities defined at the parent level. Instead of creating firm-drug entry opportunities, the entry opportunities are created at the parent-drug level. The coefficients on the parent match variables (now the only match variables) are reported in Table III. Since parent experience was not generally significant in Table II, the combination of firm and parent variables produces coefficients very similar to the firm coefficients from Table II. The marginal effects are stable since the coefficients decline slightly compared to Table II, but the pdf of the mean index rises in both columns. Overall, the conclusion is that the choice of organization level from which to analyze entry does not drive the results.

One potential econometric problem is the low proportion of ones in the data -- 2% in the regressions reported here -- which means that the results depend strongly on the shape of the tails of the normal distribution. To examine this problem I use a non-parametric method, Han's Maximum Rank Correlation, to see if the results are driven by functional form. The MRC results (so far only pill category examined) are very similar to the probit results. The second potential problem is the fact that many zeros are created where they might not belong because we do not actually know which firms were valid potential entrants. I also estimate the specifications in Table II using the second definition of potential entrants: an entrant may not be potential until it has entered for real. This restriction on potential entry increases the percentage of ones to about three and one-half. The results are very similar to those in Table II, so they are not reported separately in the paper.

It is possible that manufacturing form is such a strong predictor of entry that we should separate the different forms and the firms that manufacture them. 94% of entry cases have a greater than zero *firm form match.* Suppose a firm were a "pill firm;" such a firm would think about entering any open oral solid market, but would not even consider manufacturing injectables, oral liquids, or topical products. If this is the correct description of the decision-making process, then it has two stages: first the firm decides

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[21] Entry cost has still fallen for all firms simultaneously and the market may be able to hold additional firms, so the situation is similar except for the calculation of market size.

whether or not to enter a particular form. If that decision is positive, the firm chooses among products in the class. I focus on the latter choice by re-estimating equations above on a sub-sample of the data.

Additionally, if G(.) differs across drugs we might see systematic differences between form categories in the specifications that estimate market size. Moving to a subset of the data for analysis has the attractive side effect of generating datasets with a higher proportion of 1's - around 7%. Dependent variables equal to zero are eliminated because only firms that actually enter injectable markets, for example, are allowed to be potential entrants in injectable markets -- where those firms are relatively active compared to pill markets. Potential entrants are restricted to firms which exist, or already have at least one drug in their portfolio. The results for pills, the largest form sub-category, are reported in Table IV.

Firm form match has a smaller coefficient when entrants are restricted to be pill firms; this is logical because the other specialty firms -- with few or no matches -- are no longer potential entrants, so the variable does not predict entry as well. The therapy coefficients are similar in sign and magnitude to the full sample results, which is logical. Ingredient matches become completely insignificant; if a firm mostly concentrates on pills, there is less scope for using an ingredient in multiple different forms, for example. Therefore, the usefulness of ingredient experience in reducing entry costs declines. However, the coefficient on *firm family matches* increases since a family member is likely to also take the pill form. Hospital share loses significance, probably because most pills are more likely to be outpatient drugs.

The market size variables should not have the same coefficients if the function determining the number of entrants varies systematically by form. The coefficients decrease somewhat, and some lose significance, but their order of magnitude does not change. Changes in the market characteristics of a firm's portfolio are more powerful in predicting changes in entry within this sample. The major difference in results is a large jump in the marginal effects of the variables to three or four times the levels in Table II; however, pseudo-R^2 values do not change much. In short, the pill results are qualitatively similar to the full-sample results, while displaying some features particular to a one-form sample.

One would like to know whether the entry game described here turned out to be efficient. Did the correct number of firms enter each market? It is not possible for me to directly test the efficiency of entry because I do not have price and quantity information from post-entry competition. The only available data that might be helpful are counts of very late entry, the sort that might be correcting for perceived mistakes in the original game. However, the correlation between very late entry and under-entered markets is negative. The model that predicts total number of entrants, an ordered probit, does not have

enough explanatory power to predict mistakes. Instead, if a market is attractive for some unobserved reason, there is over-entry relative to the model's prediction and very late entrants also enter that market. Unobserved attractiveness therefore creates an opposite correlation to the one that would be generated by late entrants fixing mistakes. Exit, due to an over-entry mistake, is unlikely for the reasons described in the regulatory section of the paper.

