The Effect of Price Control Threats on Pharmaceutical R&D Investments

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ABSTRACT

This study examines how pharmaceutical R&D was impacted by two threats of price controls: Clinton's Health Security Act of 1993 and Clinton's signing of drug reimportation legislation in 2000. Firms with higher fraction of U.S. sales decreased their research intensity relative to firms with mainly foreign sales following the 1993 threat, but not the 2000 threat. Additionally, brand-name pharmaceutical firms, characterized by large R&D expenditures decreased their R&D efforts post 1993 threat relative to firms that did not engage in as much innovative R&D.

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1. Introduction

Today, the U.S. pharmaceutical industry is widely recognized as the world leader in development of innovative medications. Since the United States is the only major developed country that allows drug prices to be freely determined by the market, the industry's success is often attributed to relative lack of regulation (Vernon 2006). However, in the past two decades, legislators have repeatedly attempted to impose price controls on newly developed drugs. Given the decreased return on investments that pharmaceutical firms will receive under lower drug prices, have the firms remained truly unaffected by potential regulation?

The goal of this study is to determine whether pharmaceutical companies reduce their research and development efforts (R&D) in response to price control threats, even though such measures do not become legalized. I define price control threat as a publicized legislative bill that attempts to reduce U.S. drug prices, yet fails to become law. The two main threats analyzed are Clinton's Health Security Act of 1993 (HSA) and Clinton's signing of drug reimportation legislation in 2000. Reimportation would have allowed U.S. consumers to purchase U.S.-manufactured prescription drugs from abroad at already regulated prices, thereby introducing foreign price controls into the United States. However, drug reimportation could only be successful if the law would also prohibit pharmaceutical companies from restricting their current sales to foreign countries. If such a restriction is not imposed, the industry would be free to form private agreements with foreign clients, limiting resale of drugs back into the United States. In fact, leading pharmaceutical firms have already crafted these agreements, as Pfizer, GlaxoSmithKline, AstraZeneca, and Wyeth announced that they would stop supplying foreign pharmacies if they engaged in reimportation (Harris 2003). Nevertheless, it is likely that if drug reimportation ever becomes legalized, legislators will restrict private agreements to enable at

least some reimportation. Therefore, both the HSA and the reimportation legislation could have roughly the same effect on U.S. drug prices.

Numerous empirical studies have shown that introducing price controls will reduce R&D of pharmaceutical companies and decrease the number of new drugs that reaches the market each year. Since development of a new chemical entity (NCE) requires at least $800 million and takes over 16 years, high drug prices in the U.S. provide necessary incentive for the firms to keep investing into research (Giaccotto 2005). It is important to note, however, that these prices are not set by pharmaceutical companies in order recover R&D costs; rather, it is the large demand for medications that determines their free-market prices (Schweitzer 2007). As the economic theory suggests, companies that have been investing to the point where anticipated marginal efficiency of R&D equals marginal cost of capital will reduce their investments under price controls because R&D will receive lower returns (Vernon 2006).

Therefore, the mere threats of price controls could similarly cause pharmaceutical firms to scale back R&D due to a decrease in expected profits. However, it is also possible that the threats have no significant effect on R&D investments. This could have several explanations. Sager and Socolar (2004) argue that pharmaceutical profits might not be affected by reimportation because profit loss from reduced U.S. prices could be offset by increased quantity of drugs purchased. Another reason why firms might not respond to threats is because the price control threats I am analyzing were not perceived to be real by the firms. Since pharmaceutical companies heavily invest into lobbying, they might possess insider information on which legislative bills are less likely to pass. Also, private agreements with foreign customers can enable the firms to restrict export of medications back to the United States.

In my analysis, I utilize Compustat database together with pharmaceutical firms' annual reports and filings for the Securities and Exchange Commission. In total, I obtain financial information on 90 companies for the period between 1989 and 2007.

To evaluate firms' responses to price control threats, I compare R&D investments of pharmaceutical companies based on their vulnerability to regulation. I conduct three principal tests to estimate whether firms that would be the most affected by regulation reduce their R&D following the threats relative to firms that would be the least affected. First, I compare pharmaceutical companies based on the fraction of U.S. sales, since firms that focus on U.S. market would be more vulnerable to changes in U.S. regulation. Second, I compare the firms based on their research intensity because more intensive firms engage in more innovative R&D and will experience a greater decline in the rate of return under price controls. Finally, I compare the firms using overall level of R&D spending to capture the differences between generic and brand-name firms since the anticipated regulations target primarily brand-name products.

My results suggest that pharmaceutical firms decreased their R&D efforts in response to the 1993 threat, but not the 2000 threat of reimportation. This inconsistent response could be potentially attributed to the differential credibility of the threats. In other words, firm managers could have believed that HSA was more likely to become implemented than the reimportation legislation. It is also possible that pharmaceutical companies did not anticipate aggressive price regulation prior to 1993 and had to make unforeseen adjustments following the HSA to ensure profit maximization. In contrast, by 2000, pharmaceutical companies could have either adjusted their R&D expenditures to include the possibility of reduced drug prices or taken action to minimize the likelihood of price regulation via lobbying and private contracts with foreign clients.

However, the results of this study should be interpreted with caution as time specific treatment effect is not significant in any one period following the threats. Since the standard errors are likely to be correlated over time, it is likely that the estimated effect from the threats is overstated.

The remainder of this paper is structured as follows. Section 2 provides a summary of previous research on the relationship between price controls and pharmaceutical R&D. Section 3 provides historical background for pharmaceutical regulation in the United States and discusses threats of prices controls. Section 4 describes the data utilized. Section 5 introduces empirical strategy. Section 6 presents the discussion of results, and Section 7 concludes.

2. Literature Review

Although there is a general consensus in literature that introduction of price controls will reduce the incentives to innovate in the pharmaceutical sector, the actual estimates of this effect vary depending on empirical strategies. Previous research has shown that firms' expectations of future profitability play a crucial role in determining R&D investments (Vernon 2005). Therefore, one approach is to examine potential changes in R&D if profitability expectations of U.S. firms were to decline to the level expected in other countries. Using current pre-tax profit margins as a proxy for future profitability, Vernon (2005) analyzes R&D investments of top 14 pharmaceutical companies from 1994 to 1997 and shows that R&D intensity, defined as the ratio of R&D to total sales, could decline by 23.4 to 32.7% if the expected profitability of U.S. firms would decrease to the foreign level.

Abbotta and Vernon (2007) attempt to improve on retrospective analysis of profit margins by estimating the effect of price controls on R&D via Monte Carlo simulation method.

The authors focus on decisions by pharmaceutical firms to expand an R&D project into Phase I clinical development. Using contemporary economic information available to the firms, the authors estimate the project's net present value and evaluate whether or not the firms would choose to expand the project. Their results suggest that if U.S. prices of pharmaceuticals were decreased by 40 to 50%, which could occur if reimportation of prescription drugs from Canada were legalized, the number of early-stage R&D projects will decline by 30 to 60%.

Lichtenberg (2007) takes a different approach to analyzing the effects of price controls on pharmaceutical industry. Instead of focusing on R&D intensity or the number of R&D projects as a measure of pharmaceutical innovation, Lichtenberg seeks to capture the actual output of R&D by using the number of unique chemotherapy treatments as well as the number of published scientific articles related to drug therapy for specific forms of cancer. The author assumes that "the elasticity of investment with respect to the expected price of drugs should be at least as great as the elasticity of investment with respect to expected market size" and proceeds to estimate the price elasticity of R&D using the innovation and market size data for 18 types of cancer (p. 404). He finds that a 10% decline in drug prices would reduce pharmaceutical innovation by 5 to 6%. Surprisingly, a study by Giaccotto, Santerre, and Vernon (2005) that examines industry-level R&D intensity as a proxy for pharmaceutical innovation produces a very similar estimate for price elasticity of R&D. Using real prices for medications from 1952 to 2001, together with the industry data, researchers conclude that increasing drug prices by 10% is linked with a 6% increase in R&D intensity, lagged by one year.

