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The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period

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Estimating the Effect of Entry on Generic Drug Prices Using Hatch-Waxman Exclusivity

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Abstract:

Generic drugs play an important role in disciplining drug prices and controlling rising drug costs. However, the effect that an additional generic drug competitor has on drug prices is difficult to measure because the number of firms competing in a market is endogenously determined. We identify the causal effects of a second and a third generic competitor on generic drug prices by exploiting the 180-day period of marketing exclusivity created by provisions of the Hatch-Waxman Act. The effects of the second and third competitors on price have important implications for drug competition policy and the interpretation of theory relating price to competition in generic drug markets. We find significant biases associated with estimates that do not properly account for endogenous entry. Specifically, we find that the failure to account for endogenous entry leads to significant underestimation of the effects of two and three competitors on generic drug prices, especially among large drugs.

Keywords: pharmaceutical, prescription drugs, generic entry, price competition
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I. Introduction

The relationship between generic drug prices and competition is receiving increased attention from policy-makers concerned about rapidly growing medical care costs.[1] Many policy-makers view generic drug competition as the principal method to contain the rapid growth in drug costs, which currently represents the fastest growing segment of healthcare expenditures in the United States.[2] In addition, numerous laws, regulations and legal precedents play an important role in directly affecting drug competition by altering the structure and competitive environment of these markets. For example, the Hatch-Waxman Act has been instrumental in shaping the competitive environment for both generic and branded drugs; the Supreme Court is currently considering the legality of some types of patent litigation settlements that affect competition between branded and generic competitors; and, Medicare Part D has led to a significant change in the provision of prescription drugs for a growing proportion of the population.[3] These policies and precedents, alongside antitrust competition policy, underscore the importance of drug market competition in U.S. healthcare policy.

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[1] FTC 2011. See also http://www.ftc.gov/os/highlights/2012/topics/prescriptionDrugs.shtml, where the FTC specifically identifies drug prices in its policy mission, and, http://www.kaiseredu.org/Issue-Modules/Prescription-Drug-Costs/Policy-Research.aspx, which identifies various instruments to control drug costs.

[2] Drug expenditures have increased by over 8.5% per year during the period 2001-2011; whereas overall health expenditures have increased by approximately 6.5% over the same period (see https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf). See, also, the response to this growth made by the Secretary of Health and Human Services: http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf .

[3] The Supreme Court case is *Federal Trade Commission v. Watson Pharmaceuticals, Inc., No. 12-416*. The Hatch-Waxman Act is formally the "Drug Price Competition and Patent Term Restoration Act of 1984." Medicare Part D, formally known as the "Voluntary Prescription Drug Benefit Program," is a section of the Medicare Modernization Act, formally known as the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003."

In this study, we estimate the empirical relationship between generic drug prices and the number of generic drug competitors. Generic drugs appear to compete in homogeneous goods product markets since generic drugs invest little in marketing or other forms of differentiation, and are, by law, clinically equivalent to a reference drug. Many of the theoretical models of oligopolistic competition among homogeneous goods predict that the first few entrants in the market have larger effects on prices than later entrants.[4] Empirically testing whether these predictions are true is important for policy-makers that either rely upon "generic competition" to discipline drug costs, or are tasked to evaluate the effects of generic drug competition. The results from these tests may help evaluate the effects of government policy, since some studies have shown that drug market regulation may have a deleterious effect on the potential benefits of competition (see e.g., Danzon and Chao 2000).

Estimating the causal relationship between price and the number of competitors is difficult since entry decisions by generic competitors may be correlated with unobserved determinants of price. We address this potential endogeneity concern by exploiting the 180-day marketing exclusivity period awarded to successful patent litigants under the provisions of the Hatch-Waxman Act.[5] During the exclusivity period, the FDA explicitly limits the set of generic competitors that can market the drug. The FDA considers regulatory characteristics, such as the presence of patents, as the basis for whether a

[4] See Shapiro (1989) and Chapters 4 and 5 of Vives (2001) for more comprehensive reviews of the theory of oligopolistic competition in homogeneous product models.

[5] Prescription drug markets are subject to various exclusivity periods that correspond to patent protection, Hatch-Waxman provisions, and other regulations. This paper focuses on the 180-day exclusivity period awarded to generic manufacturers that successfully litigate against branded patents under the provisions of the Hatch-Waxman Act. Unless otherwise noted, the "exclusivity" period refers to this 180-day period.

specific generic firm can market the drug during the exclusivity period. Since these regulatory characteristics are unlikely correlated with price, the number of competing firms during the exclusivity period is likely exogenous.

We also relax the assumption of exogenous firm entry during the exclusivity period by using instrumental variables (IV). Our IV modeling strategy introduces an instrument that the prior literature has not used: whether the FDA has classified the drug formulation as a "new chemical entity" (NCE). Designation as an NCE drug by the FDA potentially facilitates competition between numerous firms during the exclusivity period by affecting the timing of generic approval filings. We demonstrate that the NCE designation is correlated with the number of generic competitors observed during the exclusivity period. Since the NCE designation only influences market structure through the timing of a regulatory filing, we argue that it is uncorrelated with unobserved determinants of price, and is thus a valid instrument.

Our results suggest that controlling for endogenous entry is an important consideration in estimating the relationship between price and market structure in generic drug markets. Failure to control for endogenous entry can lead to significant biases associated with the effects that generic drug competition has on generic drug prices. Specifically, we find that an additional competitor lowers generic drug prices by a greater extent during the 180-day exclusivity period than outside of it. For example, we find that, outside of the exclusivity period, three competitors lower wholesale generic prices by approximately 32% relative to a single generic competitor. In contrast, during the exclusivity period we

find that three competitors lower generic drug prices by approximately 48% relative to a single generic competitor. We attribute the differences in these estimates to the biases associated with endogenous entry outside of the exclusivity period. In our analysis, we also divide the sample into drugs with higher than average revenue, "large drugs," and those with lower than average revenue, "small drugs." Although the differences between the marginal effect estimates during the exclusivity period and outside the exclusivity period are economically important in the full sample of drugs, they are particularly pronounced in the sample of large drugs. They are also statistically significant in that sample.[6]

Our instrumental variable results suggest that the first three generic competitors have an even larger effect on prices than our estimates that treat entry during exclusivity as exogenous. The IV estimates provide further evidence that endogenous entry results in underestimated effects of the first three competitors on generic drug prices. All of our results suggest that accounting for these biases leads to results that are more consistent with the predictions from the relevant oligopoly pricing models.

The next sections provide a background of the theory and the literature (section II), our identification strategy (section III), a description of the data (section IV), and our estimation strategy and results (Section V). We conclude in Section VI.

[6] The differences in the marginal effect estimates during the exlucisivity period and outside the exclusivity period are not statistically significant in the sample of small drugs.