Regime Shift

The generic scandal was a large disruption that should have radically altered market players' beliefs about which firms would enter which markets. After the scandal broke, the FDA virtually stopped approving ANDAs. The industry was thrown into chaos for several years. The remaining firms would need to decide what strategies to follow in an atmosphere of great uncertainty. I divide the sample into two periods, pre-1989 and 1990 onwards.[22] Observations are assigned one of the two periods based on the ANDA's submission date since we are concerned with the decision to enter, not final approval. Using the estimated coefficients from the pre-scandal period to construct an index for post-scandal observations yields a correlation between the index and actual entry of only 0.19, as opposed to a correlation of 0.28 between the index and pre-scandal entry. The pre-scandal model loses some of its ability to predict entry when firms begin to enter unexpected markets after 1989.

The coefficients reported in Table V also show a shift in terms of which firms choose to enter which markets.[23] Coefficients on market revenue differences and hospital share differences, fall to half their former magnitude in the post-scandal period. Firms began to enter 'unusual' markets after 1989. These variables reflect firm-specific cost savings in distribution and marketing that have not changed in value due to the scandal. The drop in magnitude of the coefficients suggests that firms are not following the strategy of entering where they have entered before.

It is likely that the impact of different types of experience on costs changed as the priorities of the FDA changed. This would create new rankings in the cost distribution, altering the relative position of industry participants and changing estimated coefficients. The coefficients on the experience variables now valued by the FDA should rise, those on firm characteristics not valued by the FDA any longer should fall. For example, the *Firm Family* coefficient rises sharply; experience in a closely related drug lowers the cost of complying with stricter FDA manufacturing and testing standards. The parent family coefficient rises and becomes significant also. I interpret this as evidence that corporations actively looked for these related family products because the cost savings from the experience rose sharply. Form

[22] During the year 1989 the investigation was launched; the last 6 months of 1989 are omitted from the before and after analysis, as is the last half of 1993 and all of 1994.

[23] Using the sample without markets with entry before 1984

and therapy matches reflect more general skills of the firm and their coefficients are quite stable before and after the regime shift. Ingredient coefficients become insignificantly different from zero after the scandal, likely because experience with the particular ingredient in question is *not* helpful when the FDA is re-appraising the whole stock of approvals, looking for fraud. The increase in standard errors on the ingredient coefficients may reflect the dichotomy between 'good' experience and 'bad' experience.

VI. Negative Competition Externality

As noted in the theory section, the fact that entrants have lower costs than non-entrants is consistent with zero competitive externality or a case where the externality is negative and firms form beliefs around their own and their rivals' cost positions. Berry (1992) points out that one can distinguish between the two by increasing the number of potential entrants, while maintaining the distribution of fixed costs. If more firms enter, then a model of entry if fixed costs are below a specific threshold is supported. If the same number, although perhaps a different composition, of entrants enter, then the market can only support a fixed number of firms due to competitive externalities. This neat experiment is difficult to undertake in practice, including in this setting. However, there are two reasons to think that price and/or quantity sold per firm decline in the number of firms. First, several other authors have examined generic prices and documented a decline in price as the number of competitors increases.[24] Secondly, the significant coefficients on market size in the estimation here provide evidence that the number of entrants increases with available market revenues. There is no reason for the size of the market to affect the number of entrants in the absence of some limit to the number of profitable entrants. Instead, we should see only firms with costs below some threshold entering, presumably a random number of them in each market.

Finally, several other features of these data are consistent with the competitive model. If there is an expectation on the part of market participants that certain firms will enter, a firm that is slow in submitting its application will still find that the market has 'room' for it; a late firm may still be able to enter profitably. As a very rough test of whether these entrants might be filling 'empty' spots in the market, I calculate the correlation between firms that enter very late and that firm's predicted index using the coefficients from Table V, column 1. If late entrants made a 'mistake' by not initially entering, their estimated index values should be high relative to other potential entrants who never entered. The actual

[24] As noted above, Caves et al. (1991), Frank and Salkever (1995), Wiggins and Maness (1995).

correlation (omitting observations that entered on time) is 0.14, significant at the 1% level, for samples with and without pre-Waxman-Hatch entry.

