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THE STRATEGIC RESPONSE BY PHARMACEUTICAL FIRMS TO THE MEDICAID MOST-FAVORED-CUSTOMER RULES

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ABSTRACT

In 1990 the Federal Government included a Most Favored Customer (MFC) clause in the contract (OBRA 90) which would govern the prices paid to firms for pharmaceutical products supplied to Medicaid recipients. The firms had to give Medicaid their "best" (lowest) price in some cases, a percentage below average price in others. Many theoretical models have shown that an MFC rule commits a firm to compete less aggressively in prices. We might expect prices to rise following the implementation of the MFC rule, yet the work done to date on OBRA 90 has found this result somewhat difficult to show empirically. I also conclude that the effects of the law are small and relatively weak; however, the results are strongest where the product's characteristics match the incentives in the law. I find that after the MFC rule was implemented the average price of branded products facing generic competition rose - the median presentation's price rose about 4%. Brands protected by patents did not significantly increase price. Generics in concentrated markets should display a strategic response to the brand's adoption of the MFC. I find support for the strategic effect; generic firms raise their prices more as their markets become more concentrated. I find little change in hospital prices. The results suggest that the MFC rule resulted in higher prices to some non-Medicaid consumers of pharmaceuticals.

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Introduction

The Omnibus Budget Reconciliation Act of 1990 (OBRA 90) included a rebate program that featured a Most-Favored-Customer (MFC) clause for Medicaid reimbursement: Medicaid would pay manufacturers the lowest price offered to any buyer of the product. The rules also provided for Medicaid to purchase at a given percentage below average price if the best price was not low enough. This paper examines the (perhaps-unforeseen) effects of the policy on average pharmaceutical prices. In particular, I examine how the Medicaid Rebate rules changed prices charged by firms in different competitive positions.

Most Favored Customer clauses have been studied extensively in the Industrial Organization theoretical literature; see, for example, papers by Cooper (1986 and 1991), Png (1987 and 1991), and Salop (1986). The basic model of MFC clauses has the following features. A firm announces and commits to offering the following scheme: the lowest price it offers to any customer within a specific time period will be the price charged to the group of customers "covered" by the MFC.[1] This scheme has two main effects; the MFC will alter optimal price dispersion for any one firm, and secondly, the firm will find that competing with other firms for low-valuation consumers on the basis of price becomes more costly. Any price discount given to a marginal customer to induce a sale must be applied to all customers covered by the MFC. Theory tells us that firms that credibly adopt the MFC clause can commit to "soft" price competition. Although the literature contains many models explaining the strategic effect of MFC clauses, there has been relatively little empirical verification of the effectiveness of the policy.[2]

Although OBRA 90 is the sort of experiment that lends itself to analysis, there has been little formal work on the effects of the rebate rules. This is partially due to the difficulty of finding appropriate data and partially to the complexity of the problem. The law applied to actual prices paid per unit, not the more commonly available invoice prices (that do not include cash discounts). The MFC rules varied by retail channel, which themselves had different *ex ante* price distributions. To perform a good experiment, prices should be adjusted for long term

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[1]The firm chooses the applicable time period; it could extend the guarantee to past, future, or both sets of customers.

[2] Crocker and Lyon (1994) study the use of MFN clauses in natural gas contracts. They conclude that the main use of the facilitating practice in that industry is to allow efficient adjustment of prices in long term contracts.

contracts, and available before and after the law change from multiple retail channels. The rebate rule has subsections that differ in their expected effects on market outcomes. Therefore, prices respond to multiple forces and will not necessarily move strongly in one direction, which makes the impact of the law difficult to detect. In fact, the United States General Accounting Office (GAO) has examined the effects of the OBRA legislation on drug prices twice: once on prices paid by the Veterans Administration (VA) and Department of Defense (DOD) and once for prices paid by hospitals and HMOs.[3] In both cases the report concluded that the GAO could not determine "the extent to which price increases were attributable to OBRA." The GAO states that VA and DOD could not provide enough data to examine the question carefully. More recently, the CBO published a report examining discounts received by pharmaceutical purchasers in the wake of the rebate law.[4] That report notes that the prevalence of large discounts fell in 1991 and 1992 and attributes the drop to the Medicaid rebate legislation. However, the report does not have data from before the law took effect, so before and after comparisons are not possible. The inability to pin down a causal link between the legislation and pharmaceutical prices is frustrating in light of the economic importance of the regulations, the clear theoretical predictions of the MFC portion of the rebate rules, and the anecdotal evidence from market participants.[5]

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[3] "Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions" GAO/HRD-91-139 and "Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions" GAO/HRD-93-43.

[4] Congressional Budget Office, (1996) "How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry," CBO, Washington, D.C..

[5] "Congress recently passed a law requiring drug companies to give Medicaid the same deep discounts they give other big customers. But instead of reducing Medicaid drug prices, many companies are now raising the prices that those other big customers must pay."
"Now drug companies are increasing prices to some of those other buyers, including the Department of Veterans Affairs, prepaid health plans like the giant Kaiser Permanente group, hospitals, family planning clinics and community health centers for migrant workers, homeless people and the indigent. Health care experts say these added costs may soon trickle down to consumers in the form of higher medical costs, and ultimately, insurance premiums."
"Supporters of the 1990 legislation are furious about the drug companies' move. The chief sponsor, Senator David Pryor, Democrat of Arkansas, chairman of the Special Committee on Aging, said the price increases appeared to be "an attempt to circumvent the new Medicaid law," shift costs and nullify the savings envisioned by Congress.""
"...But a lobbyist for the drug industry, who would speak only on the condition of anonymity, said: "We are surprised that Senator Pryor is surprised. I don't know what else he would have expected. It's logical

"But instead of reducing Medicaid drug prices, many companies are now raising the prices that those other big customers must pay. ...it's logical that companies would re-examine their prices if Congress passes a law saying that Medicaid, which accounts for about 10 percent of our revenues, must get the best price given to any pharmaceutical customer in the country."
The New York Times, February 18, 1991 (remainder of quotation below)

I do not have all the information required to determine the effects of the law, but I have enough to make some progress in our understanding of its impact. My data surround the time the new rules took effect, so I can examine prices before and after the policy change. The theory section explains that the market share of Medicaid, the size of a drug's package, and the competitive structure of the market all affect the way a drug price should respond to the legislation. I then demonstrate that these variables predict price changes around the time the legislation took effect in a manner consistent with the Medicaid rebate rules. Therefore, it is likely that the rules did affect the prices of some pharmaceuticals in the US market.

I find that after the Medicaid rebate rules took effect the average price of the median presentation of a brand facing generic competition increased by about 4%. The average price of a patented drug did not respond to the legislation. This suggests that the MFC clause encouraged some branded producers to engage in softer price competition. I also find evidence that the MFC indirectly affected generic producers; generic prices rose more in concentrated markets after the legislation took effect. This suggests that generics competing against MFC-constrained branded competitors reacted strategically to their rival's constraint.

The estimates contained in this paper may not be representative of all industry outcomes for several reasons. The data I have do not include prices to HMOs (or pharmaceutical benefit

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that companies would re-examine their prices if Congress passes a law saying that Medicaid, which accounts for about 10 percent of our revenues, must get the best price given to any pharmaceutical customer in the country.""Leslie Rose, chief lobbyist for the Group Health Association of America, which represents the organizations, said: "The reports we hear from H.M.O.'s across the country are really disturbing. They are being told by drug companies that the days of discounts are over, that drug prices will be raised. Clearly, this is an unintended effect of the new law."
"Jose E. Camacho, executive director of the Texas Association of Community Health Centers, said that within weeks of passage of the Medicaid law 7 to 10 drug companies began trying to renegotiate the discount-price contracts for his organization, which buys drugs for 31 clinics serving 250,000 patients a year."
The New York Times, February 18, 1991

managers like Medco), the types of institutions likely have the pre-OBRA binding low price; it is probable that the price charged these types of customers rose more than I estimate here. All the adjustment did not occur in the time period I analyze due to the presence of long term contracts in the market. The CBO finds that discounts are still declining in 1992. Also, the data have a great deal of measurement error due to the prevalence of cash rebates that are not included in recorded prices, so the results are not as precise as one might expect from a large dataset.

