

The Incidence of the Medicare Prescription Drug Benefit: Using Asset Prices to Assess its Impact on Drug Makers*

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Abstract

In 2003, Congress introduced new legislation to subsidize prescription drug insurance for Medicare recipients; Medicare “Part D” will cost nearly \$1 trillion over the next ten years. In this paper, I analyze the incidence of this subsidy by inferring producer surplus from the stock market returns to pharmaceutical firms. I first obtain a measure of the profitability of each brand-name drug from a stock market event study around FDA approval of that drug. Then, extending the event study methodology, I estimate the impact of Part D on profits by comparing the profitability of drugs with high and low Medicare market shares, before and after the passage of the law. I find that expected profitability increases sharply for those drugs with a high Medicare market share in 2003. Structural estimates also imply that Medicare Part D significantly expanded the profits from the Medicare-eligible prescription drug market. Combining these results with other studies implies that the market estimated that pharmaceutical firms would, in expectation, receive 36% of total surplus over the next ten years, or \$205*B*, relative to 56% for consumers.

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1 Introduction

In 2003, Congress enacted Medicare Part D, a government subsidized program of prescription drug insurance for Americans aged 65 and over. Nearly 60% of seniors now receive drug insurance through Part D, and the Congressional Budget Office has forecast expenditures on this program at \$937 billion over the next ten years. Nine million seniors previously uninsured for the costs of prescription drugs have gained coverage, cutting the uninsured elderly population by 70%. In short, Medicare Part D was the largest single expansion of government-sponsored social insurance since the inception of Medicare itself in 1965.

With the enactment of such a large government program, the first question for economists is: what is the incidence of Medicare Part D? By how much did consumers and firms benefit from this intervention? Are the benefits of this bill concentrated among elderly enrollees, or did pharmaceutical firms — or any of the many other actors in the market for prescription drugs — benefit substantially? And what is the social cost of this bill relative to alternative proposals for extending coverage? The answers to these questions are not only important to understanding the impact of this massive spending bill on the healthcare sector but also speak to several broader issues in government policy. First, examining Part D may shed light on the policy-making process and the importance of various lobbying groups. Second, Medicare Part D is one of the first large-scale experiences with providing social insurance through a market-based mechanism, and so it is an important datapoint for evaluating this style of entitlement reform.

Economic theory provides only some guidance on this question. Presumably, the demand curve for prescription drugs in the economy has shifted out, and especially for those drugs sold to seniors. A standard partial-equilibrium analysis would predict increases in price, quantity, or both; from these changes one could infer the incidence for both sides of the market. But a number of additional factors complicate this simple framework for prescription drugs. First, pharmaceutical companies have market power and are often monopolies, in which case prices and quantities could, in principle, move in any direction. Second, pharmaceutical companies do not sell directly to consumers; rather, they sell to drug wholesalers, who then sell to private insurance companies. Part D could increase or decrease the surplus taken at either of these steps, and these intermediaries could also affect the market response of price and quantity. Part D also changed the market structure of the insurance industry, which could influence the relative bargaining power between insurers and either pharmaceuticals or consumers. Even the direction of change becomes an empirical matter. Thus, it is difficult to infer the incidence on firms simply from price and quantity in the consumer market.

Anecdotally, firms expected to receive large excess profits as a result of this reform. Consumer advocates and Democrats, in their opposition to the bill, made much of the restriction in the legislation specifying that government *cannot* negotiate directly with pharmaceutical firms on drugs prices, instead leaving the discussion between the firms and the insurers. Another suggestive fact

is that Rep. Billy Tauzin (R-LA), who shepherded the legislation through the House of Representatives, became the CEO of the main pharmaceutical industry lobby group just one year after the passage of the reform. He reportedly signed for a lobby-industry record of more than \$2 million per year “when the ink [on Part D was] barely dry.”¹ Furthermore, Hall and van Houweling (2008) document how pharmaceutical lobby groups contributed to influential legislators on key committees in exchange for access during the deliberations.

Most research on Part D has used reduced form techniques to measure changes in prices and quantities of drugs purchased by consumers. A number of papers use survey evidence to measure the simple changes in price and quantity observed in 2006 when seniors began receiving insurance through Part D (Yin et al. (2008), Lichtenberg and Sun (2007), Neuman et al. (2007), for instance). Others compare seniors to various control groups (Duggan and Scott-Morton (2008), Ketcham and Simon (2008), and Basu et al. (2008)). Overall, these papers conclude that, for seniors in Part D, prices fell by about 12% and quantities increased by somewhere between 5% and 30%. While these estimates are simple and direct, it is difficult to transform the consumer-side estimates into producer surplus estimates due to the complexity of the market, as discussed above. One method to estimate the surplus for pharmaceutical firms would structurally model the entire pharmaceutical market, estimate the relevant parameters, and then analyze the actual intervention (as well as potentially others) by generating counterfactual market outcomes. The data demands of such an approach would be formidable, though. Some papers have taken this structural approach for simpler elements of the health insurance market (Bundorf et al. (2008), Ho (2008a, 2008b), for instance), but no paper I know of uses such an approach to measure the impact of Part D.

In this paper I take a different approach: I use stock market data to estimate expected producer surplus directly. However, I cannot simply compare stock prices of pharmaceutical firms before and after the passage of Part D. Inferring the impact of specific events on company valuations using stock market movements requires separating the direct market response from the large volume of background noise. In practice this demands sharp information revelations that permit the use of short event study windows in which the signal-to-noise ratio is high. Ideally, for these purposes, Congress would have suddenly announced and enacted the Part D legislation; unfortunately, the passage of the bill took nearly six months, and it was widely discussed even before then. An event study of the passage of Part D legislation would yield extremely noisy and unreliable estimates.

To deal with this problem, I extend the event study methodology by analyzing the changes in event studies over time. In particular, I study the impact of FDA approval of drugs before and after the enactment of Part D, comparing drugs primarily sold to seniors with drugs sold instead to younger patients. For instance, expected profits from drugs for glaucoma should be strongly affected by Part D after 2003, since seniors make up 67% of the market, while profits from anti-

¹ *Wall Street Journal*, Editorial on February 9, 2004.

histamine drugs, with just a 19% Medicare market share, should be largely unaffected. These events provide just the kind of sharp information revelation required. I find a sharp spike in the abnormal returns to a pharmaceutical company upon the announcement of FDA approval of a drug it produces. Furthermore, both theory and the data suggest that the expectation of this “bump” in the market value of a pharmaceutical firm is proportional to the net present value of profits from that drug; thus, these event studies provide consistent and estimable proxies for expected drug profitability over the life of the drug’s patent.

I then analyze changes in the profitability of drugs over time and across drug classes. The results from these analyses show a large increase in expected drug profitability among drugs sold primarily to Medicare enrollees in 2003, just at the time of the passage of the Part D legislation. On average, FDA approvals of those drugs in the top quartile of Medicare market share increase the market value of the sponsoring firm by \$478.8M more than drugs in the lowest quartile of Medicare market share, after Part D enactment, while there is no difference in the pre-enactment period. Similarly, the projected size of the Medicare market for a drug has no impact on expected profitability before the enactment of Part D, conditional on total market size; after enactment, the Medicare market size is a strong and positive predictor of profits, reflecting the increase in profits from seniors. These estimates are robust to a variety of controls for time effects or differential trends, as well as to a number of drug-specific and firm-specific characteristics. I show further that the profitability of low Medicare market share drugs tracks that of high Medicare market share drugs very closely in the pre-reform period, both over time and at all points in the distribution of profitability, suggesting that these drugs are a good control group for those more heavily affected by the reform.

I then use my results, as well as others from the literature, to piece together an estimate of the full picture of incidence from Medicare Part D. My estimates imply that pharmaceutical firms are expected to gain a total of \$242B in NPV profits over the next ten years. Assuming a marginal cost of public funds of around 1.2 (as in Ballard et al., 1985), the deadweight loss simply from raising this extra revenue is \$44B. Elderly consumers gained approximately fifty percent more than producers, or 57% of total surplus. An estimate that reconciles the magnitudes of surplus in each part of the literature with a plausible figure for total surplus generated concludes that firms received \$199B, while consumers receive \$323B. Of this total surplus, \$405B reflects lump-sum transfers, equal to \$5,256 per person-year of added prescription drug insurance coverage.

This paper contributes to the literature first by estimating directly the producer incidence of Medicare Part D. No study has yet moved much beyond estimating the impact on price and quantity in the consumer market, and thus only this paper can include non-consumer surplus in an incidence calculation. A related contribution is to combine these estimates of producer surplus with others from the literature for other actors in the prescription drug market and then construct an overall picture of incidence. These estimates are important for understanding not only the

legislation enacted but also the political circumstances that gave rise to the legislation.

A further independent contribution of the paper, which stands on its own, is to develop a methodology of repeated stock market event studies. An increasing number of papers have relied on stock market data for estimation in a wide variety of non-financial applications, from illegal arms trading to the impact of a presidential election (for instance Cutler (1988), DellaVigna and La Ferrara (2008), Fisman (2001), Guidolin and La Ferrara (2007), Knight (2006), Jayachandran (2006), Roberts (1990), Snowberg et al. (2007)). But this paper extends the use of asset price information to study events that would otherwise be unsuitably broad or diffuse, a category that currently includes most legislation and regulation.

In the sections that follow, I first provide some background information on Medicare, Part D, and the FDA drug approval process, in Section 2. In Section 3 I calculate the event study returns at the time of FDA approval of drugs, and then in Section 4 I use these estimates to analyze the impact of Part D on drug profitability. Section 5 uses the estimates from Section 4 to calculate the aggregate incidence for the pharmaceutical industry. Section 5 also combines my estimates with those from other studies to produce a full picture of the amount and distribution of surplus from Medicare Part D. Section 6 concludes.

2 Background

Prior to the analysis, I provide background on Medicare, the political circumstances and program details of Medicare, Part D, and the FDA review process.

2.1 Medicare and Part D

Since 1965, all Americans aged 65 or over have had access to Hospital Insurance (Part A) and Medical/Outpatient Insurance (Part B) through Medicare. Individuals age 64 and below who are on permanent disability insurance have also been eligible since 1973, and they now make up 14% of total Medicare recipients. Even with Parts A and B, however, there were significant gaps in the medical insurance from Medicare. For instance, Medicare covers only 100 hospital days per episode, and does not include long-term nursing care. In addition, Medicare provided no coverage for drugs unless those drugs were administered within a hospital or other facility.

Medicare Parts A and B involve no private insurance agencies. The government pays healthcare providers directly according to a fee-for-service schedule, and patients face deductibles and copays for cost sharing. Private insurers first became involved in Medicare in 1997, when a new option known as “Medicare+Choice” (“Medicare Advantage” after 2003, or Medicare Part C) allowed individuals to take insurance instead through private providers. These companies must (by law) offer benefit packages at least as generous as those in Parts A and B, though not necessarily the exact same

set of benefits. These companies then receive a risk-adjusted fixed fee per month per enrollee (a capitation payment) in addition to payments from the enrollees. By 2008, more than 10 million or 23% of those on Medicare received insurance through a Medicare Advantage Plan (KFF, 2008a).

In 1965, the average American spent \$130 (in 2008 dollars), and \$267 per person among the elderly on prescription drugs (Acemoglu et al., 2006); nevertheless, prescription coverage was not considered a vital component of insurance. After slow growth into the 1980s, at which time prescription drugs accounted for less than 5% of national health expenditures, total real prescription costs have grown by more than 10% per year and now account for more than \$200 billion annually. Forecasts project that this strong growth will continue, and that total prescription drug costs will top \$500 billion within 10 years. Although Medicare did not include prescription coverage, nearly all of the 59% of seniors receiving retirement healthcare benefits from employers had prescription insurance. But approximately 30% of seniors had no such coverage (KFF 2008b).

It is against this background of sharply increasing drug costs — outstripping even the rapid growth in the rest of healthcare expenditures — that policy makers turned their attention to elderly prescription drug coverage in the late 1990s. This issue featured prominently in the 2000 presidential election. Both candidates promised to remedy the perceived problem but with few differences in policy proposals. Importantly, the key issue of whether government could negotiate prices directly with pharmaceutical companies had not yet surfaced. Knight (2006) confirms that neither pharmaceutical firms favored in the Bush platform nor those favored in the Gore platform substantially outperformed each other, a finding consistent with the hypothesis that the 2000 presidential election resolved little uncertainty about the likelihood or likely form of a prescription drug bill for seniors.

Prescription drug coverage then received little attention until the spring of 2003. Speaker Dennis Hastert (R-IL) brought the Medicare Modernization Act to the House floor on June 25, 2003. There was much debate over the precise design of the bill. In order to limit the total cost of the bill, amendments removed all insurance within a \$3,200 “doughnut hole” (as discussed more below). Furthermore, an amendment privatizing all of Medicare was narrowly defeated, costing the support of several prominent conservatives such as retired Majority Leader Rep. Dick Armey.² The House and Senate each passed versions of this bill over the next two days in narrow votes. After unifying the bills in conference committee and further debate over the design of the bill, the Republican leadership brought the final bill to the floor of the House of Representatives for a vote on November 22, 2003, where it passed by five votes. The legislation passed the Senate three days later by a wider margin, and the president signed the bill into law on December 8.

In Medicare “Part D,” as the coverage is known, seniors may choose, using a website, from more than 50 drug insurance plans offered within a regional market by private insurers. Basic plans must

²Proponents of this rather drastic measure did not give up entirely; the final bill included provision for a six-city trial of partly privatized Medicare by 2010.

cover at least two drugs within each therapeutic class, as well as all drugs in a select few classes, but plans may offer greater coverage or reduced copays at an additional cost that is borne by the enrollee. These plans may differ in the set of drugs covered, the copays for those covered, and the order in which generic or brand-name drugs must be tried. The standard insurance contract includes a small deductible, then 75% insurance for roughly the next \$2,500 in total spending, after which the senior must pay 100% of cost in the “doughnut hole” for the next \$3,200; above \$5,726 in total spending, the enrollee faces only 5% of cost. The government subsidizes the insurance with a risk-adjusted capitated payment to insurers, as well as reinsurance of 80% of catastrophic losses above the cap, together equal to 74.5% of the average cost in the basic plan; enrollees pay the rest. The costs of the program are substantial. According to CBO estimates, government expenditures for Medicare Part D totaled \$49.1 billion in 2007, and will run \$937 billion between 2008 and 2017.

A few other features of the bill are worthy of mention. First, the bill also subsidized large employers to maintain retiree prescription insurance to limit the crowd-out of existing plans. This was a key AARP demand, spurred on by seniors happy with their existing coverage. Second, the government is explicitly prohibited from negotiating with drug companies on price, though individual insurers may. Similarly, the government may not establish a formulary, or a restricted list of covered drugs, but must leave such practices up to the individual insurers. For seniors previously receiving drug coverage through Medicaid (dual eligibles), as well as other low income beneficiaries, Part D includes substantial premium and cost-sharing assistance. Seniors can also receive prescription coverage through Medicare Advantage as part of an integrated health insurance plan, similarly subsidized (KFF 2008b).

Although a number of papers have documented the apparent difficulty experienced by seniors in choosing the best plan to meet their needs (Heiss et al. (2007), Kling et al. (2008), Gruber (2008)), enrollment has been generally robust (Levy and Weir, 2007). In 2008, 25.4 million seniors enrolled in a Medicare Part D insurance plan, representing 57% of eligible Medicare beneficiaries. The fraction of the uninsured without drug insurance has fallen from 30% to 10%, reducing the number of seniors without coverage by more than 9 million.

2.2 FDA Approval Process

In the United States, the Food and Drug Administration (FDA) administers regulatory control over pharmaceutical products. Any product used, whether sold via prescription, used in hospitals, or “over the counter” must first receive approval from a sub-agency, the Center for Drug Evaluation and Research (CDER). Furthermore, any change to any aspect of a previously approved product — including relabelings, additions of new manufacturers, or changes to the patient population — must undergo CDER scrutiny. Finally, CDER monitors the safety of approved drugs, and, when necessary, is responsible for additional warnings or even recall. Although the FDA records the

date of any change to an approved product, as well as the initial date of approval, this paper focuses only on that initial date of approval, since rarely do the other events significantly affect a drug's profitability. For the remainder of this section, I thus focus on the process leading up to this announcement.