Thus, the literature on R&D efforts of the pharmaceutical sector clearly suggests that U.S. firms would invest less into R&D if price controls were introduced. However, previous research largely bypasses the question of whether the mere threat of price controls can have any

effect on R&D expenditures. Intuitively, if Congress publicizes a bill that aims to lower drug prices, pharmaceutical companies should take into account the possibility of that bill becoming a law and adjust their expenditures accordingly. As noted by Santerre, Vernon, and Giaccotto (2006), the threat of price controls "may provide a signal about the invasiveness of actions that the government might take tomorrow" (p. 146). Therefore, even if the threat never materializes, drug companies might expect future governmental regulations to be more stringent.

To my knowledge, only Golec, Hegde, and Vernon (2005) specifically investigate changes in pharmaceutical R&D in response to the threat of price controls. In their study, researchers examine the effects from Clinton Administration's Health Security Act of 1993, which introduced the threat of lower drug prices, yet was never passed. Golec et al. hypothesize that "managers [of pharmaceutical companies] should react [to HSA] by cutting R&D spending, either because they [...] believe some marginal projects are no longer worthwhile, or because they respond to signals sent by investors through [declining] stock prices" (p. 12). Using financial data for the years 1991 through 1995 on 111 U.S. firms specializing in pharmaceutical and biological product manufacturing, researchers estimate that firms decreased their R&D intensity by 5%, or $1 billion, in the year following HSA. To control for the variation in firm size, they use the ratio of R&D to total assets, which provides a standardized measure of investments similar to the R&D to net sales ratio. Since firm managers utilize R&D to sales ratios in the development of next year's budgets, it is reasonable to expect that the effect from the price control threat would be seen in the year following the threat (Giaccotto 2005).

However, in their analysis, Golec et al. include both the Pharmaceutical Product Manufacturing (NAICS 325412) and the Biological Product Manufacturing firms (NAICS 325414). It is possible that they underestimate the decline in R&D because Biological

Manufacturing firms produce vaccines, culture media, and blood fractions which would not be directly affected by price controls on prescription drugs (US Census Bureau 2007). Furthermore, the researchers compare actual R&D intensity to projected intensity, which is estimated on the basis of total assets, net sales, and other financial information, and substantial discrepancies between the two could have occurred even in the absence of HSA.

In my analysis, I build on Golec et al. study by analyzing the 2000 threat of price controls in addition to the 1993 threat. I focus solely on the Pharmaceutical Manufacturing firms to capture only those companies that develop prescription drugs, and, therefore, would be directly affected by price controls. I also avoid potential problems with modeling future R&D expenditures by comparing pharmaceutical companies to each other based on their vulnerability to threats.

3. Price Control/Drug Reimportation Threats

3A. *Pharmaceutical Regulation leading up to Price Controls*

Prior to 1990s, the U.S. pharmaceutical industry had strong positive relations with the government. The industry received numerous credits and tax breaks for building manufacturing plants in Puerto Rico and producing ‘me-too’ drugs that add little value to the existing pool of pharmaceuticals (Waldholz 1991). The Orphan Drug Act of 1983 provides a vivid example of the government’s patronage of the industry. Aiming to encourage development of new drugs for rare diseases, the act offered tax credits for up to 50% of the total marketing and development costs along with a seven-year exclusive right to promote the drug for the target disease (Tregarthen 1992). In reality, however, many companies were able to receive such a compensation for medications that were developed largely outside of the company and could be

sold on fairly large markets. For instance, Burroughs-Wellcome Co. managed to obtain the orphan drug classification for AZT, a common AIDS drug, even though the drug was initially developed by the U.S. government and had a substantial marketing potential (Tregarthen 1992).

Surprisingly, there was relatively little public criticism of pharmaceutical sector's tax exemptions and rising profits prior to 1990s. The industry was predominantly seen as "the most technologically advanced and profitable in the world," managing to "[link] profits to improving human life" (Goldberg 1992, p. A16). However, these profits were abruptly questioned in 1991, when the Senate Committee on Aging reported an alarming increase in drug prices. The Committee found that pharmaceutical companies raised their prices by roughly 152% during 1980s, while the consumer price index increased by only 58% (Waldholz 1991). A study by Bureau of Labor Statistics (BLS) complemented the findings of the Committee on Aging by reporting that drug prices increased 9% annually between 1984 and 1989 (Goldberg 1992). The additional fact that prices increased by 11.2% during the first six months of 1991 amplified the growing criticism of the pharmaceutical industry. Although subsequent reevaluations by the National Bureau of Economic Research suggested that BLS results were overstated due to exclusion of generic drugs whose prices increased more gradually, the public criticism of the pharmaceutical industry could not be extinguished (Goldberg 1992).

The growing backlash against the pharmaceutical sector pressured the legislators to bring down the costs of medications. At the onset of 1992, the presidential hopeful, Bill Clinton, was calling for a sweeping health care reform that would include price ceilings on newly developed medications (Golec 2005). The HSA that was proposed after Clinton took office became the first major threat to the profitability of the pharmaceutical companies in decades.

3B. *Analyzed Threats*

To date, numerous legislative bills attempted to introduce price controls in the pharmaceutical sector. In this study, I focus on the first two highly publicized threats of regulation: Clinton's Health Security Act of 1993, and Clinton's signing of drug reimportation legislation in 2000. After 2000, drug reimportation bills were introduced and debated in Congress annually until 2004 (see Table 1); however, the effect from any one threat post 2000 is difficult to isolate due to the consecutive timing of regulation proposals.

Clinton's HSA was first unveiled on September 22, 1993, and it remained a potential threat until October of 1994 when activity on the bill halted with reports/amendments by the Committees on Natural Resources along with Post Office and Civil Service (Library of Congress: Thomas 1994). The act included a number of provisions to reduce health care costs including universal coverage for outpatient drugs, introduction of purchasing groups, and drug utilization reviews. However, the most important provision to the pharmaceutical company was the establishment of Advisory Council on Breakthrough Drugs, which would be empowered to question and limit prices of newly developed drugs (Library of Congress: Thomas 1994).

The uncertainty in future drug prices caused by the HSA was clearly recognized by the pharmaceutical companies, many of which mentioned the potential negative effects of the act in their annual reports. For instance, Schering-Plough Corporation specifically stated in its 1993 annual report that, "President Clinton's health care reform proposal includes several measures that, if enacted will have an impact on operations of the Company" (Schering-Plough Corp.

1993, p. 4). Thus, the HSA presented a clear threat of lower drug prices for the pharmaceutical industry.

The second major threat of price controls occurred in 2000, when Congress approved drug reimportation legislation that would allow pharmacies and wholesalers to purchase medications from abroad at regulated prices (Griffith 2000). President Clinton signed this legislation; however, the bill included a 'poison pill' which was the "requirement that the secretary of health and human services certify that the imported drugs pose 'no additional risk' to consumers" (Stolberg 2003, p. A1). Since Clinton administration refused to guarantee the safety of imported pharmaceuticals, the bill never became law. However, even if the bill was legalized, its effect on pharmaceutical companies would have been less certain than the effect from HSA because of loopholes that would have enabled U.S. firms to severely limit reimportation. Specifically, the 2000 act would have allowed pharmaceutical companies to minimize the resale of medications back to the U.S. via withholding safety labels required for reimportation (Pear 2000). Additionally, U.S. firms could have mandated that foreign buyers resell pharmaceuticals in the U.S. at prices above those in foreign markets (Pear 2000). Thus, the direct effect on pharmaceutical revenue from the 2000 reimporation bill could have been limited. It is possible, however, that this threat of reimportation signaled to the pharmaceutical firms the likelihood of future regulatory attempts that could be more restrictive.