Although the Federal and state governments saved 150 million dollars per quarter in Medicaid expenditure by the end of the first year of the program (and $1.8 billion in 1994), to the extent that some market prices rose as a consequence of the reimbursement policy, not as much savings occurred as might have been expected. In addition, other government expenditure, such as purchases made by the V.A., increased due to these rising prices and partially offset the initial gain. Finally, some non-Medicaid consumers of pharmaceuticals that had been receiving substantial discounts paid higher prices.

The structure of this paper is as follows. The exact rules of the rebate scheme are explained in Section I. Section II discusses the theory behind the rebate rules. The pharmaceutical industry, its rules of entry, and the available data are discussed in Section III. The estimation of the effects of the MFC rule on prices is reported in Sections IV and V. Section VI concludes. Throughout the paper I use the term "price" to mean prices observed before the Medicaid rebate is taken into account; prices here are always pre-rebate prices unless explicitly described otherwise.

I. The Medicaid Rebate Rules

The Omnibus Budget Reconciliation Act of October 1990 (OBRA 90) included legislation intended to reduce government spending on pharmaceuticals for Medicaid recipients by limiting drug reimbursement prices. The Medicaid program was not receiving the low prices given to other big buyers because it reimbursed individual hospitals and pharmacies rather than purchasing in bulk. Medicaid is a large buyer whose purchases account for roughly thirteen percent of the prescription pharmaceutical market. Pharmaceutical firms engage in a great deal of price discrimination; the fact that Medicaid could not use its bargaining power to secure the normal

advantages of a large buyer in a market with significant price dispersion was part of the impetus for the legislation.

To secure better prices for Medicaid (and reduce the federal deficit) OBRA 90 provided for a voluntary program in which manufacturers could enroll their drugs.[6] The incentive for a firm to enroll was that its drugs were then guaranteed access to all state Medicaid formularies and reimbursement from the Federal program.[7] A formulary is a list of drugs approved for use by an institution. All states were required to have Medicaid "cover" all drugs participating in this scheme. In return the program required drug manufacturers to pay rebates to state and federal Medicaid programs. A rebate would represent the total dollar amount by which Medicaid had "overpaid" a firm in that calendar quarter, compared to the new low prices that were now required. Manufacturers of branded pharmaceuticals were required to sell to Medicaid at 87.5% of Average Manufacturer Price (AMP) or their "best price," whichever was lower. AMP is simply a quantity weighted average of a firm's wholesale prices. Thus if a firm sold one unit of its product to a customer at 75% of AMP, it would effectively have to sell all its Medicaid units at that price also (although the mechanism would be a rebate check). The best price could not fall below 75% of AMP in the first year of the scheme, but the floor was scheduled to drop to 50% the following year and zero thereafter. Additionally, if an innovator increased AMP of its drug by more than the increase in the Urban CPI from a baseline period (September 1990), the rebate amount owed to the government would increase by the amount the CPI change was exceeded.

The important variations in the rule are twofold. Generic products were not subject to quite the same scheme as branded products; instead, a generic product's price to Medicaid was required to be 90% of its AMP. Notice that whether a drug has patent protection or not is irrelevant; if it is the innovator, or brand, it follows the brand rule before and after patent expiration. Additionally, only outpatient drugs were subject to the OBRA program. Inpatient

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[6] Nearly every firm selling pharmaceuticals in the US enrolled in the program when it started.

[7] A couple of loopholes were available in 1991 that allowed states to have a *de facto* formulary if some effort was expended. Only 11 states had "restrictive formularies" in 1991 according to Soumerai et al (1993).

drugs, given to a patient while staying in the hospital, did not fall under the new rules.[8] Inpatient drugs include, but are not limited to, injectable drugs. A hospital can purchase oral drugs (hereafter, pills) to dispense to inpatients or to sell to outpatients. The inpatient sales are exempt from the rebate rules, whereas the outpatient sales are subject to the rebate rules. The results for pills sold to hospitals will therefore be weaker than those for pills sold to drugstores due to the mixture of inpatient and outpatient drugs in the hospital sample.

The rules required that the price used to calculate "best prices" and rebates be the *price per unit* of the drug; common units are the pill or the milliliter. Separate packaging alone would not constitute a different product with a different "best price." Rather, the firm would have to calculate the price per pill on all its packages of a given drug to find the lowest price.[9] Additionally, OBRA 90 defined AMP to be the average wholesale price available to a member of the "retail pharmaceutical trade." Only prices of goods sold to drug stores, not hospitals or HMOs, counted in the calculation of AMP. However, prices from all sectors, including non-profits, were used to calculate "best price."[10] Thus, a firm would lose revenue on all its Medicaid sales each time it sold its drug to *anyone* at a price lower than 87.5% of its AMP, while AMP itself was constructed from pharmacy prices only. The exact amount owed by each firm was calculated every quarter, using sales data from that quarter provided by each firm and

[8] My dataset consists of prices and quantities of cardiovascular drugs only; these drugs are disproportionately consumed by older patients who are often eligible for Medicare. Medicare covers the cost of hospital stays and associated inpatient drugs. I divide drugs into injectable and oral to proxy for inpatient and outpatient; although this rough division is not ideal, the government studies referenced above use it. If all the Medicaid consumers in my dataset were Medicare-eligible also, Medicaid would not pay for any injectables sold to hospitals. Therefore, since injectables are not affected by the legislation, are bought less often by Medicaid, and the dataset contains relatively few injectable observations, I eliminate injectable drugs from the study entirely.

[9] See the Appendix for a numerical example.

[10] The problem with including all sales in the calculation of best price is that other government agencies such as VA and DOD, as well as non-profit organizations, had been receiving substantial discounts. The law now required those discounts to be given to all Medicaid units. The story I heard from industry participants was that many manufacturers eliminated the discounts in the face of the MFN law. The following year a law was passed to exempt VA and DOD prices from the calculation of best price.

each state, by the Office of the Inspector General (OIG).[11] Notice that in the role of calculator of rebates, the OIG acted as enforcer of the MFC agreement and monitored all firms to detect cheating. The OIG had the ability to fine firms that violated the rules of the contract. Thus firms in the industry in 1991 could be confident their rivals were applying the MFC properly and no cheating was going on.

II The Effect of a Most Favored Customer Clause in a Market with Price Discrimination

To illustrate the effects of the Medicaid legislation, a very simple model follows where a firm's choice of optimal price is compared in regimes with and without best price or average price provisions. I initially allow Medicaid's quantity demanded to respond to price changes and in a second example assume Medicaid demand is completely inelastic. The two cases will produce somewhat different implications for the change in prices.