In drug development, researchers first identify compounds that may have therapeutic value in the body. (Firms frequently look for molecular variants on existing drugs, which can shorten this process considerably.) The molecules must then be synthesized, after which they are tested in cells or live animals to determine their impact. Although the National Institutes of Health frequently fund part or all of this basic research, it occurs entirely outside the scope of the FDA. Studies estimate that this process takes five years, on average, although there is considerable variation.

A pharmaceutical firm first contacts the FDA only after a developed drug is ready for testing in humans. The firm files an Investigational New Drug Application (IND), after which the FDA reviews the laboratory evidence that the drug is safe and potentially effective. If the FDA does not place a hold on the application, testing on humans may begin after 30 days. Since firms usually conduct these tests in cooperation with research centers or universities, the firms must also obtain local approval from the Institutional Review Board.

Drug testing in humans typically occurs in three phases. Phase 1 tests the drug in 20-80 healthy volunteers to gauge the potential for side effects, as well as the basic nature of the drug's interaction with the human body. If Phase 1 trials reveal no unexpected side effects, drugs progress to Phase 2, which focuses on the drug's potential therapeutic value. 70% of drugs in Phase 1 reach Phase 2.³ These trials include as many as 300 patients with the disease or condition in question. If the drug continues to show potential, firms proceed to Phase 3, in which its safety and effectiveness are measured in large numbers of patients. On average, 38% of drugs in Phase 2 reach Phase 3. These studies compare side effects across sub groups, identify particular counter-indications, and determine the conditions for best use. Firms eventually submit 65% of drugs in Phase 3 trials to the FDA. In total, the three phases of testing take between five and six years, on average. NPV out-of-pocket costs for firms, from development to approval, average \$1.02*B* per drug (DiMasi et al., 2003).

Once testing is complete, the firm formally files a New Drug Application (NDA), requesting that the FDA approve the drug for marketing. In order to anticipate potential areas of concern, the firms frequently speak with the FDA review team before and during Phase 3 trials. The FDA has 60 days to begin the review process; the Prescription Drug Users Fee Act of 1992 then requires action on 90% of drugs within 12 months.⁴ After review of the submitted materials, the FDA holds an advisory committee meeting on each drug, after which it may announce final approval. However,

³See Wood (2006) for this estimates, as well as the other conditional probabilities below.

⁴PDUFA 1997 lowered this 90% threshold to 10 months.

the FDA rarely announces rejection, per se; more commonly, the FDA requests additional testing to investigate worrisome side effects, after which the firm may withdraw the drug from consideration. Although only 8% of drugs that file an IND eventually gain approval, the rate is much higher for those that complete trials. The most recent data suggests that this conditional probability of approval, once an NDA is filed, averages 90%.

The FDA also allows a “fast-track” approval of drugs with a high therapeutic potential above that currently available from existing medications. Roughly 25% of approved drugs in this sample carry this designation. In these cases, the FDA may approve a drug after a larger-than-normal Phase 2 testing, judging that the benefits of speedy approval outweigh the potential for unnoticed side effects. For instance, nearly all anti-retroviral drugs for HIV patients are approved in this manner.

3 Event Studies of FDA Approval

3.1 Theory of Efficient Markets

In an efficient market (semi-strong form), all payoff-relevant public information should be immediately incorporated into the price of a freely traded asset. Although the finance literature has documented numerous apparent deviations from different forms of efficiency (see Barberis and Thaler (2003), for a survey), event studies especially over short horizons have proven a robust empirical tool in the corporate finance literature.⁵ Thus, if the FDA announces that it has approved a drug for distribution, the stock price of that firm should increase on that day to reflect this new information.

To see this more formally, suppose that firm i has submitted a drug to the FDA for approval. The market value of the firm before an FDA announcement (at $t = -1$) can be written as

$$V_{-1} = pE_0[\Pi_R] + (1 - p)E_0[\Pi_A]$$

where $s = \{A, R\}$ denotes the possible states corresponding to the FDA decisions of approval and rejection, Π_s represents profits in each of those states, and p denotes the probability of rejection. If the FDA then approves the drug at $t = 0$, the value of the company will then adjust to

$$V_0 = \Pi_A$$

where Π_A denotes the actual profits after approval. (For simplicity, suppose that profits are known with certainty upon approval). Importantly, actual profits Π_A may differ from expected profits

⁵I further discuss below how this exercise is robust to a number of potential behavioral biases, including post-announcement drift.

$E[\Pi_A | A]$, because FDA approval can vary in degree. For instance, the approval can be for a larger or smaller class of medical indications or a different demographic group than expected. Furthermore, the FDA can emphasize or de-emphasize the potential side effects of a drug through the required label, which documents the experimental findings and includes warnings of various strengths.

The event studies in paper are all conditional on approval. In this simple setting, the abnormal gains to the sponsor company are simply

$$\begin{aligned}\Delta V &= \Pi_A - pE_0[\Pi_R] - (1-p)E_0[\Pi_A] \\ &= pE_0[\Pi_A - \Pi_R] + \{\Pi_A - E_0[\Pi_A]\}\end{aligned}$$

As rewritten in the second line, the increase in the value of the company can be decomposed into two terms measuring the impact of the extensive and intensive aspects of FDA approval. The first term measures value of FDA approval, per se, and equals the probability of rejection times the expected increase in profits. The second term measures the change in profits from the degree of FDA approval. While the first term is simply proportional to total expected profits, the second could be either positive or negative. Across all FDA approvals, though, one instead measures

$$E[\Delta V | A] = pE_0[\Pi_A - \Pi_R]$$

since the second term has expectation zero, by the iteration of expectations. Thus, the expected announcement gains are proportional to the profits associated with the passage of the drug. Most importantly, this proportionality implies that percentage increases observed in announcement gains can be directly interpreted as percentage increases in actual profits. These additional profits may reflect not only the profits from the sale of the approved drug, but also the market's updated beliefs about the firm, for instance including the ability of managers to navigate the FDA approval process. The empirical strategy in Section 4 below controls for this potential.

3.2 Data and Methodology

I begin with data from the Food and Drug Administration (FDA) on the 1,604 distinct successful applications for non-generic drugs approved from 1993 through 2007.⁶ From this starting sample, I am able to match 1,034 to sponsoring pharmaceutical companies that are publicly traded in U.S. markets, either directly or through an American Depository Receipt (ADR). I attribute drugs from wholly owned subsidiaries to the parent company, and I account for ownership shares of joint ventures in the relevant few cases. Removing duplicate applications (for instance, for different doses of the same drug) and drugs used in hospitals or doctors' offices (and thus already covered under

⁶These data are publicly available from the FDA website at <http://www.fda.gov/search/databases.html>.

Medicare Part A or B) leaves 499 drug approvals from 95 companies.⁷

I match these FDA approval records with daily stock market information from the Center for Research in Security Prices (CRSP) obtained through the Wharton Research Data Services (WRDS). I augment these data with market and factor returns from Kenneth French’s website. As is standard in this literature, I follow Fama and French (1993) and control for movements in the market as well as the persistent effects of the Book-to-Market ratio, a High-Minus-Low portfolio (HML), and firm size, a Small-Minus-Big portfolio (SMB).⁸ For the approval of a drug sponsored by firm i , then, I estimate the market model

$$r_t^i = \beta_i^M MKT_t + \beta_i^{HML} HML_t + \beta_i^{SMB} SMB_t + \varepsilon_{it}$$

where r_t^i denotes the return on stock i or a market factor net of the risk-free rate on day t . I obtain estimates $\{\hat{\beta}_i^M, \hat{\beta}_i^{HML}, \hat{\beta}_i^{SMB}\}$ from daily returns in a two-year window ending six months before the drug approval date. The abnormal returns on any stock i , for any day t in the announcement window, is then

$$AR_t^i = r_t^i - \hat{\beta}_i^M MKT_t + \hat{\beta}_i^{HML} HML_t + \hat{\beta}_i^{SMB} SMB_t.$$

As is standard practice in this literature to limit the influence of outliers, I also winsorize the abnormal returns at the 5th and 95th percentiles; that is, I censor all observations outside these percentiles to those percentiles. I also calculate the dollar-valued announcement effect by multiplying the (unwinsorized) abnormal return by the market capitalization of the company at the beginning of the window. I winsorize these figures as well, using the 5th and 95th percentiles of the gains distribution. I adjust all stock prices for the CPI-U such that all dollar-valued effects are in 2008 dollars.

3.3 Event Study Returns

Figure 1 displays the average (equal-weighted) daily abnormal return to a drug sponsor for twenty days before and after FDA approval at $t = 0$. There is a sharp spike at $t = 1$, reflecting that news of FDA approval often becomes public too late in the day for incorporation in stock prices by the market close at $t = 0$. There are also positive abnormal returns (though not significant in the full sample) at $t = 0$, and a case-by-case examination of the pattern of daily abnormal returns

⁷In the case of mergers, I identify as one “company” the dominant pre-merger partner and the combined post-merger entity. Smaller partners are separate companies pre-merger. For instance, in December 2000 GlaxoWellcome and SmithKline Beecham merged to form GlaxoSmithKline. In this case, GlaxoWellcome/GlaxoSmithKline is one company and SmithKline Beecham (pre-merger) is a second.

⁸The market portfolio is the value-weighted return on all NYSE, NASDAQ, and AMEX stocks minus the one-month treasury bill rate. The other factors come from six value-weighted portfolios formed on three book-to-market bins (Value, Neutral, and Growth) and two size bins (Small and Large). HML is the difference between the average return to the two Value portfolios and the two Growth portfolios. SMB is the difference between the average return to the three Small portfolios and the three Large portfolios.

suggests that a small fraction of approvals are incorporated on the day of approval. On average, daily abnormal returns are also positive in the week before the approval, suggesting that some information pertinent to approval may be leaking before the actual announcement date. There is little post-announcement drift, though; although abnormal returns are, on average, positive in the weeks after announcement, they are not significantly so. The market appears to exhibit neither over- nor under-react to the news of approval.

To formally test whether abnormal returns at $t = 1$ are statistically different, I conduct a non-parametric rank-order test following Corrado (1989). For each individual drug approval, I determine the rank of the abnormal returns at $t = 1$ relative to other days in the $[-20, 20]$ window. After scaling so that this rank varies only from 0 to 1, I then average across all approvals. Under the null hypothesis of no abnormal returns, this statistic is distributed as the mean of 499 uniform draws on the grid $\{0, 0.025, \dots, 0.975, 1\}$.⁹ The statistic for $t = 1$ in these data is 0.5503, which falls well beyond the 99.995th percentile (equal to 0.5319). The abnormal returns at $t = 1$ are significantly greater than zero at the 0.01% level.

Figure 1 also displays the average trading volume on the days in the announcement period. To construct this average, I first normalize the volume on each day by the average daily volume within each announcement window. I then calculate the average normalized trading volume on each day in event time, after which I then multiply these estimates by the average trading volume across all days and all firms to give an appropriate scale. These volume averages show a 12% increase in average trading volume at $t = 0$ and a 23% increase at $t = 1$ relative to the other days in the sample. These movements represent 2.2 SD and 4.4 SD increases, respectively, and thus appear very large when compared to the day-to-day variation in the rest of the sample. (No other day deviates by more than 1.2 SD from the sample mean). These increases in volume are broadly consistent with the sharp release of price-relevant information corresponding to FDA approval.

Table 1 displays equal-weighted summary statistics for these abnormal return calculations across a variety of announcement windows and alternative market models. Because of the uncertainty about the precise timing of FDA approval, my primary specification measures abnormal returns from the close at $t = -1$ to the close at $t = 1$. The average abnormal return over this two-day window, shown in the first row, is 0.564% with a t-statistic of 4.0. The rest of the first panel splits the primary specification into the two separate days; as Figure 1 has already suggested, the overwhelming share of returns occur at $t = 1$. Since pharmaceutical firms vary drastically in size, it is important to convert these abnormal returns into dollar-gains to put each event study on an equal footing. The rightmost column of Table 1 shows this average, measured in millions of dollars.

⁹I account for the cases in which I do not have abnormal returns for all 41 days by running a Monte Carlo simulation of the average across uniform draws on slightly different grids between 0 and 1. Out of 1 million trials, the highest draw from the null distribution was only 0.5454.

Over the two-day window, the value of the sponsor company increases by \$162.0 million.¹⁰

The second panel of Table 1 shows alternative announcement windows. As one increases the length of the window symmetrically around $t = 0$, the abnormal returns increase. Most of this increase is concentrated in the days before the announcement; for instance, the abnormal return in the $[-3, +1]$ window of 0.827% is virtually identical to that in the symmetric $[-3, +3]$ window. Although the difference is greater for those windows beginning at $t = -6$, the difference is not statistically significant. The third panel of Table 1 presents abnormal returns calculated using two alternative market models: a first, the simpler CAPM model, accounts only for correlation with the market; and second, a model including the three factors above plus a fourth control portfolio for momentum (following Jegadeesh and Titman (1993) and Carhart (1997)).¹¹ The abnormal returns from both alternative market models are very similar to those from the three-factor model. Thus, I focus on the three-factor model for the remainder of the paper.

The fourth panel of Table 1 calculates abnormal returns with a market model that includes the three standard factors plus a portfolio measuring the average value-weighted return to a pharmaceutical industry portfolio (from the French 49-industry portfolios). This market model should differ from the primary specification in two ways. First, it will control for more market noise, since some information relevant to all pharmaceutical firms but not to the market more generally remains after controlling for the standard three factors. Second, it will reflect not only the direct effect of approval on the sponsor company but also the indirect impact on other firms. This effect could be either positive, if the approval of one drug raises the market expectation of further drug approvals, or negative, if the approved drug represents a competitor to other companies' drugs. Interestingly, these estimated abnormal returns are not significantly different, and, if anything, a bit lower than those from a three-factor model. On average, it appears that these indirect effects are small, though of course the effects could be important for a subset of events to a subset of firms.

3.4 Correlates of Approval Effects

Before proceeding to further analysis using these event-study returns, it is useful to confirm that these proxies for profitability covary with drug characteristics in a way that is consistent with the efficient markets hypothesis laid out above. To do so, I regress the dollar-valued announcement effects on a number of drug-specific characteristics catalogued by the FDA.

These estimates appear in Table 2. The first characteristic is a dummy variable equal to one if the drug received expedited review at the FDA due to its high therapeutic potential relative to existing drugs. Such drugs should be more profitable, since they presumably provide greater

¹⁰All announcement effects in this paper are reported in 2008 dollars; I use the annual CPI-U to adjust historical numbers.

¹¹This factor comes from Ken French as well; it is constructed as the difference between the average portfolio of winners (balanced across Value and Growth) minus a balanced portfolio of losers.

value-added and have fewer competitors, at least in the short run. Column (1) of Table 2 confirms that such drugs do have announcement effects that are, on average, \$242.2M larger. The second variable is a dummy variable equal to one if the drug for approval is a new molecule, and thus represents a significant advance measured scientifically. Such drugs should also be more profitable for similar reasons. Column (2) shows that drugs which are new molecules account for nearly all of the positive average announcement effect with an average boost of \$402.8M. Columns (3) and (4) examine drugs that are either orphan drugs, a legislated class for treatments of rare diseases, or drugs with an FDA “Black Box” warning, the more severe FDA statement of potential side effects or counter-indications. Neither of these variables significantly affects the announcement effect. Finally, column (5) looks for changes over time and finds that, on average, announcement effects have increased but not significantly. When combined in column (6), the dummy for being a new molecule has the greatest impact, reducing somewhat the effect of high therapeutic potential.

