

Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets

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Abstract:

Economists at the Federal Trade Commission (FTC) pursue the agency's competition and consumer protection missions. In this year's essay, in antitrust, we discuss various aspects of our hospital merger analyses as well as the effects of authorized generic drugs on consumers and competition. In consumer protection, we describe two ongoing studies on the use of credit-based insurance scores to price homeowners insurance, and the accuracy of consumers' credit reports that are provided by credit bureaus.

Keywords: antitrust, consumer credit, consumer protection, FTC, hospital mergers, pharmaceuticals

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1 Introduction

The Federal Trade Commission's (FTC) Bureau of Economics (BE) includes about 80 Ph.D.-level economists, a small group of accountants, and 25 other staff (including research analysts). Its work supports the FTC's competition (antitrust) and consumer protection missions. Most of the Bureau's efforts directly support the Commission's investigations and enforcement, but FTC economists also help promote competition-oriented policies domestically at state and federal levels, and contribute to global adoption of modern, economically-oriented competition policies. In addition, economists pursue policy-oriented economic research.

To keep our knowledge base and skills up-to-date, we undertake various research-related activities, including an annual conference on microeconomic issues relevant to our two missions. In November 2010 our third annual conference was conducted jointly with Northwestern University's Center for the Study of Industrial Organization (CSIO) and Searle Center.¹ Topics included mortgage delinquency, competition and innovation policy, advertising and consumer behavior, empirical industrial organization, and asymmetric information and consumer choice. For our fourth conference, in November 2011, our call for papers solicits contributions on topics that include advertising, information disclosure, mergers, vertical restraints in the supply chain, mortgages and credit markets, bundling, loyalty discounts, dynamic demand estimation, business practices and consumer choice, intellectual property, optimal penalties, and cost-benefit analysis in law enforcement.

2 Mergers

Merger enforcement is the bulk of our antitrust work. MergerStat reported that general merger and acquisition (M&A) activity involving US firms was about \$0.69 TR in 2010, compared with

¹ Northwestern University's CSIO website can be found at <http://www.wcas.northwestern.edu/csio/>. Northwestern University's Searle Center website can be found at <http://www.northwestern.edu/searle/index.html>.

\$1.2 TR in the pre-crisis year of 2007.² Over 1100 merger filings occurred in 2010, and the FTC challenged all or some aspect of 22 transactions.³

We examine mergers in a large number of different industries, but one of the most active recently has been hospitals. In this segment we describe the conceptual framework and related empirical analyses that we employ in a typical hospital merger investigation.

2.1 Hospital Merger Analysis

We provide an overview of the basic economic theory and the methods that may be applied in assessing the likely price effects of hospital mergers. While our case analyses rely on numerous sources of information, including documents and interviews, here we discuss only our conceptual framework and our empirical methods.

In addition to the effect on price, the analysis of hospital mergers also requires close attention to likely effects on quality, particularly clinical quality (as it has been defined by the Institute of Medicine and the World Health Organization), as distinct from hospital amenities. As stressed by Town (2011), life and health are very valuable, so even modest improvements in clinical quality may redeem otherwise problematic hospital mergers. For this reason, well-supported claims regarding clinical quality tend to be given more weight than other claims of pro-competitive merger effects. Our methods of evaluating such claims are discussed in detail in Romano & Balan (2011), and so are omitted here in the interest of brevity.

² MergerStat Review, (2011, p. 10). The data represent the dollar value of mergers, acquisitions, and divestitures involving US firms if at least 10% of the equity of a firm is transferred and a value is reported.

³ FTC Chairman's Annual Report (2011, p. 1). Retrieved from <http://www.ftc.gov/os/2011/04/2011ChairmansReport.pdf>.

2.2 Bargaining Theory

Prices in commercial hospital markets are generally determined through bilateral bargaining between managed care organizations (MCOs) and hospitals.⁴ The bargaining power of the MCO is derived from its ability to exclude the hospital from its network, thereby depriving it of patients. The bargaining power of the hospital is derived from the fact that its absence from the MCO's network makes that network less attractive to the MCO's customers. We employ a Nash bargaining framework: i.e., the joint surplus from an agreement is determined by the payoffs of the MCO and of the hospital, both with and without an agreement, and the price is set so as to split this surplus according to a split parameter that represents their relative bargaining abilities.⁵ The focus of the analysis is the potential for the merger significantly to alter the disagreement payoff of either the MCO or the hospital, resulting in significantly higher equilibrium prices, holding all else fixed.⁶

We consider a Nash bargaining game between an MCO and an independent hospital k , in which the equilibrium price p_k maximizes the objective function

$$\left[n_k p_k - c_k(n_k) - 0 \right]^\alpha \left[\left(V(\phi(p_k, p_{-k})) - \sum_j n_j p_j \right) - \left(V(\phi(p_{-k})) - \sum_{j \neq k} (n_j + n_k d_{kj}) p_j \right) \right]^{1-\alpha}.$$

⁴ In contrast, prices for most government-financed care are determined administratively, not by bargaining. According to the Healthcare Cost and Utilization Project website, in 2008 Medicare and Medicaid together accounted for about 56% of hospital discharges (<http://hcupnet.ahrq.gov>). According to the American Hospital Association, in 2008 government payments represented about 55% of the U.S. total. (<http://www.aha.org/aha/trendwatch/chartbook/2010/chart4-5.pdf>). Managed care organizations take many forms. Generally, MCOs assemble a network of hospital and health care providers; they often, but not always, play a role in paying for care through an insurance function.

⁵ We assume Nash Bargaining because it is standard and tractable. If the true bargaining game was a different one, the calculations would change, but the main conceptual points discussed below would remain the same.

⁶ The analysis focuses on changes in the disagreement payoffs, and does not specifically contemplate how the merger may affect the split parameter. This is because only changes in disagreement payoffs necessarily arise from the elimination of horizontal competition.

Here, n_k denotes the (expected) number of patients covered by the MCO treated at hospital k ;⁷ $c_k(n_k)$ denotes the (expected) incremental cost of treating n_k patients; ϕ denotes the profit-maximizing premium conditional on bargaining outcomes with each of the other hospitals (collectively indexed as $-k$);^{8,9} $V(\phi(p_k, p_{-k}))$ denotes the gross equilibrium payoff (before payments to hospitals) of the MCO under the agreement with hospital k ; $V(\phi(p_{-k}))$ denotes the disagreement payoff of the MCO (before payments to hospitals); and d_{kj} denotes the diversion ratio from hospital k to hospital j .¹⁰ The disagreement payoff of the hospital with respect to that MCO is typically assumed to be zero.¹¹ The parameter $\alpha \in (0,1)$ denotes the split of the joint surplus.

The basic principles of competitive effects analysis in this theoretical framework are fundamentally similar to those in standard differentiated products markets in which prices are posted by firms. Changes in the disagreement payoffs of the hospitals or of the MCO, and hence

⁷ For tractability we assume that, conditional on inclusion, n_j does not depend on the negotiated hospital prices. In most instances, we have found that the most common health insurance products significantly limit or eliminate out-of-pocket price variation over within-network hospitals. Similarly, we have found little evidence that physicians respond to within-network out-of-pocket price variation in their admitting patterns. Hence, we usually find that differences in within-network prices do not play a significant role in a patient's choice of hospital. Prices may indirectly influence the n_j through the premium ϕ : Higher prices cause higher premiums, which cause some people to drop their insurance, which in turn affects the n_j . While the dropping of insurance coverage is a significant issue for social welfare, the effect of an individual hospital's own prices on its number of patients is usually very small.

⁸ For simplicity of notation, we suppress the premiums of competing MCOs in the MCO's payoff function.

⁹ For notational convenience we use p_{-k} to denote the prices of the other hospitals, but we do not assume that all other hospitals are necessarily in the MCO's network. However, the model is most naturally applied to a situation in which all MCO/hospital combinations reach an agreement. In our experience, this is a common outcome.

¹⁰ The exclusion of any hospital from the MCO may lead to changes in the negotiated prices and/or network inclusion status of other hospitals. For simplicity, we ignore that here, so the bargaining model captures the effect of an exclusion prior to any other contracts' being renegotiated or to any other hospitals' being added to the MCO's network. This is less of a disadvantage if, as is commonly the case, all hospitals are included in the network.