Elastic Medicaid Demand

The market has distinct submarkets indexed by *i*. A firm can charge different prices across submarkets, but must charge the same price to all customers within the submarket (examples of submarkets are chain pharmacies, HMOs, hospitals). I assume each submarket has its own simple demand curve for the elastic portion of the market of the form: $q_i = a_i - bp_i$. Each submarket sells some Medicaid units, a fraction γ of quantity q_i, although no one knows exactly which units will be sold to Medicaid ahead of time. Therefore, the firm must choose one price for the submarket. (The underlying intuition does not depend on the assumptions of linear demand, same slope across submarkets, or constant proportion sold to Medicaid.) Without any regulation the Medicaid and non-Medicaid segments of the market are identical:

$$\Pi_{no\ rebate} = \gamma \sum_i (p_i - c) q_i(p_i) + (1-\gamma) \sum_i (p_i - c) q_i(p_i)$$
$$p_i^* = \frac{a_i + bc}{2b} \qquad (1)$$

Where profit is π and the optimal price for the i^{th} market is p_i^*. When best price legislation is

[11] The data are highly confidential; only the Health Care Financing Administration (HCFA) sees the figures.

introduced, the profit expression changes:

$$\Pi_{best\,price} = \gamma \sum_{i=1}^{N} (p_i - c) q_i(p_i) + (1-\gamma) \sum_{i=1}^{N} (p_j - c) q_i(p_j)$$

$$p_i^* = \frac{a_i + bc}{2b} \qquad p_i \neq p_j \tag{2}$$

$$p_j^* = \frac{(1-\gamma)(a_j + bc) + \gamma(cbN + \sum_i a_i)}{(1-\gamma)2b + \gamma 2bN} \qquad p_i = p_j$$

Where N is the total number of markets and p_j is the minimum price. The new optimal p_j is higher than $(a_i+bc)/2b$ because a_j is less than all other a_i. When the firm maximizes the best price profit function with respect to customer j's price and customer j has the minimum price, the derivative has an additional positive term compared to the original case. The firm will earn more profits if it can raise its minimum price.

A rule that mandates a discount to some customers based on average price will also alter the firm's profit function.

$$\Pi_{average\,price} = (1-\gamma) \sum_{i=1}^{N} q_i(p_i)(p_i - c) + \gamma \sum_{i=1}^{N} q_i(\bar{p}(1-\alpha))(\bar{p}(1-\alpha) - c) \tag{3}$$

Where p is the average price and α is the percentage discount below AMP that Medicaid gets. This problem turns out to be very complex and a general solution is beyond the scope of the paper. The intuition, however, is fairly straightforward. Medicaid consumers across all submarkets are paying a percentage below average price that is almost surely not optimal in any of the submarkets. The firm can change optimal prices slightly with only a second-order loss from the non-Medicaid consumers. The altered prices will change average price and have a first-order effect on the amount of profits earned from Medicaid consumers. Whether prices move

up or down depends on whether optimal prices are below or above the Medicaid price and the relative size and elasticity of the different submarkets. Since the OBRA legislation mandated a price for Medicaid that was *well below a quantity-weighted average price*, it is likely that a firm's optimal response would be to raise price: the higher the firm sets its price to non-Medicaid customers, the higher are its profits from Medicaid consumers.

Inelastic Medicaid Demand

The second framework assumes that Medicaid demand is perfectly inelastic. Since the Medicaid final consumer does not pay for the drug he or she consumes, we might think that Medicaid consumers do not respond to price changes at all. Of course, states can change aspects of their Medicaid programs, such as eligibility rules, in response to price. However, states may not have responded to the OBRA 90 legislation very quickly because of the speed of the bill's passage, uncertainty over how the program would work, and delays in collecting data. Therefore, I briefly explore the results of assuming Medicaid demands a fixed quantity of pharmaceuticals and is completely unaffected by price, while the rest of the market has a normal demand curve. If Medicaid demand is fixed (m_i, for example) and the firm is required to sell to the non-Medicaid consumers due to political pressures, the optimal price without regulation is $(a_i+bc+m_i)/2b$.[12] Price increases with the size of the inelastic segment, and, in particular, is above the optimal price for non-Medicaid consumers. If an MFC is imposed in this framework, higher prices will fall to $(a_i+bc)/2b$, but again, the low prices will rise to $(a_i+bc+\Sigma m_i)/2b$.[13]

Once again the average price rule is very complex and I do not present a general solution. After the rules take effect, Medicaid prices depend entirely on prices charged to other consumers. A firm can reduce its 1991 price to the optimal price for non-Medicaid consumers (no inelastic demanders in the market) which increases profits from that group, but causes the firm to receive a very low price on its Medicaid sales. In order to get the Medicaid price higher, the firm can

[12] I assume political pressure requires the firm to sell to both types of customers. Charging infinity to Medicaid and not selling to any other buyer would not last very long.

[13] Higher prices fall because the firm no longer sells at that price to the inelastic consumers. Therefore, the firm prefers to price more optimally for the non-Medicaid segment and increase quantity sold there.

contemplate increasing prices to non-Medicaid consumers. The envelope theorem says it is worth increasing prices slightly at least. The extent to which the firm is willing to raise prices further will depend on the market share of Medicaid and the elasticity of demand of the other consumers. These two effects, the jump down in price due to the reduction in importance of the inelastic customers, and the increase due to the externality, have opposite signs and it is not clear *a priori* which effect will dominate in any given situation.

To summarize, this basic discussion predicts that OBRA will cause brands to alter their prices in response to several incentives. The best price legislation always gives a firm an incentive to raise its lowest prices. The average price legislation has opposing effects. Prices rise because Medicaid prices depend on other prices; however, when Medicaid demand is inelastic prices can fall, again because the inelastic consumers are not as important in the demand curve, so the optimal price is lower.

Note that *either* best price *or* average price was binding at any one time for any one branded presentation. If a concentration's lowest price was below 87.5% of AMP, its Medicaid sales were subject to the best price rule; if its lowest price was above that level, they were subject to the average price rule. A firm would have calculated the profits for each concentration of each brand under both alternatives and chosen a price distribution that maximized profits. After the legislation was passed each rule generated a significant share of rebate revenue; no one rule was preferred by all firms. Half of single-source brands gave discounts of more than 30% and half of brands facing generic competition gave discounts of more than 50% in 1991.[14]

Generics were exempt from the best price rule, but had to sell to Medicaid at 90% of their average price. Thus only the average price provision affected generic firms directly, and it should have had the effects described above. A zero-profit firm facing an average price provision would be forced to raise its prices to keep profits non-negative. To the extent that generic firms were perfectly competitive and earning zero profits, this is another reason to expect prices to have risen.

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[14] CBO page 36. Health and Human Services has published a report (Sullivan (1992)) concluding that the "best price" rule is not the dominant source of rebate revenue compared to the "average price" provision. Their analysis, however, looks at prices after the MFC legislation had passed, when firms had altered their price distributions. Thus we don't know how much dispersion existed *ex ante*, but only that the legislation did not completely deter firms from discounting below 12% of average price in 1991.

The OBRA incentives may also have created strategic effects. Cooper shows in a model with two firms but uniform prices, that even a firm that *unilaterally* institutes MFC pricing alters its own best response function so that equilibrium prices for both firms are higher. Intuitively, the MFC causes price discounts to become more expensive, which discourages their use. Rivals are aware of the altered incentives and that knowledge changes their own behavior. Oligopolistic firms that are competing for the same customers, as therapeutic substitutes do, will become less aggressive in price competition under an MFC, giving market prices another opportunity to rise. The price responses of generic firms will also depend on the strategic aspect of the MFC and how many generic firms are in the market with the competitive brand. When the brand is constrained by an MFC, its best response function shifts and its rival(s) has an incentive to raise its price. If the MFC firm has many generic rivals, all producing a fairly homogeneous product, each of the rivals has much less incentive to give a soft response; there are many firms in the market whose best response functions haven't moved. Since only the brand has shifted its best response function, there may be no (or very little) price rise by generic rivals.[15] On the other hand, if there are few generic competitors, their price will shift noticeably in response to the softer competition caused by the MFC and generic prices will rise.

The cap on price increases imposed by the OBRA rules eliminates the gain from raising prices too fast. In particular, a firm would not want its average price to increase at faster than the rate of inflation or it would have to subtract *more* than the difference off the price to Medicaid.[16] Therefore, a firm has no incentive to raise average price in order to increase the price Medicaid pays for a drug -- once the rate of inflation has been reached. This part of the rule is very important as it limits the responses to the incentives created by OBRA.

Types of players

Manufacturers of pharmaceuticals fall into two main categories. The first category consists of "innovator" firms; they undertake research and development to discover new drugs and bring them to market. Once approved by the FDA, such drugs are marketed under a proprietary, or brand, name by the innovator. A second type of firm is a generic or imitator firm.