In the final columns of Table 2, I regress the announcement effects on actual yearly sales for 2006, which is available for the 200 top selling drugs in the trade publication *MedAdNews*. I can match these data to 89 drugs in my sample; of those drugs I cannot match, approximately half were approved before my sample begins in 1993 and half are sponsored by foreign companies without ADRs or private companies. The coefficient is significant, at 0.211. To transform this coefficient into an estimate of p , the probability of rejection, I use these data to construct a rough measure of NPV profits for each drug, which I calculate equals sales times 3.87.¹² The coefficient on NPV profits is then 0.055. Since this estimate of realized profits is also an estimate of expected profits, this value suggests that the residual probability of rejection at the time of approval, p in the model above, is about 5%. This estimate compares well with the conditional probability of approval upon reaching phase 3 trials of 10%. Given the uncertainty in the construction of my estimate of profits, as well as the noise between the expectation and the realization of profits, the standard error on the actual estimate of such a probability is much higher. However, the reasonable magnitude of this coefficient gives further support to the hypothesis that the event study returns in the stock market are in fact reasonable proxies for the profitability of drugs.

¹²I assume a 5% annual growth rate in sales and a 10% annual interest rate. I assume that drugs have a 12 year patent life, after which they generate no profits. I assume that the marginal cost of producing drugs is 0, but that marketing and sales account for 20% of sales (see Angell, 2004). I assume that 80% of revenue is generated from the United States. I then multiply by 0.65 to find NPV after-tax profits. I also censor Lipitor to the second highest value; this drug had sales over \$14B, more than 250% greater than the second bestselling drug, and drives the entire regression otherwise.

4 The Impact of Medicare Part D

4.1 Theoretical Impact of Medicare Part D

To investigate the potential impact of Medicare Part D on profits for pharmaceutical firms, I begin by operationalizing the model of efficient markets from Section 3.1 above. The observed abnormal gains to a pharmaceutical company c at the time of FDA approval t of one of its drugs d , denoted below as y_{dct} , contains three terms: First, the expected profits from the drug d , denoted π_{dct} , scaled by the probability of rejection p ; second, the impact from the degree of FDA approval, a mean zero shock ξ_{dct} that is heteroskedastic in the size of underlying profits π_{dct} ; and finally ε_{ct} , the residual market noise in the stock of the pharmaceutical company. Combining these terms yields the equation

$$y_{dct} = p\pi_{dct} + \xi_{dct}\pi_{dct} + \sigma_c\varepsilon_{ct} \quad (1)$$

with $E[\xi_{dct}] = E[\varepsilon_{ct}] = 0$ from the efficient markets assumption.

I now make the assumption that the impact of Medicare Part D on pharmaceutical profits is constant, in proportional terms, across Medicare markets for drugs. This assumption rules out non-linear effects as a function of either Medicare market size or total market size.¹³ These increases in profits could come through any number of channels, for instance changes in the price or quantity at which drugs are sold to consumers or in the relative profit shares of pharmaceutical firms and insurance companies. Thus, the profits of a given drug increase linearly in the Medicare market size. Interpreting this assumption through the lens of equation (1), Medicare Part D increases expected profits π_{dct} , so that the post-Part D process of abnormal gains will be

$$y_{dct} = (1 + \delta MMS_{dct})(p + \xi_{dct})\pi_{dct} + \sigma_c\varepsilon_{ct} \quad (2)$$

where MMS denoted the Medicare market share of the drug and δ is the increase resulting from Part D. Note that the increase in value from Medicare Part D impacts both the underlying profits term ($p\pi_{dct}$) and the FDA shock term ($\xi_{dct}\pi_{dct}$). Intuitively, the program not only creates bigger drugs on average, it also increases the variance in profits upon approval.

Figure 3 plots the predicted distributions with and without Part D. Here, I assume that $\pi_{dct} \sim \text{Gamma}(\alpha, \lambda)$, $\xi_{dct} \sim \text{Normal}(0, \sigma_{FDA}^2)$ and $\varepsilon_{dct} \sim \text{Normal}(0, \sigma_\varepsilon^2)$, and I pick rough parameter values to match the data: $p = 0.1$, $\lambda = 1500$, $\alpha = 1.4$, $\sigma_{FDA}^2 = 0.01$, $\sigma_\varepsilon^2 = 700$, and $\delta = 4$. I then simulate 10,000 draws from each distribution, and plot the resulting distributions for the hypothetical pre-Part D and post-Part D data generating processes. The mean of the distribution shifts upwards, which is directly evident from the generating equation since $E[y_{dct}] = (1 + \delta MMS_j)\pi_{dct}$.

¹³This assumption does not imply complete separability of the Medicare and non-Medicare markets for drugs, so long as the effect on aggregate profits is linear in the Medicare market share.

Importantly, however, this is not a pure mean shift of an otherwise stable distribution; rather, there is a pronounced effect on the shape of the distribution that moves mass from the middle to the upper tail. There are two contributing forces to this shift. First, since Part D increases the distribution of profits π_{dct} proportionally, there are larger absolute gains in the upper part of the distribution. Second, the increase in the variance of the FDA shock ξ_{dct} spreads out the observed distribution of abnormal gains. In the lower tail, the increase in variance is somewhat offset by the increase in mean, so that it appears there is no effect. But in the upper tail, these two forces push in the same direction, further amplifying the initial mean shift.

4.2 Data and Summary Statistics

I now merge the excess gains results with a measure of the medicare market share (MMS) for each drug. However, MMS is potentially endogenous to the Medicare Part D reform. For instance, consider two hypothetical identical drugs, one approved before the reform and one after. Suppose that Part D increases usage of this drug among the elderly. In this case, Part D, in increasing the profits from selling this drug, would mechanically increase its MMS, biasing any estimates of the true impact upwards.

To deal with this potential bias, I instead match each drug to its “therapeutic class,” as categorized by the Lexicon classification system.¹⁴ This taxonomy is that used in the Medical Expenditure Panel Survey (MEPS) as either the “subclass” or “subsubclass,” whichever is the finest applicable classification. There are 302 different classifications in total, plotted in Figure 4 with the average yearly market size. The most common classes are “HMG-CoA Reductase Inhibitors” (cholesterol drugs), “Proton Pump Inhibitors” (stomach acid control drugs), and “Selective Serotonin Re-Uptake Inhibitors” (SSRI antidepressants). Therapeutic class is thus specific not only to the disease or condition but also to the mode-of-action. I then measure the average medicare market share of sales for each class, as measured in the MEPS data, between 1998 and 2002, in constant dollars.¹⁵ I then impute this estimate of MMS to all drugs within the class, no matter the specific date of approval.

Summary statistics for the final sample of drugs appear in Panel A of Table 3. In the matched sample of drug announcements, pharmaceutical stocks on average gained 0.563% in the two-day announcement window, which implies gains of \$162.0 million. There is substantial heterogeneity, though; 5% of announcements added more than \$2.765 billion to the market value of the sponsor, while 5% removed more than \$1.888 billion. Medicare enrollees, on average, account for 32% of revenues for the drugs in my sample, though individual drugs range from as low as 1% MMS (contraceptive aids) to 89% MMS (chelating agents, used to treat lead or arsenic poisoning). 28%

¹⁴For drugs which appear in MEPS, I can observe this match directly; for those not in MEPS, I use the Lexicon database (privately available for purchase from Lexicon at <http://www.multum.com/Lexicon.htm>).

¹⁵As a check, I also measure the market share of seniors; there is a 0.95 correlation between the two series.

of approvals in the sample occur after the enactment of Part D.

How do these statistics differ between drugs with high and low Medicare market share? For a first look at these differences, I group drugs into those with MMS in the top quartile of the sample, and those in the lowest quartile. I then calculate a kernel density estimate of the distribution of announcement effects for these groups of drugs. Figure 5 plots these distributions immediately after (Figure 5A) and before (Figure 5B) the “event” year of 2003.¹⁶ Although the two distributions are nearly identical in the pre-reform period, there is a clear divergence, especially in the upper tail, in the post-reform years. This pattern qualitatively matches that predicted by equation (2) well. However, it appears from these figures that the “Low MMS” group is changing across the event window more than the “High MMS” group.

A primary concern in any analysis of a specifically timed policy is that the estimation will attribute broader unrelated changes to the program in question. For instance, if there are strong differential time trends, a discontinuity-based analysis might improperly estimate an effect where there is none. The key question in these circumstances is: when is the differential effect most concentrated?

To investigate the timing patterns more finely, Figure 6A focuses in on the upper tail of the distribution, and plots, for high and low MMS drugs by year, the probability that a drug has an announcement gain in the top quartile for the full sample, which is above \$454M; I label these drugs “blockbusters.” Figure 6A shows a “boom” of drug blockbusters in the late 1990s and a sharp fall off in the early 2000s. This time pattern matches the approval boom in the pharmaceutical industry in the late 1990s, in turn reflecting advances in biotechnology in the late 1980s; indeed, many of the highest selling drugs today were approved in this period, such as Lipitor (December 1996), Advair (August 2000), Plavix (November 1997) and Nexium (March 2000), the top four grossing drugs in 2006. After these strong years, the number of large selling drugs fell off; only 19 of the 100 top selling drugs in 2006 were approved after 2001, as compared with 50 during 1996-2001.

Importantly, however, patterns of blockbuster drugs move together for high and low MMS drugs throughout the boom of the late 1990s and the bust of the early 2000s, but in 2003 the lines begin to permanently diverge, after which a nearly constant gap remains through the end of the sample in 2007. The comovement of these series in the early period, as shown in Figure 6A, suggests that the differences between pooled samples in Figure 5 do represent causal impacts of Medicare Part D, and not simply the movement of underlying trends. Figure 6B shows the similar picture for drugs in

¹⁶These estimates use a Gaussian PDF as the kernel. I approximate the optimal bandwidth following a standard formula $h^* = 1.06\sigma n^{-\frac{1}{5}}$, where σ represents the standard deviation of the sample data and n the number of observations (see Pagan and Ullah, 1999). To standardize the plots, I use standard deviation for the four samples combined, so that $\sigma = 1123$. I use the mean group size, so that $n = 43.5$. Thus, $\hat{h}^* = 560.0$. Silverman (1986) suggests an alternative formula that is $h^* = 0.79Rn^{-\frac{1}{5}}$, where R is the interquartile range of the data, in which case $\hat{h}^* = 213.0$. These less smoothed estimates of the four densities appear in Appendix Figure 2; the substantive message is the same as in Figure 5.

the lowest quartile of announcement gains; the cutoff here is $-\$137M$. Here too, the high and low MMS drug groups move together throughout the pre-enactment period, but the series continue to be quite similar in the post-2003 period; once again, the different distributions in Figure 5 accurately reflect the time patterns for the high and low MMS groups, and do not hide broader differential time patterns.

4.3 Reduced Form Results

From equation (2) above, we know that the impact of Medicare Part D should be linearly increasing in the Medicare market *size* of the drug, not the market *share*. Furthermore, market size is lowest at extreme values of Medicare market share, as plotted in Figure 4; there is a clear inverse U-shape to the distribution. Intuitively, drugs that are only consumed by either seniors or non-seniors must be specifically targeted in a way that tends to rule out a large potential market. In addition, an extreme value of MMS mechanically restricts the potential market size to either seniors or non-seniors. All this implies that I cannot simply interact a post-Part D dummy variable with the MMS variable measured above. If I did so, I would implicitly expect the largest profit increases to occur for drugs with 100% MMS, but these drugs have such small markets that profitability cannot increase by much.¹⁷

Instead, I group drugs into balanced bins. I form three groups comprising those drugs in the top quartile of MMS (“High MMS”), those in the bottom quartile of MMS (“Low MMS”) and those within the interquartile range (“Mid MMS”). In the full sample, these cutoffs are 16.6% MMS for the “Low MMS” bin and 40% MMS for the “High MMS” bin. Panel B of Table 3 displays the group-specific means for a number of variables; as desired, these drug groups are balanced across a number of covariates, as well as the average of announcement gains in the pre-reform period. These groups are also very closely balanced in the share of approvals in the post-reform period. There are large differences in the average abnormal gains in the post-enactment period, though; “High MMS” drugs’ approval bumps increase by nearly 50% to $\$290.5M$, while “Low MMS” drugs’ approvals, on average, actually produce losses after 2003.

From equation (2) we know that

$$\begin{aligned} E[y_{dct} \mid X_{dct}, t < 2003] &= pE[\pi_{dct}] \\ E[y_{dct} \mid X_{dct}, t > 2003] &= (1 + \delta MMS_j) pE[\pi_{dct}] \end{aligned}$$

¹⁷The correct regression must interact a post-Part D dummy with MMS *times market size*. This is a more complicated specification, due to the imputation of drug-specific market size from class market size. I do estimate this below in Section 4.4.

Thus, the difference

$$\Delta = E[y_{dct} | X_{dct}, t > T] - E[y_{dct} | X_{dct}, t < T] = \delta MMS_j p E[\pi_{dct}]$$

consistently estimates the total impact on profits from Medicare Part D for a group of drugs. To control for changes in $E[\pi_{dct}]$ or p over time, one would calculate the double difference across those drugs with different values of MMS_j .

Thus, I estimate the impact of Medicare Part D in the data using a difference-in-difference estimator. That is, for drug d in MMS group j at time t , I estimate the equation

$$y_{dcjt} = \alpha + \beta Post_t + \gamma \kappa_j^{MMS} + \lambda Post_t * \kappa_j^{MMS} + \chi X_{dcjt} + f(t) + \varepsilon_{dcjt} \quad (3)$$

where κ_j^{MMS} represents a dummy variable for each drug group, $Post_t$ is a dummy variable for approval after December 8, 2003, X_{dcjt} is vector of drug characteristics, and $f(t)$ is a control for time. (For more flexible functions in time, the coefficient β will not be separately identified). I include dummy variables indicating high therapeutic potential, orphan drug status, the imposition of an FDA “Black-Box Warning” upon approval as controls, and a new molecular entity. I cluster standard errors by sponsoring firm.¹⁸

Results from estimating equation (3) appear in Table 4. Column (1) presents the simplest specification, comparing only the means of each MMS bin, before and after the law passage. There are no significant differences between the groups before Part D’s enactment, but there are large and significant differences after. On average, drugs with a Medicare market share above 40% saw \$411.8M extra dollars added to the value of the sponsoring firm, relative to drugs with MMS less than 16%. Column (2) adds a linear control for time to the simple dif-in-dif, while Column (3) adds the full slate of covariates. The differences from column (1) are very stable, even increasing a bit with the addition of the covariates. Additional specifications not included in Table 4 reveal that the inclusion of the control for high therapeutic potential explains nearly all of the difference between the estimate of \$404.7M in Column (2) and \$478.8M in Column (3). Among the covariates, only the dummy for a new molecular entity is significant, reflecting the results above in Table 2.

Columns (5) and (6) mirror the specifications in columns (2) and (3), but I include year fixed effects to control for changes over time. As one might suspect from the non-linear time patterns in Figure 6, the year dummies themselves are highly significant; but since all drugs move together in the pre-Part D period, the inclusion of these more flexible controls for time has little effect on the parameter estimates of interest. The shrinking degrees of freedom in the model does mean

¹⁸In some cases, winsorizing may affect the estimates of standard errors. To investigate this possibility, I use a block bootstrap (block size = 20) to sample datasets and then standard errors (following Horowitz, 2001). These standard errors are neither larger nor smaller on average, and with little difference in magnitude for each estimate.

that the p-values for the estimates of the impact of Part D rise slightly above 0.05. But since this added flexibility does not change the estimates, I use the estimate from column (3) as the primary specification.