II. Background

Generic drugs are defined by a unique combination of ‘active ingredients,’ strength, and dosage forms. Federal law requires each generic drug manufacturer’s product to be bioequivalent to a reference drug specified in the approval application to the FDA, where the reference drug is usually the relevant strength and dosage form of the branded drug. Generic drugs are sold in auctions to retail pharmacies, and are rarely advertised, either to consumers or to physicians. The marketing practices of generic drugs often reflect almost no attempt at differentiation from other versions of the same product. Indeed, generic drug manufacturers usually market the drug under the name of the active ingredient, such that several generic drug producers market the product under the same name. For example, each of the producers of generic Prilosec markets its product simply as “omeprazole,” the active ingredient in the reference drug, Prilosec.

Many oligopolistic competition models of homogeneous goods, including homogeneous product Cournot competition, predict steep declines in prices with only a few competitors. However, some drugs are observed with many actively marketing manufacturers (i.e., greater than ten). Moreover, some empirical studies of generic drug market competition find that generic drug prices continue to decline in the number of competitors well past four competitors. This result is consistent with some oligopoly models, including homogeneous Cournot competition models, but is inconsistent with others, such as homogeneous Bertrand under certain cost assumptions.

The early empirical studies of generic drug competition impose restrictive functional relationships between price and the number of manufacturers, such as linear or quadratic competitor terms. Estimates from these studies suggest that a large number of firms are necessary to achieve competitive prices (e.g., Caves et. al. 1991, Grabowski and Vernon 1992, Frank and Salkever 1997, Wiggins and Maness 2004). For example, the coefficient estimates from Caves et al. (1991) predict that a drug market with 15 competitors has a predicted price that is less than half of that of a market with three competitors.

More recent studies estimate flexible model specifications that allow for comparisons of differential marginal effects of specific competitors (i.e., dummy variables for each competitor). Reiffen and Ward (2005) find economically small and statistically insignificant differences between prices in markets with one generic firm and markets with fewer than four generic firms. Their estimates imply that later entrants (greater than three) cause larger price effects than earlier entrants (less than four). Regan (2008) employs a different drug sample to consider differential pricing patterns using a specification similar to that of Reiffen and Ward (2005). However, in constrast to Reiffen and Ward (2005), she finds that all generic competitors, other than the first one, have small pricing effects. She finds that no competitor, other than the first one, has an effect on generic drug prices that is statistically different from zero. These results are consistent

with Bertrand competition against the *branded* drug (i.e., only a single generic competitor is necessary to achieve marginal cost pricing).[7]

Resolving this conflicting evidence about the nature of generic drug competition has important implications for merger enforcement and cost containment policies. For example, a review of a recent generic drug firm merger provides insight into the policy decisions of the antitrust enforcement agencies.[8] We observe that the Federal Trade Commission (FTC) required seven divestitures among products currently marketed by both parties in the recent Watson-Actavis merger. Each of the seven divestitures were among products with fewer than six actively marketing competitors prior to the merger. It follows from this observation that an effective merger policy relies upon accurate estimates of the relationship between price and the number of competitors, especially when the number of competitors is small.

Our paper reconsiders the empirical relationship between competition and generic drug prices by exploiting the 180-day exclusivity provision of the Hatch-Waxman Act. We describe our identification strategy in the next section.

[7] Regan (2008) offers a mildly different interpretation of some of her results. In her generic drug pricing equation, she suggests that the coefficient estimates on the dummy variables that represent the latest entrants (i.e., entrants 4-5, and 6+) "increase in magnitude suggesting that the degree of price competition increases with entry." However, neither estimate is larger than 1% relative to a single generic competitor, and both are statistically insignificant.

[8] http://www.ftc.gov/opa/2012/10/watson.shtm

III. FDA Regulation and Model Identification

In order to estimate the causal relationship between generic drug prices and the number of marketing competitors, the empirical strategy must control for market characteristics correlated with both the number of firms and price. However, unobserved factors that attract entry, such as unobserved determinants of either demand or costs, may also help to explain price. Failing to control for these unobserved market characteristics could bias estimates of the effects of competition on price. Figure 1 illustrates the importance of this issue in the market for generic drugs. This figure considers the relationship between price and competition for two sets of drugs with different entry profiles. The solid line represents drugs that are never observed with more than four manufacturers. The dotted line represents drugs eventually observed with at least five competing generic manufacturers. We are agnostic about what explains the differences in whether these drugs are attractive to enter, although cost and demand conditions are likely important. Each point in the figure represents the average relative generic price, indexed against the average price facing a single manufacturer for markets facing two, three, and four competitors.[9]

The two sets of drugs have very different pricing profiles. Drugs that eventually attract at least five competitors face a steep decline in prices with respect to the number of competitors considered in the Figure. In contrast, drugs that do not attract more than four

[9] Figure 1 reflects information contained in the first 24 months of generic competition. The relative price is the ratio of generic drug prices at time t to brand prices in the quarter prior to generic entry. See section IV for a more in-depth discussion of how these prices are constructed.

manufacturers during our sample have a shallow pricing profile. These profiles are interesting since, together, they can generate the pricing patterns found in some of the previous literature of generic drug competition. Drugs that attract five or more competitors are rarely observed with fewer than five entrants, and drugs that do not attract more than four entrants are never observed with more than four entrants.[10] Thus, a regression pooling both sets of drugs would falsely create the appearance that the effects of the first few competitors are small (i.e., the shallower slope), and then the effect jumps discretely between four and six competitors (i.e., from the shallow sloped line to the steep sloped line).[11]

Our formal empirical model attempts to control for this type of potentially endogenous selection by exploiting terms and provisions of the Hatch-Waxman Act. The Hatch-Waxman Act currently governs FDA marketing approval requirements for generic drugs, and has done so since 1984. The Act establishes the terms and requirements of the Abbreviated New Drug Application (ANDA) process, a process which, in 1984, significantly reduced the costs of gaining generic marketing approval.[12] In addition, the Act also requires ANDA applicants to certify that it will not violate patents listed in the

[10]Among drugs eventually attracting more than five entrants, 26% of months are observed with fewer than five manufacturers, including months during exclusivity. Excluding the exclusivity period, this figure falls to 16%. Overall, drugs that eventually attract more than five manufacturers account for less than 18% of months with fewer than five manufacturers.

[11] Reiffen and Ward (2005) find results that are consistent with these types of discrete jumps in markets with greater than 4 competitors.

[12] Conditional upon demonstrable bioequivalence to a reference drug, the ANDA process allows generic drug applicants to rely upon clinical trial evidence provided in the original New Drug Application (NDA). Prior to the Hatch-Waxman Act, the generic filer was required to conduct its own clinical trials. Due to the expense of performing clinical trials, generic firms have rarely entered without an ANDA submission since passage of the Act.

FDA's Orange Book.[13] However, in order to encourage generic firms to pursue entry prior to expiration of claimed patent protection of questionable patents. To do so, a generic drug manufacturer must first submit to the FDA a "Paragraph Four" ANDA in which it certifies that (a) its generic drug will not infringe patents listed in the FDA's "Orange Book," and/or that (b) the relevant Orange Book patents are invalid.[14] The applicant must also provide notice of its certification to the NDA filer, and any other patent holders. The Paragraph Four application must also include a detailed statement that explains why the applicant believes the patent is invalid or will not be infringed. Paragraph Four applicants that are designated by the FDA as the first applicant to file a sufficiently complete application are eligible to win an award of 180-days exclusivity, conditional upon a successful patent challenge.