¹¹ Hospitals that are outside an MCO's network may still attract a positive number of that MCO's patients, which means that the disagreement payoff will be positive. However, as noted above, a common outcome is that all hospitals/MCO combinations in a given area do reach agreement. In such instances, there would be little basis on which to estimate the disagreement payoff of the hospital. It may be feasible to estimate this disagreement payoff in settings in which network exclusions are observed.

price effects, are increasing in the diversions between the merging hospitals and in their pre-merger bargaining power. If the hospitals are substitutes and bargain separately post-merger, their disagreement payoffs (and, hence, equilibrium prices) rise because each hospital now takes into account the fact that its merger partner will recapture some of the lost volume if it fails to reach an agreement.

If, as is typical, the hospitals instead bargain on an all-or-nothing basis, the disagreement payoff of the MCO will decrease because the cost to the MCO of failing to reach an agreement with the merged hospitals will exceed the sum of the costs of failing to reach an agreement with them separately, again only if the hospitals are substitutes. To see this, recall that the bargaining power of a hospital comes from the diminution in the value of the MCO's network if it is excluded. This diminution is mitigated by the presence of proximate alternatives. When a hospital merges with one of those alternatives and then the merged entity bargains on an all-or-nothing basis, absent an agreement, patients whose first choice was one of the hospitals and whose second choice was the other would be forced to use their third choice instead, which further diminishes the value of the MCO's network. If the hospitals are not substitutes, there are no patients for whom this will be true, so the cost of failing to reach an agreement with both hospitals is equal to the sum of the costs of failing to reach agreements with them separately, and so there will be no effect on price. Hence, in both separate and all-or-nothing bargaining, the magnitude of the price effect depends on the diversions between the merging hospitals.¹²

2.3 Diversion Analysis

We typically begin our empirical analysis by estimating the diversion ratios between the merging hospitals. This can be done using individual-level inpatient hospital discharge data that are (usually) readily available through state agencies. Therefore, this analysis is typically employed as a screen early in an investigation. These state discharge data usually contain a number of key variables, including the treating hospital, the patient's age, gender, 5-digit ZIP code, primary

¹² It is straightforward to show that merger effects under all-or-nothing bargaining can be larger or smaller than under separate bargaining.

payer type, and clinical information such as diagnosis related group (DRG) and diagnosis and procedure codes. We may also utilize data on hospital-specific characteristics. We begin the diversion analysis by estimating a standard conditional logit model of individual hospital choices.¹³ The specification of consumer preferences is based on the random utility model

$$U_{ij} = X_{ij}\beta + Z_j\gamma + \varepsilon_{ij},$$

where X_{ij} denotes a set of interactions between observed patient and hospital characteristics, Z_j denotes a set of hospital characteristics, and ε_{ij} denotes an idiosyncratic term assumed to be an IID draw from the Type I Extreme Value distribution.¹⁴

This specification seeks to model preferences over hospitals as flexibly and in as refined a manner as possible. Since sample sizes tend to be very large (often greater than 10,000), the model specification can be quite rich. The vector X_{ij} usually includes the average drive time from the centroid of the patient's ZIP code of residence to the street address of the hospital. Disutility of travel may be allowed to vary by, among other things, the type and acuity of the clinical condition of the patient, age, gender, and whether the admission was for an emergency. We may also allow patient preferences for specific hospitals to vary by age and to depend on the type and acuity of the patient's clinical condition. The vector Z_j may comprise hospital characteristics such as bed capacity, teaching status, or quality measures, or may consist of a set of hospital-specific fixed-effects.¹⁵

¹³ As noted earlier, we have found that within-network price variation has little or no effect on volumes. Hence, we typically focus on diversion arising from a hypothetical network exclusion, as opposed to a hypothetical increase in the price that MCOs and hospitals negotiate.

¹⁴ It may be appropriate to relax the IID assumption in some settings. For example, it may be appropriate to permit correlation in the idiosyncratic terms across hospitals within a system. A nested logit model may be employed in such a circumstance.

¹⁵ It is well-known that given of a choice set of $K+1$ alternatives, including an outside option, up to K observable product attributes can be fully captured using a full set of product-specific fixed-effects. That is to say, the predictions of the model using K product attributes will be exactly the same as the predictions using K fixed-effects. Since the number of observable hospital attributes is typically less than the number of products in the choice set, the

Since preferences on travel time and over hospitals are allowed to vary by condition type and acuity, this approach addresses the “Silent Majority Fallacy” problem discussed in Capps et al. (2001) and Elzinga and Swisher (2011). That is, the choice model, and hence the diversion and merger simulation analyses described below, distinguish between a circumstance in which some patients are observed to travel longer distances because the disutility of travel is relatively low from one in which they are observed to travel longer distances because they have a particularly strong reason to travel (e.g., in order to access services that are not available locally) despite travel costs that are relatively high.

The parameter estimates from the choice model are used generate a full set of fitted choice probabilities. Given the IID Extreme Value assumption, the fitted probability that patient i

chooses hospital k is defined as $\text{prob}_{ik} = \frac{\exp\{X_{ik}\hat{\beta} + Z_k\hat{\gamma}\}}{\sum_j \exp\{X_{ij}\hat{\beta} + Z_j\hat{\gamma}\}}$. Given these probabilities, the

predicted diversion ratio from hospital k to hospital l is

$$d_{kl} = \left(\sum_i \text{prob}_{il|k} - \sum_i \text{prob}_{il} \right) / \sum_i \text{prob}_{ik},$$

where prob_{il} denotes the fitted probability that patient i is treated at hospital l (with the analogous definition applying to prob_{ik}) and $\text{prob}_{il|k}$ denotes the fitted probability that patient i is treated at hospital l under the hypothetical exclusion of hospital k .^{16,17}

fixed-effects specification fully captures variation in preferences over quality and other hospital attributes, observed and unobserved, that systematically affect patient preferences, and, hence, observed choices.

¹⁶ As is standard in such models, we interpret actual patient choices as a realization of a process that is stochastic from the perspective of the analyst. Such models generally have the property that the fitted probabilities for a given patient are close to the observed choice frequencies for other patients with similar observable characteristics.

¹⁷ This formula for the diversion ratio assumes that the patient volume at the hypothetically excluded hospital would drop to zero. But this is not necessarily the case, as some patients do use out-of-network hospitals. However, estimating the reduction in patient volumes due to a network exclusion is impossible in most instances, because there are often no network exclusions in the area and timeframe that is being examined, or, if there are, the identity of the MCO providing primary coverage is often not available. For cases in which we can estimate the effect of a network exclusion on patient volumes, the diversion formula is modified to be

It is well known that if one estimates a conditional logit applying data on relevant individual consumer characteristics, then diversions at the level of the consumer are proportional to that consumer's fitted choice probabilities, but diversions at the product level are not proportional to product level shares. The reason is that information on individual consumers makes it possible to identify variation in valuation of product characteristics across consumers. Hence, the model generates reasonable substitution patterns in that hospitals that are closer in product characteristics space to the hypothetically excluded hospital are predicted to capture a disproportionate (relative to observed shares) share of the diverted patients. See Berry (1994, pp. 246-247).¹⁸

This simple analysis has the important property that it is largely insensitive to the inclusion of competitively irrelevant geographic areas or hospitals. Unlike share-based concentration measures, it does not require, and in fact has no role for, a geographic market definition. Generally, we start with a broad patient population and a choice set consisting of a broad range of alternative hospitals. However, any claim that these should be made broader still is easily accommodated by simply including data on the additional ZIP codes and/or hospitals in the analysis. In contrast, a share-based concentration measure has the disadvantage of being highly sensitive to geographic market definition.

$d_{kl} = (\sum_i prob_{il \setminus k} - \sum_i prob_{il}) / (\sum_i prob_{ik} - \sum_i prob_{ik \setminus k})$, where $prob_{il \setminus k}$ and $prob_{ik \setminus k}$ denote the predicted probabilities of l and k under the hypothetical exclusion of k . In these cases, we have found only trivial differences in the estimated diversions using the two formulae.

¹⁸ Since hospital characteristics are interacted with patient characteristics, and the predicted hospital volumes are, in effect, integrated over the empirical distribution of patient characteristics, the distribution of patient characteristics serves as a “mixing distribution” in the same manner as a parametric mixing distribution that is applied to a simple logit model in a setting in which only product-level shares are observed: e.g., Berry, Levinsohn, and Pakes (1995). In some instances, it may be appropriate to add parametric mixing distributions to the patient-level choice model. For example, we have experimented with adding mixing distributions for household income (interacted with travel time) to the conditional logit model. In this model, patient-level diversions are not proportional to the predicted choice probabilities. However, we have found almost no difference in the estimated hospital-level diversions in the mixed conditional logit compared to the standard conditional logit model. The nested logit model discussed above also eliminates proportional diversion at the patient level to some degree.