Since 62 of the 96 firms in my sample submitted multiple drugs for approval within my sample, I can also perform the analysis entirely using within-firm comparisons. This specification accounts for the many differences in observable firm-level characteristics, such as size, leverage, and research budget, as well as a number of unobserved variables including a firm's efficiency in dealing with the FDA. Columns (4) and (7) add firm fixed effects to the specifications in columns (3) and (6) respectively.¹⁹ The estimates of the impact of Part D increase quite a bit; using only within-firm variation, Part D increased the announcement bump from high MMS drugs by \$791.7M, in column (4). These estimates are not statistically different from those in columns (3) and (6), but they highlight the robustness of this finding to a number of potentially endogenous factors that vary across firms. Firm-level characteristics do not drive these results.²⁰

The implied magnitude of these coefficients is large. For instance, take the preferred estimate of \$478.8M from column (3). The pre-Part D mean announcement effect for drugs in the high MMS group is \$198.6M, and the average MMS in this group is 0.56, implying that the average Medicare market size before Part D is \$111.4M. Thus, profits from the Medicare market would need to increase by 429% to account for these results. Can this figure make sense? There is a difference in 0.46 in average MMS between these two groups, which implies that the abnormal announcement returns for the average drug in the market, with MMS of 0.32, increased by \$329M. This represents some fraction of the total discounted profits that a drug now expects to earn as a result of Part D. To put this number in perspective, consider the increase in the fraction of seniors with insurance coverage. Estimates suggest that, in 2007, 30% of the elderly, or 12.5 million seniors, either gained or significantly increased their prescription drug coverage, relative to 2004 before Part D was available. Furthermore, the fraction of seniors in the US, as well as the fraction uninsured, is projected to rise significantly as the baby boom begins to retire over the next fourteen years. By 2017, there will be 56 million seniors, of whom 20 million would have been uninsured but for Medicare Part D (if current growth rates continued). All told, these figures imply an increase in 120 million discounted person-years of added elderly insurance from Medicare Part D. Thus, the increase in market value of \$329M per drug represents \$2.78 per formerly uninsured person-year per drug, or about one pill per person per year.

¹⁹When necessary, I account for the merger of firms, as when estimating the model for abnormal returns above in Section 3. For instance, Pfizer purchased Warner-Lambert in 2000; in this case, I treat Pfizer as one company before and after the merger, but Warner-Lambert as a separate company before 2000. I have also run this specification counting Pfizer pre-2000 and Pfizer post-2000 as different firms. The standard errors increase, but the coefficients are substantively unchanged and remain significantly larger than 0 at the 5% level.

²⁰These regressions are, of course, run on slightly different samples. Omitted specifications show that the increase in the coefficient is not the result of simply restricting the sample to only those firms with multiple drug approvals.

Figure 5 above suggests that the impact of Part D on drug profitability was not simply a shift in the mean; to investigate the distributional impacts more formally, I estimate the equation

$$1\{y_{dcjt} \geq k\} = \alpha + \gamma MMS_j + \lambda Post_t * MMS_j + \chi X_{dcjt} + \nu_t + \varepsilon_{dcjt} \quad (4)$$

for each k in the support of y_{dcjt} . For a given k , regressing a dummy variable equal to one if $y_{dcjt} \geq k$ on only a constant term would estimate (one minus) the empirical CDF function for announcement gains at point k . Analogously, equation (4) estimates the impact of Medicare Part D on the empirical CDF of announcement gains at point k , as identified through the same difference-in-difference approach as above. Since the lefthand side variable in this specification is not affected by the winsorization of announcement gains (so long as k falls between the 5th and 95th percentiles of the distribution), this specification is robust to the particular degree of censoring and thus provides further confirmation of the results above. I include year fixed effects in this specification.

Figure 7 plots the estimates of the interaction coefficient λ from equation (4) at each value between the 5th and 95th percentiles of y_{dct} , along with 2-standard-error bands that are clustered by sponsoring firm. The estimates show no significant impacts in the negative range of the distribution, but then a significant reduction in the empirical CDF in a range between \$500M and \$2B. These estimates are significantly less than 0 at the 1% level in many places. Note that the distributional impact closely matches that predicted by the model above, with the largest relative effects seen in the right tail. Since the underlying distribution of profits is skewed, and the FDA approval shock also increases in variance, the net impact appears as a movement of mass from the middle to the upper tail of the distribution.²¹

4.3.1 Alternative Hypotheses

The primary threat to identification in this analysis is omitted variable bias. If there is some factor affecting the announcement gains from FDA approval that changes differentially for higher MMS drugs, relative to lower MMS drugs, in 2003, than these regressions no longer yield unbiased estimates of the impact of Part D on firm profits. Figure 6 provides some evidence against this possibility in general; given the observed comovement of the high and low MMS drug series before 2003, such a change would have to have been sharply concentrated in 2003, rather than occur over the course of several years. Nevertheless, there are two primary potential sources of this bias: the probability of approval and the underlying profits from drugs. I now analyze the potential for either of these variables to create bias in the results.

²¹Estimating equation (4) is a conceptually similar exercise to running quantile regressions, except that above I minimize square error to estimate the empirical CDF rather than minimizing weighted absolute deviations. As a further robustness check, I estimate quantile regressions using the same set of righthand side variables as in equation (4). The results are qualitatively similar to those in Figure 7, although the quantile regressions have considerably less power.

A first concern is that the probability of approval shifted due to changes in FDA procedure during this period. Unfortunately, the FDA does not publish data on applications that are rejected, and so I am unable to investigate this concern directly.²² As described in Section 2.2, the FDA approval process has been consistent since the passage of the Prescription Drug Users Fee Act in 1992. There is some evidence that the standard for approval became more stringent following the withdrawal of Vioxx from the market in late 2004, but there is no evidence that this tightening (or any other change) differentially affected high MMS drugs relative to lower MMS drugs. The flow of approved drugs yields some information on the approval rate. These figures appear, broken out by MMS group, in Appendix Table 3. There is no evidence that the flow of High MMS drugs has shifted relative to other groups, although an increasing submission rate for high MMS drugs could mask an increase in the probability of rejection. Even with drug-level data on rejections, though, most likely I could not rule out an increase of a few percentage points, and so this does remain an important weakness of this analysis. But in order to completely account for the results above, the probability of rejection would have to have increased to 15% for high MMS drugs while falling to 0% for low MMS drugs. Such a shift seems unlikely, given the available data. Dimasi (2001) analyzes the attrition rates for drugs within different pharmaceutical classes across the entire process of testing and FDA approval, and finds little systematic variation across drugs with high or low Medicare market share.

The probability of rejection might also vary mechanically with the level of underlying profits. For instance, if investors investigated the potential for approval more for larger drugs, then the probability of rejection would fall as profits increased. Of course, this negative correlation would lead to a *downward* bias in my results. But a positive correlation could bias my estimates too high. To investigate this possibility, I take my estimates of actual NPV profits from Section 3.4 and look for non-linearities. The linear and quadratic fits for the data appear in Appendix Figure 1 — the lines are virtually identical. The point estimates suggest that the probability of rejection for the largest drugs is only 1.5 percentage points less than for the smallest drugs, a magnitude which would affect my results by less than 10%, or less than 20% of a standard deviation. Of course, I cannot reject changes of a few percentage points in p , the probability of rejection, but neither can I find any evidence, statistical or anecdotal, of such a change.

The second potential channel of bias is underlying profits. For instance, if the type of drugs developed and submitted to the FDA changed after Part D, there could be bias in my estimates. As the population of the United States ages, the focus of research may gradually shift over time to focus more on drugs consumed by the elderly (and the baby-boom generation in particular), as in Acemoglu and Linn (2004). But there is no evidence of a change in focus towards drugs for the

²²The FDA refused my repeated requests for these data, or for some aggregation of these data. For what it is worth, the FDA confirmed that the average approval rate was 90%, and that it did not change significantly through this period.

elderly in the years just at the time of the passage of Medicare Part D. Appendix Figure 3 shows the number of drugs in each MMS group approved by the FDA; there is no discernable difference in the time patterns across groups, and certainly no sharp change in 2003. Pharmaceutical firms may also have responded to the passage of Medicare Part D by submitting for approval more drugs for the elderly from their queue, and such an endogenous composition change could also have biased the results. However, as a practical matter, the relatively short four-year window in which I observe drug approvals after the reform rules out such effects. The FDA approval process alone takes an average of 1.3 years to complete, and so even the most recently approved drugs in my sample were submitted to the FDA in 2006. Furthermore, the clinical trials process takes an average of 5 years, so that any drugs approved in my sample would have already entered testing long before Part D passed. Since the total process from synthesis to approval takes more than 6 years, pharmaceutical firms would have had to anticipate the passage of Part D legislation in 1996 to appropriately time the approval of new drugs in such a way as to create bias in these results. Appendix Figure 3 further confirms that such a change did not occur. Although the impact of Part D on the process of drug development remains an important aspect of the long run impact of the law change, the potential for this particular bias in this study seems limited.

A related concern is that the increase in stock market values at the time of approval reflects more than simply the profits from that drug. For instance, investors might update their assessments of the capability of managers to shepherd a drug through the FDA approval process in general, which would increase the expected profits from other drugs in development. However, this assessment effect would only bias my estimates if it occurred differentially for high MMS drugs, relative to low MMS drugs, and just in 2003; essentially, Medicare Part D would have to have changed the way investors update from FDA approval. While I cannot rule out this possibility, I can find no evidence of such a shift.

Deviations from efficient markets could also potentially bias my estimation. However, any such effect would have to bias the announcement gains for high MMS relative to lower MMS drugs, and would have to begin at just the time of the passage of the Part D legislation. Since each type of drug is sponsored by a wide array of pharmaceutical firms both before and after the reforms, nearly all standard behavioral biases in financial markets are ruled out. In addition, the results above suggest that the most common behavioral tendency around the release of information, post-announcement drift, is not present. Although various behavioral factors may combine to increase or decrease the effective value of p , relative to market efficiency, this too would not bias the estimation of the parameters of interest in this paper.

4.4 Accounting for Market Size

In the previous section, I established that there are large differences in the patterns of announcement effects between high and low MMS drugs which arise in 2003, the same year as the passage of Part D. That empirical exercise is somewhat divorced from the precise theory of announcement effects developed above. Thus, I now attempt to directly estimate the parameter measuring the proportional impact of Medicare Part D on profits from seniors.

To recall, I model the data generating process for announcement effects in Section 4.1 as

$$y_{dct} = (1 + \delta MMS_d)(p + \xi_{dct})\pi_{dct} + \sigma_c \varepsilon_{dct}$$

for drug d from company c in year t . The term π_{dct} represented the expected profits, conditional on approval, in a non-Part D world. Then ξ_{dct} represented the shock from the nature of FDA approval, δ the impact of Part on the profits for the drug among seniors, and ε_{ct} the shock arising from unrelated market movements in the announcement window.

Above, I formed groups of drugs in which MMS_d and π_{dct} were roughly the same. But another, more direct method for estimating equation (2) is actually to include the term π_{dct} , thus controlling for latent expected profits directly. If one could observe this variable, then in a regression of the form

$$y_{dct} = p\pi_{dct} + \delta p Post_t * MMS_j * \pi_{dct} + \beta \mathbf{X}_{dct} * \pi_{dct} + \varepsilon_{dct}$$

would directly estimate the parameter of interest δ (where the control vector \mathbf{X}_{dct} includes not only the standard control variables, as above, but also the lower order interaction terms between π_d , $Post_t$, and MMS_j).

Since I cannot observe latent profits π_d , I instead estimate it for each drug using the overall market size of the therapeutic class. Following Acemoglu and Linn (2004), I estimate the relationship

$$\ln(MKT_{dj}) = \alpha + \beta \ln(MKT_j) + \varepsilon_{dj}$$

for drug d in therapeutic class j . After predicting

$$\hat{\pi}_d \propto \widehat{MKT}_d = \exp\{\hat{a}\} MKT_j^{\hat{\beta}}$$

in the pre-Part D sample (as with Medicare market share above), I then estimate the equation

$$y_{dj} = \beta \hat{\pi}_d + \lambda Post_t * MMS_d * \hat{\pi}_d + \beta \mathbf{X}_{dct} * \pi_{dct} + \varepsilon_{dct}.$$

I include all control variables from equation (3), as well as year fixed effects. Since the righthand side variable of interest is constructed, I estimate confidence intervals for the coefficients of interest

using a non-parametric block bootstrap of the entire procedure.²³

To see the intuition for this specification, consider instead estimating the equation

$$y_{djt} = \beta \hat{\pi}_{dct} + \lambda MMS_j * \hat{\pi}_{dct} + \varepsilon_{dct} \quad (5)$$

separately in the sample before and after the reform. This procedure regresses abnormal returns on both total market size and medicare market size. In the pre-reform regression, the Medicare part of the market should have no independent effect on profits beyond that of the total market size; thus, the coefficient λ should not be significantly different from zero. But in the post-passage period, those drugs with a larger Medicare Market size, conditional on the total market size, will show increased profits due to Part D. Thus, we predict that $\lambda > 0$ after the law. Furthermore, the ratio $\frac{\lambda}{\beta}$ provides an estimate of δ , the proportional impact of Medicare Part D on the profits from seniors. In all the results below, I scale the righthand side variables so that the coefficient measures the effect at average values of variables with which market size has higher interactions.

In the first stage, my data predict a drug-specific market size proportional to $\widehat{MKT}_d^{0.83}$ with a standard error of 0.27. This estimate is highly significant. This concave relationship between total market size and drug-specific market size reflects the greater entry of drugs into larger markets, consistent with the high-fixed cost production structure of drugs. Since the market size estimates all come from the fixed MEPS sample period 1998-2002, I inflate the market size estimates in line with growth of the entire pharmaceutical market though 2007. I similarly inflate the Medicare market shares by the demographic changes in the population, averaged (with discounting) over the expected future patent lifetime of the drug. The estimated market size variable ranges up to \$5.4B per year, roughly the average size of drugs in the cholestorol drug market (which is the largest).

Table 5 presents estimates from this approach. I begin in column (1) including only the estimated market share, to gauge the performance of this estimated variable. The estimate of 0.093 is statistically significant, and the magnitude aligns well with the relationship between abnormal returns and estimated NPV profits from Section 3.4 above. Since NPV profits as approximated in Section 3.4 above were roughly 3.5 times annual sales, the scaled coefficient of profits in this specification would be 0.027, which is somewhat smaller (though not statistically different from the estimate of 0.055 above). However, the market size in this regression is estimated, as opposed to the actual sales data used above, and so a slightly smaller coefficient is to be expected.

Column (2) of Table 5 presents the first evidence of the impact of Medicare Part D. The coefficient of interest is that on the interaction of Medicare market size and the *Post* dummy, in the fourth row. The impact of Medicare market size increases dramatically after the passage of Part D to 0.565. Without additional controls, this estimate is only significant at the 10% level;

²³I run 10,000 replication, drawing blocks of 20 observations, following Horowitz (2003).

in columns (3) and (4), however, with the addition of the standard bevy of control variables from above, the estimate becomes significant. These estimates imply that the Medicare market generated significantly more profits for pharmaceuticals after the enactment of Part D; in contrast, there is no significant difference between the profits from Medicare and non-Medicare markets in the period before Part D, and there is also no difference in the profit generation of the non-Medicare market between the two time periods. The final four columns of Table 5 run the specifications separately on the pre- and post-Part D samples. The results are broadly consistent.

From these estimates I can also obtain a direct estimate of the parameter δ in the model above. To do so, notice in the theoretical analogue to the estimating equation that $\delta = \frac{\Delta}{\beta}$. The bottom row of Table 6 provides this estimate, with standard error (from the bootstrap). The point estimates are generally between 5 and 6.5, although some very large values lie within the confidence intervals due to the uncertainty in the denominator. The point estimates are quite large, although the confidence intervals include values that are perhaps more reasonable. These estimates also align with the economic magnitudes from above in Section 4.3, which suggested an increase of 429% in profits from the Medicare market. Note that this does not imply a 500% increase in sales, just in profits. For instance, pharmaceutical firms may have to spend very little on marketing or advertising for the marginal pill sold, and may even be able to reduce existing marketing costs due to the increased use of formularies.

5 Aggregate Incidence of Medicare Part D

Thus far I have estimated the impact of Medicare Part D on the effect of announcement of FDA approval on each drug. These estimates seem to imply that pharmaceutical firms are expected to enjoy higher profits as a result of the reform, but they do not provide an aggregate magnitude. I now calculate the total economic incidence as implied by the results above.

5.1 Aggregate Incidence for Pharmaceutical Firms

The figures so far have included only the additional value added to the sponsoring company on the day of announcement of FDA approval. At many approvals, though, there may be an offsetting reduction in value for companies with competing drugs.