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[15] See Cooper (1986) for a theoretical treatment.

[16] See CBO Box I, p.15.

After patent expiration, any firm may submit an Abbreviated New Drug Application, or ANDA, to the FDA.[17] The generic firm must show its product is bioequivalent to the original branded product. Once its ANDA is approved and the original patent has expired, a generic firm may legally make and sell the product. Thus, some drugs have two categories of manufacturers, the brand and one or more generics.

The variety of competitive conditions in the pharmaceutical industry will prove useful in predicting which prices will be most affected by the rebate rules. I classify all brand (also called "pioneer" or "innovator") drugs that have patent protection as "patented brands."[18] Note that a patented brand continually faces competition from therapeutic substitutes, despite its patent protection.[19] The level of competition when a brand has lost patent protection can be characterized by the number of generic firms also manufacturing the drug at any given time. I refer to a brand in a market with one or more generic firms as a "competitive brand." The final class includes all the generic manufacturers. This class can be further broken down into ANDA holders and labelers; the definition of labelers will be given below.

Table I lists the expected effects on pre-rebate average price by competitive class and retail sector at the imposition of an MFC rules. The pre-rebate mean price is exactly what my data record; the prices in the data should respond to the imposition of the MFC and average price clauses according to the strength and prevalence of the MFC, average price, and strategic effects.

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[17] I identify which firms are participating, or have permission to participate, in each market with the FDA's Approved Drug Products and Therapeutic Equivalents. This publication details which ANDAs have been granted; it reports the exact concentration, form, date of approval, and firm receiving the ANDA.

[18] Sometimes two firms discover a drug independently and share the patent or are both licensed to manufacture and market a drug by the inventor. Although the market structure is a duopoly rather than monopoly, I classify these observations with "patented brands."

[19] Some brands are still monopolies but have lost patent protection; no generic has entered that particular market. I call these drugs "off-patent brands," but end up excluding them from the analysis due to lack of useable observations.

Table I: Expected Changes in Average Price Due to Incentives in the MFC Rules by Competitive Class and Distribution Channel

Outpatient Drugs Only	Δ P	
	Drugstore	Hospital
patented brand (innovator on patent)	most-favored-customer: + average: ?	most-favored-customer: +
competitive brand (innovator w/generic competition)	most-favored-customer: + average: ?	most-favored-customer: +
generic	average: ? to maintain zero profit: + strategic m-f-c: +	to maintain zero profit: + strategic m-f-c: +

Usually when industry prices and profits rise we expect to see entry by firms wanting a share of the profits. Patented drugs are obviously protected from entry by their patent. Generic manufacturers are, in general, not protected from entry. However, a generic entrant must receive approval from the FDA before it can begin selling a generic drug. The approval process takes eighteen months, on average, after the application is submitted. The firm would normally spend several months preparing the application. Thus, the earliest an entrant (encouraged to enter by the new profitability of the market) would normally appear would be towards the end of 1992, well outside my sample period.

From a firm's point of view, the most important question might be how much (and in what direction) post-rebate revenues change.[20] To find the post-rebate mean price, the researcher must know where in the distribution the Medicaid purchases fall. If Medicaid sales are already at the low end of the price distribution, the direct payments required by the scheme will not lower firm revenue by very much. On the other hand, if Medicaid sales are often to

[20] "Is this a good bill or a bad bill? ...It also depends on who you are. If you market major products that had previously been denied formulary access and do not discount deeply, this is probably a pretty good bill. If, on the other hand, your products are multi-source, your growth products are very expensive, and/or you discount heavily, you have your work cut out for you."
Medical Marketing and Media, February 1991

small pharmacies without bargaining power, the rebate amount might be large. In general, the direct effect of the rebate and the expected strategic effect of reduced competition and higher prices oppose one another and their relative strengths cannot be precisely evaluated without individual invoice data from firms and Medicaid purchase data that is collected by HCFA.

III. Data Description

The observations that make up the data for this study are fairly complex. To make the structure clear, Table II illustrates the fields that make up each observation. The first element of an observation is the "drug," or specific chemical entity, which may be called by its generic or brand (proprietary) name. A drug can be manufactured by the NDA holder and any ANDA holders that exist. The drug comes in one or more forms; a form is solid (e.g. tablet), liquid, or other (e.g. patch); most drugs come in only one form and some have two forms. The drug-form can be further divided into different concentrations, for example, 250mg or 500mg. The drug-forms in this dataset have an average of 3.67 concentrations each. Several drugs have as many as seven different concentrations, one has twelve, which is the maximum in the dataset. The final choice variables for the manufacturer are the packaging and number of units. Tablets can come in bottles of many sizes, from 2 to 1,000, or in unit dose packages which have, by definition, one unit. Liquids can be packaged in bottles, bottles with droppers, or vials. Each presentation is a unique combination of drug, labeler, form, concentration, number of units and packaging. Adding information on revenue, quantity, month, and year turns a presentation into an observation. All the observations in a presentation have the same drug, labeler, form, concentration, number of units, and packaging data. The previous pharmaceutical literature has largely worked with the most common (highest revenue) dosage form to avoid these complex dimensions. I hope to be able to add more depth to the analysis with the additional information.

Table II: The Structure of an Observation in the Dataset				
	Examples			
Drug	atenolol	methyldopa	p r e s e n t a t i o n	o b s e r v a t i o n
Labeler	ICI	MSD		
Form	tablet	oral liquid		
Concentration	100mg	50mg/ml		
Number of Units	1000	10mlx10		
Package	bottle	bottle		
Month	01	12	time series variation	
Year	1990	1991		
Revenue	111.11	111.11		
Quantity	999	999		

Data

The data were collected by IMS America, a firm that provides detailed data about pharmaceutical sales in the US. IMS provided the Cardiovascular subset of their *Drugstore Audit* and *Hospital Audit* from 1989 through 1991. Cardiovascular drugs is one of the largest (in revenue terms) classes of prescription pharmaceuticals and has experienced considerable innovation in the post-WWII period. Therefore there are many drugs and competitive classes represented in the dataset as well as about six billion dollars in annual revenue. The Audits are created by monthly sampling of warehouse, chain pharmacy, and independent pharmacy invoices for observations on the wholesale price. No sales to HMOs are included in these samples. Then the individual invoices are combined, transformed from a sample into national-level data, and reported as an estimate of national revenue and quantity. The individual invoice information is never reported.

Hospital prices have more measurement error than drugstore prices because hospitals receive more cash discounts than pharmacies and, in addition, the number of observations is

smaller. Cash discounts are cash returned to the customer after buying a certain quantity of a drug, a particular mix of drugs, or a specific dollar amount with one wholesaler, that do not appear on invoices. Discounts are nearly impossible to trace, quantify, and assign to a particular product, and yet are an important component of the market. If invoice prices change and cash discounts compensate, the data will show a change when none has occurred. However, the rebate rules explicitly instructed firms to include cash discounts in their calculation of best and average prices; thus the rule did not provide any incentive for firms to alter their rebate (v. invoice) policies. However, some flexibility in assigning cash rebates will minimize observed change and the existence of rebates adds considerably to measurement error in the data.[21]

IMS takes out a large fraction of all price dispersion before the data are seen by anyone. I do observe one source of dispersion in my data: a type of quantity discounting. For example, tablets can come in bottles of 10 or 1,000. The latter size might not be very practical for a small pharmacy although the cost per pill is usually lower. Manufacturers also use special types of packaging to take advantage of heterogeneous consumers. Proprietary convenience packaging like "accudose" packs that mark a patient's daily dose contain the same chemical entity as simpler presentations but cost much more. IMS also reports payment sources, including Medicaid, for some drugs in the sample.