2.4 Merger Simulation

In this section, we present our approach to merger simulation, which is derived from the above theoretical framework. While our approach can be adapted to either separate or all-or-nothing post-merger bargaining, we present the latter case only since that is the most common.

Solving the first-order condition of the Nash objective function with respect to the equilibrium price (and applying the Envelope Theorem¹⁹) yields the expression

$$(1) \quad p_k = \alpha \frac{V(\phi(p_k, p_{-k})) - V(\phi(p_{-k}))}{n_k} + (1-\alpha) \frac{c_k(n_k)}{n_k} + \alpha \sum_{j \neq k} d_{kj} p_j.$$

For a multi-hospital system which bargains on an all-or-nothing basis, we have for each hospital j in system S

$$\sum_{j \in S} n_j p_j = \alpha \left(V(\phi(\{p_j\}_{j \in S}, p_{-S})) - V(\phi(p_{-S})) \right) + (1-\alpha) \sum_{j \in S} c_j(n_j) + \alpha \sum_{j \in S} n_j \sum_{k \notin S} d_{jk} p_k.$$

Since this relationship is identical for each hospital in the system, we create a system-level analog to (1) by dividing through by the total volume of the system. This gives

$$(2) \quad p_S = \alpha \frac{V(\phi(\{p_j\}_{j \in S}, p_{-S})) - V(\phi(p_{-S}))}{\sum_{j \in S} n_j} + (1-\alpha) \frac{\sum_{j \in S} c_j(n_j)}{\sum_{j \in S} n_j} + \alpha \frac{\sum_{j \in S} n_j \sum_{k \notin S} d_{jk} p_k}{\sum_{j \in S} n_j},$$

where p_S denotes volume-weighted average price.^{20,21}

¹⁹ $\frac{\partial V(\phi(p_k, p_{-k}))}{\partial p_k} = \frac{\partial V(\phi(p_k, p_{-k}))}{\partial \phi(p_k, p_{-k})} \frac{\partial \phi(p_k, p_{-k})}{\partial p_k} = 0$ since ϕ is chosen to maximize V .

²⁰ Deriving a single expression for a system that bargains on an all-or-nothing basis is consistent with theory since, if volumes are not sensitive to prices, then the allocation of prices across the system is immaterial.

The expressions in (1) and (2) indicate that in equilibrium the hospital system receives a fraction α of the equilibrium per-patient value that the MCO gains from the system's inclusion in the MCO's network. Comparative statics on (1) and (2) with respect to a small exogenous change in patient preferences that affect the payoffs of the MCO indicate that the system would also receive a fraction α of the additional value generated by the change.

The merger simulation exercise is a least-squares regression based on (1) for independent hospitals and on (2) for multi-hospital systems. We do not have a direct measure of $V(\phi(\{p_j\}_{j \in S}, p_{-j})) - V(\phi(p_{-S}))$. Estimating it for each MCO/hospital system combination by jointly modeling and estimating the oligopoly game played by MCOs and the MCO/hospital bargaining games would be difficult, in part because the time cost would be prohibitively high in the context of a typical antitrust investigation, and also because the data burden placed on MCOs and their customers would be very high. Hence, we seek a proxy variable that can readily be computed using discharge and claims data that are obtained from state agencies and MCOs. Such a proxy should reflect the intuition that the difference in payoffs for the MCO should be determined primarily by the value-added of the hospital or system to the MCO's provider network from the perspective of consumers (i.e., by how much less attractive consumers would find an insurance product that excluded that hospital or system). We use the *willingness-to-pay* (*WTP*) measure that is presented in Town and Vistnes (2001) and Capps et al. (2003), which is specifically constructed to capture this notion of value-added.^{22,23}

²¹ The last term in (1) and (2) captures price complementarities between competing hospitals in that they capture the component of the disagreement payoff of the MCO that depends on which hospitals patients will divert to and the prices at those hospitals. The current hospital merger simulation literature does not incorporate these complementarities. Models that ignore them limit the focus of the analysis to the first-order price effects that result directly from the potential elimination of competition between the merging firms, and therefore generally produce smaller merger effects. We are currently exploring models that do account for these interactions.

²² See Capps et al. (2003) for a detailed derivation of *WTP*. To briefly summarize, the *WTP* of system S is defined as $E_\varepsilon [\max_{k \in G} \{U_{ik}\}] - E_\varepsilon [\max_{k \in G \setminus S} \{U_{ik}\}]$, where G denotes the set of hospitals in the MCO's network, for the observed characteristics (demographic and clinical) of patient i and the set of hospital characteristics. This is then integrated over the distribution of patient characteristics. As such, it measures the value-added of system S to the provider network from the perspective of the MCO's enrollees.

Holding constant the number of patients treated at a given system S , its WTP is larger if there are relatively few proximate alternatives because some patients will be forced to use much less preferred alternatives if S is excluded from the MCO's network. Similarly, WTP is larger if the component hospitals of S are close substitutes for one another because, if system S bargains on an all-or nothing basis, the exclusion of the entire system from the MCO's network will also cause some patients to use much less preferred alternatives.

Since WTP is a proxy for $V(\phi(\{p_j\}_{j \in S}, p_{-j})) - V(\phi(p_{-S}))$, and given the relationship defined in (1) and (2), the merger simulation exercise is based on a least-squares regression of case-mix adjusted prices on WTP per discharge (WTP_PD), rather than WTP itself. Since this measure of bargaining power is defined on a per-discharge basis, it does not predict that a large system will have a high price simply because it has a large patient volume.²⁴ Rather, the extent to which a large system has a large WTP_PD is driven by the closeness of substitution between the component hospitals, not its overall patient volume. A hospital with few discharges, but with few proximate competitors, will have a high WTP_PD compared to a hospital with the same number of discharges but many proximate competitors. In contrast, a large hospital with many close competitors may have a large number of discharges but many of those patients may only slightly prefer it to their next best alternative. Such a hospital will have a low WTP_PD . Also, like the diversion analysis discussed above, the simulation exercise does not depend on an a priori market definition.

Mergers introduce discrete changes in $V(\phi(\{p_j\}_{j \in S}, p_{-j})) - V(\phi(p_{-S}))$, which means the feedback of price changes into premiums (both the MCO's and its competitors') and then into

²³ There are other possible proxies for hospital bargaining power that may be applied, though they are less directly related to the value-added intuition described here. These include the *hospital-specific HHI* measure that is described in Capps and Dranove (2004).

²⁴ In this framework, merger effects are due solely to reduction in competition, meaning that a merger between hospitals that are not substitutes would have no effect on price. If we allowed for the possibility that MCOs or hospitals' payoff functions are concave, then "pure size" effects would become possible. However, this effect will only be significant if hospitals and MCOs are meaningfully different in the concavity of their payoff functions. There is empirical evidence that such pure size effects are small; see Sorenson (2003).

the MCO's payoff functions will not necessarily be negligible. Hence, (1) and (2) are first-order linear approximations of the true relationship. Balan and Brand (2011) evaluate the effect of this approximation by using simulated data to calculate "true" merger effects and then comparing them to the effects that are predicted by the simulation method described here. Preliminary results suggest that the simulations do reasonably well, with some tendency to under-predict the true effects.

Prices are derived from claims-level data obtained from MCOs, which are aggregated to the discharge level and then adjusted for case-mix. Cost data may be obtained directly from hospitals or from the Centers for Medicare & Medicaid Services (CMS) cost reports.

The specification of the regression model hews closely to (1) and (2), but may vary as case-specific circumstances suggest. While omitted variable bias is an important consideration, the inclusion of any additional variables beyond *WTP_PD* and cost must come with a strong argument that it is not already captured by those two variables. MCO and year fixed-effects satisfy this condition and are commonly included. In contrast, any attribute that theory suggests should affect patient preferences over hospitals, and, hence, the value-added of hospitals to the MCO's network, should be captured in *WTP_PD*. Similarly, if the attribute is costly to produce, the higher costs should be captured in the cost measure. For example, hospital quality affects preferences and can be costly to produce. If the conditional logit model contains hospital fixed-effects and interactions of these fixed effects with patient-level indicators of clinical condition, *WTP_PD* will capture patient preferences over quality measures and variation in preferences over quality by clinical condition.²⁵ Therefore, in this framework, there generally is no rationale for including quality measures as separate explanatory variables in the regression if the available cost measure captures the cost of producing the quality measures.