To estimate this effect, I first look for potential competitors in the MEPS data. For each new approval between 1996 and 2005 (a total of 411 drugs), I calculate the market share of each brandname drug sold in the same therapeutic class in the three years up to and including the year of the new approval.²⁴ I can identify 731 competitors to 232 new drugs. For instance, this procedure

²⁴To keep the signal-to-noise ratio high, I drop drugs with market shares less than 5% or total sales less than \$1M.

identifies the major competitors to Lipitor (approved in 1996) as Pravachol (64% share), Lescol (22% share), and Zocor (13% share). I then match these competitor drugs to the companies owning the patent, removing those competitors produced by the same company as the newly approved drug (106 of 731) and those for which I have no financial data (117 of 731). I then calculate the abnormal returns in dollar terms over a two day window around the announcement of FDA approval of the new drug, using the exact procedure described in Section 3 above. The sum of the dollar-valued announcement effects across each of the competitors is the total offset due to competition.

Netting out the losses to competitors, the pharmaceutical industry actually loses \$16.9M, offsetting more than the entire average gain to the firm with the newly approved drug of \$181M. This is consistent with many models of monopolistic competition, in which the entry of an additional competitor reduces aggregate producer surplus. There are also 179 new drugs without competitors, which have an average sponsor announcement effect of \$185M. Averaging over these two groups yields an average gain of \$183M for the sponsor firm and a loss of \$111M for competitors. I must also account for the competitor drugs for which I cannot match to a company traded in the US, of which there are 117. This adds 23% to the number of competitor drugs. These missing drugs appear similar to the matched competitor drugs both on market share and market size; thus, I inflate the \$111M by 23% to \$136M. On net, the industry gains \$46M, or 24.8% of the profits for the sponsoring company.

I now combine the direct and indirect effects to estimate the financial market's estimate of the aggregate incidence of Medicare Part D for the pharmaceutical industry. From the reduced form analysis above, we know that, on average, each drug sees a \$329M larger bump at the time of approval. From the results in the previous paragraph above, the competitive impact of a drug approval offsets 75.2% of direct impact, so that the net extra profits for the industry is \$83M per drug. Assuming that the market probability of rejection at the time of approval is 10%, this implies \$829M extra profits over the lifetime of each drug. An important assumption here is that the probability of approval does not covary with the size of underlying profits. If such a correlation were non-zero, then Jensen's inequality would imply that I could not simply divide by the average probability of rejection, but instead I would need to form a drug-by-drug estimate. However, the evidence in Appendix Table 1 suggests that there is no evidence of such a correlation.

A few more assumptions are necessary to arrive at a total incidence figure. I must specify how profits evolve over the lifetime of the drug. I assume that profits grow by 5% each year, though there is a one-time 80% drop after the twelve-year patent life. (Together, these assumptions imply that drugs generate 89% of profit before going off patent.) I must also account for approved drugs from companies not traded in the US; from MEPS, I can measure that my sample contains 80% of the total US market sales of brand name drugs. Finally, fewer drugs (especially large drugs) are being developed than are going off patent, reflecting the boom of profitable approvals in the late

1990s. To correct for this “hump shape” of profitability, I use the fraction of large drugs approved as in Figure 6, and assume that future drug development is constant at the average level for the “Low” group after 2003. Adding over the projected profits for 2008-2017 and discounting at 10% per year, we arrive at the total: drug makers gain \$242.1*B* in profits on drugs.²⁵

Table 6, Panel A probes the sensitivity of this result to the various assumptions implicitly included in it. In the middle of the table, the \$242*B* in bold uses the same assumptions as above. Around it, I recalculate the total profits figure, varying four of the assumptions made above: the market probability of rejection at the time of approval, the ratio of net industry profits to gross profits, the assumed annual growth rate of profits for a drug, and the falloff in profits after patent expiry. The profits growth rate and the drop-off after patent expiry make vary little difference, since it simply reallocates the \$829*M* in extra NPV profits between years. Since the probability of rejection scales up the abnormal returns, varying this figure can change the estimate by quite a bit; for instance, decreasing the number to 7.5% increases the total profits figure to \$323*B*. The net profit rate also impacts the number directly. (Though I estimated this number above, there is quite a bit of noise around the point estimate of 25.2%.) Decreasing the net profit rate to 12.5% would decrease the total profits figure to \$121*B*.

What might account for the remainder of these profits? One possibility is that Part D changed the relationship between pharmaceutical firms and insurance companies or drug wholesalers. For instance, Part D dramatically altered the structure of the prescription insurance market for those aged 65+. Insurance companies now compete for enrollees with more than 50 competitors in each market. If the profits of these insurance companies have decreased, it might further add to the share taken by pharmaceutical firms. Part D may have also changed pharmaceutical firms’ use of input factors, which could further contribute to profits. If these additional funds allow firms to finance a greater share of their operations out of retained earnings, profits could also increase. At this point, the strength of the reduced-form nature of the approach here, in its ability to capture the aggregate impact of many effects, is also a weakness in that I cannot directly attribute the resulting estimates to one or another particular source.

5.2 Overall Incidence and Welfare

I can now combine the estimates in this paper with other estimates in the literature to construct the distribution of the total incidence of Part D.

The first and most obvious group to include in this calculation is Medicare enrollees. There are three components of consumer surplus, represented in Figure 8. First, holding prices and quantities constant, government now subsidizes insurance plans, represented by region 1 in Figure 8. By law,

²⁵I assume here a 10% discount rate, equal to the weighted average cost of capital for the major firms in the pharmaceutical industry.

the payments to insurance companies, combining premium support and catastrophic reinsurance, are fixed at 74.5% of average cost to the insurer. Data from Lichtenberg and Sun suggest that seniors pay out-of-pocket for 34% of prescription drug costs, so this subsidy accounts for 50% of total prescription drug consumption by the elderly. The government only provides this subsidy for those in a Part D plan; furthermore, those previously receiving prescription drug coverage from Medicaid receive no additional subsidy; thus, 43% of seniors receive this lump sum. There is no data on the prescription drug costs of these seniors relative to others, so assuming that average costs are the same, the direct government subsidy equals \$20.6*B* in 2008. Adding over a ten year horizon after growing this figure in line with projected drug spending, and discounting with a 10% discount rate, the total discounted surplus to consumers is \$199.8*B*.

The second component to consumer surplus is reduction in costs through the change in prices paid on previously consumed drugs, represented in Figure 8 by region 2. On average, the existing literature estimates that average prices fell by 12% for Medicare recipients. To calculate aggregate surplus from these figures, I simply calculate 12% of current spending by seniors. In 2004, the last year for which HHS provides an age-breakdown of spending, total senior payments for prescription drugs were \$55.7*B*. Assuming that spending would have continued to grow at the pre-Part D per senior average of 9.29%, this calculation estimates counterfactual spending of \$97.3*B* in 2008. Thus, consumer surplus from reduction in prices is \$11.7*B* in 2008. To project this number forward, I assume that per person pharmaceutical payments from seniors would have continued to grow at 9.29%. Furthermore, Duggan and Scott-Morton suggests that nearly all of this surplus accrued to those who gained insurance through Part D; thus, I inflate this figure by the estimated increase in the number of uninsured seniors, rather than the total number of seniors (as calculated above). Discounting future sums at 10%, the total reduction in payments is \$140.2*B*. This figure does not include those on disability insurance, who account for 14% of Medicare eligibles. This increases the total surplus from reduction of payments to \$163.1*B*.

The final, and most elusive, component of consumer surplus reflects the value of the new drugs consumed above the new price, represented in Figure 8 by region 3. As in a standard market, this value should be positive, since consumers would have purchased any drugs whose value exceeded their cost. However, in the market for prescription drugs, the value of new drugs stems not from the difference between the old and new full drug price, but rather the change in old out-of-pocket (OOP) costs, reflecting the marginal cost of drugs. There is only scattered literature investigating the consumer surplus of marginal prescription drug consumption. If the demand curve is linear, though, this gain will equal half of the difference between the cost of new drugs at old OOP costs with that at new OOP costs. Alternatively, I can bound the size of this surplus below by zero and above by the product of the change in OOP costs and the increase in quantity.

The literature, on average, estimates a 17% increase in quantity, along with a 16% decrease in

OOP costs. However, since the increase in quantity came primarily from those gaining insurance, the decrease in OOP costs is substantially greater; Duggan and Scott-Morton (2008) estimate the drop at 80%. From Basu et al. (2008), the average OOP cost for seniors is \$14.20 per month in 2006. Adding across months and counterfactually uninsured enrollees yields a surplus of \$909M in 2008 from the increase in consumption of prescription drugs. The discounted sum of ten years is \$29.6B if the demand curve for prescription drugs is linear, and the figure must lie between \$0B and \$59.2B. Of course, consumers may over- or under-estimate the true consumption value of prescription drugs. For instance, consumers may under-consume due to an inadequate consideration of future benefits relative to current costs from either present bias or projection bias. But without significant evidence, this estimate seems appropriate as a ballpark figure. Totalling the three different components of consumer surplus, the total discounted figure is \$392.5B.

Employers and unions offering prescription drug coverage within retirement packages also benefited from Part D.²⁶ Under the “Retiree Drug Subsidy” (RDS) provision of MMA 2003, the government subsidizes those already providing prescription drug insurance to seniors to reduce the crowd-out of insurance as part of retirement packages (as in Cutler and Gruber (1996)). In particular, the government subsidizes 28% of gross prescription drug costs, tax free, below \$5,600 per enrollee (in 2008). CMS estimates for 2008 that this amount averages \$751 per enrollee, roughly matching the capitation payment to insurance companies offering stand-alone coverage under Part D. If the prescription drug insurance provided for retirees does not change, this subsidy accrues entirely to the retirement package provider. Plans should not change for those already retired, since retirees have no basis on which to renegotiate their package. Standard wage suggests that workers should eventually capture some of this surplus, as the retirement package and labor supply adjusts for what is, effectively, an employment subsidy. However, there has been little research on this aspect of Part D and the employment responses to it; thus, for this incidence calculation, I assume that 100% of the subsidy accrues to the employer. It is also possible that firms increased the generosity of their plan in order to qualify for the threshold; survey results from McArdle et al. (2004) suggest that most firms were actually considering increasing the use of step therapies and other demand management systems to fall more in line with Part D. It is possible that firms did not follow through on planned decreases in coverage, in order to qualify for the RDS, but there is no direct evidence for such an effect.

What is the overall total for the retiree drug subsidy? There were 6.8 million registered enrollees for the retiree drug subsidy in 2006, the latest year for which CMS has published data. I assume that this number grows proportionally with the number of seniors in the population, while the average

²⁶Unions sometimes manage these programs, and thus the subsidy might be split between unions and workers in those cases. There is no research to my knowledge on the split of surplus in such cases, and so I lump them together for these purposes. If state governments pay directly for retiree insurance, they would also benefit from Part D in this way.

subsidy grows at 6% per year, slightly faster than the increase in the per enrollee limit to account for the more rapid increase in drug costs. Under these assumptions, in 2008, I estimate that employers should receive \$5.4*B* in 2008. Over a ten year horizon, discounting at 10% per year, employers receive \$52*B*. Since these payments are tax free, this sum directly represents surplus.

Combining the previous calculations, the total surplus is \$686.5*B*. Note that the total spending over ten years is \$471*B*, which reflects the discounted value of the raw \$937*B* headline spending figure. To account for the true welfare cost of this revenue, I assume a marginal cost of public funds of 1.2, and so the total welfare cost of raising the revenue is \$565*B*. By these figures, Part D created \$121.5*B* of welfare, and \$215.5*B* in surplus beyond the direct money spent.

Where could the \$215.5*B* come from? To produce welfare beyond the dollar amount spent, surplus must somewhere be created rather than simply shifted. The only potential for surplus generation calculated above is the value to consumers from the increase in the quantity of consumed drugs. But since OOP costs are low, and quantity increases even among the previously uninsured have been modest, this gain to total surplus is small. Above I estimated the part of this surplus that accrues to consumers at \$29.6*B*; producers gain another \$14.8*B*. This yields a total increase in surplus of \$44.4*B*, not nearly enough to account for the entire figure. There are also other aggregate efficiency gains not included above. One such source of surplus could be decreased administrative costs for prescription drug insurance. Woolhandler et al. (2003) estimates that administrative overhead for all health insurance account for \$259 per person in the United States, more than five times higher per capita than in Canada, totalling \$78*B* per year. If prescription drug insurance became more efficient, the savings could be substantial. Drug companies may also have reduced expenditure on marketing efforts in response to the increased use of formularies in Part D drug plans.

But even if all of these sources of surplus are substantial, it may not account for the entire \$215.5*B*. The estimates used above are not entirely consistent, then, as they overallocate the surplus. One potential explanation is that the analysis here reflects NPV producer surplus, while the existing literature instead measures surplus in the short run. In this case, the long run increase in quantity might be larger and price decrease smaller than in the short run. A final alternative is that these different approaches simply yield different estimates of the allocation of total surplus. Part D may also have transferred rents from parts of the market left out of this analysis — for instance, insurers or drugs wholesalers — to consumers and pharmaceutical firms.

A different approach is to work backwards from an estimate of total surplus. Without a fuller picture of the impact of Part D on the pharmaceutical drug market, it is impossible to estimate precisely such a figure. But suppose that I take a generous view of the unmeasured sources of welfare discussed above (as well as a generous view of the US Congress) and assume that total surplus exactly equals the welfare cost of the revenue, \$565*B*. The estimates above now provide a

sort of bound on the allocation of surplus, as one allocates the $\$121.5B$ in surplus reduction to either producers or consumers. In the most consumer friendly scenario, producers gain only $\$120.5B$. On the other hand, if producers gain the entire $\$242B$, consumers would receive only $\$271B$. This number would be consistent with a 4.4% decrease in drug prices. Between these two extremes is the case in which each side receives the same fraction of total surplus, thus allocating the $\$103B$ reduction pro rata; here, consumers receive $\$323B$ (implying a 8% price reduction for consumers) and firms $\$199B$. These numbers are each well within the confidence intervals of the estimates from different parts of the literature, and so this scenario may be the best guess from the literature as a whole.

Medicare Part D involves both lump-sum transfers and marginal subsidies; these surplus calculations highlight this mix between redistribution and behavior change. For instance, $\$199.8B$ of this surplus comprises direct lump-sum transfers to Medicare enrollees. The government could subsidize prescription coverage in the same way for Medicare enrollees on the margin without a net subsidy, which would remove the redistribution to the Medicare eligible while still providing the missing market in individual prescription drug plans for seniors. Furthermore, the government could tax back, in a lump-sum, the extra profits to firms, while leaving the marginal incentives for drug development unchanged. Eliminating these two transfers, the government would be able to reduce the revenue raised by distortionary taxes by $\$405B$ over ten years. If the marginal cost of public funds is 1.2, this revenue would create a social welfare gain of $\$81B$ from the reduction in deadweight loss.²⁷ Since Part D increases the number of seniors with insurance by 77 million person-years over 10 years, these transfers represent $\$5,256$ per person-year of additional insurance. This ratio is slightly higher than similar figures (as in Lichtenberg and Sun, 2007) using only consumer data.

6 Conclusion

In this paper I have used stock market data to analyze the impact of Medicare Part D, the largest expansion in the social welfare state in more than a quarter-century. Anecdotally, pharmaceutical firms had a great deal of influence on the design of Part D and were quite happy with its final structure; these estimates imply that financial markets agree with this sentiment. I estimate event study returns around FDA approvals of drugs and then analyze how these proxies for profitability change differentially over time between high and low Medicare market share drugs. This empirical strategy isolates a sharp increase in the market estimate of drug profitability just at the time of the passage of Medicare Part D in 2003, concentrated among those drugs sold most to seniors. Reduced form specifications estimate a $\$478.8M$ increase in the average stock market reaction to the approval of a high MMS drug, relative to low MMS drugs. Directly estimating a model of stock

²⁷See Ballard et al. (1985) or Auerbach and Hines (2001), for instance.

market reaction confirms the magnitude of the increase in profits from the Medicare market after Part D. These coefficients imply that the total surplus gained by pharmaceutical firms is \$242*B* over the next ten years of the program. Combining this estimate with those in the rest of the Medicare Part D literature, I estimate that firms gained 35% of the total surplus from Part D, as compared to 57% to consumers. These results also suggest that the lump-sum transfers in this program are much larger than the surplus creation; I estimate that each added person-year of insurance costs \$5,256 in lump-sum transfers to consumers and firms. Understanding this massive legislation is valuable in its own right and constitutes the first contribution of this paper.