Our identification strategy relies upon the terms and conditions associated with the 180-day exclusivity period. During the exclusivity period, the FDA will not grant marketing approval to any ANDA other than a 'first-filer.' This feature implies that all drugs are observed with a limited number of firms competing during the exclusivity period, regardless of whether the drug eventually attracts numerous competitors. However, under some circumstances, the FDA allows multiple generic competitors to market during exclusivity. For example, the brand firm may market an "authorized" generic (AG) under

[13] The length and terms of the marketing restrictions associated with the Hatch-Waxman Act often depend upon the approval conditions of the associated reference drug, such as whether the FDA designated the drug as a new chemical entity (NCE). For example, all New Drug Applications approved by the FDA are subject to at least a 3-year marketing "exclusivity" period. The associated exclusivity is 5 years for a drug designated as a NCE. In addition, the FDA does not accept ANDA filings prior to 4 years following the introduction of a NCE. See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm for more information.

[14] Paragraph IV refers to the relevant provision of the Hatch-Waxman Act.

the authority of the branded product's New Drug Application. The FDA may also designate more than one applicant as a "first-filer" if multiple applicants file on the same day.[15]

The ANDA approval process is sufficiently complex such that any applicant, unencumbered by other regulations, would be unlikely to file a sufficiently complete ANDA on exactly the same day as any other applicant. However, if the FDA designates the reference drug as an NCE, then the FDA imposes an extended filing prohibition that increases the likelihood that multiple filers file an ANDA on the same day (i.e., the day the prohibition expires), and are therefore designated as "first filers" by the FDA. The regulation prohibits potential generic applicants from submitting an ANDA application until 4 years following the introduction of an NCE brand drug.[16] This extended filing prohibition, which is only associated with drugs designated as an NCE, is often enough time for a firm to substantially complete an ANDA application.

We exploit these features of the Hatch-Waxman Act to identify the effect of competition on price. We begin by estimating the effect of competition on prices during the 180-day exclusivity period. We treat the exclusivity as a period of exogenous entry since a drug that might otherwise attract many entrants only competes with a few competitors during

[15] See "Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day," for a detailed discussion of multiple first filers. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072851.pdf

[16] A 5-year period of exclusivity is granted to new drug applications for products containing chemical entities never previously approved by FDA either alone or in combination. Applications may be submitted after 4 years if they contain a certification of patent invalidity or noninfringement. (Accessed February 28, 2013) http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.htm

exclusivity. We show how endogenous entry may bias the estimates of competition by comparing the estimated effects of competition during exclusivity to the estimated effects outside of it, where unobserved determinants of entry are uncontrolled.

Next, we relax the assumption that entry during the exclusivity period is exogenous. We use instrumental variable (IV) techniques to model the number of competitors during exclusivity as a function of the NCE designation and the annualized pre-entry market size of the drug (measured in dollars). Our IV strategy treats both the NCE designation and the pre-entry market size of the drug as valid instruments. As described above, drugs classified as NCEs are associated with lengthy regulatory prohibitions that increase the likelihood of multiple first-filers. However, the FDA, an independent government agency, designates a drug as an NCE years in advance of generic drug competition. Consequently, designation of the branded drug as an NCE is unlikely correlated with generic pricing.

The previous literature has extensively used market size to instrument for the number of generic competitors since the size of a drug has no obvious theoretical relationship with price (e.g., Caves et al. 1991, Frank and Salkever 1997, and Regan 2008). Many of the arguments for its use as a valid instrument in the previous literature extend to the exclusivity period. In addition, branded drugs are more likely to introduce an AG into large drug markets (FTC 2011), and larger drugs attract more ANDA filings (Scott-Morton 1999). However, the entry restrictions of the exclusivity period may mute some of the power that market size has in explaining the number of competitors.

IV. Data

Our analysis employs monthly wholesale data from IMS Health (IMS).[17] IMS reports unit and dollar sales information separately for every prescription drug sold in the United States. The sample considers oral solid medications sold during April 2003 through December 2010.[18] We define a drug to be the combination of molecule (i.e., active ingredient), dosage form, strength, and therapeutic class. For example, the 10 mg and 20 mg tablet formulations of benazepril, an ACE inhibitor, are two distinct drugs in our sample. We omit over-the-counter medications, decongestants, and vitamins since these drugs contain numerous chemicals that are difficult to track and change periodically.[19] In addition, many of these drugs are frequently sold as over-the-counter medications through channels not covered well in our dataset. We combine IMS sales data with Hatch-Waxman information obtained from the FDA to identify Paragraph Four certifications, drugs with exclusivity periods, and dates associated with exclusivity.

We construct monthly generic drug prices, p_{dt}^{g}, by aggregating total dollar sales across all generic manufacturers for a specific drug and then dividing by the total quantity of pills involved in the sale. Following standard practice in the literature (Caves et al. 1991), we scale each generic price by the corresponding branded drug's pre-entry price, p_{d}^{b}, to

[17] IMS Health, IMS National Sales Perspectives™, January 2003 to December 2010, Retail and Non-Retail Channels.
[18] An oral solid medication is defined as a drug packaged as a capsule or a tablet dosage form.
[19] We also omit any drug with a generic-to-pre-entry revenue ratio greater than 5.

arrive at a price measure that is comparable across drugs, $p_{dt} = p_{dt}^{g} / p_{d}^{b}$.[20] The pre-entry brand price, p_{d}^{b}, is constructed to be the sales-weighted price per pill during the three-months preceding generic entry.[21] Similarly, we construct market size to be the annualized aggregate pre-entry branded dollar sales for each drug during the three months prior to generic entry.

IMS sales information is also used to identify both the number of manufacturers marketing the drug and the date of generic entry. We define generic entry as the first month in which any generic firm has positive dollar sales in our sample. We limit the sample to consider only oral solid prescription medications that begin to face generic entry during our sample. We define the number of competitors during each period as the number of generic firms with positive dollar sales during the month (after accounting for infrequent sales of small firms).[22]

In order to identify drug sales during exclusivity periods, we combine the IMS sales data with information from the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (a.k.a., the "Orange Book"). The Orange book provides information about whether the brand drug faced a Paragraph Four challenge and the period of exclusivity, if there is one.

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[20] Since p_{d}^{b} corresponds to the brand drug's price averaged over the three months prior to generic entry, the term does not require a time subscript.

[21] Pre-entry brand price is constructed as the total dollar sales of the drug during the 3-months prior to generic entry divided by the total unit (i.e., pill) sales during the same period.

[22] Our definition of a competitor omits re-packagers and treats several firms with similar names as the same firm (e.g., Watson and Watson Labs). In addition, we treat firms as market participants unless observed without sales for four consecutive months. The date of exit for these firms is backdated to the last month observed without sales.