²⁵ As noted above, *WTP_PD* will capture quality, or any other hospital attribute that consumers value, whether the model directly includes those attributes or employs hospital fixed effects only. The value of *WTP_PD* would be exactly the same under both specifications. If some observed hospital attributes may be altered by a merger, then those attributes could be included as explanatory variables so the effect of the potential change can be examined. In this case, the model must exclude a number of hospital fixed effects that are equal to the number of included attributes.

Including variables that are highly correlated with the bargaining power measure, but that in fact act on prices only through the bargaining power measure, as separate regressors can lead to incorrect inference due to collinearity. In addition, it is straightforward to show that if the sample size is small (as is often the case) or if the error variance is high, including these regressors, or other spuriously correlated variables, can produce highly unstable coefficient estimates (even though the least-squares estimator remains, strictly speaking, unbiased) and can significantly reduce the power of hypothesis testing. Hence, in the small sample case, it is particularly important that the specification of the model be carefully guided by theory – particularly in terms of whether and how other explanatory variables should be included.²⁶ This is in contrast to the hospital choice model discussed earlier, in which the number of observations is usually very large. The small number of observations in the merger simulation regression model (typically less than 200) make this a salient issue.²⁷

Direct measures of average cost may or may not be included in the regression. While including some measure of average cost may be preferable, we have found, in some circumstances, that costs may be jointly determined with prices, particularly for non-profit hospitals. For example, it may be the case that hospitals that receive higher reimbursements are more likely to make significant investments in office amenities, marketing efforts, or other expenditures that have little to do with the incremental cost of providing patient care. These expenditures may contaminate the available cost measure, and therefore bias downward the estimated coefficient

²⁶ Note that the approach to model specification in this framework is fundamentally different from a regression model that retrospectively estimates the treatment effect of a merger using a differences-in-differences approach. In the differences-in-differences analysis, the pre- and post-merger bargaining power of hospitals is not modeled. Hence, any attribute that may affect prices through patient preferences over hospitals could be included as a separate explanatory variable. In a prospective analysis in which the bargaining game between hospitals and MCOs is directly considered, attributes that affect prices through patient preferences over hospitals should be reflected in the underlying utility model, and, hence, in the bargaining power measure.

²⁷ The unit of observation is typically a system/MCO/year combination. Hence, there may be several observations from a given system/MCO contract period. Since these observations are not independent, we typically cluster standard errors within system/MCO combinations. This has an effect that is similar to reducing the number of observations.

on WTP_PD . Hence, it may be preferable to include proxy variables that indirectly measure the exogenous variation in costs in lieu of the direct cost measure.

Finally, the fact that the dependent variable in the regression model is a case-mix adjusted price may reduce the necessity of including any cost measure. Once prices are case-mix adjusted, the only relevant exogenous cost variation should be limited to the cost of direct healthcare inputs such as supplies or, perhaps, labor inputs. In many instances, there may be little reason to think that input costs will vary significantly across hospitals within a given area on a case-mix adjusted basis.

Given the estimated regression model, it is straightforward to generate a predicted price effect that is consistent with the bargaining model. The relevant question in an all-or-nothing bargaining setting is whether the merged hospitals will be able to extract higher prices from an MCO together than they could, on average, separately. Hence, the model generates a predicted change relative to the volume-weighted average pre-merger price (or predicted “but-for” prices if they are likely to be substantially different). Following Capps et al. (2003), the predicted level effect of a merger between system S and hospital k relative to the volume-weighted average pre-merger price is given by

$$\hat{\beta} \left(WTP - PD_{Sk} - \frac{n_s}{n_s + n_k} WTP - PD_s - \frac{n_k}{n_s + n_k} WTP - PD_k \right),$$

where $\hat{\beta}$ denotes the estimated regression coefficient on WTP_PD .^{28,29} We assume that the relationship between WTP_PD and price is unaffected by the change in market structure. This is

²⁸ Since WTP_PD is a proxy variable for $[V(\phi(p_k, p_{-k})) - V(\phi(p_{-k}))]/n_k$, the regression coefficient β captures both the split parameter α and the underlying regression coefficient between WTP_PD and $[V(\phi(p_k, p_{-k})) - V(\phi(p_{-k}))]/n_k$ which converts WTP_PD , measured in “utils”, to dollars.

²⁹ Since the prediction of the model is on the volume-weighted average price of the post-merger system, there is no specific prediction for each hospital involved in the transaction. As noted above, this is consistent with theory since under all-or-nothing bargaining, and if volumes are not sensitive to price, the allocation of the predicted price effect across the merging hospitals is immaterial.

consistent with assuming that the split parameter in the bargaining model is unaffected by the merger. The predicted effect will be close to zero if either $\widehat{\beta}$ is close to zero or the estimated diversions between S and k are close to zero.³⁰

We note that this analysis may also be used to define antitrust (geographic and product) markets. While this application may seem to be of limited value since the merger simulation already provides direct evidence on the likely competitive effects, it may nonetheless be useful for other components of the overall antitrust analysis.

Finally, we emphasize that the empirical analysis described here is only one part of the antitrust analysis of a proposed hospital merger. Documentary and interview evidence and other economic analyses are other key components. The merger simulation exercise is, therefore, just one part of the body of evidence that is considered in the evaluation of whether a given merger is likely to substantially lessen competition.

3 Authorized Generic Drugs and the Potential for Entry Deterrence

Hospitals comprise only one part of our health care antitrust agenda. In addition, we examine consolidations and market behavior in all areas of the health care sector including pharmaceuticals. In this segment, we describe the results of our latest research on the effects on drug prices and on patent challenges of “authorized generic” (AG) drugs: a generic version of a drug that is produced by the firm that holds the patent on the branded drug. As part of the response to growing competition with generic drugs,³¹ brand-name drug firms sometimes

³⁰ Merger-specific efficiencies that involve cost reductions can be evaluated in the same way: the post-merger cost minus the volume-weighted average of the pre-merger costs.

³¹ An FTC Report on Authorized Generics (2011) reported that, on average, a brand company that faces competition from just one generic competitor loses 70% of pre-generic revenue within the first six months of facing generic competition.

introduce AGs. AGs are approved by the U.S. Food and Drug Administration (FDA) as brand-name drugs, but are marketed as generic drugs.³²

The competitive effects of AGs are theoretically ambiguous. Although competition from AGs may contribute to lower generic drug prices (Berndt et al., 2007), AGs could deter generic entry in markets that require patent challenges to gain entry (Hollis and Liang, 2007).³³ Members of Congress have requested that the FTC consider these issues and examine the impact of authorized generics on competition in the prescription drug marketplace, which was initially considered in a 2009 interim report, and is now the focus of the final FTC authorized generic report (FTC, 2011).

The regulatory framework governing generic entry via patent challenge is laid out in the Hatch-Waxman Act.³⁴ Under the law, a generic company can ask for FDA approval prior to the expiration of the patents that cover the branded product if the generic claims that the patents are invalid or not infringed and if it gives notice of its claims to the brand company. These are referred to as “Paragraph IV” filings in reference to the relevant section of the Act. Such a challenge usually results in an infringement suit being filed by the brand firm.

A key provision of the Hatch-Waxman framework is the grant of 180 days of marketing exclusivity to the first generic manufacturer that seeks entry via such a challenge once entry has occurred. During this period the FDA may not approve subsequent generic entrants for the same

³² For example, AGs are typically priced lower than the brand.

³³ The economics literature addressing the effects of entry-deterrance is large. The literature addressing the entry-deterrance effects of product proliferation in differentiated product markets may be particularly relevant. See, for example, Scherer (1979) and Schmalensee (1978).

³⁴ The Hatch-Waxman Act is formally known as the Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No 98-417, 98 Stat. 1585 (1984). The Act requires a generic applicant to certify that its version does not violate the patents that are associated with the reference drug by referring to relevant paragraphs of the Act. Paragraph I certifies that the reference drug has no patents; Paragraph II certifies that the reference drug only has expired patents; Paragraph III certifies that the reference drug has unexpired patents, but that the applicant intends to wait until its expiration to market their drug; and Paragraph IV certifies that the reference drug has unexpired patents that the applicant asserts it does not violate either because the patent is invalid or because its generic drug does not infringe the patent.

drug product. The rationale for this prize is that it will encourage generic firms to challenge weak or narrow patents by singling out a specific challenger in an attempt to prevent a free-rider problem.³⁵ However, the Act does not prohibit an AG from marketing during exclusivity because the AG can rely upon the FDA's approval of the brand. Competition with the AG during the 180-day exclusivity may lower prices and take share from the first-filer, reducing the revenues that a patent challenger earns following a successful patent challenge.³⁶ As we confirm below, AGs reduce the expected reward from a successful challenge, thereby reducing generic manufacturers' incentives to challenge patents in the first instance, but the question is by how much.