The second and broader contribution is to illustrate the use of repeated stock market event studies to analyze the incidence of major legislation. Legislated reforms rarely involve the kind of sharp information revelation required for an event study. But by calculating repeated event studies over time and then analyzing how the results change, one can increase the signal-to-noise ratio high enough to allow causal inference from financial markets. This new methodology should allow the extension of the asset-price approach to study events that would otherwise be unsuitably broad or diffuse. For instance, to measure the impact of changes in the drilling rights of oil companies within the US, one might examine the sensitivity of these firm's stocks to oil prices before and after the regulation. To measure the producer incidence of regulation to limit tax evasion in the purchase of diesel fuel (as in Marion and Muehlegger, 2008), one could analyze the response of producer stocks to oil prices. One might similarly measure the impact of tariffs or trade barriers by comparing the responsiveness of the market values of importing or exporting firms to foreign exchange fluctuations before and after a change in the law. In general, any repeated profit-relevant information flow should be enough to judge the impact of legislation or regulation on those profits.

There are, of course, a number of caveats to this research, each of which point to potentially fertile grounds for future work. All of these estimates reflect market expectations of additional profits to pharmaceutical firms, not a measurement of profits themselves. Thus, this paper is a complement to, not a substitute for future analyses of the actual impact of Part D on the prescription drug market. As time passes, researchers will be able to see, for instance, whether in fact the demographic increase in the elderly population, combined with the increase in the fraction of seniors with insurance, creates the large profits for pharmaceutical firms predicted here.

A second limitation is this work's focus on the profits of pharmaceutical firms and then consumer surplus. Part D may well have affected the surplus of a number of other actors in the prescription drug market, such as drug wholesalers, insurance companies, the employees of pharmaceutical firms, pharmacists, and doctors. Future research should look to shed more light on the impact of Part D on these other agents.

Future work should also investigate the research response by pharmaceutical firms to Part D. Acemoglu and Linn (2004) suggest that, by increasing the market for drugs for the elderly, Part D

should encourage innovation. Since only five years have elapsed since the passage of Part D, it is too early to analyze this effect empirically. But the welfare gains from these new drugs probably are large, so understanding these impacts will be crucial to any complete analysis of the long run effects of Part D.

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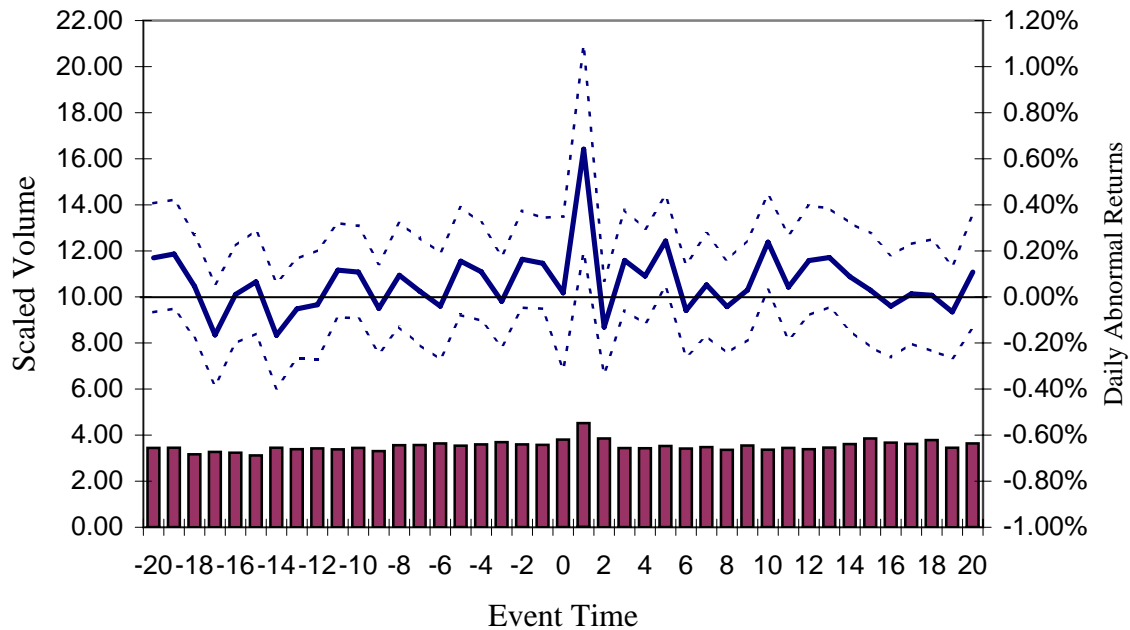
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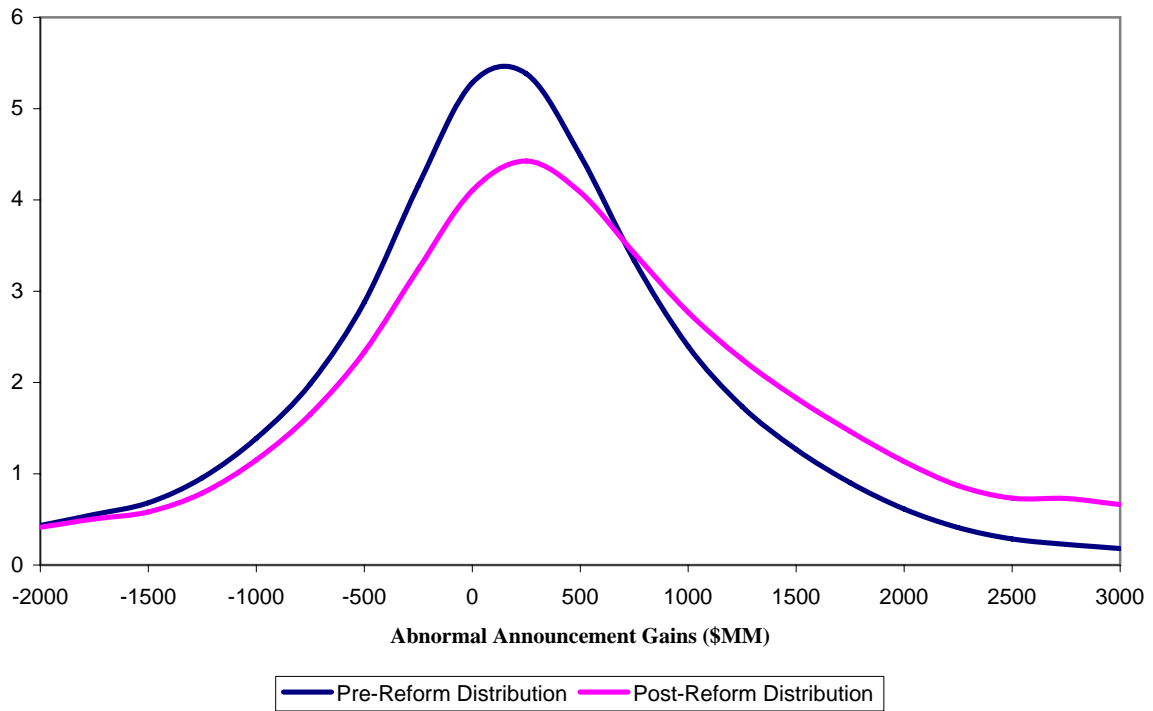
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Figure 1: Abnormal Returns and Scaled Volume, in Event Time



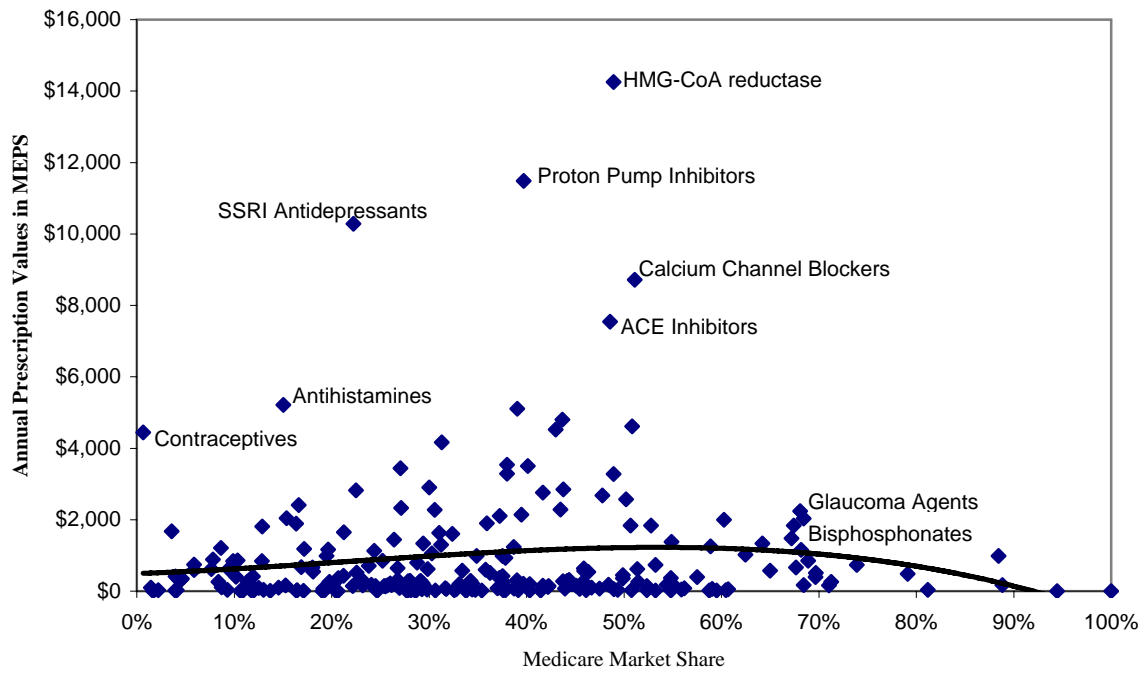
This figure plots daily abnormal returns and standardized trading volumes in the days around an FDA announcement of a drug approval. I line up the event windows so that the FDA approves each drug on day 0; note that the big spike occurs on day 1, since frequently the information is released too late in the day to be incorporated into prices on day 0. Daily abnormal returns are calculated using a three-factor market model which is calibrated in a two-year window ending six months before the announcement date. I winsorize the daily abnormal returns at the 5th and 95th percentiles before taking an equal weighted average across drug approvals. To calculate standardized volume, I first calculate the average trading volume, for each drug approval, across the entire 41-day window here. I then divide the volume in each day by this drug-specific average volume to get a "standardized volume." I average these figures across drugs, after which I reinflate the averages by the sample average volume of 3.52 million shares traded.

Figure 2: Simulated Impact of Medicare Part D



This figure plots densities from Monte Carlo simulations of the distribution of announcement effects with and without Medicare Part D, following the data generating process in Section 4.1, p. 14.

Figure 3: Market Size and MMS of Therapeutic Classes



This figure plots the average annual market size and average Medicare market share for each therapeutic class. These data come from the MEPS Prescription Drug File. I calculate the Medicare market share as the total fraction of sales accounting for by Medicare eligibles between 1998 and 2002. I calculate the average annual market size as the average annual sales during 1998 through 2002, equal weighted across years. The trendline is the regression line fit after regressing average sales on a constant term, MMS, and MMS squared.

Figure 4A: Distribution of Announcement Gains by MMS, 2004-2007

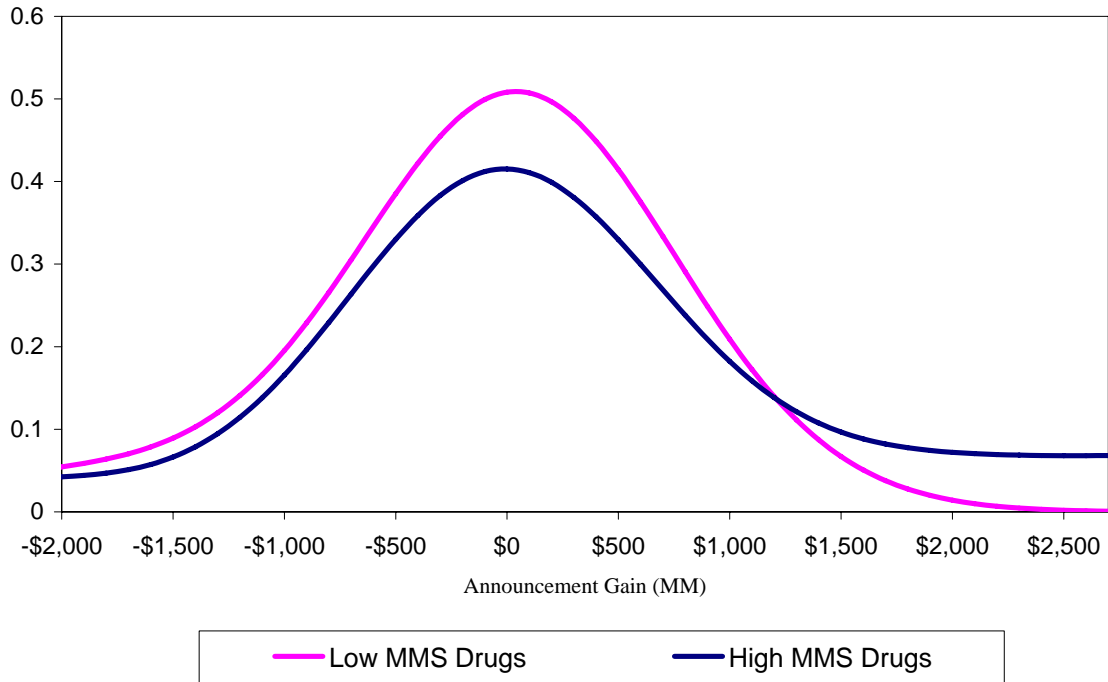
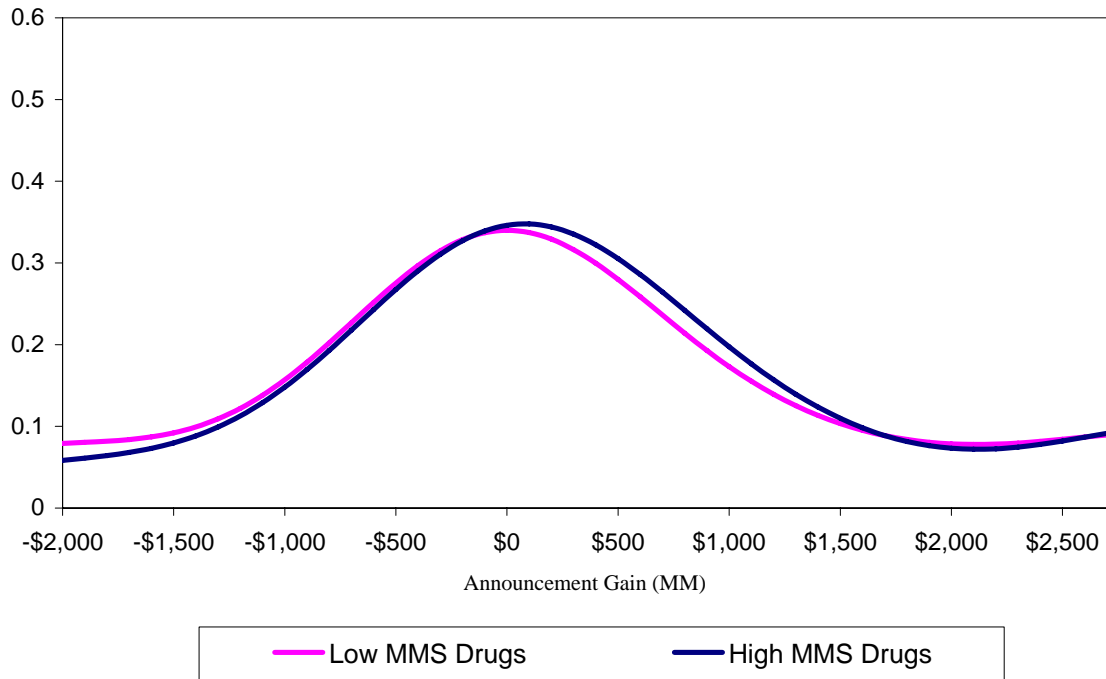


Figure 4B: Distribution of Announcement Gains by MMS, 1997-2002



These figures present kernel density estimates of the distribution of announcement effects for FDA approvals. I use a Gaussian kernel with bandwidth of 560 for each plot. High and low MMS drugs are those drugs with MMS in the top or bottom quartiles of the sample, that is above 40% or below 16.6%. There are 33 and 34 datapoints in the High and Low MMS densities in Figure 4A; there are 51 and 56 observations in the High and Low MMS densities in Figure 4B.