Table 1 presents summary statistics for the drugs used in our analysis. The first two data columns provide information for the entire sample of drugs used in the analysis. Data columns three and four provide the same information for the sample of drugs observed during the 180-day exclusivity period. Data columns five and six provide the same information for drugs during the period following an exclusivity period among drugs with successful Paragraph Four patent challenges.

The full sample contains 403 drugs (i.e., molecule-strength-dosage form-therapeutic class combinations) representing 146 distinct molecules. Brand sales of drugs with exclusivity are, on average, larger than drugs without an exclusivity period. Drugs with exclusivity have slightly more than $285 million in annualized pre-entry brand sales, whereas the overall sample has $241 million. In addition, not all Paragraph Four challenges successfully result in an exclusivity period. Approximately 75% of drugs in our sample face a Paragraph Four challenge, but only 42% of drugs have an exclusivity period.

Notably, drugs with exclusivity periods tend to face less generic competition during exclusivity than the full sample of drugs, but face more competition outside of exclusivity than the full sample of drugs. For example, Table 1 shows that none of the drugs in our sample faces more than three competitors during an exclusivity period (data column 3), but drugs that had an exclusivity (i.e., successful Paragraph Four challengers) are more likely to face greater than three competitors outside of exclusivity than are drugs in the overall sample (comparing data columns 1 and 5). This pattern is consistent with the

exclusivity period restricting the number of competitors for precisely those drugs that would otherwise attract entry.

We expand on this point by considering the relationship between the number of competitors and market size. Figure 2 compares the relationship between market size and the number of competitors for two samples: (1) drugs with exclusivity periods observed during the 180-day exclusivity period; and, (2) drugs from the overall sample (including drugs with exclusivity periods) observed during the first six months of generic competition. Figure 2 plots, separately for the two samples, the average number of generic entrants during the first six months after initial generic entry against the sales revenue deciles as defined by the entire sample. In the overall sample, higher sales decile drugs clearly face more competitors than lower sales decile drugs. Indeed, the two highest sales deciles face, on average, at least seven generic competitors, whereas drugs in the lowest two sales deciles face, on average, approximately two competitors. The strong relationship between market-size and the number of competitors suggests that, in the overall sample, market size is an important determinant of entry by generic firms.[23] However, during exclusivity, drugs never average more than two competitors, regardless of the sales decile. Moreover, the average number of observed competitors is nearly constant for the entire sample, regardless of market size.

[23] Much of the prior literature (e.g., Caves et al. 1991, Frank and Salkever 1997, and Regan 2008) has acknowledged this relationship by using market-size as an instrumental variable in similar specifications. Panattoni (2011) and Scott Morton (1999) find direct evidence that market-size is an important determinant of generic firm entry.

Figure 2 demonstrates that the exclusivity period appears effective at muting the explanatory power of an important observed determinant of the number of competitors, market size. If the exclusivity period mutes the effects of observed determinants of competition, such as market size, it also likely mutes the importance of unobserved determinants of competition, as well. This property suggests that the variation in competition during exclusivity is likely sufficiently random such that the number of firms is exogenous for purposes of our estimation.

V. Estimation and Results

In order to determine the effects of competition on generic drug prices, we estimate a regression of generic drug prices against a set of drug characteristic controls and the number of competitors using equation 1:

$$(1)\ \ln p_{dt} = \sum_{k=1}^{K=11} \delta_k (man_{dt}^k \cdot (1 - ex_{dt})) + \sum_{k=2}^{K=3} \gamma_k (man_{dt}^k \cdot ex_{dt}) + X_{dt}\beta_x + Z_d\beta_z + \phi_i + \phi_t + \varepsilon_{dt}$$

The dependent variable, $\ln p_{dt}$, is the natural logarithm of the sales-weighted price per pill for drug *d* during month *t*, normalized by the pre-entry brand price.[24] The variables of interest are the parameters associated with the number of generic competitors, man^k, such that $man^k = 1$ if the number of competitors is equal to *k* and zero otherwise.[25] The number of generic competitors is interacted with whether the observation occurs during a

[24] This transformation of the pricing variable allows for an intuitive interpretation of the coefficients of interest. For example, δ_2 = -0.1 implies that a second generic competitor is expected to lower the average generic price by 10% relative to a market with a single manufacturer. In addition, this transformation provides an infinite support.

[25] Competitive effects from >10 firms are captured using a single indicator.

180-day exclusivity period, ex. The coefficients on the exclusivity interaction terms, γ_k, represent the effects of competition during exclusivity, and the coefficients on the non-exclusivity interaction terms, δ_k, represent the effects of competition outside of exclusivity.

The model includes fixed effects for the active ingredient (molecule) of the drug, ϕ_i, and the calendar month, ϕ_t.[26] The regression also includes controls for drug characteristics that vary over time within a drug, represented by X, such as the age of the drug since generic entry.[27] We also control for drug characteristics that vary across drugs within a molecule but are fixed over time, such as dosage form, which is represented as Z. In addition, we account for correlation in prices over time and within molecules using standard errors that cluster at the molecule level.

We limit the sample to the first 18 months of generic drug marketing. The 18-month period is long enough to provide significant pricing variation following the exclusivity period, but is also comparable to the timing and duration of the exclusivity period, which is only six-months and always occurs immediately following the initiation of generic competition.[28] We exclude the first and seventh month of generic competition since the

[26] The number of competitors does not vary over time within a drug during the exclusivity period. Consequently, our model cannot include drug fixed effects and separately identify the effects of competition.

[27] We define age as the number of months since the drug began facing generic entry. The variable, X, also includes a constant.

[28] The results are not sensitive to this time period restriction. Estimates from models with as many as 24 months and as few as 12 months of generic competition have quantitatively similar results.

first month often represents a month of partial sales and month seven sometimes represents a mix of exclusive and non-exclusive days.

Table 2 presents the baseline results of the effects of competition on generic drug prices. The marginal effects of an additional competitor are reported separately for the periods inside and outside of the 180-day exclusivity period (i.e., the estimates γ_k and $\delta_k - \delta_1$ from equation 1, respectively). All effect estimates (i.e., inside and outside of exclusivity) are reported separately for three samples that correspond to different control groups. The first data column represents the effects measured from the full sample of drugs and provides the standard errors beneath the coefficient estimates in parentheses. Data column 2 is the analogous result from the sample of drugs facing a Paragraph Four challenge. Limiting the sample to drugs facing Paragraph Four challenges reduces the selection bias associated with having an exclusivity period, since all drugs in the Paragraph Four sample are selected in the same way (i.e., they all face a Paragraph Four challenge). The last data column represents the sample of drugs that face successful Paragraph Four challenges (i.e., all drugs in the sample have an exclusivity period). This sample is unlikely to have any selection issues since nearly every drug in the sample has both a period during exclusivity and a period outside exclusivity.[29] However, this limitation also reduces the size of the sample and results in dramatically larger standard errors outside of the exclusivity period.

[29] Drugs introduced after April 2010 are only observed during the exclusivity period.