The discouragement of entry is only a potential issue if the AG causes the returns from the 180-day exclusivity period to become insufficient to induce patent challenges. If the introduction of an AG does not deter a patent challenge, then competition from the AG both during and following exclusivity may contribute to lower generic prices. Consideration of the net effects of AGs should weigh the benefits that are associated with such competition against any entry deterrence effects. This calculation depends on the magnitude of pricing effects and the types of drugs deterred (if any).

In an effort to characterize the importance of the deterrence effect, the final authorized generic report provides a broad characterization of the role that AGs have in the marketplace for prescription drugs (FTC, 2011). The principal analysis develops a model that characterizes affected challenges by the market size of the drug and the generic's belief that it can successfully challenge the brand's patent protection. Econometric estimates of the effects that AGs have on

³⁵ In some circumstances, Hatch-Waxman allows the FDA to designate more than one firm as the first-filer. Multiple first-filers would share the 180-day exclusivity period. Despite this possibility, the majority of 180-day exclusivity periods in our sample are observed with a single first-filer, though data for markets with multiple first-filers are included in the analysis to help separately identify the impact of the AG from the impact of increasing the number of suppliers.

³⁶ First-filers and patent challengers are related terms, but are not identical. A first-filer is the status of specific generic firms that file their paragraph IV ANDA application before other applicants. Patent challengers are any generic firms that file an ANDA under the paragraph IV requirements of the Hatch-Waxman Act and either launches their ANDA version of the product or literally challenges the patents in court.

the prices of generic drugs and the revenues of first-filers both during and following the 180-day exclusivity are used to calibrate the model. We find that AGs may deter entry into relatively small drug markets: in particular, drugs that are located in the bottom sales decile. In the following sections, we more fully describe our model and our results.

3.1 Estimation Strategy: AG Effects on First-Filer Revenues and Generic Prices

The empirical analysis of entry incentives into markets for drugs that are protected by patents considers the effect that an AG has on generic drug prices and the expected revenues of the first-filer applicant(s) both during and following the 180-day exclusivity period. The analysis uses information from the FDA combined with monthly wholesale price and expenditure data from IMS Health (IMS).³⁷ These data provide a detailed description of many drug characteristics, which are used to define a “drug,” for purposes of the analysis, as the combination of active ingredient(s)-strength-therapeutic class and dosage form.³⁸ The analysis that is summarized here only considers oral solid drugs that were marketed during 180-day exclusivity periods occurring during the period January 2003 through December 2008.³⁹ Information that was obtained from

³⁷ The dataset used is the IMS Health, IMS National Sales Perspectives™, January 2003 to December 2008, Retail and Non-Retail Channels, Data Extracted February 2009. The channels included in our NSP sample are: Chain Stores, Clinics, Federal Facilities, Food Stores, HMOs, Home Health Care, Independents, Long-Term Care, Mail Service, Misc-Other, Misc-Prisons, Misc-Universities, and Non-Federal Hospitals. The analysis that is summarized here aggregates over these channels.

³⁸ Sales information is also used to construct the number of competing firms and the entry date. The number of competing generic firms is defined to be the number of generic firms with positive sales during the month. Generic entry is defined as the first month in which any generic firm (including an AG) is observed with positive dollar sales. Exit is defined to be three consecutive months of zero sales following a month with positive sales. If such an exit is observed, the exit date is defined to be the month following the last month observed with positive sales.

³⁹ Oral solid medications are defined using the “doseform” and the “three-letter code” variables that are provided by IMS. The sample also omits decongestants and vitamins. Those drugs are often sold without a prescription outside of channels tracked by IMS. See Appendix I of the FTC Report for a complete list of therapeutic classes that are omitted and the dosage forms that are included.

the FDA is used to determine whether a drug faced a patent challenge and the dates of any exclusivity arising from the challenge.⁴⁰ First-filers are identified in the data as generic firms with positive sales during exclusivity that are not AGs.

First-Filer Revenues During the 180-day Exclusivity Period

The first-filer's revenues that are associated with the 180-day exclusivity period can be affected by the presence of an AG competitor. This effect is estimated by regressing first-filer revenues against drug characteristics and an indicator for whether an AG was introduced. The formal specification is presented as equation (3):

$$(3) R_{dt}^f = \alpha + \beta_{ag} ag_{dt} + \sum_{j=2}^4 \beta_{mj} man_{jdt} + \sum_{j=2}^4 \beta_{agi} ag \cdot man_{jdt} + \delta_{year} + \delta_{tc} + \delta_{df} + \delta_{months} + \varepsilon_{dt} .$$

The dependent variable, R_{dt}^f , is the first-filer revenues for drug d in month t as a fraction of pre-entry brand revenues. Pre-entry brand revenues are measured as the average of brand revenues during the quarter immediately preceding generic entry. R_{dt}^f is regressed against fixed-effects for the calendar year, δ_{year} , therapeutic class of the drug, δ_{tc} , dosage form, δ_{df} , and months since generic entry first occurred, δ_{months} . The variable of interest is the indicator variable, ag , which is equal to one if an AG is present in the market during month t , and equal to zero otherwise.⁴¹ The AG indicator is interacted with indicators that reflect the number of manufacturers that were present in the market to allow the effect of an AG to vary flexibly by the number of competitors in the market.⁴²

⁴⁰ FDA information was supplemented and verified using data that were subpoenaed from the pharmaceutical firms.

⁴¹ An AG is included in the count of the number of manufacturers. For example, a market with a first-filer and no AG has one generic manufacturer, and a market with an AG and a first-filer has two manufacturers.

⁴² Due to the possibility of multiple first-filers, some drugs are observed with as many as four manufacturers during exclusivity. However, the analysis of deterrence considers only markets with a single generic competitor. In markets with multiple first-filers, the deterrence effect of an AG is likely to be small.

The impact of AG competition on the proportion of pre-entry brand sales a lone first-filer can expect to earn in revenues during the 180-day exclusivity period can be calculated as $\beta_{ag} + \beta_{ag2} + \beta_{m2}$, and dividing this by the average (normalized) revenues of a lone first-filer, \bar{R} , gives the percentage impact of AG entry on the first-filer.

First-Filer Revenues Following the 180-day Exclusivity Period

Following the 180-day exclusivity period, independent generic firms can observe the presence of an AG and adjust the entry decision accordingly. Consequently, the analysis of first-filer revenues following the 180-day exclusivity considers the effects of displacing a generic drug (an Abbreviated New Drug Application (ANDA) generic) by an AG rather than the effect of facing an additional AG competitor.⁴³ As in the analysis of first-filer revenues during exclusivity, this effect is estimated by regressing normalized first-filer revenues following exclusivity against fixed-effects for the year, therapeutic class, dosage form, and months since generic entry first occurred. However, the analysis following exclusivity accounts for more than ten competitors, and limits the analysis to the 2.5 years following the first 180-days of generic entry.

Generic Drug Prices

The evaluation of patent challenge incentives also makes use of the effect that an AG has on generic drug wholesale prices. These effects are estimated using specifications that are analogous to those of the first-filer revenues regressions. The specifications differ in that generic drug prices are constructed by dividing the aggregate dollar expenditures on generic drugs by the total extended units (e.g., the total “pills”) during the month, rather than considering only the sales

⁴³ To investigate the assumption that an AG more-or-less displaces one ANDA generic, data on the number of generics that are present in markets two years after first generic entry was analyzed to determine if entry patterns differed in AG markets. Controlling for pre-entry brand sales, the number of generic competitors that are present in the market after two years, including the AG, was not statistically different between markets with an AG and those without.

from the first-filer.⁴⁴ Generic prices are normalized by the quantity-weighted pre-entry brand price in the quarter immediately preceding generic entry.

3.2 Estimation Results

The empirical analysis begins with a plot of the mean of normalized revenues for the first filer, the brand drug, the AG, and “other generic firms” over time. These revenues are normalized by pre-entry brand revenues immediately preceding generic entry, which is analogous to the calculation for the dependent variable in the revenues regressions. Figures 1a and 1b plot these measures over time, as stacked area graphs, for markets with and without an AG competitor. Two patterns emerge from these figures. First, the graphs demonstrate that generic products quickly take a large share of the market from the brand, earning between 55-70% of the revenue share during the first six months of entry. Second, the figures reveal that the first-filer and the AG are able to keep most of their share for the duration of the sample. These firms appear to benefit from a “first-mover advantage” that extends well past the end of exclusivity. The average combined contemporaneous revenue share of first-filers and AGs never falls below 50% over the three-year period despite facing three-to-four other competitors, on average, following expiration of the 180-day exclusivity.