4. Data

4A. *Financial Information on Pharmaceutical Firms*

In order to analyze changes in R&D as a response to threats of price controls, I use financial data on pharmaceutical companies between 1989 and 2007 from Compustat database. The unit of observation is one company in a specific quarter. This firm-level data allows me to conduct a more precise analysis than is possible with industry-level information because it enables a comparison of pharmaceutical companies to each other on the basis of sales, research intensity, and R&D spending.

In total, I collect consistent information on 90 pharmaceutical firms within the study period. These firms are classified as Pharmaceutical Product Manufacturing, which means that they develop and produce "ampoules, tablets, capsules, vials, ointments, powders, solution, and suspensions" (U.S. Census Bureau 2007, p.1).

The start year of 1989 was chosen due to insufficient financial data for most companies prior to that date. Since the first threat of price controls happens in 1993 and does not recur until 2000, the study period does capture the investment trends not yet affected by the threats.

4B. *Data on geographical sale distribution*

The information on geographical distribution of sales was obtained from the companies' annual reports as well as 10-K forms filed for the Securities and Exchange Commission. Since firms are not required to report geographical sale distribution, many pharmaceutical companies omit this information from their records. In total, I trace geographical distribution of sales for 22 major pharmaceutical companies from Compustat dataset, with 13 companies conducting more

than 50% of their sales within the U.S. (Group 1) and 9 companies conducting less than 50% of their sales in the U.S. (Group 2). The summary statistics for the two groups of companies are reported in Table 2.

The year 2000 was chosen because geographical sale information prior to 1997 is scarce, and only a small number of companies report it prior to 2000. If firms did not report their sale distribution in 2000, I used distribution from the next available year. For example, Icos Corp. separates its sales by geographical area only beginning in 2003. Therefore, I apply the 2003 distribution to place this company into one of the groups.

4C. *Shortcomings of the Data*

The significant amount of noise inherent in the data complicates analysis. It is possible that R&D efforts of domestic and foreign, research-intensive and non-intensive, generic and brand-name firms could have deviated from each other due to factors other than anticipated changes in the U.S. regulatory system.

Additionally, my estimates of the effect from the 2000 threat of drug reimportation are possibly more accurate than the estimates of the response to 1993 threat due to the lack of consistent geographical data. However, the data from companies that provide consistent records from 1997 to 2004 suggest that most firms sold the majority of their products within the same geographical regions since 1990s. For instance, Valeant Pharmaceuticals International, a pharmaceutical company developing neurology and dermatology medications, sold 18%, 36%, and 35% of its products within the U.S. in 1997, 2000, and 2003, respectively (Valeant Pharmaceuticals Annual Report 1997, 2000, 2003). However, one company in my analysis could have substantially changed its fraction of U.S. sales between 1993 and 2000: Bausch & Lomb reported 51% of U.S. sales in 1997, 42% in 2002, and 39% in 2004. I include this firm in

group 2 because, in 2000, Bausch & Lomb was already in process of diversifying away from the U.S. market, which would minimize the impact from the 2000 threat. As a robustness check, I repeat my analysis of 1993 threat without this company and obtain similar results.

Another significant drawback of the data is small sample size of firms with mainly foreign sales. In terms of potential bias, the main difference between the companies that I include in my study and the ones that I omit due to the lack of geographical data is the firm size. Intuitively, larger pharmaceutical companies are more likely to reach out to foreign markets, sell a significant portion of their products abroad, and report their sales by geographical region to highlight their international operations. Smaller companies are more likely to sell their products entirely within the country of origin, which would remove the necessity to report their regional sales.

Thus, my analysis of pharmaceutical companies on the basis of U.S. sales includes only relatively large companies. Since I am essentially comparing large U.S. companies that have diversified into foreign markets to foreign companies that sell a fraction of their products within the U.S., the effect from the price control threats could be underestimated. To strengthen the analysis, I would include smaller U.S. companies that conduct their sales entirely within the U.S., as well as smaller foreign companies that do not sell their products in U.S.. However, the scarcity of clear geographic information is restricting this approach.

5. Empirical Strategy

In this study, I conduct three separate tests comparing pharmaceutical firms on the basis of A) the fraction of U.S. sales, B) research intensity, and C) total level of R&D expenditures.

5A. *Comparing Pharmaceutical Firms based on Proportion of U.S. Sales*

Evaluating changes in firm-level R&D on the basis of geographical distribution of the firms' sales provides the strongest test for determining the effect from price control threats. I expect that the firms with higher fractions of U.S. sales will be more affected by the potential decrease in U.S. drug prices since their revenue is more heavily dependent on the U.S. market. In contrast, firms that derive their revenue from abroad will be less affected by U.S. price controls since they have already adjusted their expenditures in response to established regulations in foreign countries. To conduct this test, I create two groups of pharmaceutical companies:

1) Firms that conducted over 50% of sales within the U.S. in the year 2000 (domestic firms), and

2) Firms that conducted 50% or more of their sales abroad the same year (foreign firms).

Figure 1 shows that the average R&D investments of the two groups increased at about the same rate throughout the early 1990s. However, in 1995, the companies with low percentage of U.S. sales substantially increased their R&D expenditures, while the companies that mainly focus on the U.S. market did not[1]. Since the 1993 threat of price controls was officially announced at the end of the third quarter, and it persisted until the second quarter of 1994, it is reasonable to expect to see an effect in the early 1995.

The increase in R&D expenditures of foreign firms around 1999 complicates the analysis of the 2000 threat of price controls. Since there were no major threats of U.S. price controls between 1995 and 2000, the diversion in R&D patterns between the domestic and foreign firms

[1] Average R&D expenditures of firms with small U.S. sales exhibit a somewhat step-wise pattern because financial information on three such companies (Roche, GlaxoSmithKline, and AstraZeneca) was only available annually.

is likely to be caused by factors unrelated to U.S. drug price regulation. Additionally, the spikes in average R&D of the domestic firms in 2003 and 2004 suggest that the effect from the 2000 threat of drug reimportation was very limited.

Since the firm-level comparisons using total value of R&D expenditures can be confounded by the variation in firm size and structure, I conduct my analysis on R&D/Total Assets ratio, which captures research intensity, rather than R&D spending[2]. Figure 2 presents average R&D/Total Assets ratios for the two groups of firms. Between 1991 and 1994, both foreign and domestic firms were increasing their research intensity at roughly similar rates. However, in 1995, foreign firms more than doubled their research intensity, while the domestic firms showed only modest increases. Given the timing of the 1993 threat, it is likely that at least some portion of this discrepancy could be attributed to the introduction of potential price regulation in the United States.

The analysis of the 2000 threat using R&D/Total Assets ratio is more complex than the analysis of 1993 threat due to significant differences in the trends for foreign and domestic companies between 1996 and 2000. However, the domestic firms consistently decreased their R&D intensity between 2000 and 2004, while the foreign firms continued to invest about the same fraction of their assets into R&D. This could be partially attributed to the effect from the 2000 threat, which would discourage R&D investments by the U.S. companies more than it would affect the investments of firms that mainly target foreign markets.

[2] When I estimate the effect from price control threats using levels of R&D spending in place of research intensity, I obtain similar results.

To formally estimate the differences between research intensities of firms with large and small U.S. sales in the periods following the 1993 threat of price controls, I implement a difference-in-differences analysis:

$$R\&D/Total\ Assets = \alpha + \beta_1\, U.S.\ Firms + \beta_2\, Post\ 1993\ Threat + \\ + \beta_3\, U.S.\ Firms * Post\ 1993\ Threat + u_t + e$$

where *U.S. Firms* is a binary variable that takes a value of 1 for all firms that conduct over 50% of their sales within the U.S.; *Post 1993 Threat* is variable that takes a value of 1 for all periods after the 1993 threat of price controls; and u_t captures annual fixed effects. The interaction term, *U.S. Firms*Post 1993 Threat*, is a difference-in-differences estimator that measures the difference in research intensity between foreign and domestic firms after the threat. When estimating the effect from the 2000 threat, I replace *Post 1993 Threat* variable with *Post 2000 Threat*, and the interaction term becomes *U.S. Firms * Post 2000 Threat*.