Figure 5A: Probability of a High Announcement Effect Drug

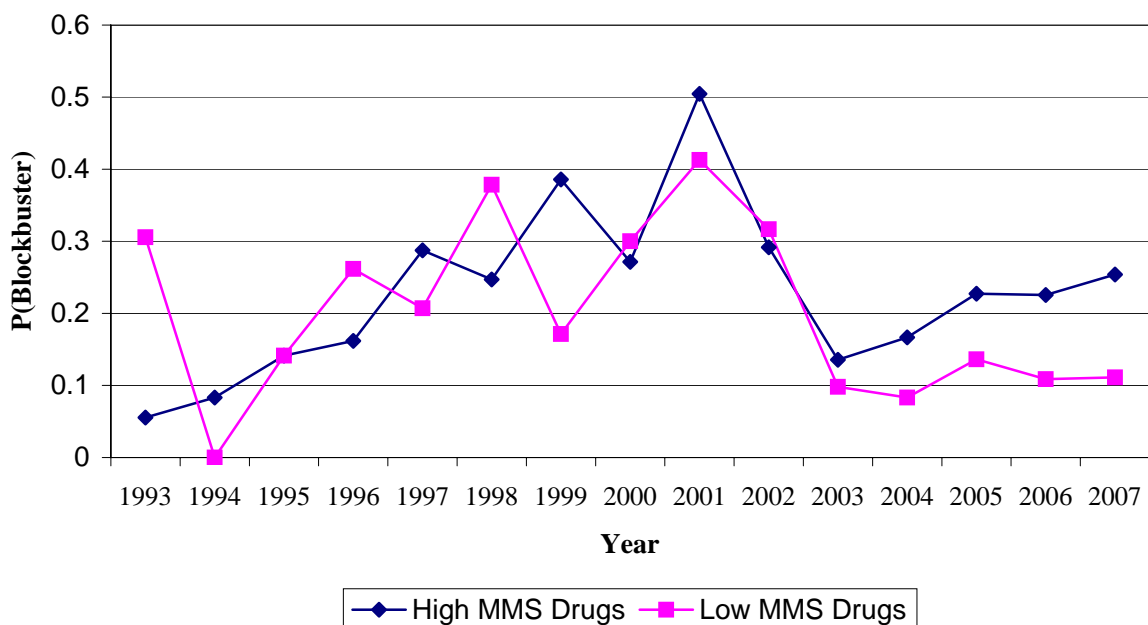
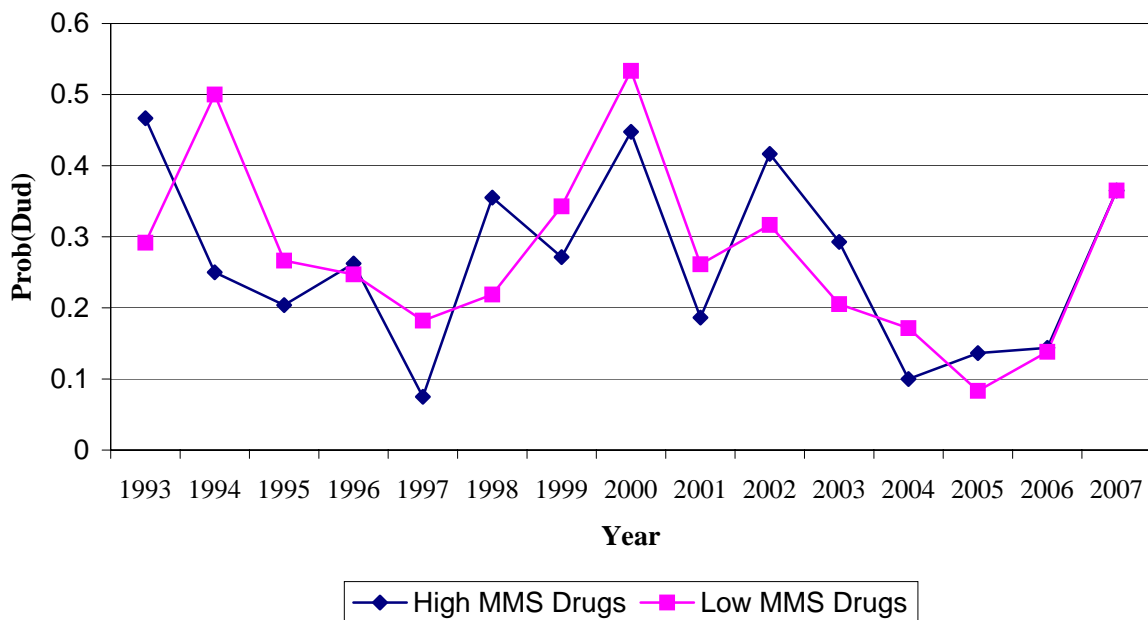
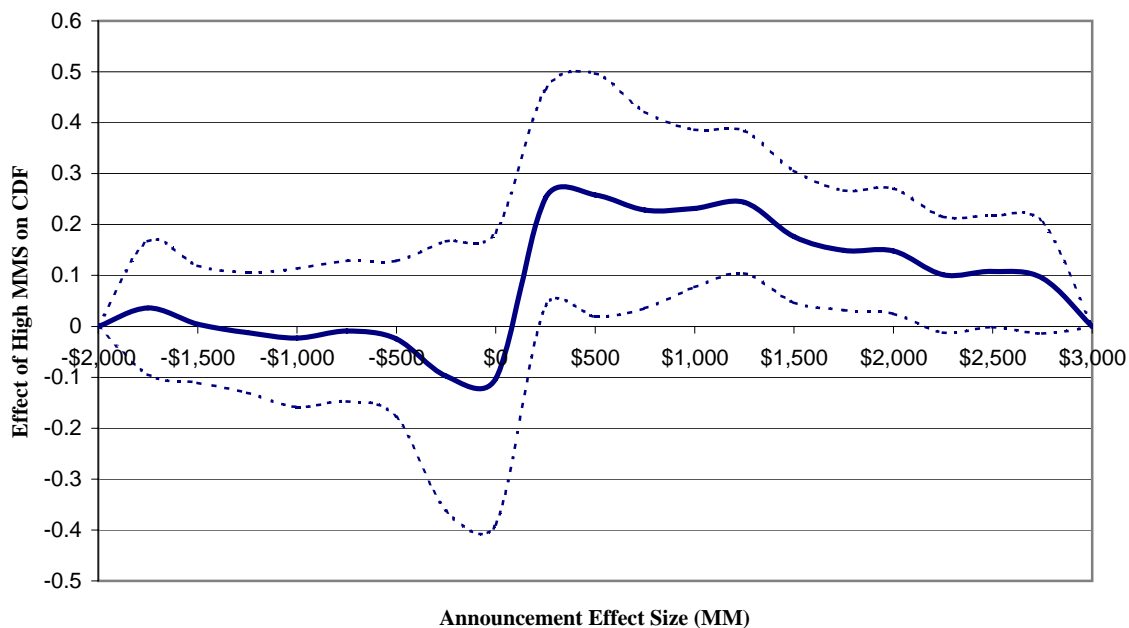


Figure 5B: Probability of a Low Announcement Effect Drug



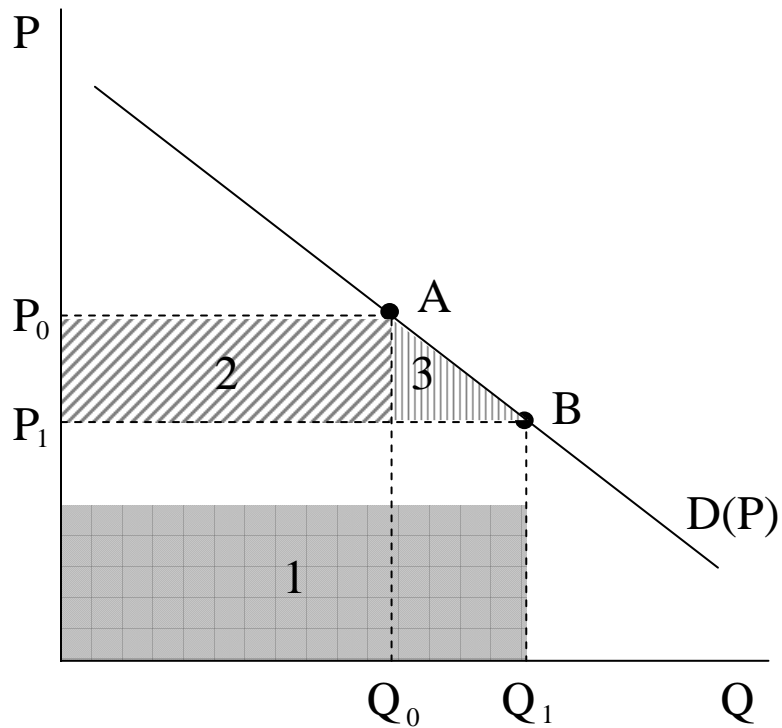
These figures plot, by year and MMS group, the fraction of drugs approved in the top (Figure 5A) and bottom (Figure 5B) quartiles of the pooled distribution of announcement effects. Thus, a "high announcement effect" drug is one with real dollar-valued abnormal returns above \$433M; while "low announcement effect" drugs are those below -\$139M. The MMS group are those drugs above and below the median value in the sample, 31.2%.

**Figure 6: Effect of Medicare Part D on Distribution of Announcement Gains
Difference Between High and Low MMS Drugs**



This figure plots the coefficients from a series of regressions. At point k on the x -axis, the lefthand side variable is a dummy variable equal to 1 if a drug announcement effect is larger than k . On the righthand side are the variables in Column (6) of Table 4: a dummy variable for High MMS, Medium MMS, these variables interacted with a post-Part D dummy variables, dummy variables for High Therapeutic Potential, New Molecule, Orphan Drug, FDA Warning, and year fixed effects. The coefficient plotted is that on the interaction between a post-Part D dummy variable and the High MMS dummy variable. Standard errors are clustered by firm; dashed lines represent two-standard-error bands.

Figure 7: Components of Consumer Surplus



This figure displays the three sources for increases in consumer surplus from Medicare Part D. In Part D, the government subsidizes 74.5% of the average total cost of coverage, for those with a plan through Part D. This subsidy is a transfer to those enrollees, represented by area 1. Part D also caused average prices for seniors to fall, as in Duggan and Scott-Morton. This lowers the price paid from P_0 to P_1 , which reduces cost on drugs previously purchased (Q_0) by area 2. Finally, Part D increased usage from Q_0 to Q_1 . Consumer surplus increases by area 3, the value of new drugs to consumers. In the prescription drug market, though, the relevant prices are not the total prices (as are relevant for area 2) but the out-of-pocket costs.

Table 1: Summary Statistics for Announcement Effects

Window	Control Portfolio	Mean	Std. Dev.	Mean Gains (\$MM)
[-1,+1]	3-Factor	0.564%	0.130%	162.0
[-1,0]	3-Factor	0.091%	0.079%	41.3
[0,+1]	3-Factor	0.482%	0.103%	105.1
[-3,+3]	3-Factor	0.827%	0.205%	288.7
[-3,+1]	3-Factor	0.853%	0.168%	189.3
[-6,+6]	3-Factor	1.402%	0.274%	247.6
[-6,+1]	3-Factor	1.135%	0.219%	116.5
[-1,+1]	CAPM	0.528%	0.103%	125.0
[-3,+1]	CAPM	0.773%	0.171%	141.6
[-1,+1]	4-Factor	0.536%	0.128%	160.6
[-3,+1]	4-Factor	0.838%	0.169%	182.1
[-1,+1]	3-Factor + Pharma	0.502%	0.087%	144.3
[-3,+1]	3-Factor + Pharma	0.670%	0.113%	148.8

Each line represents the mean abnormal return from a different market model. For each market model, I estimate betas in a two year window ending six months before the announcement date. 3-Factor models include the market, high-minus-low, and small-minus-big in the market model. CAPM includes only the market, while the 4-factor model also includes u-minus-down. Data for each factor, as well as the risk-free rate, from Kenneth French's website. I winsorize all figures at the 5th and 95th percentiles to reduce the impact of outliers.

Table 2: Correlates of Announcement Gains

<i>Explanatory Variables:</i>	<i>Dependent Variable: Announcement Gains (\$MM)</i>							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
<i>Constant</i>	101.8* (47.5)	11.9 (35.7)	149.4* (50.4)	149.0* (57.4)	111.1 (59.2)	-84.4 (82.6)	-122.3 (206.2)	-122.3 (206.2)
<i>High Therapeutic Potential</i>	242.2* (70.3)					104.4 (82.2)		
<i>New Molecule</i>		402.8* (85.4)				382.7* (93.2)		
<i>Orphan Drug</i>			130.8 (123.0)			-55.9 (124.1)		
<i>FDA Warning</i>				70.3 (101.2)		55.4 (104.3)		
<i>Time</i>					5.8 (6.1)	8.4 (7.2)		
<i>2006 Sales</i>							0.211* (0.102)	
<i>Estimated NPV Profits</i>								0.055* (0.026)
<i>N</i>	499	499	499	499	499	499	89	89

Each column represents a different regression. The lefthand side variable is the dollar gains in abnormal returns to the stock of a pharmaceutical company, with a 2 days window around the announcement of FDA approval of a drug. These abnormal returns are calculated relative to a 3-factor market model, calibrating for each company in a two year window ending six months before the announcement of approval. "High Therapeutic Potential" is a dummy variable equal to 1 if a drug received expedited review from the FDA. "New Molecule" is a dummy variable equal to 1 if a drug was classified scientifically as a new molecule, as opposed to a derivative from an already approved molecule. "FDA Warning" is a dummy variable equal to 1 if the FDA placed a "black box warning," the most severe form of warning, on the drug's mandatory label. These three variables are all generated from the administrative filing information at the FDA. Time is a continuous variable measured in years, relative to 1992. Estimated NPV profits equals actual 2006 sales (from MedAdNews, July 2007 Issue) times 3.87 (times 0.8 for US share of sales, times 0.8 for gross margin and SG&A, times 0.65 for taxes, times 9.3 to reflect the discounted value of profits over a 12-year patent life with profits growing at 5% and an interest rate of 10%). * indicates significance and the 5% level.