The pace at which generic entrants command share and the ability to hold onto that share suggests that the reward from the 180-day exclusivity period is substantial. However, in markets where an AG is present, the figures suggest that the first-filer splits these rewards with the AG. Moreover, the total size of the market, measured as a fraction of pre-entry brand revenues, is smaller in markets where an AG is present than in markets where an AG is not introduced.

The markets that are presented in Figures 1a and 1b represent two sets of drugs: one with and one without an AG. These drugs may differ in characteristics other than whether an AG was introduced, such as the number of eventual generic competitors that are faced in the market. The

⁴⁴ All analyses normalize the dependent variable by the relevant pre-entry brand statistic (i.e., prices and revenues). This normalization implies that the decision to consider the unit of analysis to be pills is identical to the decision to consider the unit of analysis to be the average daily dose.

differences in the first-filer revenues across markets may be attributable to these other factors, rather than the AG. The regression models attempt to control for these factors by including drug characteristics such as the therapeutic class and the number of competitors.

The effects of an AG on revenues and prices from the regression models are calculated and presented in Tables 1 and 2, respectively. The results are presented separately during and following exclusivity periods using estimates from un-weighted and sales-weighted regressions. The econometric estimates are largely consistent with the representation of market dynamics that are found in the figures. Table 1 reveals that first-filers facing an AG earn between 40-52% less revenue during exclusivity than do first-filers in markets without an AG. Following exclusivity, the AG effect estimates are also large and economically important. These results are consistent with the shared “first-mover advantage” also seen in Figures 1a-1b. Table 2 suggests that the AG is responsible for 12.8%-13.5% lower wholesale prices during exclusivity. This result is consistent with the smaller overall market observed in the figures. The price effect of the AG following the exclusivity period is statistically insignificant, although the coefficients are negative.

3.3 Incentives to File Paragraph IV Challenges

The price and revenue analyses suggest that the 180-day exclusivity period provides a potentially substantial reward for first-filers, but the introduction of an AG significantly reduces the size of the reward. Consequently, the introduction of the AG has the potential to deter entry, but its importance in affecting the decision to challenge a patent depends on the costs that are associated with challenging a patent and the size of the rents from the 180-day exclusivity.

To address these issues, we develop a simple model of the potential first-filer’s decision to issue a challenge that incorporates the costs of challenging patents and the rents associated with winning the challenge. The model is calibrated using estimates from the empirical analysis and cost estimates that were obtained from generic manufacturer responses to FTC-issued

subpoenas.⁴⁵ The model is used to characterize the generic's beliefs that it will prevail and the market sizes of drug markets that potentially could be affected by the introduction of an AG. In the model, a potential patent challenge results in the following expected profit function:

$$(4) \quad E[\Pi] = p(\text{win}) \cdot [\pi_{\text{excl}}(\text{AG}) + \pi_{\text{post}}(\text{AG})] + (1 - p(\text{win})) \cdot [\pi_{\text{non-excl}}] - L - A .$$

Equation (4) is constructed such that the expected profits from issuing a challenge, $E[\Pi]$, depend on the probability that the challenger wins patent infringement litigation, $p(\text{win})$; the total profits conditional on winning; patent litigation costs, L ; and FDA filing costs, A . If the challenger wins the litigation, the first-filer earns π_{excl} for 180-days during exclusivity and π_{post} for 2.5 years following exclusivity.⁴⁶ These earnings depend on whether an AG is introduced. If the challenger loses the litigation, the first-filer earns $\pi_{\text{non-excl}}$, which is independent of an AG. Filing and litigation costs are incurred regardless of outcomes.

The model assumes constant marginal costs, identical brand and generic costs for the same drugs, and identical brand margins across drugs. Under these assumptions, the profits that a first-filer earns following a successful litigation can be re-written as a function of normalized first-filer revenues during and following exclusivity, \hat{r}_f and \bar{r}_f , normalized generic price discounts during and following exclusivity, \hat{p}_f and \bar{p}_f , pre-entry brand revenues, r_b , and brand profit margins, m .

$$(5) \quad \pi_{\text{excl}} + \pi_{\text{post}} = [(\hat{p}_f - (1 - m)) \cdot \hat{r}_f \cdot r_b] / (2 \hat{p}_f) + 2.5 \cdot [(\bar{p}_f - (1 - m)) \cdot \bar{r}_f \cdot r_b] / (\bar{p}_f)$$

In equation (5), first-filer revenues during exclusivity, \hat{r}_f , and following it, \bar{r}_f , are normalized by the brand revenues that immediately precede generic entry. Similarly, generic prices during

⁴⁵ Many respondents did not report cost information for various reasons, often explaining that the firm did not track the information separately by drug. Estimates are simple means from the provided data and do not attempt to adjust for selection in reporting. Industry figures provide similar estimates. See FTC (2011) for a more detailed description of these issues.

⁴⁶ We use 2.5 years because our regression analysis allows us to follow drug markets for three years.

exclusivity, \hat{p}_f , and following it, \bar{p}_f , are normalized by brand prices that immediately precede generic entry. Substituting equation (5) into equation (4) and imposing a zero-profit condition on non-exclusive entry allows for the expected profits calibration.⁴⁷ The calibration is performed twice, once under the expectation that an AG will not be introduced, and again under the expectation that an AG will be introduced with certainty.⁴⁸ In the first calibration (i.e., no AG), the price and revenue values are replaced with the corresponding sample averages for markets that do not contain an AG. In the second calibration (i.e., AG), these averages are discounted by the price and revenue AG effects from the un-weighted regressions.

The values that are used in each set of calibrations are presented in Table 3. Both calibrations use the mean litigation and ANDA submission costs from the subpoenaed responses, which are also reported in Table 3. Marginal costs were approximated by using wholesale pricing data from markets with greater than 10 generic competitors under the theory that prices will fall to a level that is close to marginal costs in these markets. Generic prices average approximately 10% of the pre-entry brand price in these markets with a large number of competitors, so we assume that the marginal cost of producing the drug is 10% of the pre-entry brand price. The analysis is not sensitive to this assumption.⁴⁹

Figure 2 characterizes the win probabilities and market sizes of drugs for which a potential challenger, under the assumptions of the model, would be indifferent between challenging and not. The figure provides separate “break-even” curves for firms that do and do not expect to face an AG. Areas above these curves represent situations where a challenge would be expected to be profitable, and areas below them represent circumstances where the challenge is expected to be

⁴⁷ The zero-profit condition has two functions. It allows us to characterize the set of drugs for which a potential challenger is indifferent between challenging and not. It also implies that expected operating profits of an entrant that comes in after exclusivity must be equal to the filing costs, i.e. $\pi_{non-excl} = A$.

⁴⁸ These assumptions may lead to a finding of a larger deterrence effect than allowing the expectation of facing an AG to depend upon market characteristics.

⁴⁹ Consistent with this, a 2004 Morgan Stanley report that analyzed the impact of AG entry on first-filers also assumed pre-generic entry brand profit margins of 90%; see Goodman et al. (2004).

unprofitable. The area between the AG and non-AG curves represents situations where a challenge would be deemed to be profitable only if an AG is not expected to enter. The difference in the win probabilities required to induce a challenge depends on the size of the market.⁵⁰

Figure 2 provides the cumulative sales density for drug markets in the sample to facilitate a characterization of relative market sizes. As can be seen in the figure, the difference between the AG and non-AG win probabilities necessary to induce a challenge can be large in relatively small markets. For example, a generic company considering a challenge in a \$15 million market would require a 41% chance of winning to induce a challenge if the potential challenger did not expect an AG. The same challenger would require a win with certainty under the expectation of facing an AG. Over the entire range of market sizes, the ratio of between the break-even win probabilities without and with an AG remains very close to 4:10. However, the absolute AG effect is much smaller in large markets. For example, expectation of AG entry in a \$250 million market would only cause the win probability required to induce a challenge to increase from 2% to 5%.

Figure 2 also demonstrates that drug markets that account for the vast majority of sales have low entry thresholds. For example, markets above \$130 million in sales would require less than a 10% chance of winning patent litigation to induce a challenge. In these markets that account for the vast majority of sales (85% of sales), weak and narrow patents are likely to be challenged, regardless of whether potential challengers expect to face an AG.