Table 3 presents the results from these series of regressions. The coefficient on the interaction term for the 1993 threat is large (given that the average R&D/Total Assets ratios of the firms are low), negative, and statistically significant at 1%. The coefficient on the interaction term for the 2000 threat is also negative, yet is much smaller and is significant at 5%.

However, the estimates of time specific treatment effect post 1993 threat question the accuracy of the above analysis. As Figure 3 shows, U.S. firms did not significantly decrease their research intensity compared to foreign firms in any one quarter following the threat.

5B. *Comparing Pharmaceutical Firms based on Research Intensity*

In the second test of firms' response to price control threats, I use Compustat financial data from 81 pharmaceutical companies to compare firms on the basis of their research intensity.

I omit 9 firms that mainly sell their products abroad and focus on the U.S. companies. Essentially, this test aims to separate generic from brand-name firms, since generic companies conduct comparatively less innovative R&D and would typically have lower research intensities. Generic firms will be less affected by the threat of price controls/drug reimportation since the prices of generic drugs in the U.S. are already low and were not the subject of the regulatory threats.

To estimate the effect from the 1993 threat, I divide pharmaceutical companies into two groups:

1) Firms with higher than average research intensity in 1993, and
2) Firms with research intensity below average in 1993.

This classification results in 27 pharmaceutical firms in group 1, and 54 companies in group 2. Additional summary statistics are available in Table 4. It should be noted that the average intensity of firms in group 1 is about twice the magnitude of research intensity in group 2. However, companies in group 2 are much bigger and invest larger sums of money into R&D. The latter fact could complicate the analysis because it implies that some of the large brand-name companies fall under the low research intensity category, and the two groups do not distinguish between generic and brand-name companies as well as desired.

The graph of average R&D/Total Assets ratios for the two groups of companies does not show a significant effect after the 1993 threat (Figures 4). Prior to 1993, the research intensity of both groups was declining at about equal rates. After the first price control threat, the intensities of both groups remained roughly constant until 2000. A small peak in 1995 in research intensity of group 2 together with a lack of such an increase in group 1 appear to suggest that the effect from 1993 could have been significant, yet small in magnitude.

The effect from the 2000 threat of drug reimportation is even less apparent in the data. To study this effect, I divide the 81 pharmaceutical companies into similar groups; however, I am using the firms' research intensity in 2000, rather than in 1993, to place the companies. As Figure 5 shows, the research intensities for both groups were roughly decreasing between 1998 and 2000. However, between 2000 and 2002, the research intensity of the firms in group 1 was declining, while the intensity of firms in group 2 was growing at a modest rate. This pattern could be at least partially attributable to the 2000 drug reimportation threat, as the more research intensive companies scale back their efforts in anticipation of decreased profits. The significant variation between the research intensities prior to 2000, however, suggests that the trends are influenced by other factors besides U.S. price regulation, and the results of statistical analysis should be interpreted with caution.

My difference-in-differences estimation of the effect after 1993 threat takes the following form:

$$R\&D/Total\ Assets = \alpha + \beta_1\, Research\text{-}Intensive + \beta_2\, Post\ 1993\ Threat + \\ + \beta_3\, Research\text{-}Intensive * Post\ 1993\ Threat + u_t + e$$

where *Research-Intensive* is a binary variable that takes a value of 1 for all U.S. pharmaceutical firms whose R&D intensity exceeded the average in 1993. *Post 1993 Threat* is defined as 1 for all periods following the 1993 threat, and u_t captures the annual fixed effects. The interaction term, *Research-Intensive*Post 1993 Threat*, is a difference-in-differences estimator that measures the discrepancies in R&D/Total Assets ratios for groups of firms with high and low research intensities. To estimate the effect from the 2000 threat, I replace *Post 1993 Threat* variable with *Post 2000 Threat*, defined as 1 for all periods after Clinton signed the 2000 drug reimportation legislation.

The results from these estimations are shown in Table 5. The coefficient on the interaction term for the 1993 threat is negative, yet only marginally significant, and the coefficient on the interaction term for the 2000 threat is not statistically significant, implying limited effect from 1993 threat and no effect after the 2000 threat. The time specific treatment effect from 1993 threat also shows no significant change in R&D efforts of research intensive companies in any one quarter following the threat (Figure 6).

5C. *Comparing Pharmaceutical Firms based on R&D Expenditures*

Since previous analysis does not precisely distinguish between generic and brand-name firms, I conduct another test in which I compare U.S. pharmaceutical firms based on the total level of R&D expenditures. Intuitively, firms that invest greater dollar amounts into R&D are likely to be large brand-name pharmaceutical firms that would be directly affected by price controls on prescription drugs. Thus, I repeat the steps of the above analysis and divide 81 U.S. pharmaceutical companies into two groups:

1) Firms with quarterly R&D expenditures above average in 1993, and

2) Firms with quarterly R&D below average in 1993.

To estimate the effect from the 2000 threat, I place the pharmaceutical companies into the two groups using quarterly R&D expenditures in 2000.

The graph of the average R&D expenditures of the two groups shows similar growth trends in R&D expenditures prior to 1993 (Figure 7). However, around 1995, there is a small peak in R&D among companies that invested below the average, with no corresponding increase in the R&D spending among companies that invested above the average. This could be partially

attributed to the 1993 threat; however, it is also possible that other factors could have driven the modest increase in expenditures among low-investing firms.

The effect from the 2000 threat is measured using classification of companies on the basis of their R&D expenditures in 2000. Figure 8 shows that the R&D expenditures of the two groups of companies followed a similar pattern in the years leading up to the threat. However, in 2002 and 2003, firms with above the average R&D expenditures significantly increased their investments, while the firms with lower R&D spending did not demonstrate such an increase. Therefore, the data suggests that the 2000 threat of drug reimportation did not have a significant negative effect on the relative investments of large pharmaceutical firms.

The difference-in-differences analysis has the following specifications:

$$Ln(R\&D) = \alpha + \beta_1 \, Large\ R\&D + \beta_2 \, Post\ 1993\ Threat + \\ + \beta_3 \, Large\ R\&D * Post\ 1993\ Threat + u_t + e$$

where *Large R&D* is a binary variable that takes a value of 1 for all firms whose quarterly R&D expenditures in 1993 exceed the average. The interaction term, *Large R&D * Post 1993 Threat*, captures the difference in percent changes of R&D spending between firms that invest large sums into R&D and firms that invest relatively little following the threat of price controls. As in previous regressions, I replace *Post 1993 Threat* variable with *Post 2000 Threat* to estimate the effect from the 2000 drug reimportation threat.

The results reported in Table 7 show a small negative coefficient on the interaction term, *Large R&D*Post 1993 Threat* that is significant at 5%, and an insignificant coefficient on the interaction term of *Large R&D*Post 2000 Threat*. Thus, the effect from the 1993 threat appears to be minor, while the effect from the 2000 threat is non-existent. However, time specific effect

from 1993 threat is once again not significant in any quarter following the threat (Figure 9).

6. Discussion

Overall, three principal tests in which I compare pharmaceutical companies on the basis of U.S. sales, R&D intensity, and total level of R&D expenditures appear to suggest a negative effect from the 1993 threat and a smaller and potentially insignificant effect from the 2000 threat. However, time specific treatment effects question the validity of these conclusions.

The difference-in-differences analysis comparing foreign and domestic firms shows a large negative effect on the domestic firms after 1993 threat and a smaller negative effect after the 2000 threat. Specifically, magnitudes of coefficients on the interaction terms show that the domestic firms decreased their R&D intensity after the 1993 threat by 0.03 compared to the foreign firms, while the 2000 threat resulted in only 0.01 decline in relative research intensity of the domestic firms (Table 3). These results seem to support the hypothesis that the possibility of price controls could have had a negative effect on R&D investments of the pharmaceutical firms.