Using the results of the entry regressions in Table V, it is possible to create a proxy for a firm's guess at its own cost position which can then be compared to the realized entry decision. Each firm has a rank order in each market according to its index value from Table V column 1. The lowest cost firm - with the highest index value - gets a one, the second lowest cost firm, a two, etc.. I then estimate a reduced form model of the size of each market where the dependent variable is the total number of firms entering.[25] This allows me to obtain a value for the predicted number of entrants for each market. A firm will believe it belongs in a market and others will not enter if its rank order is equal to or less than the expected number of entrants. *Below* is a dummy variable that takes a value of one when this condition is true. *Below* essentially picks up an interaction between the firm's being low cost and the market being big enough. *Below* has a significant coefficient of about 0.5 (.07) if included in the regression of Table V column 1, while the other coefficients remain stable; it is a strong predictor of entry into a market.[26] A similar result can be obtained by using a *Top10* dummy variable that takes a value of one when the firm has one of the ten lowest costs in the market. Of course, the estimated standard errors reported by these regression are too low because they do not take into account the estimation error involved in creating the variables. However, one can see that entry is positively affected by more than just having low absolute costs, being a low *relative* cost potential entrant is crucial.

Some of the features of the regime shift are consistent with a negative competitive externality. For example, it is more difficult to predict firm behavior in the latter period, likely because firms begin to enter markets unlike those they have entered previously. The percentage of correctly predicted entry falls between regimes, from 41% to 31% (correctly predicted non-entry is 97% and 98%, before and after the scandal, respectively).[27] We also know that the reorganization at the FDA caused application times to rise significantly. Expected profits and therefore the optimal number of entrants in any given market should have declined after the scandal hit. This is supported by the drop in the hospital revenue and

[25] The results of this ordered probit regression are not reported in the interests of brevity.

[26] The coefficient (std error) of *below* using only the post-scandal sample for creation and estimation is 0.53 (.19).

[27] The vast majority of observations are not entries, so the coefficients are small and very few observations have estimated index values greater than zero. For the purposes of forming a useful statistic, I define "correctly predicted" observations to be those with an estimated index greater than negative one. The mean index is approximately -2.8.

chronic revenue coefficients. The combined effect of all the revenue coefficients results in large markets attracting fewer entrants in the post-scandal period than before.[28]

When regimes shift firms must develop new priors on who will enter to avoid losses from over-entry. In this example, fewer firms entered markets of a given size after the scandal. This is likely to have been due to bureaucratic delay and it might also have been caused by uncertainty about which other firms were planning to enter. Consumers are worse off to the extent that this uncertainty reduces entry and leads to higher prices. Consistency in FDA policies and priorities is therefore probably socially beneficial so that firms can form priors on who will enter with as much confidence as possible.

Conclusions

The results in this paper demonstrate that heterogeneity among potential entrants can be used to predict entry by those firms into markets with differing characteristics. The technical and market characteristics of a generic pharmaceutical firm's portfolio determine which markets it is most likely to enter. The more experience a firm has with the form, therapy, or ingredient that characterizes an entry opportunity, the more likely it is to enter that market. This confirms the predictions of a basic model of entry with fixed costs: we should see low cost entrants entering. The lower costs that come from experience could be interpreted as "capabilities" or "resources," commonly used terms in the strategy literature. For example, a firm's research staff might have an organizational capability in a certain area, or the firm might have a resource in its distribution channels. However, a potential entrant's parent's experience with the drug, its therapeutic area, and form are marginal or insignificant predictors of entry by the subsidiary firm. Firms later indicted in the generic scandal have above normal entry rates during the time in which they were allegedly bribing FDA officials. Several methods for creating a set of potential entrants are introduced, but the results are robust to methodological variation.

Markets with more pre-patent expiration revenue attract more entry by generic firms, as do markets with more sales to hospitals and those where the drug treats a chronic condition. This result provides evidence for the notion that profits per firm decline in the number of entrants; smaller markets can support fewer entrants. Entrants must form expectations about their rivals' entry plans in order to avoid entering markets where an additional firm will drive net profits into the negative range. The

[28] However, during the post-scandal sample period there may have been entrants that submitted applications for these markets and were still waiting for approval at the time I collected my data. These entrants are not included in the data because the sample ends. I attempt to correct for this latter problem by omitting markets that open up in the final eighteen months of the sample, but some bias likely remains.

simultaneous nature of entry in the industry leads to an additional interpretation of the entry coefficients: specialization is profitable for firms because of the severe profit risk in the case of over-entry. An examination of late entrants and the effect of a firm's rank order of entry cost indicate that beliefs about *relative*, rather than absolute, levels of cost may be playing a role in entry decisions.