The coefficient estimates suggest that the effect of two competitors lowers prices from between 13.7% and 22.6%, relative to a single competitor. Although these effects are large in magnitude, they are imprecisely estimated and statistically insignificant (at the 5% confidence level) in all models, both inside and outside of exclusivity. In contrast, the effect of three competitors is statistically significant in all specifications, both inside and outside of exclusivity. The effects of three competitors are always large in magnitude, ranging from between -31.5% and -54.3%, but are larger during the exclusivity period than they are outside of exclusivity. Indeed, in the full sample of drugs, the effect of three competitors is 17 percentage points larger during exclusivity than outside of it. Although we find economically large differences between the exclusivity and non-exclusivity periods, the difference estimates are imprecisely estimated and are rarely statistically significant.

Next, we consider the effects of competition separately for large and small drugs. Allowing the effects to vary by the size of the drug accounts for demand side conditions that may affect the nature of competition. We define a large drug to be any drug with a market size greater than the mean of our sample, where market size is measured as the annualized pre-entry branded sales in the three months prior to generic entry. The analysis is performed by interacting whether a drug is large with the competitive variables of interest. Specifically, we estimate equation 2:

$$\ln p_{dt} = large_{dt} \cdot [\sum_{k=1}^{K=11} \delta_k^l (man_{dt}^k \cdot (1 - ex_{dt})) + \sum_{k=2}^{K=3} \gamma_k^l (man_{dt}^k \cdot ex_{dt})] + (1 - large_{dt}) \cdot [\sum_{k=1}^{K=11} \delta_k^s (man_{dt}^k \cdot (1 - ex_{dt})) + \sum_{k=1}^{K=3} \gamma_k^s (man_{dt}^k \cdot ex_{dt})] + X_{dt}\beta_x + Z_d\beta_z + \phi_i + \phi_t + u_{dt} \quad (2)$$

Equation 2 is analogous to equation 1, except that we include interaction terms of the competitor variables with an indicator for whether the drug is large, *large*. The omitted category is the effect of one competitor during exclusivity for large drugs. Table 3 reports the effects of two and three competitors on prices during and outside of the exclusivity period, separately for large and small drugs. During the exclusivity period, the marginal effects of two and three competitors are always larger for large drugs than they are for small drugs. However, outside of exclusivity, a comparison of the marginal effects between large and small drugs reveals no pattern.

The effect of two competitors is never statistically significant in any of the samples, large or small. However, the point estimates suggest that two competitors can lower prices anywhere between 4.1% and 37.7%, depending on the sample and whether the drug is inside or outside of exclusivity. The effects from two competitors are typically larger during exclusivity than outside of it, except in the case of the sample of large drugs limited to drugs with exclusivity periods.

The magnitude of the effects of three competitors, relative to a single competitor, are always very large, both inside and outside of exclusivity. Estimates of the effects range between 18.0% and 73.3%, depending on the sample and whether the drug is observed during or outside of exclusivity. During exclusivity, the p-values for the effect estimates never exceed 5.2%, and thus the results are statistically significant, or almost statistically

significant, in every sample.[30] However, the effects of three competitors are always larger during exclusivity than outside of exclusivity. These differences can be large in magnitude. Among large drugs, the differences exceed 35 points in two of the three samples.[31] The effect of three competitors during exclusivity is also larger among large drugs than among small drugs in all three samples. Moreover, the differences between the effects inside and outside exclusivity are more pronounced among larger drugs than among smaller drugs. Among large drugs, the differential is statistically significant in two of the three samples, but the differential is never statistically significant among small drugs.

These results suggest that failure to control for endogenous entry could potentially underestimate the effects of three competitors on prices, especially among large drugs. In addition to affecting the direct inference for these competitors, the underestimated effects could potentially lead to overestimates of the marginal effects attributed to later competitors.[32] Further exacerbating this issue is the observation that the marginal effects of two and three competitors are typically larger (during exclusivity) among large drugs then they are among small drugs. If large drugs eventually attract more competitors, then failing to account for these demand-side factors could also lead to biases that overstate the effects of later competitors, as illustrated in our discussion of Figure 1. Numerous

[30] The p-value is 5.2% during exclusivity for the small drug full sample and the small drug sample of successful paragraph IV drugs. The effects of three competitors during exclusivity is always statistically significant among large drugs.
[31] The difference is not statistically significant among large drugs with successful paragraph IV challenges.
[32] To see this, suppose that the cumulative effect of four competitors is estimated accurately (e.g., 75%), but the cumulative effect of three competitors is underestimated (e.g., estimate = 50% and true value = 70%). The estimated marginal effect of the fourth competitor would be 25%, but the true marginal effect would be 5%.

papers have found that larger drugs attract more competitors outside of exclusivity (see e.g., Scott Morton 1999 and Panattoni 2011). Consequently, our results suggest that both the differences in the effects between large and small drugs, and the differences in effects during and outside of exclusivity among both large and small drugs, could lead to overestimates of the effects of later competitors.

Instrumental Variables and the Exclusivity Period

The exclusivity period restricts entry such that only a few competitors compete for drugs that would normally attract many entrants. However, the number of competitors observed during exclusivity may still be endogenously determined if, for example, low-cost drugs systematically attract an authorized generic competitor, or manufacturers with wider portfolios of drugs command a pricing premium over manufacturers with limited portfolios.[33] We address these potential sources of endogeneity during exclusivity by modeling the number of competitors during the period using instrumental variables (IV).

Table 4 provides motivation for using an NCE indicator and the natural log of market size as instruments. Market size and NCE have are positively correlated with the number of generic competitors during the exclusivity period, with correlations of .20 and .23, respectively. The first data column of Table 4 provides the mean of market size in millions of dollars, conditional on the number of generic competitors. Average market

[33] As an example of portfolio effects, one might believe that OLS could incorrectly estimate the effects of competition within a molecule if one of the competing manufacturers offers the full suite of dosage forms during exclusivity, whereas the other competing firm offers only a subset of them.

size nearly doubles between one and two competitors, although two and three competitors have similar market sizes. The third and fifth columns present the distribution of the number of manufacturers among drugs without and with an NCE, respectively. Half of drugs without an NCE designation are marketed by a single manufacturer during the exclusivity period. In contrast, only 29% of NCE drugs are marketed by a single manufacturer.

Our IV specification considers the effect of generic competition on generic drug prices during the exclusivity period by estimating a two-stage model represented by equations 3 and 4:

(3) (stage 1) $m_{dt} = X_{dt}\theta_x + Z_d\theta_z + V_d\eta + \tau_i + \tau_t + \upsilon_{dt}$

(4) (stage 2) $\ln p_{dt} = \pi\hat{m}_{dt} + X_{dt}\xi_x + Z_d\xi_z + \lambda_i + \lambda_t + \zeta_{dt}$

The first stage dependent variable, m_{dt}, is the number of generic manufacturers competing for sales in drug d during month t.[34] The second stage dependent variable is the natural logarithm of the relative generic drug price for drug d during month t, the same dependent variable as in equation 1.