The IMS data have two important features. The first is that what IMS refers to as the "manufacturer" is not always the actual manufacturer; instead it is the labeler. A manufacturer may label all or part of its own output. It may also sell all or part of its output to one or more labelers who put their own firm name on the package. The labeler, not the manufacturer, is responsible to HCFA for the Medicaid Rebate on all its products. Thus each labeler has its own AMP and rebate amount which could differ from other firms selling the identical product. I can identify the true set of manufacturers allowed to make a given drug because each one must have filed an NDA or an ANDA with the FDA. However, some manufacturers sell all their output to labelers, in which case they will never show up as an IMS manufacturer. The manufacturer and the labeler are synonymous for brand observations, but many generic drugs have multiple

[21] Additionally, pharmaceutical companies sometimes sell products as a bundled package; they combine a sale item with a full price item and charge one price for the two. The prices imputed by the Office of Inspector General average away the deep discount, thus concealing a potential "best price." Bundling therefore also contributes to firms' ability to conceal change.

labelers. In this paper I focus on only one generic class, the distributors, and do not analyze the ANDA holder category. ANDA holders have data that are unexpectedly difficult to work with, perhaps because they have a different set of customers and different types of contracts than generic distributors. ANDA data are significantly more problematic to analyze and are omitted from the analysis hereafter.

I drop any drug in the IMS dataset which is not listed in the FDA Orange Book[22], my main source of information on the state of competition in the market. I also drop those observations for which I cannot identify the competitive class due to some anomaly in the market, those whose labeler is "Manufacturer Not Stated," and also those that have internally inconsistent reported units. The remaining data are described in Table IV.

IV. The Problem of Identifying Price Changes Due to OBRA

The prices given by the data exhibit two main patterns. The first is a step-like pattern; prices are flat for several months and then rise by a small amount. The increases typically come at irregular intervals and vary somewhat in size. The other pattern is really a lack of pattern, a scatter of points perhaps sloping up or down. A clear upward jump in January 1991 is not visible to the casual observer. A simple statistic that should be illuminating is a comparison of price growth before and after the law for drugs affected and unaffected by the legislation. The GAO tried this and finds that HMO outpatient drug prices increased faster in the year after OBRA was implemented than the year before, while hospital drug prices did the opposite, but does not feel confident in attributing that difference to OBRA.[23] I perform the same exercise with drugstore and hospital outpatient drugs and report the results in Table III. Not only do hospital growth rates increase more, which was not predicted, the standard deviations are very large while the mean changes are quite small. This methodology makes it difficult to conclude that one group had a significantly larger price increase than another.

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[22] See Note 17. About 10 chemicals are listed in the IMS dataset and not in the Orange Book.

[23] ibid 1993. p2. Their methodology compares price growth between July 1989 and July 1990 to growth between July 1990 and January 1992.

Table III. Oral Cardiovascular Price Growth, Before and After Rebate Rules				
mean log difference and standard deviation	Drugstore	Obs.	Hospital	Obs.
June 89 - July 90	-.019 .290	1772	-.036 .368	964
Oct 90 - Sept 91	.008 .322	1817	.012 .326	1024

Another approach that should be helpful is to look at whether price changes around the time of OBRA's implementation are correlated with characteristics that give the firm an incentive to raise price. The framework discussed above predicts that price changes in response to the Medicaid Rebate Rules will depend on several characteristics of an invoice. However, my dataset contains no invoice information; the analysis will have to use averaged values for a presentation.

Medicaid's market share (*Medicaid Share*) in 1990 of a particular drug will determine the strength of the incentive to raise prices for any given price distribution. The effects of both the best price and the average price rules will depend on the importance of sales to Medicaid. In the extreme case of no Medicaid sales, the firm will have no direct reason to change its prices (although it may respond to the incentives and choices of other firms). Unfortunately the variable *Medicaid Share* is available for only about half the observations in the dataset. The values this variable takes depend on the formulary rules in different states in 1990 and Federal Medicaid reimbursement rules. The Federal program limited reimbursement of state Medicaid expenditures for competitive brands to the price of available generics. A state therefore had an incentive to restrict use of competitive brands since it would not be fully reimbursed for them.[24] The mean value of *Medicaid share* is lower in the competitive brand class than among generics or patented drugs.

The best price rule gives firms an incentive to increase their lowest prices. Since the data only report average prices, it seems as though we cannot make use of this incentive. However, large package sizes usually have a lower unit price than small packages, whether due to lower

[24] See Soumerai et al for a description of state Medicaid policies and their effects.

per unit costs or price discrimination. If the largest packages are sold at the lowest prices, large packages will be more likely to find the "best price" provision binding. In such a case, firms will want to raise the price of larger package sizes more. Smaller packages with higher unit prices will not see as large a rise. We should see package size predicting price increases under the best price legislation and for competitors of firms subject to the best price rule. The variable *Relative Size* is defined to be a package's own size (e.g. 100 tablets) over the largest size available for that drug and firm (e.g. if 1000 is the largest size, Relative Size=100/1000=.1). *Relative Size* varies from 0.0017 to a maximum of one. Note that package size is fixed, although the quantity sold of different package sizes may change over time.

More price dispersion raises the probability of a brand finding the MFC binding and therefore increasing its lowest prices. In the case of competitive brands, the level of competition may affect the level of price dispersion. Borenstein and Rose (1992) find that competition is positively associated with price dispersion. A greater number of generic competitors or a lower Herfindahl Index would therefore imply a stronger price rise on the part of the brand to avoid the negative impact of the legislation. Similar reasoning extends to patented brand duopoly markets.[25] The variables *Drugstore Herf* and *Hospital Herf* are Herfindahl indices for the Drugstore and Hospital markets respectively, calculated over the number of labelers (including brands) selling a drug in December 1990. *Number of ANDAs* measures the number of firms which have been approved by the FDA to manufacture the product by the end of 1990. Notice that this is a fundamentally different measure of competition than the number of labelers listed by IMS, on which the Herfindahl variables are based.

To illustrate the difficulty of picking up the effects of the OBRA legislation, I regress the log difference in drugstore price (over fifteen months) on concentration in the market, the market share of Medicaid, and the relative size of the package. The results are reported for the three main classes in Table IV. The results are extremely inconclusive; very little is significant, let alone of the predicted sign. However, this regression does not control for characteristics of the drugs which may be affecting price movements. A drug's prices have trends due to exogenous factors such as changing technology, changing demand, and seasonal effects, although we expect

[25] A duopoly market is one where each firm has its own brand name, but the two firms are selling the identical product. (Usually because a foreign firm has licensed the product to two US firms.)

to see presentation variation within the drug. Hence, it is very difficult to identify small changes in prices with this method and the explained variation is very low. The problem with interpreting Tables III and IV is that we are trying to explain any change due to the legislation *and* overall trends in different drugs. The effects of the legislation will be small and are likely to be swamped by important trends in technology and demand when aggregate changes are examined. Exploiting the time series available for each presentation goes some way toward solving this problem.

V. Estimation of Price Shifts at the Implementation of OBRA

In this section I estimate the magnitude and sign of any change in prices at the implementation of OBRA 90. The dependent variable is one of two variables: Drugstore Price or Hospital Price, for three competitive classes. Although quantity data are available, they are extremely difficult to fit well because of the many outliers and differing buying patterns across presentations. The results are very unstable, so I do not discuss them in the paper, but focus on prices.

Brands

I examine the behavior of price over the two years surrounding January 1, 1991, the first effective date of the new policy. The basic regression uses log price as the dependent variable. The log form of the dependent variable allows shift and trend terms to be expressed in percent changes and therefore be estimated as a constant across presentations and drugs. Since every drug is experiencing different demand and supply conditions, it is important to allow for different growth rates and seasonal patterns across drugs. Therefore, every presentation of every drug has its own intercept and time trend. Additional variables accounting for quarterly movements in price and quantity are included.[26] These controls produce adjusted R^2's of over 0.8 in all regressions.