Nevertheless, graph of the time-specific treatment effect (Figure 3) reveals that there was no significant negative effect on research intensity of the domestic firms in any one quarter following the threat. This finding implies that the large negative coefficient suggesting a substantial decline after 1993 threat might not be as accurate as implied. It is likely that the standard errors in the difference-in-differences analysis are correlated across years, making the interaction coefficient appear more significant than it actually is.

The difference-in-differences analysis comparing the domestic pharmaceutical firms on the basis of their research intensity suggests that the effects from 1993 threat was only marginally statistically significant, while the 2000 threat caused no differential response among pharmaceutical firms (Table 5). The time specific treatment effect post 1993 threat also suggests

that firms' response to the threat was not considerable (Figure 6). However, the interpretation of these results is complicated by fact that few of the larger pharmaceutical firms producing brand-name products were classified as low-intensive firms. These firms would have been directly affected by the drug reimportation, and, therefore, this test does not precisely distinguish between firms on the basis of their vulnerability to the threats. The marginally significant results reported in Table 5 could underestimate the effect of price control threats.

Comparing firms on the basis of total R&D expenditures allows me to more accurately distinguish between the generic and brand-name firms in my sample. The difference-in-differences results suggest that pharmaceutical firms that invest large dollar amounts into R&D did not increase their expenditures post 1993 threat as much as the pharmaceutical firms that were initially less innovative (Table 7). The 2000 threat produced no differential response between two groups of firms. However, once again, the time specific treatment effect post 1993 threat is not significant in any quarter, implying that the difference-in-differences estimates are imprecise due to correlated error terms (Figure 9).

The overall results are not conclusive. On one hand, difference-in-differences estimates are consistent with the hypothesis that 1993 threat was perceived as real by the pharmaceutical companies, leading to a substantial decreased in R&D efforts, while the 2000 threat of reimportation was not considered likely to become law. On the other hand, time specific treatment effect graphs show no significant effect from the 1993 threat in any quarter. Additionally, factors other than anticipated changes in the U.S. regulatory system could have affected firms' R&D efforts. In this case, relative R&D decline of firms post 1993 can be only partially attributed to threats of price controls, and the measured effects can overestimate firms' response to potential regulation.

7. Conclusion

As legislators introduce and debate new price regulations, it is important to understand whether or not such debates have a significant impact on the investment decisions of private firms. Given the importance of pharmaceutical industry to public health, it is essential to establish whether the mere threats of price controls/drug reimportation have a negative effect on the industry's R&D expenditures

Although the results of this study do not definitively answer the question of whether the threats of increased regulation reduce R&D efforts of pharmaceutical firms, the study presents an approach to measuring firm response that has not been previously applied to this question. Comparing pharmaceutical firms on the basis of their vulnerability to price control threats provides a valuable alternative to modeling firm behavior. However, an improvement upon the standard difference-in-differences analysis is needed in order to measure potential changes in R&D between groups of firms more accurately.

Table 1. The Threats of Price Controls/Drug Reimportation

Date	Threat
September 22, 1993	President Clinton publicizes his Health Security Act of 1993 (Golec 2005).
October 28, 2000	Clinton signs drug reimportation legislation (Griffith 2000).
July 11, 2001	House passes drug reimportation provision in 324-101 vote (Lueck 2001).
July 31, 2002	Senate approves reimportation bill (Lueck 2002).
July 23, 2003	House passes reimportation legislation, allowing reimportation from 26 countries including Canada (McGregor 2003).
October 22, 2003	Senate introduced Pharmaceutical Market Access Act of 2003 (Pilon 2004).
April 22, 2004	Legislators Daschle and McCain introduce a bill that would allow reimportation from Canada and other industrialized nations (Bowe 2004).
August 23, 2004	Illinois launches a reimportation program, allowing its residents to by pharmaceuticals from approved pharmacies in EU and Canada (Bowe 2004b).

Table 2. Summary statistics for pharmaceutical firms based on fraction of U.S. sales

	Group 1 Firms with >50% U.S. Sales	Group 2 Firms with ≤ 50% U.S. sales
Number of Firms	13	9
Average % of U.S. sales	75.5	41.4
Average R&D Expenditures (mm)	304.86 (500.6)	807.87 (1427.9)
Average R&D/Total Assets	0.0419 (0.046)	0.0559 (0.062)
Average Total Assets (mm)	12,285 (19,193)	10,259 (17,405)
Average Net Sales (mm)	2,282 (3,053)	5,584 (9,394)

Note: Standard deviation is shown in parenthesis.

Table 3. Difference-in-differences regressions comparing pharmaceutical firms based on fraction of U.S. sales. The dependent variable is R&D/Total Assets.

	(1)	(2)	(3)	(4)
U.S. Firms	0.010	0.0104	-0.009**	-0.009**
	(0.006)	(0.006)	(0.004)	(0.004)
Post 1993 Threat	0.023*	0.034***		
	(0.012)	(0.008)		
Post 2000 Threat			-0.007	-0.010
			(0.013)	(0.007)
U.S. Firms * Post 1993 Threat	-0.030***	-0.030***		
	(0.007)	(0.007)		
U.S. Firms * Post 2000 Threat			-0.014**	-0.014**
			(0.006)	(0.006)
Annual Fixed Effects	yes	no	yes	no
Time Trend	no	yes	no	yes
Observations	1443	1443	1443	1443
R^2	0.0548	0.0458	0.0548	0.0404
Adjusted R^2	0.0422	0.0425	0.0422	0.0371

Note: *U.S. Firms* is a binary variable defined as 1 for all firms that sold over 50% of their products abroad in 2000. *Post 1993 Threat* is defined as 1 for all periods after the announcement of Health Security Act of 1993. *Post 2000 Threat* is defined as 1 for all periods after Clinton signed drug reimportation bill. Standard errors are shown in the parenthesis. The individual coefficient is statistically significant at the *10%, **5%, or ***1% level.

Table 4. Summary statistics for pharmaceutical firms based on research intensity.

	Analysis of 1993 Threat		Analysis of 2000 Threat	
	Group 1A	**Group 2A**	**Group 1B**	**Group 2B**
	Firms with high research intensity in 1993	**Firms with low research intensity in 1993**	**Firms with high research intensity in 2000**	**Firms with low research intensity in 2000**
Number of Firms	27	54	25	56
Average Research Intensity	0.125 (0.188)	0.065 (0.271)	0.130 (0.220)	0.065 (0.257)
Average R&D Expenditures (mm)	9.023 (18.00)	100.5 (309.5)	8.187 (19.32)	97.542 (304.20)
Average Total Assets (mm)	148.97 (355.78)	4,067 (11,989)	151.29 (412.25)	3,927.67 (11,797.08)
Average Net Sales (mm)	12.53 (44.04)	722.42 (1,923.57)	15.18 (52.54)	695.53 (1,893.43)

Note: Standard deviation is shown in parenthesis.

Table 5. Difference-in-differences regressions comparing U.S. pharmaceutical firms based research intensity. The dependent variable is R&D/Total Assets.

	(1)	(2)	(3)	(4)
Research-Intensive	.089***	.088***	.067***	.067***
	(.017)	(.017)	(.009)	(.009)
Post 1993 Threat	.015	.036*		
	(.030)	(.019)		
Post 2000 Threat			-.014	-.035**
			(.032)	(.014)
Intensive* Post 1993 Threat	-.034*	-.033*		
	(.019)	(.019)		
Intensive* Post 2000 Threat			-.004	-.004
			(.015)	(.015)
Annual Fixed Effects	yes	no	yes	no
Time Trend	no	yes	no	yes
Observations	5513	5513	5513	5513
R^2	0.0195	0.0168	0.0204	0.0188
Adjusted R^2	0.0157	0.0159	0.0168	0.0179

Note: *Research-Intensive* is a binary variable defined as 1 for all firms whose R&D/Total Assets ratios exceeded the average in either 1993 or 2000. *Post 1993 Threat* is defined as 1 for all periods after the announcement of Health Security Act of 1993. *Post 2000 Threat* is defined as 1 for all periods after Clinton signed drug reimportation bill. Standard errors are shown in the parenthesis. The individual coefficient is statistically significant at the *10%, **5%, or ***1% level.