Table 3: Summary Statistics

Panel A				
Variable	Mean	Std. Dev.	Min	Max
Excess Return	0.56%	2.90%	-4.46%	7.06%
Gains (\$MM)	162.0	1005	-1889	2765
Medicare Market Share	0.32	0.18	0.01	0.89
Therapeutical Potential?	0.25	0.43	0	1
Orphan Drug?	0.10	0.30	0	1
FDA "Black Box" Warning?	0.18	0.39	0	1
Post-2003	0.28	0.45	0	1

Panel B			
Variable	High MMS	Mid MMS	Low MMS
N	124	250	125
Gains (\$MM) (full sample)	217.0 (1082.0)	150.0 (973.6)	131.5 (993.3)
Gains (\$MM) (pre-2003)	198.6 (1062.1)	153.1 (1035.0)	187.8 (1100.1)
Gains (\$MM) (post-2003)	290.5 (1120.5)	194.6 (823.6)	-96.1 (613.7)
Medicare Market Share	0.56 (0.12)	0.30 (0.07)	0.10 (0.04)
Therapeutical Potential?	0.23	0.24	0.28
Orphan Drug?	0.08	0.11	0.08
FDA "Black Box" Warning?	0.17	0.23	0.11
Post-2003	0.26	0.29	0.27

Notes: The variables Excess Return and Gains represent abnormal returns, calculated over a two day window, relative to a 3-factor market model calibrated in a two year window ending six months before announcement. These variables are each Winsorized at the 5th and 95th percentiles to reduce the influence of outliers. Medicare Market Share reflects the share of expenditure from medicare eligible patients within a drug's therapeutic class (the finest Lexicon level available) in MEPS data between 1998 and 2002. Therapeutic Potential, Orphan Drug, and FDA "Black Box" Warning are each administrative classifications of drugs from FDA filings. Post-2003 represents a dummy variable equal to 1 if the drug was approved after December 8, 2003. In Panel B, a drug is classified as "High MMS" if MMS > 0.4, and "Low MMS" if MMS < 0.166.

**Table 4: Effect of Medicare Part D on Announcement Gains
by Medicare Market Share Bucket**

<i>Explanatory Variables:</i>	<i>Dependent Variable: Announcement Gains (\$MM)</i>						
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
<i>HIGH*Post-Law</i>	411.8* (195.6)	404.7* (197.8)	478.8* (239.1)	791.7* (331.5)	398.0 (215.2)	465.9 (262.8)	851.0* (379.3)
<i>MID*Post-Law</i>	375.2* (172.5)	368.9* (173.9)	381.7 (204.1)	630.0* (300.1)	359.9* (180.9)	369.6 (215.4)	617.8 (325.1)
<i>HIGH</i>	-25.2 (89.6)	-21.1 (90.0)	-35.7 (101.9)	-174.2 (115.9)	-66.6 (113.6)	-8.0 (105.5)	-143.0 (124.6)
<i>MID</i>	-84.6 (120.9)	-75.8 (177.3)	-65.8 (120.3)	-106.7 (167.8)	-2.4 (90.9)	-55.5 (118.2)	-96.5 (166.3)
<i>Therapeutic Potential?</i>			145.6 (88.3)	141.3 (172.2)		153.7 (89.5)	154.3 (174.2)
<i>Orphan Drug?</i>			-77.6 (121.7)	-54.2 (169.5)		-55.5 (119.4)	-32.0 (157.0)
<i>FDA Black Box Warning?</i>			46.3 (100.3)	61.3 (159.3)		63.9 (114.5)	97.2 (183.1)
<i>New Molecular Entity?</i>			377.0* (94.4)	450.5* (111.1)		370.1* (102.2)	441.0* (122.4)
<i>Time</i>		19.5 (13.9)	25.0 (14.3)	26.4 (19.3)	-	-	-
<i>Post-Law Dummy</i>	-312.6* (146.4)	-444.0* (185.9)	-502.0* (198.2)	-710.7* (269.5)	-	-	-
<i>Fixed Effects</i>	<i>None</i>	<i>None</i>	<i>None</i>	<i>Firm</i>	<i>Year</i>	<i>Year</i>	<i>Year, Firm</i>
<i>N</i>	499	499	499	465	499	499	465

Each column represents a separate regression. The dependent variable in each column is the dollar-valued abnormal returns to a pharmaceutical company from the market close the day before FDA approval to the market close the day after. I calculate these abnormal returns using a standard 3-factor market model, with betas calculated on return data in a two-year window ending six months before FDA approval. I winsorize the dependent variable at the 5th and 95th percentiles of the pooled distribution to reduce the reliance on outliers. I classify the Medicare Market Share of a drug based on the average MMS for all drugs in the particular therapeutic class between 1998 and 2002 in the MEPS data. I cluster all standard errors at the firm level, accounting for pre-merger differences in firms. * denotes a coefficient that is statistically different from 0 at the 5% level.

**Table 5: Effect of Medicare Part D on Announcement Gains
by Medicare Market Size**

<i>Explanatory Variables:</i>	<i>Dependent Variable: Announcement Gains (\$MM)</i>							
	<i>Full Sample</i>				<i>Pre-2003</i>		<i>Post-2003</i>	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
<i>Market Size</i>	0.093* (0.035)	0.095* (0.041)	0.125* (0.049)	0.112* (0.045)	0.111 (0.067)	0.111 (0.066)	0.055 (0.054)	0.346 (0.197)
<i>Medicare Market Size</i>		0.128 (0.215)	-0.020 (0.224)	-0.029 (0.229)	-0.218 (0.267)	-0.247 (0.275)	0.497 (0.270)	0.529* (0.260)
<i>Market Size * Postlaw</i>		-0.022 (0.082)	-0.028 (0.051)	-0.073 (0.075)				
<i>Medicare Market Size * Postlaw</i>		0.565 (0.341)	0.603* (0.281)	0.610* (0.272)				
<i>Therapeutic Potential?</i>			-0.039 (0.105)	-0.027 (0.105)		0.120 (0.162)		-0.219 (0.127)
<i>Orphan Drug?</i>			-0.049 (0.108)	-0.042 (0.110)		-0.503 (0.363)		0.197 (0.113)
<i>New Molecule?</i>			0.282* (0.068)	0.286* (0.071)		0.353* (0.118)		0.203* (0.093)
<i>Time</i>				0.008 (0.009)		0.018 (0.011)		-0.045 (0.033)
<i>Estimate of δ</i>	-	6.305 (-1.76,31.5)	5.104* (0.69,16.8)	6.456* (0.73,27.8)	-	-	9.060	1.529
<i>N</i>	499	499	499	499	359	359	133	133

Note: These estimates are from a two-stage estimation. I first estimate the drug-specific market size from the class-specific market size; the exponential coefficient is 0.83 with standard error 0.27. I then use this estimate of market size in the second stage. The lefthand side variable is the dollar-valued abnormal returns to a pharmaceutical company's stock from the day before FDA approval to the day after. I measure class-specific size and medicare market share in the MEPS during a fixed period 1998-2002 for all drugs, after which I adjust over the sample for prescription drug growth and demographic shifts. I generate standard errors from a non-parametric block bootstrap with block size equal to 20. * denotes a coefficient that is statistically different from 0 at the 5% level.

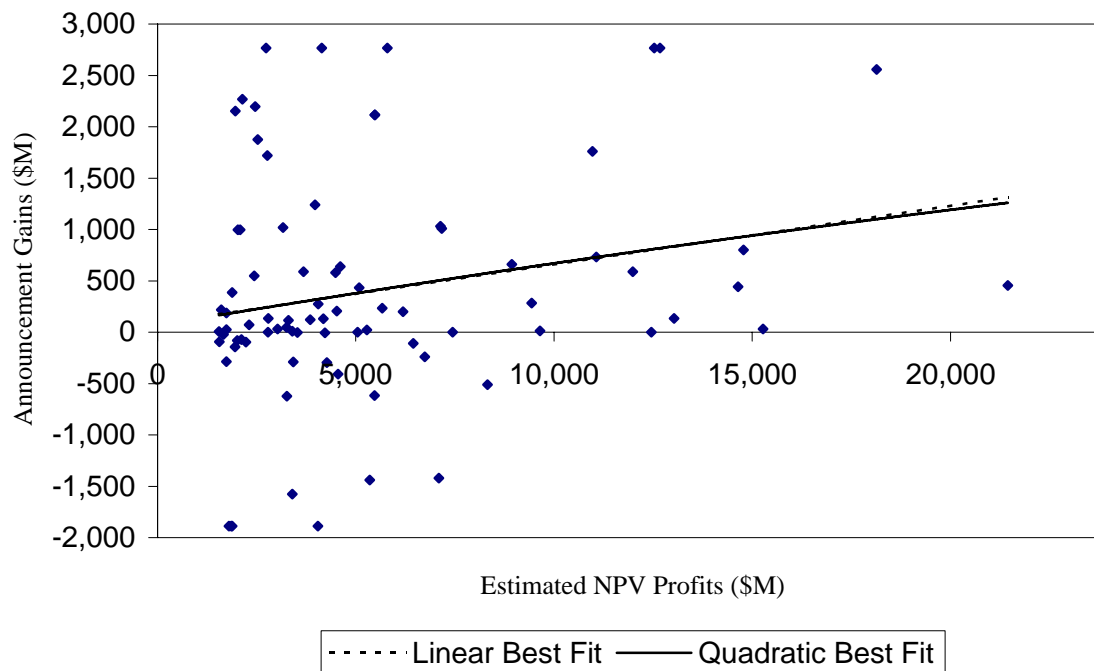
Table 6: Sensitivity Analysis of Aggregate Incidence Calculations

<u>Profit</u>	<u>Post-Patent</u>	<u>Prob(Reject)</u>								
		<u>Net Profit Rate</u>								
		7.5%	10%	12.5%	7.5%	10%	12.5%	7.5%	10%	12.5%
<u>Growth Rate</u>	<u>Profit Drop</u>	12.5%	12.5%	12.5%	25%	25%	25%	37.5%	37.5%	37.5%
3%	90%	\$159	\$119	\$95	\$317	\$238	\$190	\$476	\$357	\$286
5%	90%	\$161	\$121	\$96	\$321	\$241	\$193	\$482	\$362	\$289
7%	90%	\$162	\$122	\$97	\$324	\$243	\$194	\$486	\$365	\$292
3%	80%	\$160	\$120	\$96	\$320	\$240	\$192	\$480	\$360	\$288
5%	80%	\$161	\$121	\$97	\$323	\$242	\$194	\$484	\$363	\$290
7%	80%	\$163	\$122	\$98	\$325	\$244	\$195	\$488	\$366	\$293
3%	70%	\$161	\$121	\$96	\$321	\$241	\$193	\$482	\$362	\$289
5%	70%	\$162	\$122	\$97	\$324	\$243	\$194	\$486	\$365	\$292
7%	70%	\$163	\$123	\$98	\$327	\$245	\$196	\$490	\$368	\$294

Each cell represents a different estimate of producer surplus, generated from the estimate of \$329M per drug (from Table 4). Down the columns, I vary the distribution of this surplus across the lifetime of a drug, by varying the profit growth rate and the drop in profits after patent expiry. Across the rows, I vary the ratio of net industry surplus gain to sponsor company surplus between 12.5% and 37.5% (the net profit ratio), as well as the probability of rejection at the time of approval between 7.5% and 12.5%.

Appendix

Figure A1: Drug Announcement Gains and Estimated NPV Profits



This graph plots the data points and regression line from column (8) of Table 2, as well as the corresponding quadratic fit line. The announcement gain is the abnormal return to a sponsor company's stock over a two-day window around FDA approval of a drug. The estimated NPV profits equal the actual sales of each drug in 2006 times 3.87.

Figure A2A: Distribution of Announcement Gains by MMS, 2004-2007

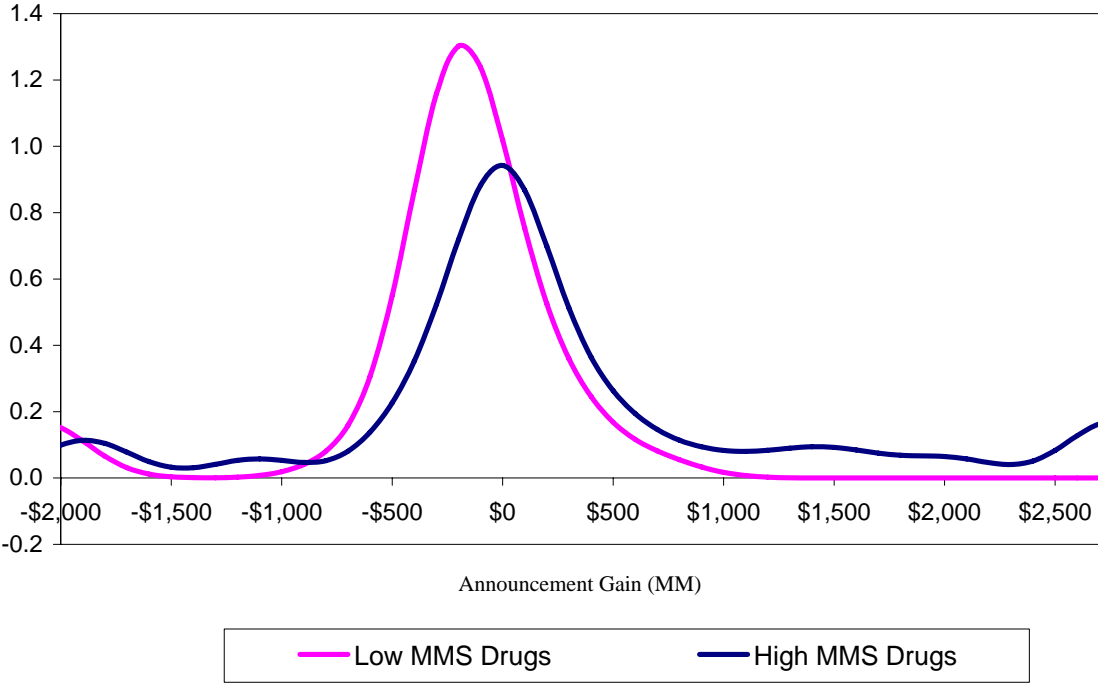
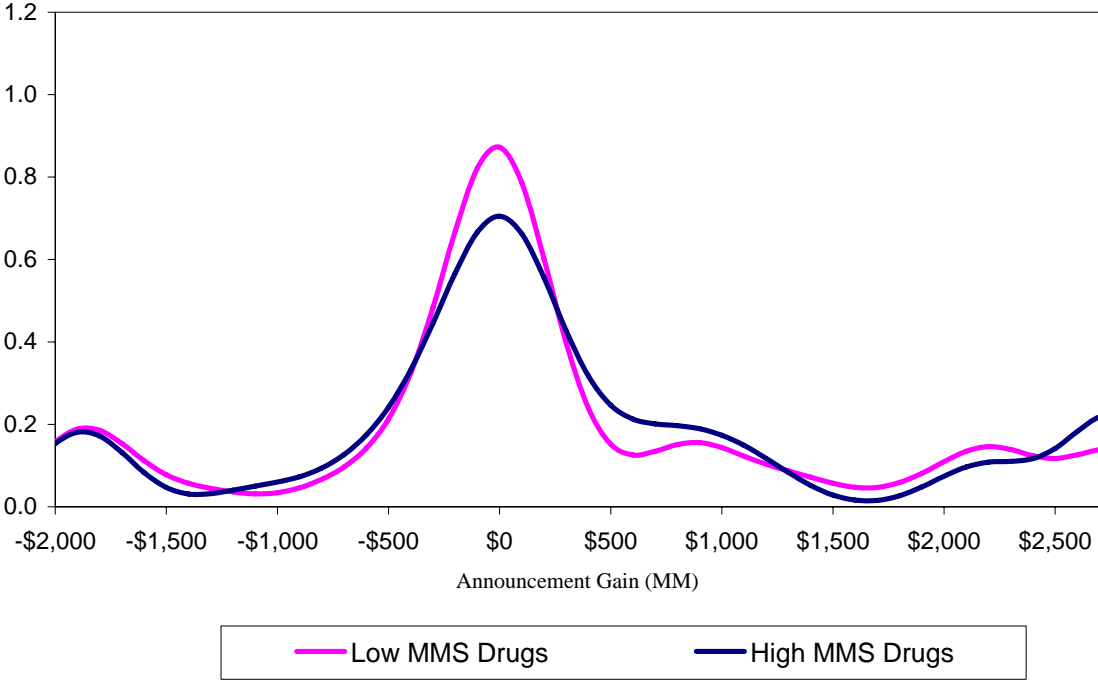


Figure A2B: Distribution of Announcement Gains by MMS, 1997-2002



The figures reproduce the kernel densities in Figures 4A and 4B, using instead a bandwidth of $h = 213$.

Figure A3: Number of FDA Approvals per Year, by MMS