Each of the explanatory variables described in section IV is interacted with the *Rule Dummy*. *Rule Dummy* is zero until the legislation takes effect and one thereafter. Each equation also includes *Rule Dummy* on its own which will capture class-specific shocks to price not related

[26] For example, quantities sold are about 20% higher in Mar, June, Sept, and December than the other months of the year. Prices are more likely to change in Jan, April, July, and Oct than other months.

to any of the variables discussed above. For a branded class the equation is:

$$\begin{aligned}\log P_i &= \beta_1 MedicaidShare_i * RD + \beta_2 RelativeSize_i * RD \\ &+ \beta_3 DrugstoreHerf_i * RD + \beta_4 NumberOfANDAs_i * RD \\ &+ \beta_5 RD + CONTROLS_i + \epsilon_i\end{aligned} \tag{4}$$

where the controls are presentation time trends, quarterly shifts, and presentation intercepts. I analyze both hospital and drugstore markets separately; P_i is either drugstore price or hospital price. The results for brands are reported in Table VII.

The competitive brand class, as expected, has the results most consistent with the theory. The coefficients on the first three explanatory variables have the predicted sign and are significant at conventional levels. A larger *Medicaid Share* increases average price, which indicates the legislation is creating an overall incentive to increase price. The coefficient on *Relative Size* shows that larger packages experience a larger average price increase, evidence that they may be disproportionately represented among 'best' prices. The positive coefficient on *Number of ANDAs* is consistent with the relationship found in Borenstein and Rose (1992); more competitors increase price dispersion which in turn increases a firm's incentive to raise its lowest prices, increasing average price. The coefficients on *Rule Dummy* and *Drugstore Herf* are both negative and insignificant. The regression fits well, which we can see in the adjusted R^2 of 0.96. Although the first three coefficients are positive, not all presentations are predicted to have the same response when the law takes effect. I construct the total effect of the variables reported in Table VII ($X\beta$) for each presentation. The median change is 4.3% while the mean change across presentations is 4% with a standard error of .9%. In total, the average price of competitive brand pills rises after the law takes effect. This number can be contrasted to the average monthly price increase in this class of 0.2% (although some presentation prices grow much quicker or slower).

Competitive brand hospital price is predicted to rise less than drugstore price because some of the hospital drugs are used for inpatients and are not subject to the regulation. The only significant coefficient is that of *Relative Size* which is larger than the drugstore coefficient; the others are insignificant, either because the incentives are too weak to move all hospital prices or

because of the additional measurement error created by cash rebates. The mean presentation time trend in the hospital regression is negative, which is consistent with hospitals negotiating low prices for brands because of competition from generics. The combined effect of all the variables is a just significant six percent increase on average. In sum, in the competitive brand class it looks as if the MFC and the average price provision combined are working to increase drugstore prices of those presentations with the strongest match to the incentives in the bill.

Patented brands face competition from therapeutic substitutes, and their competitors are subject to the same incentives as themselves. To the extent brands compete against therapeutic substitutes, the strategic effect of the MFC should apply to patented brand pricing. However, if the level of price dispersion is lower due to lack of generic alternatives, then the chance that the MFC is binding in the drugstore or hospital sector is lower. Patented brands may be more affected by the average price provision than competitive brands. However, patented brands are also likely to be bumping up against the inflation constraint already and therefore may have no "room" to raise prices, regardless of the effectiveness of the MFC or average price provisions. The results in Table VII show that the specific predictors of the increase in prices are insignificant for patented brands, although *Rule Dummy* is positive and significant at the 6% level. Overall price levels may have moved up, but in the absence of correlation between prices and the incentives in the legislation, it is unclear that OBRA had any effect on patented brands. It is interesting to note that patented brand time trends are larger than competitive brand trends, which is consistent with stronger price growth in the class. Again, the hospital regression yields no significant coefficients.

Generic Estimation

Measures of market concentration are included in the generic regressions although many researchers view generic competitors as zero-profit price-takers playing a Bertrand game. There is a substantial literature that suggests the generic industry is not playing a Bertrand game. Wiggins and Maness (1995), Frank and Salkever (1995), and Caves et al. (1991) all document that generic price decreases steadily with the number of generic suppliers. Generic prices could respond to the incentives of the average price provision if they face a downward-sloping demand curve. The herfindahl variables will have positive coefficients if prices increase more when

concentration is high, for example.

The specification for generic producers contains an additional variable. *Brand Medicaid Share* is the share of the Medicaid market sold by the competitive brand in 1990. Competitive brand and generic markets are matched so that the variable is the Medicaid share of the relevant competitive brand for each generic. The purpose of including this variable is to track when the generic's competitor is facing a large MFC or average price incentive due to a large amount of Medicaid sales. Such a competitor will respond more strongly to the legislation, thereby engendering a stronger change in the generic's optimal price. Due to the large number of presentations in the generic classes, each drug-form gets its own time trend that is forced to be equal across presentations in the drug-form.[27] The equation to be estimated for the generic class is:

$$\begin{aligned} \log P_i &= \beta_1 MedicaidShare_i * RD + \beta_2 RelativeSize_i * RD \\ &+ \beta_3 (DrugstoreHerf_i \; or \; NumberOfANDAs_i) * RD \\ &+ \beta_4 BrandMedicaidShare_i * RD + \beta_5 RuleDummy \\ &+ CONTROLS_i + \epsilon_i \end{aligned} \tag{5}$$

The variable *Medicaid Share* is not included in the specification for hospital price. There is no reason why a generic product's hospital price should be influenced by its Medicaid share, since the rebate amount does not depend on generic hospital prices at all. However, generic hospital prices could be affected by the brand's behavior in the hospital market. This depends on the brand's Medicaid share, the size of the package, and the concentration in the market, so all these variables are included.

The simple generic results are displayed in Table VIII. The two sides of the table use different measures of concentration in the market, either a herfindahl index or the number of ANDAs extant in 1990. A larger *relative size* significantly increases prices across all specifications. In column one, the herfindahl index and the product's Medicaid share have positive coefficients, which is consistent with the theory, but they are only significant at the nine and twelve percent levels, respectively. Since the average price provision has an ambiguous

[27] Testing this restriction on brands reveals it cannot be rejected in about half the drugs.

effect on prices, the lack of significance of *Medicaid Share* could be expected. In both drugstore regressions the coefficient on *Brand Medicaid Share* is significant and negative. This result is unexpected, contrary to the incentives described above, and also very robust. More research is needed to ascertain why a generic firm should lower prices for these presentations. The herfindahl results on the lefthand side of the table are weak, with size the only variable behaving as expected.

The specifications using *Number of ANDAs* as the measure of market concentration are somewhat better. In column three, drugstore prices fall with the imposition of the law for markets with a larger *Number of ANDAs*. Again, the coefficient on *Relative Size* is positive and significant and that of *Medicaid Share* is positive but insignificant. The negative coefficient on *Brand Medicaid Share* persists in both drugstore regressions. However, in the hospital sector products facing a brand with considerable sales to Medicaid may raise prices more than others (eleven percent significance). The hospital results are consistent with the strategic effect of the MFC. Perhaps this is because hospitals are likely to be getting low prices from branded manufacturers and these low prices trigger the MFC. Generic time trends are small and negative, in contrast to the positive brand trends.

The presentations which are most likely to display the strategic effect most strongly are those where package size and Medicaid share are high, giving the brand an incentive to raise price, and the number of generic players is few, giving the generic an incentive to respond to softer brand pricing. In principle one could include an interaction term of all three variables, but the interpretation of a triple interaction term is awkward. Instead, in Table VIII I restrict the sample to larger values of one of the variables, and include an interaction term composed of the other two. The interaction terms should have positive coefficients. I also report the results of a regression restricting the sample to markets where there are fewer than ten outstanding ANDAs.

A perfectly clean test of the strategic effect would use hospital data, because the law provides no *direct* incentive to change hospital prices. However, the hospital data is confounded with inpatient drugs, so I use drugstore data where the average price provision does affect generic drugstore pricing. However, the average price provision creates no incentive for a generic firm to increase prices of large presentations more than others, or to increase prices on presentations where the brand's Medicaid share is higher, so the use of drugstore data should not be biasing

my results.