The first stage models the number of competitors as a function of fixed and time-varying drug characteristics, represented by X and Z, respectively. We also include molecule and calendar-month fixed effects, which are represented as τ_i and τ_t, respectively. The drug

[34] One drawback of a linear specification in the first stage is censoring. Replacing m_{dt} with $\ln m_{dt}$, a log-lin specification, provides an infinite support. A log-lin specification in the first stage and log-log in the second stage produces the same conclusions as the specification described above.

characteristics and fixed effects for molecule and time are also included in the second stage pricing equation, and are analogous to the variables included in equation 1. However, time and age effects are limited to reflect that the sample includes only those periods that occur during 180-day exclusivity. Stage 1, equation 3, also includes a set of excluded instruments. The set of instruments excluded from the price regressions are fixed drug characteristics, represented by V_d in equation 3.

The second stage pricing equation models price as a function of the same drug characteristics and fixed effects included in equation 1. However, we limit attention to the exclusivity period and estimate the effect of generic competition using the coefficient on the manufacturer term, $\hat{m}_{dt}$, which is predicted from the first stage estimation results. Although no drug faces more than three competitors (see Table 1) during the exclusivity period, our IV specification imposes a log-lin relationship between competition and prices, such that the marginal effect of the third manufacturer is the same as the second manufacturer. Since this specification does not enable us to directly compare the IV results to those provided in Tables 2 and 3, we also separately estimate an OLS regression that also imposes a log-lin specification. We use compare results from this estimation to those of the IV estimations to identify any potential biases associated with the exogenous treatment of competition, and the direction of that potential bias.

We estimate three IV specifications such that each specification represents the same model (i.e., equations 3 and 4) using a different set of instruments. The first specification employs as an instrument a discrete variable that indicates whether the FDA designated

the drug a NCE. The second specification considers the natural logarithm of market size as an instrument. The third specification includes both the NCE designation and market size as instruments.

Table 5 reports estimates of effects from additional generic competitors on prices from these models, alongside estimates from a log-lin specification without instrumentation, but during exclusivity. The IV manufacturer coefficient estimates are are quite close together and are always larger than the OLS coefficient estimate. These results suggest that the exogenous treatment of entry *during the exclusivity period* understates the average effect of an additional generic competitor. Moreover, these differences are large in magnitude. Indeed, the IV estimates are three times as large as the OLS estimate. The differences between the NCE-only specification and the OLS specification are the most modest, but even this comparison suggests that OLS severely underestimates the average effect of an additional generic competitor.

When market size is the only excluded instrument, the specification provides the largest effects. However, the estimate is imprecise and is statistically significant at the 10% level. In contrast, all the effect estimates from specifications that include the NCE designation are statistically significant. Table 5 also reports some diagnostic statistics that enable us to evaluate the suitability of our proposed instruments. An instrument that is both correlated with the variable of interest (i.e., the number of manufacturers) and uncorrelated with the principal error term (here, generic drug prices) after controlling for the other observables is relevant and valid. The first stage F statistics provide a measure

of the instruments' relevance, i.e., whether the set of instrumental variables correlates with the variable of interest, the number of competing generic drug manufacturers. By this measure, the NCE indicator is a relevant instrument. Both specifications that include the NCE instrumental variable have first-stage F values that are statistically different from zero at traditional levels of significance. In addition, each specification that includes the NCE has a first-stage F-statistic that is greater than 10.[35] These results suggest that the NCE instrument successfully predicts the number of competitors, and thus satisfies the relevance criterion for an instrument.

Although much of the previous literature has used market size to instrument for the number of competitors outside of exclusivity, our results during exclusivity suggest that market size is a weak instrument. We cannot reject the hypothesis at any conventional level of statistical significance that market size alone does not explain the number of competitors.[36] However, the specification that includes both market size and the NCE designation has a first-stage F-statistic that is larger than 10, but is smaller than that of the NCE alone.

In the over-identified model (i.e., the model that includes the NCE indicator and market size), we also report the Hansen J-statistic for over-identification. We use this statistic to test whether the instruments are appropriately excluded from the second stage regression.

[35] Stock et al (2002) suggest that first stage F statistics less than 10 may indicate that the instrument set is not relevant or "weak," even if the first-stage F-statistic is statistically significant at conventional significance levels.

[36] As we demonstrate in Table 4, we find an unconditional correlation between market size and the number of competitors during exclusivity. However, controlling for drug characteristics, such as molecule fixed effects, attenuates this relationship.

With a p-value of 0.95, we fail to reject that the J-statistic is different from zero in the over-identified specification. Failure to reject provides some statistical support that our instruments satisfy the validity criterion, i.e., that the set of instrumental variables is uncorrelated with the error term in the price regression.

To the extent that the diagnostic statistics are informative about the validity and relevance of our instruments, there is strong evidence in favor of using the NCE indicator as an instrument since it is correlated with the variable of interest and uncorrelated with the error-term in the second stage. Although some evidence suggests that market size is a weak instrument and should not be used as an instrument during the exclusivity period, the similarity of the IV point estimates and the statistics in the over-identified specification weakly support its inclusion.

Regardless of which instrument set we consider, the coefficient estimates from our IV regressions predict larger competitive effects than our OLS estimates during exclusivity. Since our OLS estimates during exclusivity predict larger competitive effects than our OLS estimates outside exclusivity, these results imply that the competitive effects outside of exclusivity may understate the effects of price by the earliest entrants in the competitive sequence.

VI. Conclusion

The relationship between competition and generic drug prices is a fundamental issue for understanding rising drug costs. This relationship has important implications for merger enforcement and health care cost containment policy. We demonstrate that endogenous entry may introduce important biases in the estimated relationship between price and the number of generic competitors. Consequently, careful empirical analysis is necessary to identify this relationship.

We control for potentially endogenous drug entry by exploiting both the 180-day exclusivity period awarded to generic drug applicants, and the filing prohibition associated with a drug designated as a new chemical entity (NCE). We find that an additional competitor lowers generic drug prices by a greater extent during the 180-day exclusivity period than outside of it. We interpret this finding as evidence of bias in the estimates of generic entry performed outside of the exclusivity period, where endogenous entry is uncontrolled. These differences are economically important in all samples, and among large drugs, the differences are often statistically significant.

Using the NCE designation as an instrumental variable during the exclusivity period suggests that even the effect estimated during the exclusivity period may understate these effect estimates, exacerbating the effects of endogeneity bias.

Although a great deal of empirical work has attempted to estimate the relationship between competition and prices in the generic drug industry, our results suggest that endogenous entry introduces an attenuation bias in the estimates of the effects of the second and third competitors on price, which biases marginal effect estimates of later entrants. Moreover, our results suggest that the bias is potentially very large, especially among high revenue drugs.