Table 6. Summary statistics for pharmaceutical firms based on R&D expenditures.

	Analysis of 1993 Threat		Analysis of 2000 Threat	
	Group 1A	**Group 2A**	**Group 1B**	**Group 2B**
	Firms with large R&D in 1993	**Firms with small R&D in 1993**	**Firms with large R&D 2000**	**Firms with small R&D in 2000**
Number of Firms	10	71	12	69
Average Research Intensity	0.028 (0.014)	0.094 (0.265)	0.030 (0.021)	0.095 (0.268)
Average R&D Expenditures (mm)	471.318 (549.498)	8.212 (30.098)	410.534 (534.495)	8.095 (31.487)
Average Total Assets (mm)	18,790.97 (20,715.56)	232.381 (607.208)	16,510.1 (20,304.19)	226.688 (607.334)
Average Net Sales (mm)	3,434.315 (3,038.844)	31.31238 (90.82145)	2,970.594 (3,066.915)	33.556 (100.328)

Note: Standard deviation is shown in parenthesis.

Table 7. Difference-in-differences regressions comparing U.S. pharmaceutical firms based the level of R&D expenditures. The dependent variable is ln(R&D).

	(1)	(2)	(3)	(4)
Large R&D	5.39***	5.38***	4.574***	4.575***
	(.131)	(.130)	(.078)	(.078)
Post 1993 Threat	.230	.104		
	(.182)	(.110)		
Post 2000 Threat			.084	-.029
			(.213)	(.094)
Large R&D* Post 1993 Threat	-.370**	-.362**		
	(.148)	(.148)		
Large R&D* Post 2000 Threat			.067	.066
			(.125)	(.125)
Annual Fixed Effects	yes	no	yes	no
Time Trend	no	yes	no	yes
Observations	5603	5603	5603	5603
R^2	0.5837	0.5840	0.5414	0.5417
Adjusted R^2	0.5821	0.5836	0.5396	0.5413

Note: *Large R&D* is a binary variable defined as 1 for all firms whose R&D expenditures exceeded the average in either 1993 or 2000. *Post 1993 Threat* is defined as 1 for all periods after the announcement of Health Security Act of 1993. *Post 2000 Threat* is defined as 1 for all periods after Clinton signed drug reimportation bill. Standard errors are shown in the parenthesis. The individual coefficient is statistically significant at the *10%, **5%, or ***1% level.

Figure 1. Average R&D investments of pharmaceutical firms with large vs. small fraction of U.S. sales.

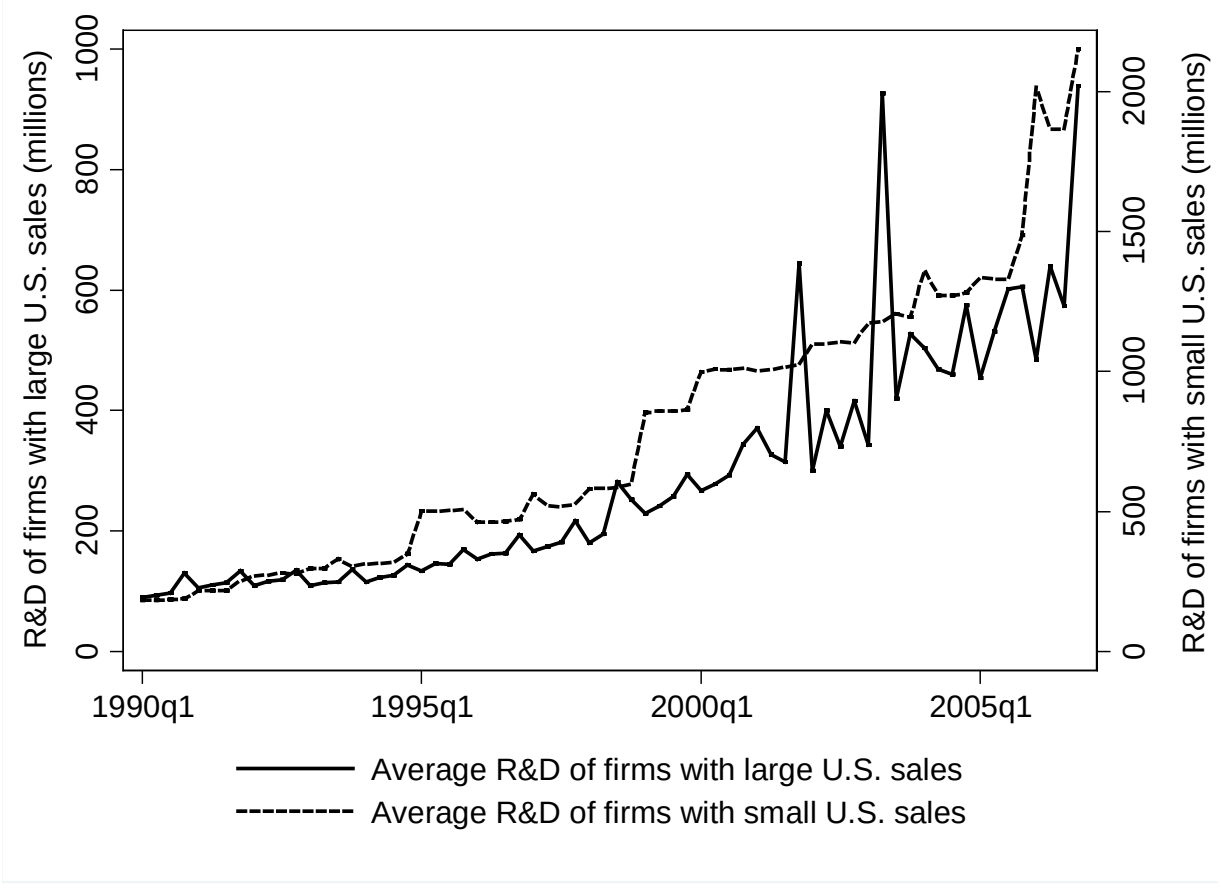
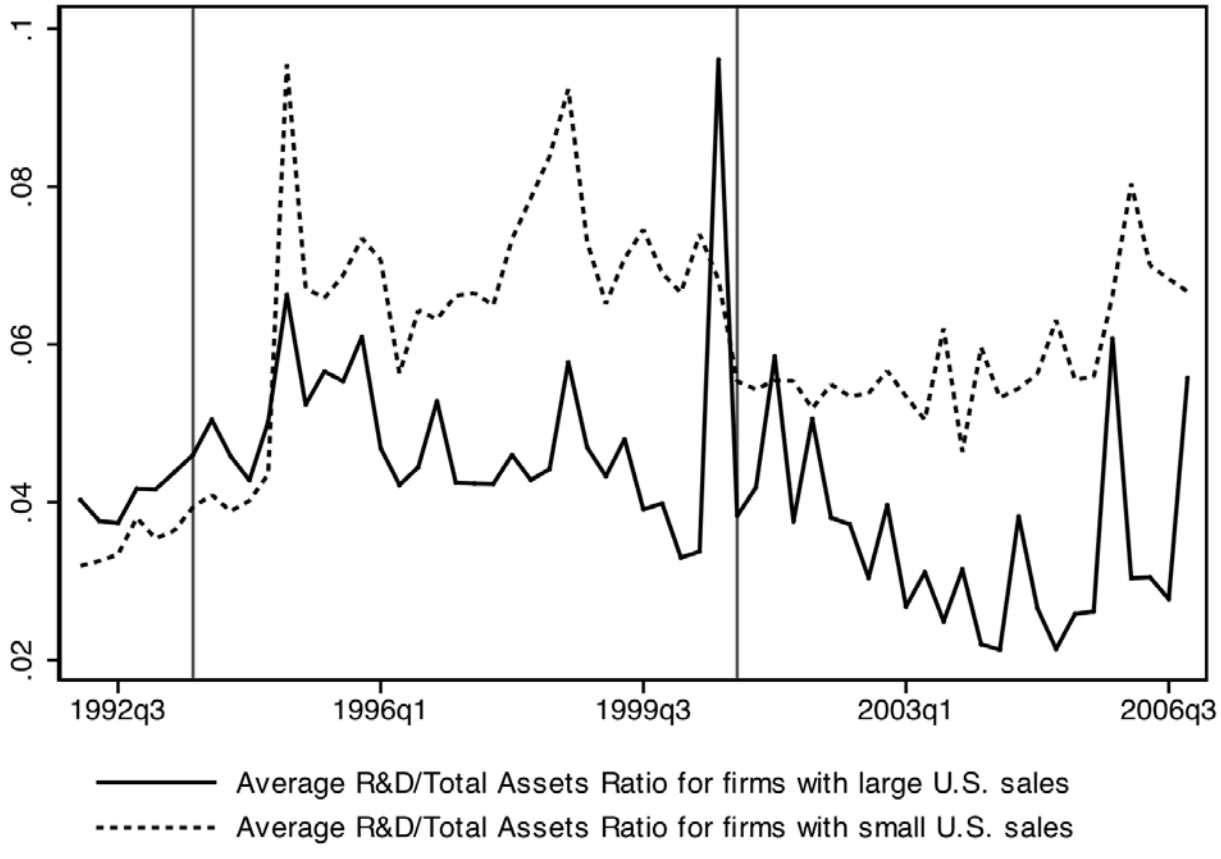
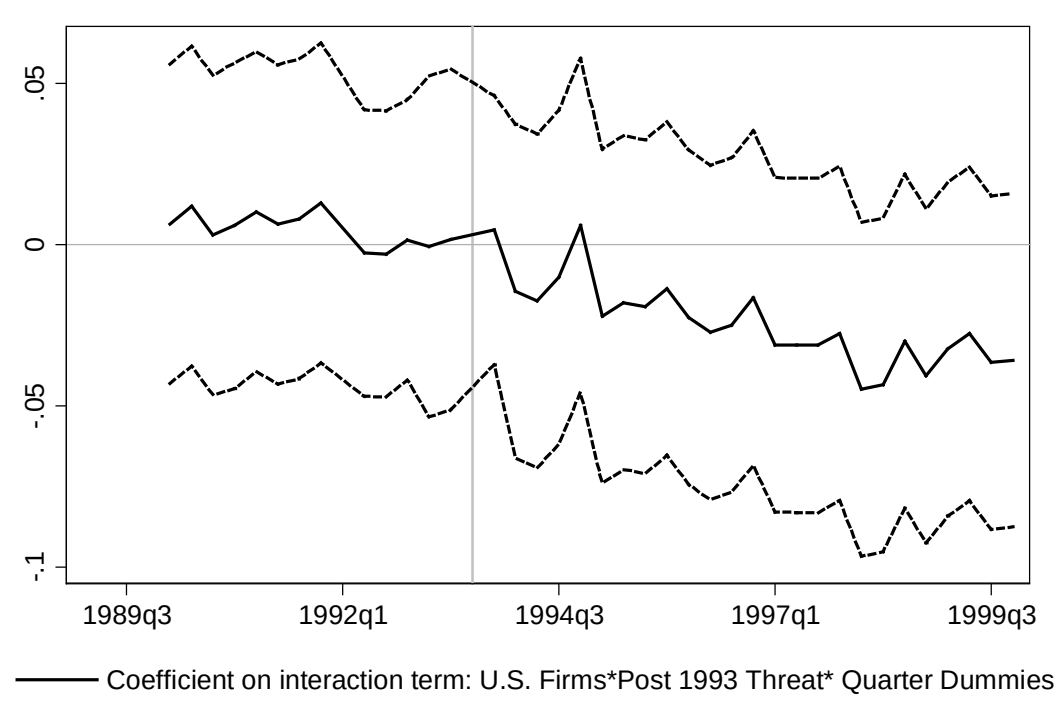