The results for generic drugstore prices (only) are displayed in Table IX. The coefficient on *Number of ANDAs* increases in magnitude compared to the full sample result; the effect of increased concentration on price is stronger when the market is less competitive to begin with. *Relative Size* is again positive and significant, and somewhat larger than the coefficient in the unrestricted sample. *Brand Medicaid Share* is still negative, but declines in magnitude and is insignificant. This variable seems to have a stronger effect in more competitive markets with more ANDAs. *Medicaid Share* is insignificantly different from zero in both regressions. In the concentrated markets *Rule Dummy* becomes significantly positive, but *Rule Dummy* is also controlling for the effects of the average price provision. The total effect of all the variables is approximately zero on average, as in Table VIII.

The interaction results display further evidence for the existence of a strategic effect in the generic segment of the market. All the interaction terms have positive coefficients, but the interacted variables on their own have negative signs; the interpretation of the overall change in a variable is reported in the last lines of the table. The net effect of increasing any of the three variables of interest is to increase generic price when the law changes, although some increases are close to zero. The most important result is that when the sample is restricted to concentrated markets, increasing either package size or brand Medicaid share raises the generic price upon imposition of the law. When the sample is limited and the interaction included, increasing *Brand Medicaid Share* from .05 to .15 in a concentrated market raises the price change in response to the law by six percent. Similarly, if *Relative Size* moves from 0.4 to 1, generic prices increase by three percent more when the law takes effect. This suggests that generic producers in a less competitive environment respond strategically to the actions of the brand in the market. The more incentive the brand has to raise the price of a particular product, the more likely the generic equivalent of that product shows a price increase also. Columns three and four of Table IX are symmetric regressions that display similar, though somewhat weaker, results.

Other Variations

I tested the results reported above by running the same specifications on data from 1989-1990 rather than 1990-1991. In these regressions the *Rule Dummy* turns to one in January, 1990.

If the results are due to a regularity of the pharmaceutical market that I am not controlling for, the 1990 results will be similar to the 1991 results. None of the coefficients on the *Rule Dummy* variables are at all similar. Most coefficients are not significant; a few significant coefficients appear in the regressions on hospital price. For the reasons discussed above, I consider the hospital results in the paper to be less reliable. To check robustness, I investigate other functional forms of the price regressions. One outlier drug affects the competitive brand and generic results quite strongly because its Medicaid share is more than twice that of the next highest drug. I do not have a good explanation for why its Medicaid share is so high, I drop those observations from the sample and the results reported here.[28] Otherwise, the results are quite robust.

Merck & Co already had a MFC scheme in place for Medicaid sales in 1990.[29] If Merck is constrained by its own MFC pre-OBRA, its prices will not change in the expected manner after OBRA. I re-estimate the regressions above without including Merck observations. The results are almost identical to those of the whole sample. A self-imposed and self-monitored MFC might not have been very credible to competitors, hence Merck might not have been different.

VI. Conclusions

The results presented here do not show textbook responses to the OBRA legislation by pharmaceutical prices in either magnitude or significance. As noted above, the rules are quite complex. In particular, they do not imply that we should see prices rise for all presentations of all drugs. However, if we look for responses among groups of products most strongly affected

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[28] The drug nifedipine has a value for Medicaid share of .43. This is extraordinary considering that the drug faces generic competition and the range for the rest of the competitive brand sample is 0 to .18. Additionally, the drug has two branded suppliers and only one has a high share, which is suspicious. (The other firm has a Medicaid share of about .2.)

[29] "In 1990 the Company initiated its Equal Access to Medicines Program (EAMP) on its single source products under which it offered its "best price" discount to state Medicaid programs that grant open access to the Company's products. The Omnibus Budget Reconciliation Act of 1990 largely reflects the Company's approach, subject to implementing regulations."
Annual Report, Merck & Co., 1991

by the legislation, the expected responses are visible, though small. In particular, brands facing generic competition raised some average prices after OBRA was implemented, and, crucially, prices increased for those products with characteristics corresponding to incentives in the legislation. The average drugstore price of a branded drug facing generic competition increased by about four percent. In particular, drugstore prices rose for large package sizes, for drugs where Medicaid was a large purchaser, and in markets with many generic competitors. Although Federal and state governments reduced pharmaceutical expenditure, and therefore had to collect that much less in taxes, some non-Medicaid consumers paid higher prices for some products, and some pharmaceutical firms may have become better off. These price changes illustrate the risk with MFC clauses: MFCs have distributional consequences that may be unanticipated.

I find little evidence that brands protected by a patent responded to the MFC. None of the characteristics corresponding to the incentives in the legislation are significant in predicting price changes. This may be due to the inflation cap suppressing a response to the best and average price provisions or less dispersion in *ex ante* prices. Hospital prices are poorly measured; this fact combined with weaker incentives for the hospital market results in almost no significant coefficients in the hospital regressions for either brands or generics.

Secondly, generic pharmaceutical prices responded to the price increases of the competitive brands. The average presentation did not experience a price increase, but those in concentrated markets, with large package sizes and high sales to Medicaid, had significant price increases. The result that the number of generic manufacturers in the market affects generic response to brand pricing provides empirical support for the strategic effect of the MFC postulated by Cooper (1986) and others. Generics in markets with few competitors are the only firms that could possibly have strictly benefitted from the legislation. Although generics had to rebate about one and one-half percent (ten percent of fifteen percent) of their sales to Medicaid, price increases on some presentations combined with likely quantity gain could have offset the rebate payments for firms with the right product mix.

A remarked upon above, the estimates reported here may not apply to all segments of the industry. The data I have do not include prices to HMOs (or pharmaceutical benefit managers

like Medco), the types of institutions likely have the pre-OBRA binding low price.[30] The price cap restricting overall price growth to the rate of inflation probably restrained some price increases we might have expected under the other incentives in the law. It is therefore not surprising to find that these data show the expected results of the MFC for only a few competitive classes and sales channels of drugs. However, it is important to note that, in principle, an MFC's indirect effect on competition could completely counteract the desired, direct effect on expenditure. Because the data report average prices it is impossible to examine the change in the distribution of prices within and across channels. Such an examination would reveal more subtle and interesting effects of the legislation and should be area of future research.

[30] "Federal officials and health care administrators say that for all but Medicaid patients, this year is bringing another pile of higher drug bills. Congressional aides said that veterans hospitals face $150 million in higher drug expenses, up 21 percent. Kaiser Permanente, the country's largest health maintenance organization, said its drug costs would rise by $140 million, or 31 percent."
The New York Times, May 11, 1991

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Table IV: Changes in Drugstore Prices, Oct. 1990 - Dec. 1991[31]

Dep Var: $\ln(P_{dec\ 91}) - \ln(P_{oct\ 90})$	Patented Brand	Competitive Brand	Generic
Medicaid Share	-.373 (.213)	-.496 (.100)	-.267 (.382)
Relative Size	.008 (.017)	-.026 (.023)	.031 (.040)
Drugstore Herf	.116 (.038)	---	---
Number of ANDAs	---	-.003 (.001)	-.008 (.002)
Medicaid Share of the Competitive Brand	---	---	-.150 (.198)
Adjusted R^2 Obs.	.052 135	.098 133	.021 478

[31] An observations in this regression is a presentation; the time series aspect of the data has been collapsed into the dependent variable. The log difference of prices before and after the legislation are regressed (OLS) on presentation characteristics.