AGs have the potential to deter generic entry into markets that require patent challenges. However, they may also lower generic prices in the markets in which they enter. Although we find evidence that AGs have economically important effects on the revenue incentives of

⁵⁰ In Figure 2, the sales for a “market” are aggregate dollar sales of drugs across strengths and therapeutic classes within a dosage form. Many challengers enter into multiple strengths of a dosage form in a patent challenge. \$65 million is the median market in the sample, but drug markets that represent more than \$400 million in annual sales account for more than half of all sales.

potential challengers, these effects are only likely to deter entry into relatively small drug markets.

4 Consumer Protection

4.1 Homeowners Insurance and Credit-based Insurance Scores

Over the past decade, insurance companies increasingly have used information about credit history, in the form of credit-based insurance scores, to make decisions about whether to offer automobile and homeowners insurance to consumers, and if so, at what price. Insurance companies use these scores as a factor when estimating the number or total cost of insurance claims that prospective customers (or customers who renew their policies) are likely to file.

The 2003 Fair and Accurate Credit Transactions Act (FACTA) made comprehensive changes to the nation's system of handling consumer credit information, and directed the FTC to conduct an inquiry into the effects of credit-based insurance scores and submit a report to Congress.⁵¹ The FTC was asked to include a description of how these scores are created and used; an assessment of the impact of these scores on the availability and affordability of the relevant financial products; an analysis of whether scores act as a proxy for membership in racial, ethnic, and other protected classes; and an analysis of whether scoring models could be constructed that are effective predictors of insurance risk but have smaller differences in scores among racial, ethnic, and other protected classes. A report on the use and effects of credit-based insurance scores in *automobile* insurance markets was released by the Commission in July 2007.⁵² A companion study of credit-based insurance scores and *homeowners* insurance is currently underway.

Regarding the homeowners insurance study, the FTC used its 6(b) authority to compel the nine largest homeowners insurance groups in the nation to provide the necessary policy and claims data. These nine insurance groups represent over 50% of the market in terms of dollars in

⁵¹ 15 U.S.C. § 1681.

⁵² See Federal Trade Commission, (2007). That study is summarized in Michael Baye et al. (2008), at 221-228.

premiums written. The Commission requested and obtained policy- and claim-level information on all homeowners insurance policies (except condominium and renters policies) that were in force at each of the nine insurers during mid-2004 through mid-2007: approximately 47 million policies. In addition, the Commission requested data from each insurer on applications and price quotes for prospective customers during a 12-month period from early 2008 through early 2009.

At this point we have extracted a stratified random sample from the insurers' data (oversampling policies with claims). These data are being combined with credit history information for each policyholder from a credit reporting agency and race and ethnicity data from the Social Security Administration (SSA).

Using the claims data and a standard set of insurance rating variables from the policy data, in addition to credit-based insurance scores, we will run risk models by peril (e.g., fire, wind-hail, theft) to examine the relationship between credit history and the risk that a claim will be filed. Then we will analyze the potential for scores to act as a proxy for race and ethnicity among several protected classes of consumers. To do this we can compare the estimated coefficients for the score variable in risk models that include controls for race/ethnicity versus models that do not.

Our focus will then turn to the impact of these credit-based scores on insurance premiums that are paid by consumers. The coefficient of the score variable in the claim risk analyses will already provide an initial sense of this impact, but in order to obtain a more precise estimate of the impact of scores on premiums, we will run *premium* regressions with all of the rating variables, including scores. We will calculate the impact on average premiums within protected classes of consumers as well as across such groups. Finally, we will look at the application and quote data, to examine the relationship between credit-based scores and the likelihood of up-take by the consumer and/or rejection by the insurer.

4.2 A Study of Credit Report Accuracy

The FACT Act of 2003 also requires that the FTC conduct a study of credit report accuracy. That study will address the following questions: Regarding consumer alleged errors, what proportion

is material to creditworthiness? In turn, what proportion of material allegations is confirmed as erroneous by the existing credit reporting dispute process? If a credit report is drawn at random, what is the probability that the report would contain one or more material errors? Further, focusing on consumers and their credit standing, the study will estimate the proportion of American consumers who would encounter one or more material errors across their three credit reports. The study will reveal the main types of errors, their relative frequencies, and the impact of such errors on a consumer's ability to access credit.

A nationwide survey is currently in the field. Given the cost of the sampling procedure and the credit report review process, the target sample size (1000 consumers and 3000 credit reports) is relatively small. That sample should, however, allow us to draw statistically reliable and projectable conclusions regarding the accuracy of credit reports for the population of consumers.⁵³

We started with a very large random sample—200,000 individuals—from the population of interest: people with credit histories at the three national credit reporting agencies (i.e., Equifax, Experian, and TransUnion). This broad sample comprises the master list of all potential respondents, including a subgroup of about 28,000 solicited consumers and a further subgroup of 1,000 participants. The individuals on the master list have a distribution of credit scores that is statistically the same, at very refined levels of partition, as the national distribution of scores. As the invitations were sent to the potential participants in progressive waves, the credit scores and the major demographic characteristics of respondents have been analyzed to ensure that the ultimate study participants conform to national norms and are representative of the population.

⁵³ Another study of credit report accuracy was recently released by the Policy and Economic Research Council (PERC) for the Consumer Data Industry Association (CDIA), which is the credit reporting industry trade association. That study is modeled in part on the FTC's approach to measuring credit report accuracy. PERC finds that about 19% of reports may contain data errors as judged by the consumer respondents, but that only a small percentage – on the order of 0.5% -- are likely to have a significant adverse impact on a consumer's credit worthiness. The FTC report will contain commentary on the PERC study.

In addition to answering interesting questions about the accuracy of credit reports, the study will evaluate a potential response bias in our sample of participants. We will have access to the credit scores and the redacted credit reports for all non-respondents: the 27,000 solicited consumers (identified only by ID numbers) who did not participate. We will compare respondents to non-respondents on an array of attributes, including credit scores, major demographics (age, gender, regional diversity), and other important categories of credit report information, such as the number of active credit cards, total credit card balances, late payments (30, 60, 90+ days late), number of trade lines currently delinquent, accounts or tradelines that have been sent to collection, reported bankruptcy, liens on property, and the time span of the consumer's file. Conducting a detailed comparison of respondents and non-respondents will allow us to assess rigorously the degree to which the respondents and their credit reports are representative of the population.

5 Conclusion

Health care is one of the most important industries examined by the FTC. Our hospital merger analyses use a wide array of information, with one important component being the rigorous examination of data on the choices of hospitals by patients and prices paid for care by private insurers. That empirical analysis has proven useful in several recent investigations and litigations in the hospital industry. Similarly, empirical work is important in our policy making in the pharmaceutical arena. Our study of the price effects of authorized generics will provide the FTC and other policy-makers with a better understanding of the impact of entry into generic markets by incumbent drug makers. On the consumer protection front, empirical work is also at the forefront of policy development, with ongoing studies including the effects of credit scoring on the price and availability of homeowners insurance, and the accuracy of credit reports and the impact of errors on consumers' ability to obtain credit.

Figures and Tables

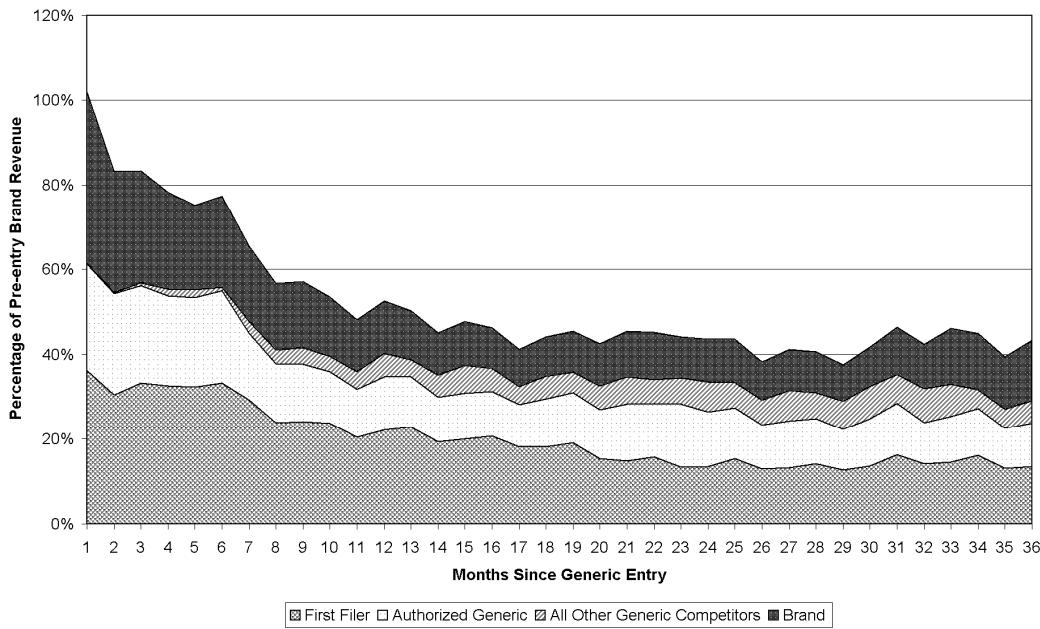


Figure 1a: Average Percent of Pre-Entry Brand Revenue Following Generic Entry by Firm Type in Exclusivity Markets Facing an Authorized Generic