The generic scandal caused a regime shift with several outcomes. First, the priorities of the FDA changed so that the effects of experience on entry costs changed. In particular, experience with a drug's family increased the probability of entry, while ingredient experience became unhelpful. The drop in the coefficients on revenue differences and hospital market share differences suggest that firm strategies changed; firms began branching into markets that differed from their previous products so that the pre-scandal model of entry loses predictive power. These results are consistent with the breakdown of entry expectations because of legal and regulatory upheaval. Entry inefficiencies likely resulted during the period of breakdown, although these are difficult to measure. FDA approval policies that are consistent over time and publicized to potential entrants are likely to make it easier for firms to form accurate expectations about their rivals' cost positions and thereby make efficient entry decisions.

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Table Ia: Summary Statistics[29] Categories of Observations and Market Size Regressors					
Number of generic entries post-Waxman-Hatch					1233
Of those, number complete observations					1178
Of those, number of on time or slightly late entries					936
number of very late entries					242
Obs. in portfolios before Waxman-Hatch (11/84)					3535
Generic entries if no pre-Waxman-Hatch markets included (complete obs, on time & slightly late)					768
Obs. in expanded dataset (with potential entry cases)					48216
Obs. where prob. entry to be estimated (not portfolio or incomplete)					42059
Of those, obs. if potential entrants must previously exist					33979
obs. if must exist and no pre-Waxman-Hatch markets					23811
obs. if no pre-Waxman-Hatch markets					29052
generic entries: not very late, complete observations	obs	mean	std. dev.	min.	max.
total revenue	936	75793	109934	72	619645
ln revenue	936	10.33	1.53	4.28	13.34
hospital ln revenue	936	8.16	1.54	2.40	12.15
hospital rev. share	936	.267	.346	.009	1
chronic drug	936	.482	.500	0	1
single strength market	936	.046	.209	0	1
firms indicted in scandal	936	.239	.427	0	1
approval time	936	564.7	374.5	60.8	2585.4
number incumbent brands	936	1.18	.912	0	18
pre-WH generic entry	936	1.26	4.46	0	47
patent year	936	85.97	2.85	84	97
applications per firm	936	27.8	17.6	1	60
applications per drug	936	6.77	4.69	1	18

[29] The maximum patent expiration year is 1997 because the dataset contains one tentative ANDA approval that was granted three years before patent expiration; the firm could be trying to credibly commit to the market to deter additional entry.

Table Ib: Cost of Entry Regressors						
match variable N=42059	mean	std. dev.	min	max	mean enter=0	mean enter=1
firm form	6.73	17.85	0	121	6.01	38.3
parent form	3.65	13.54	0	122	3.66	3.28
firm therapy	.994	2.54	0	26	.936	3.58
parent therapy	.620	2.33	0	28	.615	.850
firm family	.023	.204	0	7	.021	.099
parent family	.017	.210	0	9	.017	.022
firm ingredient	.084	.487	0	17	.077	.377
parent ingredient	.059	.490	0	20	.057	.112
diff. from revenue in portfolio	50360	87749	0	619645	50067	63250
diff. from hospital share in portfolio	.327	.352	0	1	.330	.166
form of drug						
pill			19233			
extended release pill			1100			
inject			11357			
topical			2299			
oral liquid			5382			
eye			2565			
other			123			