Figure 2. Average R&D/Total Assets ratios for firms with large vs. small fraction of U.S. sales.



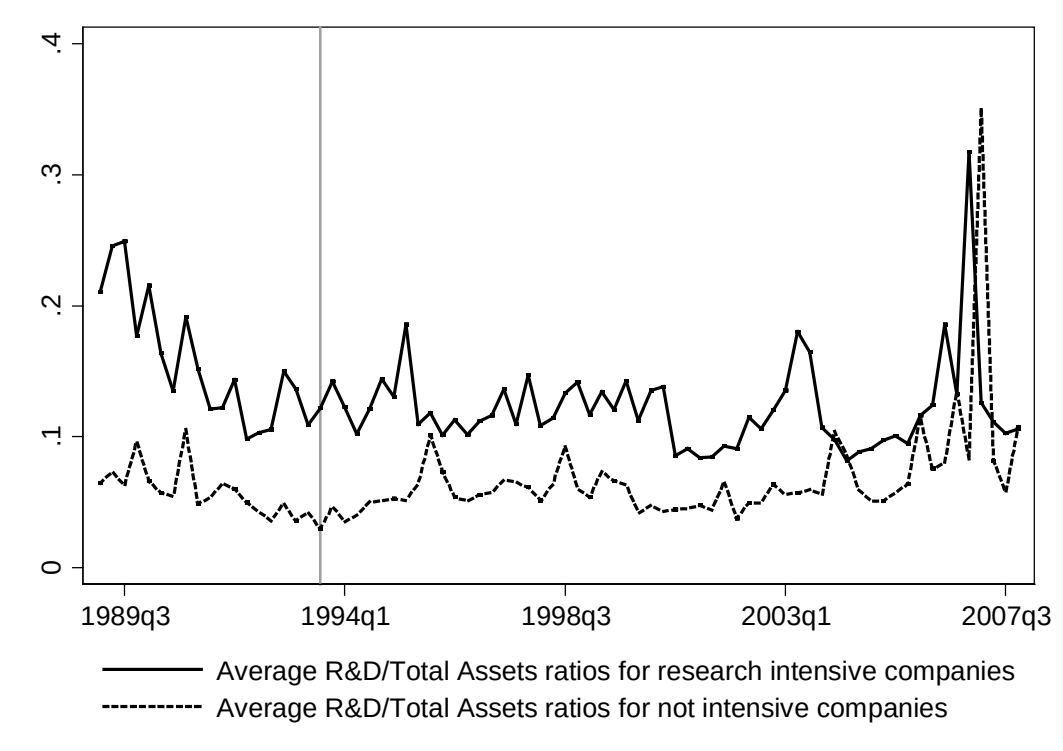
Note: Vertical lines show 1993 and 2000 threats of price controls.

Figure 3. Comparing pharmaceutical companies via U.S. sales: time-specific treatment effect from 1993 threat of price controls.