Table V. Summary Statistics for Presentations

Total presentations: 3109	N	Mean	Std Dev	Min	Max
Annual Revenue	2955	2.27E06	1.4E07	21	3.26E08
Number of ANDAs	3088	8.22	6.77	0	28
Share of Medicaid (% rev)	1602	.137	.061	0	.431
Hospital Herfindahl	3071	.462	.280	.106	1
Drugstore Herfindahl	3052	.365	.270	.106	1
Duopoly Dummy Variable	3109	0.213	0.409	0	1
Relative Package Size	3109	0.396	0.387	0.0017	1
Number of Concentrations per Drug-Form	3109	3.67	1.84	1	12

Number of Presentations 3109	Pill	Liquid	Patch or Spray	Extended Release Pill
Patented Brand	196	18	0	30
Competitive Brand	233	55	5	54
ANDA Holder	670	53	1	66
Generic Distributor	1341	30	79	219
Off-Patent Brand	32	22	5	0

Number of Drug-Forms:	original data	> outpatient > only	outpatient and medicaid share known
Patented Brand	42	37	25
Competitive Brand	51	38	13
ANDA Holder	49	38	12
Generic Distributor	46	37	13
Off-Patent Brand	30	18	3

Table continued on next page...

Table VI. Summary Statistics Continued

Presentations by Competitive Class:					
Patented Brands:	244				
Annual Revenue ($)	225	2.10E07	4.58E07	291	3.26E08
Relative Package Size	244	0.580	0.412	0.006	1
Drugstore Herf	228	0.864	0.211	0.500	1
Hospital Herf	230	0.863	0.190	0.506	1
Medicaid Share (% rev)	165	0.077	0.040	0	0.299
Duopoly (% obs)	244	0.340	0.475	0	1
Competitive Brands:	347				
Annual Revenue	344	3.25E06	7.94E06	62	1.09E08
Relative Package Size	347	0.392	0.392	0.0017	1
Drugstore Herf	334	0.430	0.295	0.106	1
Hospital Herf	345	0.524	0.285	0.106	1
Medicaid Share	157	0.067	0.085	0	.431
Number of ANDAs	347	7.34	6.36	1	23
Number of Labelers	347	15.63	10.33	1	37
Generic Labelers:	1669				
Annual Revenue	1561	2.88E05	2.34E06	21	5.40E07
Relative Package Size	1669	0.381	0.376	0.005	1
Drugstore Herf	1661	0.301	0.199	0.106	1
Hospital Herf	1660	0.411	0.236	0.106	1
Medicaid Share	825	0.157	0.047	0	0.283
Number of ANDAs	1669	8.68	6.14	1	28
Number of Labelers	1669	21.13	8.75	1	37
CB Medicaid Share	852	0.084	0.102	0	0.431

Table VII: Brand Average Price Changes in January 1991[32]

	Competitive Brand		Patented Brand	
Dep. Var.: Ln Price	Drugstore	Hospital	Drugstore	Hospital
Medicaid Share*RD	.4154 (.1889)	-.5268 (.6962)	-.4432 (.2742)	-.0130 (.1417)
Relative Size*RD	.0464 (.0194)	.1413 (.0738)	-.0261 (.0217)	.0117 (.0111)
Number of ANDAs*RD	.0025 (.0010)	-.0041 (.0041)	---	---
Drugstore Herf*RD or Hospital Herf*RD	-.0264 (.0350)	-.0825 (.1225)	-.0402 (.0484)	-.0589 (.0319)
Rule Dummy	-.0140 (.0242)	.1243 (.0992)	.0972 (.0504)	.0506 (.0313)
Number of Observations Number of Presentations	2991 131	2939 131	3246 147	3109 136
Adjusted R^2	0.964	0.883	0.937	.980
Total effect of listed variables: mean and s.e.	0.040 (.009)	0.066 (.034)	.009 (.012)	.001 (.006)
Monthly growth rates of presentations	-.132 to .030; mean= .002	-.083 to .060; mean= -.009	-.144 to .084; mean=.008	-.016 to .032; mean=.003
Quarterly changes	.003 (.007)	-.014 (.026)	.006 (.009)	.010 (.005)

[32] Equation (4) is estimated. Standard errors are in parentheses. The sample for each column includes all observations in the indicated competitive class. The dependent variable is the log of price in the appropriate distribution channel. Intercepts for each presentation and presentation time trends are included but not reported. Both brands' drugstore prices have mostly small, positive time trend coefficients. After -.132, the next lowest time trend is -.016 in the competitive brand drugstore regression. The competitive brand hospital regression shows considerable variability across presentation time trends, unlike the patented brand results.

Table VIII: Generic Price Changes in January 1991[33]

Dep. Var.: Ln Price	Drugstore	Hospital	Drugstore	Hospital
	Herfindahl in Drugstore or Hospital Market		Number of ANDAs	
Brand Medicaid Share*RD	-.2433 (.1053)	.3184 (.1992)	-.3024 (.1058)	.3516 (.2054)
Relative Size*RD	.0430 (.0112)	.0525 (.0227)	.0394 (.0112)	.0527 (.0227)
Measure of Market Concentration*RD	.0725 (.0426)	.0433 (.0728)	-.0031 (.0011)	.0017 (.0020)
Medicaid Share*RD	.2191 (.1421)	---	.1048 (.1390)	---
RD	-.0705 (.0289)	-.0286 (.0301)	.0026 (.0282)	-.0388 (.0340)
Number of Observations Number of Presentations	12875 740	6280 472	12875 740	6280 472
Adjusted R^2	0.969	0.944	0.969	0.949
Total effect of listed variables: mean and s.e.	-0.017 (.010)	.021 (.018)	-.017 (.010)	.018 (.018)
Monthly growth rates of drugs	-.005 to .025; mean=.003	-.004 to .019; mean=.005	-.005 to .024; mean=.003	-.004 to .020; mean=.005
Quarterly changes	-.004 (.005)	-.029 (.009)	-.005 (.005)	-.027 (.009)

[33] Equation (5) is estimated. Standard errors are in parentheses. The sample in each column includes all observations in the indicated competitive class; the dependent variable is the log of price in the appropriate distribution channel. Presentation intercepts are included in the regression but their coefficients are not reported. Drug time trends are described but not reported.

Table IX: Strategic Effect in Generic Price Changes with restricted samples (drugstore only)[34]

Dep. Var.: Drugstore Price		Number of ANDAs<10	Drugstore Herf>.2	Relative Size>.2	Brand Medicaid Share>.04
Number of ANDAs*RD		-.0207 (.0033)	----	---	---
Brand Med%*Relative Size*RD		---	2.489 (.4245)	---	--
Drugstore Herf*Brand Med%*RD		---	---	8.152 (1.427)	---
Drugstore Herf*Relative Size*RD		---	---	---	.3935 (.1006)
Drugstore Herf*RD		---	.0828 (.0555)	-.3203 (.1007)	-.0404 (.0587)
Relative Size*RD		.0624 (.0128)	-.0148 (.0256)	.1104 (.0206)	-.0222 (.0276)
Brand Medicaid Share*RD		-.1725 (.1047)	-.6521 (.2797)	-1.547 (.2906)	-.0281 (.1672)
Medicaid Share*RD		-.1882 (.1345)	.6904 (.2963)	-.0770 (.2043)	.4760 (.2737)
RD		.0981 (.0286)	-.1437 (.0515)	-.0166 (.0487)	-.1077 (.0587)
No. Obs.		6057	5872	6094	6463
Adjusted R^2		0.983	0.983	0.979	0.976
Total effect of listed variables: mean and s.e.		-.011 (.012)	-.018 (.014)	-.010 (.013)	-.014 (.028)
Marginal Effects at: BrMed=.05 Drugstore Herf=0.2 RelSz=0.4	If RelSize + .6 If Brand Med% + .1		.034 .066	---	---
	If DHerf + .1 If Brand Med% + .1		---	.009 .008	---
	If DHerf + .1 If RelSize + .6		---	---	.012 .034

[34] Equation (5) with an additional interaction term is estimated. Standard errors are in parentheses. Regressions include presentation intercepts which are not reported. The restricted samples are designed to include approximately half of the dataset; the observations with the highest value for ANDAs, Medicaid Share, and Relative Size, respectively, form the three samples. The exact cutoff for each variable is listed at the head of each column.