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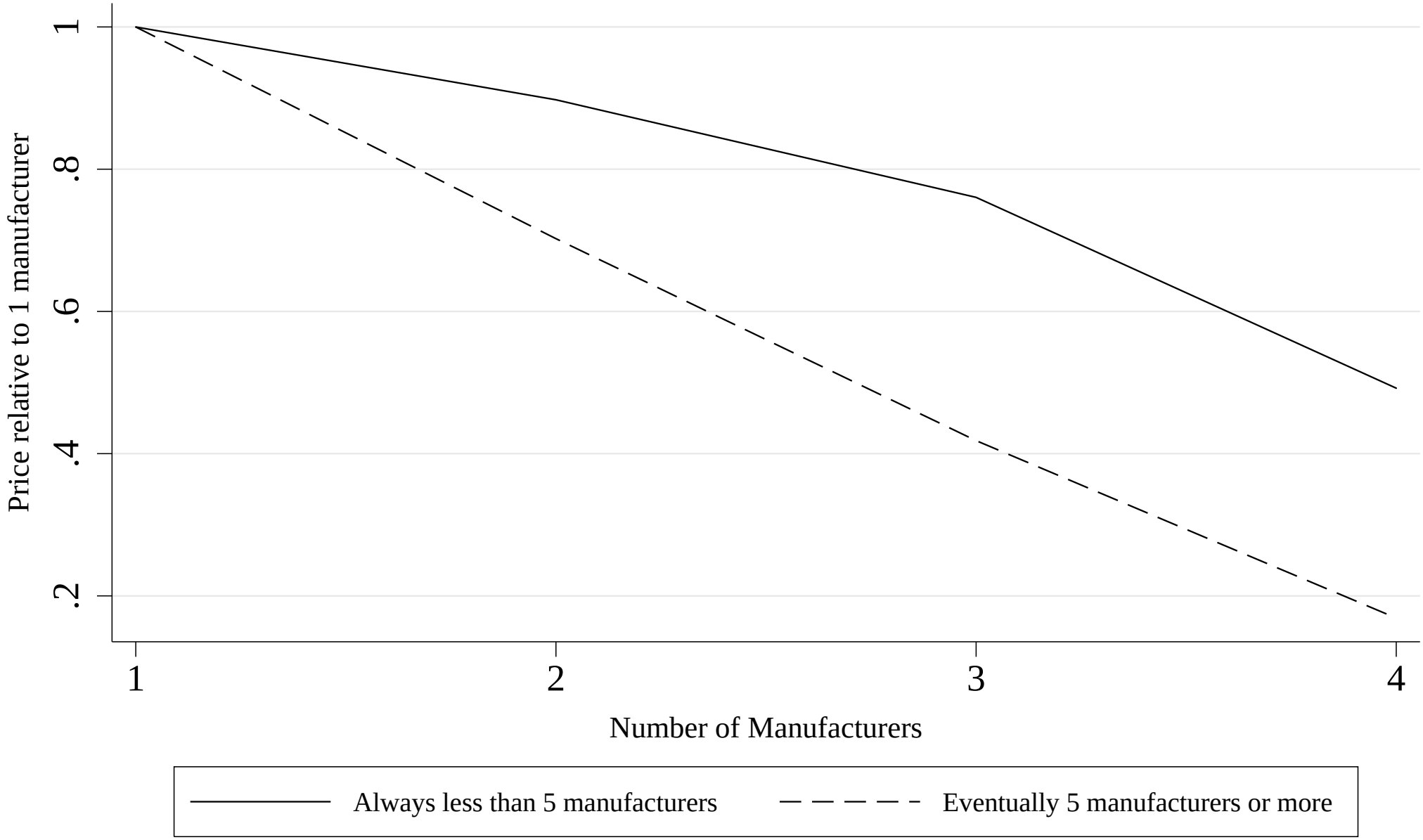
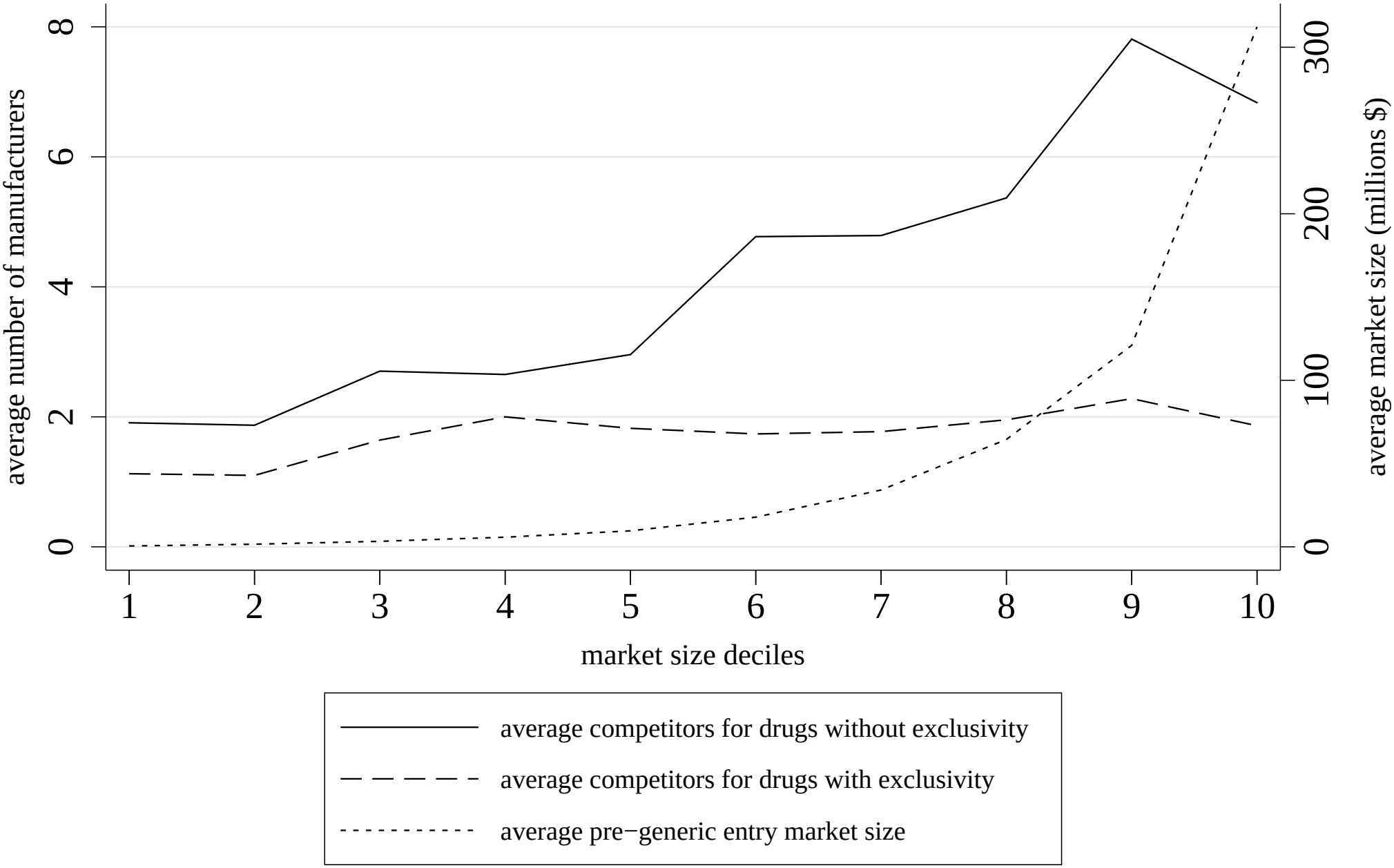
Figure 1: Relative price by number of manufacturers in first 24 months of generic competition

Separately by entry profile



Data source: author's calculations from IMS

Figure 2: Relationship between market size and number of generic competitors by exclusive and non−exclusive drugs



Data source: author's calculations from IMS during the first six months of generic competition.