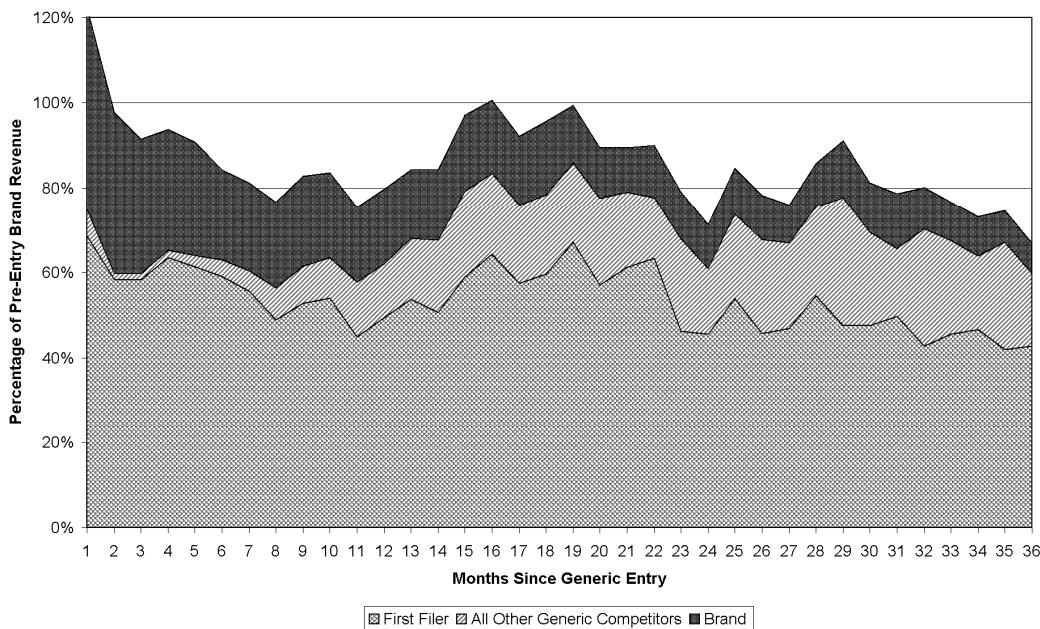


Figure 1b: Average Percent of Pre-Entry Brand Revenue Following Generic Entry by Firm Type in Exclusivity Markets that Do Not Face an Authorized Generic

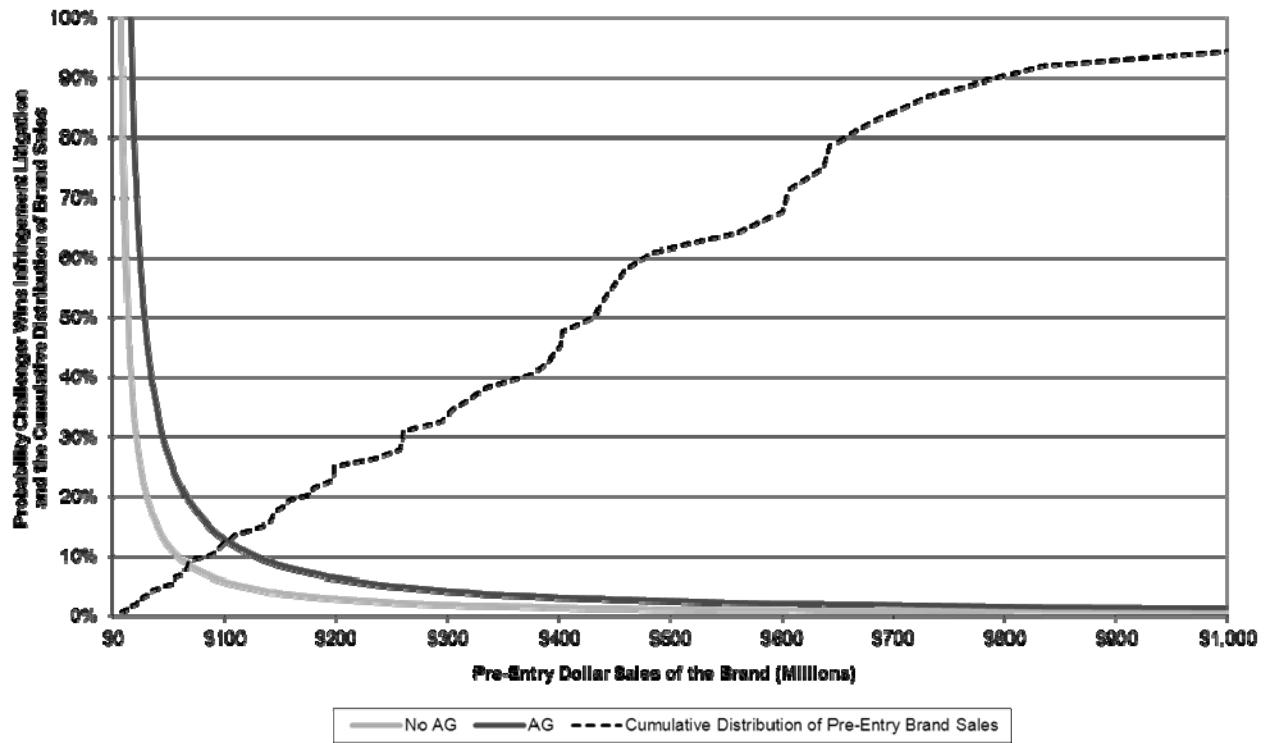


Figure 2: Characterization of Markets that Induce Challenges with and without Expectation of Facing an Authorized Generic Competitor

	<i>Revenues During 180-day Exclusivity</i>	
	Unweighted	Sales Weighted
Additional AG Competitor (Standard Error)	-52.0%** (10.6%)	-39.6%** (10.8%)
Mean of First-Filer Revenues (R^f)	0.70	0.51
Sample Size	630	630
	<i>Revenues Following 180-day Exclusivity</i>	
	Unweighted	Sales Weighted
AG Displaces a Competitor (Standard Error)	-52.5%* (22.8%)	-62.3%* (29.5%)
Mean of First-Filer Revenues (R^f)	0.31	0.24
Sample Size	2070	2070

*Statistically significant at the 5% level; **Statistically significant at the 1% level
Standard errors clustered at the molecule level

Table 1: The Effect of Authorized Generic Introduction on First-Filer Revenues

	<i>Prices During 180-day Exclusivity</i>	
	Unweighted	Sales Weighted
Additional AG Competitor (Standard Error)	-12.8% ^{**} (2.8%)	-13.5% ^{**} (2.4%)
Mean of Normalized Prices in Markets Facing Only Independent Generics	0.80	0.83
Sample Size	673	673
	<i>Prices Following 180-day Exclusivity</i>	
	Unweighted	Sales Weighted
AG Displaces a Competitor (Standard Error)	-13.0% (10.8%)	-6.0% (20.4%)
Mean of Normalized Prices in Markets Facing Only Independent Generics	0.39	0.27
Sample Size	2212	2212

*Statistically significant at the 5% level; **Statistically significant at the 1% level
Standard errors clustered at the molecule level

Table 2: The Effect of Authorized Generic Introduction on Generic Wholesale Prices

Model Variable	Variable Description	No AG	AG
L	Litigation Costs	\$ 5 million	\$ 5 million
A	ANDA Submission Costs	\$ 1 million	\$ 1 million
		<i>During 180-day Exclusivity</i>	
		No AG	AG
\hat{P}_f	Mean Generic Price as % Pre-Entry Brand Price	0.80	0.70
\hat{r}_f	Mean First-Filer Revenue as % Pre-Entry Brand Revenue	0.70	0.34
		<i>Following 180-day Exclusivity</i>	
		No AG	AG
\bar{P}_f	Mean Generic Price as % Pre-Entry Brand Price	0.39	0.34
\bar{r}_f	Mean First-Filer Revenue as % Pre-Entry Brand Revenue	0.31	0.15

Table 3: The Values Used in The Expected Profits Calibration

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