Table II: Basic Entry Results				
Dep Var: Enter	market size estimation		market size dummies	
restriction:	basic	no pre-WH entry	basic	no pre-WH entry
firm form match	.040 (.002)	.043 (.002)	.044 (.002)	.048 (.002)
firm form match squared	-.00029 (.00002)	-.00030 (.00002)	-.00032 (.00002)	-.00033 (.00002)
parent form match	-.004 (.001)	-.003 (.001)	-.004 (.002)	-.003 (.002)
firm therapy match	.057 (.015)	.057 (.017)	.075 (.013)	.080 (.016)
firm therapy match squared	-.0017 (.0008)	-.0017 (.0009)	-.0020 (.0007)	-.0021 (.0008)
parent therapy match	.005 (.007)	.011 (.008)	.011 (.008)	.024 (.009)
firm ingredient match	.047 (.023)	.078 (.027)	.077 (.025)	.130 (.033)
parent ingredient match	.063 (.034)	.033 (.043)	.070 (.027)	.042 (.033)
firm family match	.222 (.054)	.285 (.083)	.269 (.050)	.336 (.072)
parent family match	.027 (.060)	.087 (.068)	.023 (.066)	.077 (.079)
Diff from recent portfolio revenue	-3.58E-06 (6.43E-07)	-3.82E-06 (7.05E-07)	-4.12E-06 (7.77E-07)	-4.84E-06 (8.00E-07)
Diff from recent hospital share	-1.04 (.117)	-1.12 (.139)	-1.61 (.122)	-1.60 (.151)
Firm implicated in scandal	.129 (.050)	.083 (.060)	.120 (.045)	.069 (.053)
Revenue	3.09E-06 (5.90E-07)	3.07E-06 (4.64E-07)	---	---
LnRevenue	-.183 (.036)	-.189 (.043)	---	---
LnRevenueWH	-.026 (.005)	---	---	---
LnHospitalRev	.272 (.033)	.298 (.038)	---	---
LnRev*Chronic	.056 (.028)	.060 (.036)	---	---
Second Strength Revenue	-1.56E-06 (3.95E-07)	-1.76E-07 (3.83E-07)	---	---
chronic	-.458 (.284)	-.499 (.376)	---	---
constant	-2.56 (.185)	-2.75 (.242)	-.990 (.637)	-.943 (.721)
Obs	42059	29052	42059	29050
LogLikelihood	-332912	-2535.4	-3025.7	-2266.3
Pseudo R^2	.258	.285	.326	.360
ϕ(meanX*β)	.021	.022	.013	.012

(Robust standard errors in parentheses. Market size dummy variables included but not reported in columns three and four.)

Table III: Parent Results **Entry Opportunities formed using Parents and Cost Variables based on Parent Portfolios**		
Dependent Variable: Enter	No pre-WH entry	
restriction:	Market size estimation	Market size dummies
parent form match	.030 (.002)	.033 (.003)
parent form match squared	-.00016 (.00002)	-.00018 (.00002)
parent therapy match	.041 (.013)	.065 (.015)
parent therapy match squared	-.00096 (.00060)	-.0014 (.0006)
parent ingredient match	.072 (.022)	.096 (.026)
parent family match	.181 (.060)	.205 (.065)
Diff from recent parent portfolio revenue	-3.66E-06 (7.07E-07)	-4.77E-06 (8.17E-07)
Diff from recent parent hospital share	-1.11 (.142)	-1.77 (.167)
Firm implicated in scandal	.072 (.057)	.078 (.062)
Revenue	2.98E-06 (6.56E-07)	---
LnRevenue	-.200 (.044)	---
LnHospitalRev	.306 (.040)	---
LnRev*Chronic	.055 (.034)	---
Second Strength Revenue	-1.59E-06 (3.44E-07)	---
constant	-2.65 (.232)	-1.22 (.153)
Obs. LogLikelihood Pseudo R^2 ϕ(meanX*β)	27065 -2662.9 .238 .027	27063 -2387.7 .315 .017

(Robust standard errors in parentheses. Market size dummy variables included but not reported in column two.)