Table 1: Summary statistics

			Drugs with Exclusivity Periods			
	All Drugs		*During Exclusivity*		*Outside Exclusivity*	
Variable	*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*
Time-Varying Characteristics						
Generic Price Relative to Pre-Entry Brand Price	0.478	0.299	0.735	0.135	0.433	0.263
Average Number of Manufacturers	4.33	3.62	1.72	0.72	4.77	3.43
Generic Competitors = 1	0.227	0.419	0.440	0.497	0.174	0.380
Generic Competitors = 2	0.211	0.408	0.404	0.491	0.154	0.361
Generic Competitors = 3	0.130	0.336	0.156	0.363	0.154	0.361
Generic Competitors > 3	0.432	0.495	0.0	0.0	0.518	0.500
Fixed Characteristics						
Faced a Paragraph IV Challenge	0.750	0.434	1.000	0.000	1.000	0.000
Market Size (Millions)	241	406	285	415	292	419
Tablet	0.610	0.488	0.532	0.500	0.571	0.497
Capsule	0.116	0.321	0.129	0.336	0.103	0.304
Chewable Tablet	0.009	0.094	0.012	0.108	0.013	0.113
Orally Disintegrating Tablet	0.050	0.218	0.064	0.246	0.058	0.234
Extended Release Capsule	0.047	0.211	0.064	0.246	0.051	0.221
Extended Release Tablet	0.168	0.374	0.199	0.400	0.205	0.405
Unique Molecules	146		58		53	
Unique Drugs	403		171		156	
Drug-Months < 25 Months Since Entry	8413		788		2533	

Notes: Data source IMS Health National Sales Perspective April 2003 - December 2010 (IMS). Pre-entry brand prices calculated using 3 months prior to generic entry. Market size is the annualized sales of brand drugs for the 3 months prior to generic entry and is measured in millions of December 2008 dollars. Competitor count is the contemporaneous number of competitors during the period.

Table 2: Estimates of the effects of a second and third generic competitor on generic drug prices

Variables	*Overall*	*Paragraph IV*	*Drugs with Exclusivity*
Price Effects Outside Exclusivity			
Two Competitors	-0.137*	-0.226*	-0.195
	(0.077)	(0.134)	(0.183)
Three Competitors	-0.315**	-0.429**	-0.509**
	(0.109)	(0.172)	(0.227)
Price Effects During Exclusivity			
Two Competitors	-0.134	-0.160	-0.158
	(0.159)	(0.170)	(0.171)
Three Competitors	-0.483**	-0.518**	-0.543**
	(0.189)	(0.196)	(0.179)
Adjusted R-Squared	0.928	0.923	0.921
RMSE	0.262	0.274	0.242
Clusters	146	80	58
N	5993	3766	2301

Notes: *Statistically significant at the 10% level. **Statistically significant at the 5% level. Data source IMS. The sample is limited to the first 18 months of generic competition. All models include molecule and calendar-month fixed effects. Overall and Paragraph IV drug samples also include age fixed effects. Robust standard errors that are clustered by molecule are reported. The effect of one competitor outside of exclusivity, δ_1, is -0.07, 0.04, and -0.02 for the samples, respectively.

Table 3: Estimates of the effects of a second and third generic competitor on generic drug prices, separately for "small" and "large" drugs

	Overall		*Paragraph IV*		*Drugs with Exclusivity*	
Variables	*Small*	*Large*	*Small*	*Large*	*Small*	*Large*
Price Effects Outside Exclusivity						
Two Competitors	-0.127	-0.041	-0.218	-0.171	-0.155	-0.377
	(0.083)	(0.106)	(0.140)	(0.115)	(0.183)	(0.299)
Three Competitors	-0.306**	-0.180	-0.421**	-0.347**	-0.538**	-0.490
	(0.119)	(0.146)	(0.195)	(0.147)	(0.268)	(0.294)
Price Effects During Exclusivity						
Two Competitors	-0.239	-0.317	-0.291	-0.347	-0.201	-0.269
	(0.256)	(0.277)	(0.274)	(0.291)	(0.267)	(0.272)
Three Competitors	-0.556*	-0.664**	-0.610**	-0.733**	-0.578*	-0.626**
	(0.284)	(0.281)	(0.303)	(0.290)	(0.292)	(0.266)
Adjusted R-Squared	0.930		0.925		0.922	
RMSE	0.260		0.270		0.240	
Clusters	146		80		58	
N	5993		3766		2301	

Notes: *Statistically significant at the 10% level. **Statistically significant at the 5% level. Data source IMS. The sample is limited to the first 18 months of generic competition. All models include molecule and calendar-month fixed effects. Overall and Paragraph IV drug samples also include age fixed effects. Robust standard errors that are clustered by molecule are reported.

Table 4: Correlation of excluded instruments and competitor count during the exclusivity period

	Market Size	*SE*	*Non-NCE*	*SE*	*NCE*	*SE*
1 Competitor	185.6	324.0	0.506	0.503	0.291	0.457
2 Competitors	365.9	485.1	0.341	0.477	0.419	0.496
3 Competitors	326.1	405.0	0.153	0.362	0.291	0.457
Correlation	0.153			0.230		
Drug Count			85		86	

Notes: Data source IMS. Market size is the annualized sales of brand drugs for the quarter prior to generic entry measured in millions of dollars. Competitor count is the maximum number of competitors marketing the drug during the exclusivity period.

Table 5: OLS and IV estimates of the effects of an additional competitor on generic drug prices

Estimator	*OLS*	*Instrumental Variables*		
Instruments		*NCE*	*ln(MS)*	*NCE & ln(MS)*
Coefficient	*Estimate*	*Estimate*	*Estimate*	*Estimate*
Second Stage Estimates (Dependent Variable = ln (Price))				
No. of Manufacturers	-0.102**	-0.296**	-0.308*	-0.298**
	(0.014)	(0.046)	(0.178)	(0.049)
First Stage Estimates (Dependent Variable = Manufacturer)				
NCE	n/a	1.873**	n/a	1.835**
		(0.360)		(0.355)
ln(MS)	n/a	n/a	0.034**	0.030*
			(0.016)	(0.015)
Estimation Diagnostics				
First Stage F	n/a	27.1**	4.7**	15.4**
J Statistic	n/a	n/a	n/a	0.005
P-value of J Statistic	n/a	n/a	n/a	0.946
First-stage Partial R^2	n/a	0.098	0.019	0.113
Clusters	58	58	58	58
N	788	788	788	788

Notes: *Statistically significant at the 10% level. **Statistically significant at the 5% level. Data source IMS. All models include molecule, month and age fixed effects. Robust standard errors that are clustered by molecule are reported.