Table IV: Entry Results for Pill Subsample				
Dep var: Enter	market size estimated		market size dummy variables	
restriction:	basic	no pre84 entry	basic	no pre84 entry
firm form match	.021	.025	.019	.023
	(.003)	(.003)	(.003)	(.003)
firm form match squared	-.00012	-.00014	-.00010	-.00013
	(.00002)	(.00003)	(.00002)	(.00002)
parent form match	-.005	-.004	-.006	-.005
	(.002)	(.002)	(.002)	(.002)
firm therapy match	.042	.053	.079	.095
	(.022)	(.025)	(.021)	(.023)
firm therapy match squared	-.0010	-.0016	-.0020	-.0027
	(.0011)	(.0012)	(.0010)	(.0011)
parent therapy match	.015	.027	.030	.047
	(.012)	(.014)	(.013)	(.014)
firm ingredient match	.018	.041	.010	.061
	(.035)	(.043)	(.036)	(.049)
parent ingredient match	.031	-.007	.025	-.002
	(.058)	(.067)	(.063)	(.068)
firm family match	.300	.444	.422	.518
	(.128)	(.193)	(.100)	(.152)
parent family match	.030	.038	.081	.061
	(.110)	(.119)	(.100)	(.112)
Diff from recent portfolio revenue	-2.67E-06	-2.80E-06	-3.38E-06	-3.89E-06
	(5.89E-07)	(6.66E-07)	(6.59E-07)	(7.11E-07)
Diff from recent hospital share	-.433	-.569	.082	.411
	(.335)	(.468)	(.561)	(.522)
Firm implicated in scandal	.078	.040	.068	.031
	(.063)	(.075)	(.055)	(.063)
Revenue	1.02E-06	9.90E-07	---	---
	(5.15E-07)	(5.78E-07)		
LnRevenue	.071	.033	---	---
	(.066)	(.085)		
LnRevenueWH	-.034	---	---	---
	(.006)			
LnHospitalRev	.129	.199	---	---
	(.057)	(.074)		
LnRev*Chronic	.101	.092	---	---
	(.041)	(.046)		
Chronic	-.909	-.787	---	---
	(.422)	(.491)		
Second Strength Revenue	-1.25E-06	-1.29E-06	---	---
	(4.38E-07)	(4.84E-07)		
constant	-3.68	-3.92	-.720	-2.64
	(.357)	(.431)	(.531)	(.571)
Obs	9490	6828	9490	6826
Log Likelihood	-1893.7	-1509.2	-1737.6	-1360.0
Pseudo R^2	.153	.171	.222	.251
ϕ(meanX*β)	.083	.092	.066	.071

(Robust standard errors in parentheses. Market size dummy variables included but not reported in columns 3 and 4. Sample consists of potential entrants that exist and have a pill in their portfolio by 1994.)

Table V: Before and After the Generic Scandal				
Dependent variable: Enter	market size estimation no market with entry before W-H		market dummies no market with entry before W-H	
	before	*after*	*before*	*after*
firm form match	.045	.032	.050	.038
	(.003)	(.005)	(.002)	(.005)
firm form match squared	-.00032	-.00021	-.00035	-.00024
	(.00003)	(.00005)	(.00003)	(.00005)
parent form match	-.0034	-.004	-.0026	-.0088
	(.0018)	(.003)	(.0020)	(.0046)
firm therapy match	.061	.039	.0869	.065
	(.022)	(.034)	(.0188)	(.035)
firm therapy match squared	-.0018	-.0008	-.0019	-.0023
	(.0012)	(.0017)	(.0011)	(.0018)
parent therapy match	.003	.040	.018	.046
	(.010)	(.014)	(.011)	(.016)
firm ingredient match	.073	-.013	.115	.133
	(.028)	(.108)	(.034)	(.258)
parent ingredient match	.051	-.303	.054	-.149
	(.047)	(.161)	(.035)	(.247)
firm family match	.221	1.80	.258	1.83
	(.086)	(.520)	(.074)	(.516)
parent family match	.043	1.85	.007	1.91
	(.090)	(.724)	(.094)	(.727)
Diff from recent portfolio revenue	-5.16E-06	-3.03E-06	-6.70E-06	-2.79E-06
	(1.24E-06)	(4.74E-07)	(1.42E-06)	(7.45E-07)
Diff from recent hospital share	-1.24	-.570	-1.91	-.379
	(.168)	(.286)	(.149)	(.270)
Firm implicated in scandal	.218	---	.228	---
	(.061)		(.056)	
Revenue	3.93E-06	3.55E-06	---	---
	(1.34E-06)	(7.03E-07)		
LnRevenue	-.223	-.125	---	---
	(.056)	(.079)		
LnHospitalRev	.355	.116	---	---
	(.050)	(.078)		
Chronic	-.896	-.347	---	---
	(.511)	(1.03)		
LnRev*Chronic	.097	.043	---	---
	(.049)	(.092)		
Second Strength Revenue	-1.54E-06	1.60E-06	---	---
	(8.84E-07)	(3.97E-06)		
constant	-2.84	-2.17	.369	-3.32
	(.297)	(.448)	(.608)	(.1.12
Obs	23623	4568	23621	4180
LogLikelihood	-2050.5	-380.7	-1804.6	-290.4
Pseudo R^2	.313	.233	.394	.307
ϕ(meanX*β)	.020	.025	.010	.018

(Robust standard errors are in parentheses. Market dummy variables included but not reported in columns three and four.)