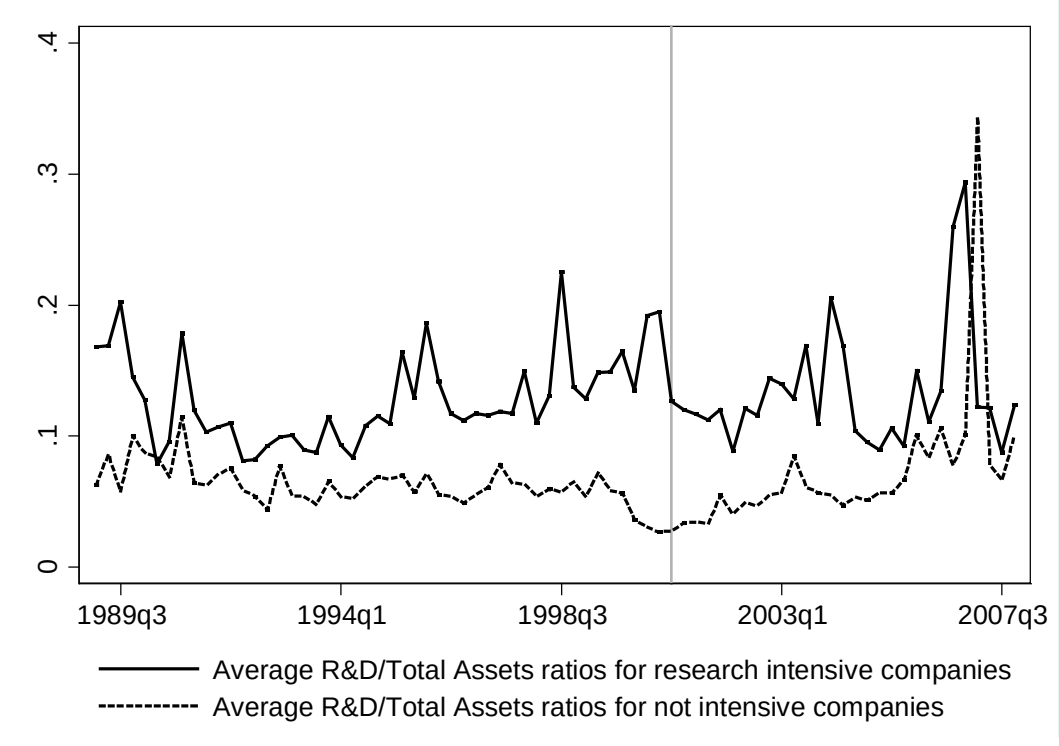
Note: Vertical line marks 1993 price control threat. The dashed lines show 95% confidence interval for the interaction term. To estimate the pre-trend, I substitute *Post1993* variable with a dummy variable which equals 1 for all periods post 1990.

Figure 4. Average research intensity of firms that invest large fraction of their assets into R&D in 1993 vs. firms that invest a smaller fraction of assets.



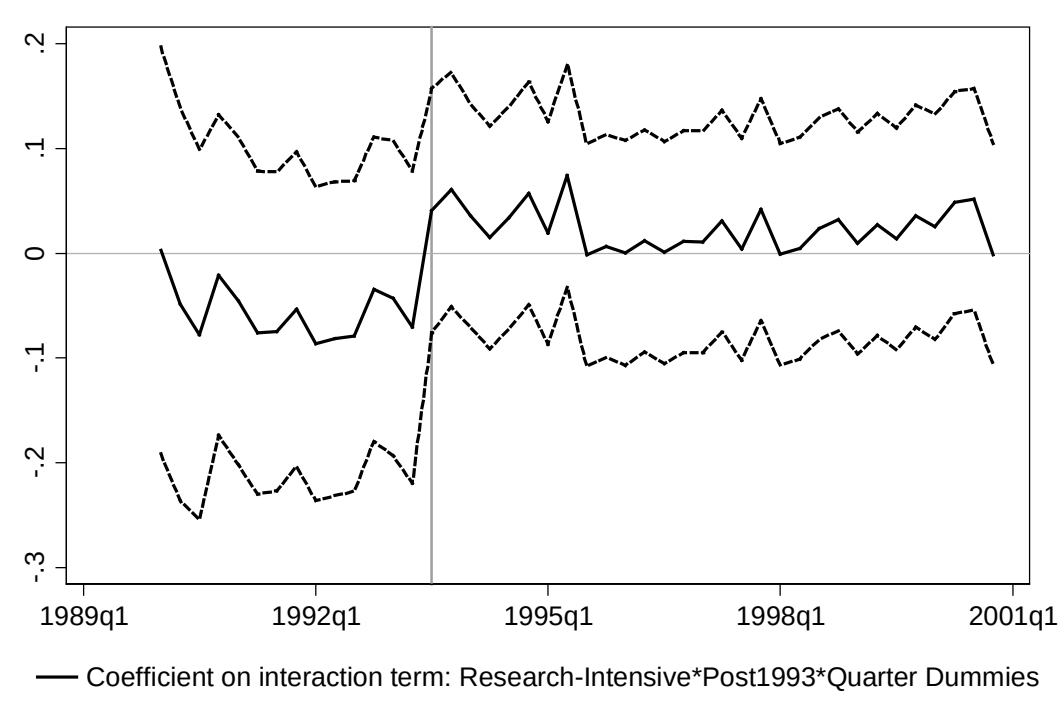
Note: Vertical line shows 1993 threat of price controls.

Figure 5. Average research intensity of firms that invested large fraction of their assets into R&D in 2000 vs. firms that invest a smaller fraction of assets.



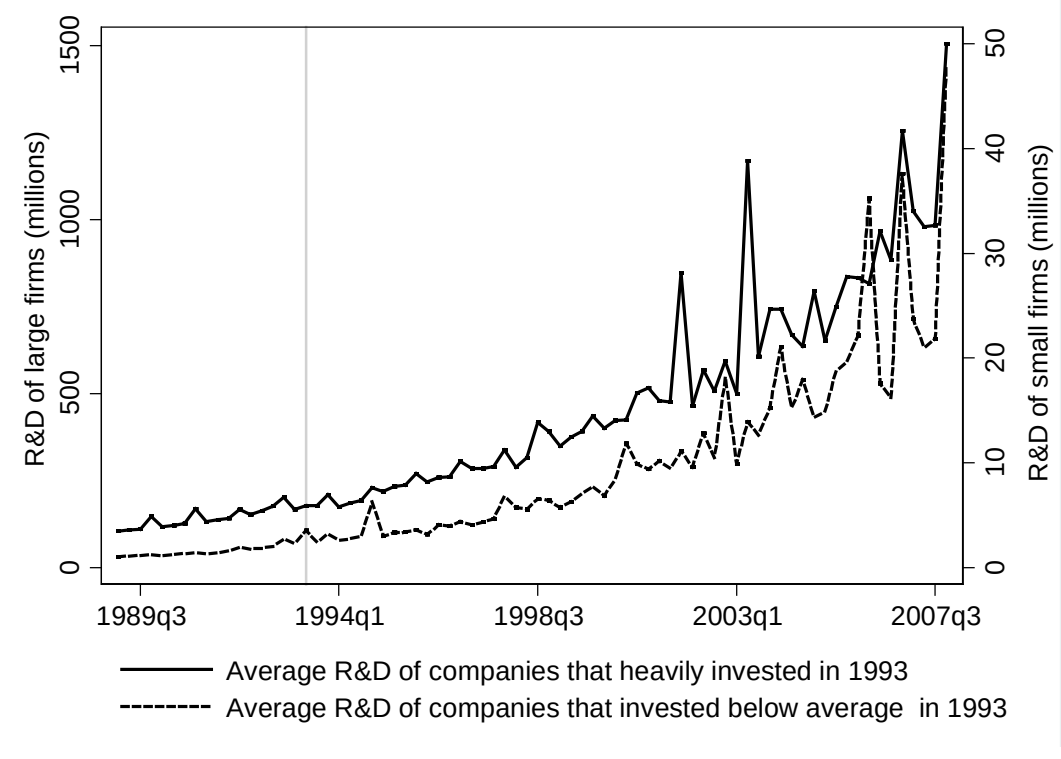
Note: Vertical line shows 2000 threat of price controls.

Figure 6. Comparing pharmaceutical companies via research intensity: time-specific treatment effect after 1993 threat.



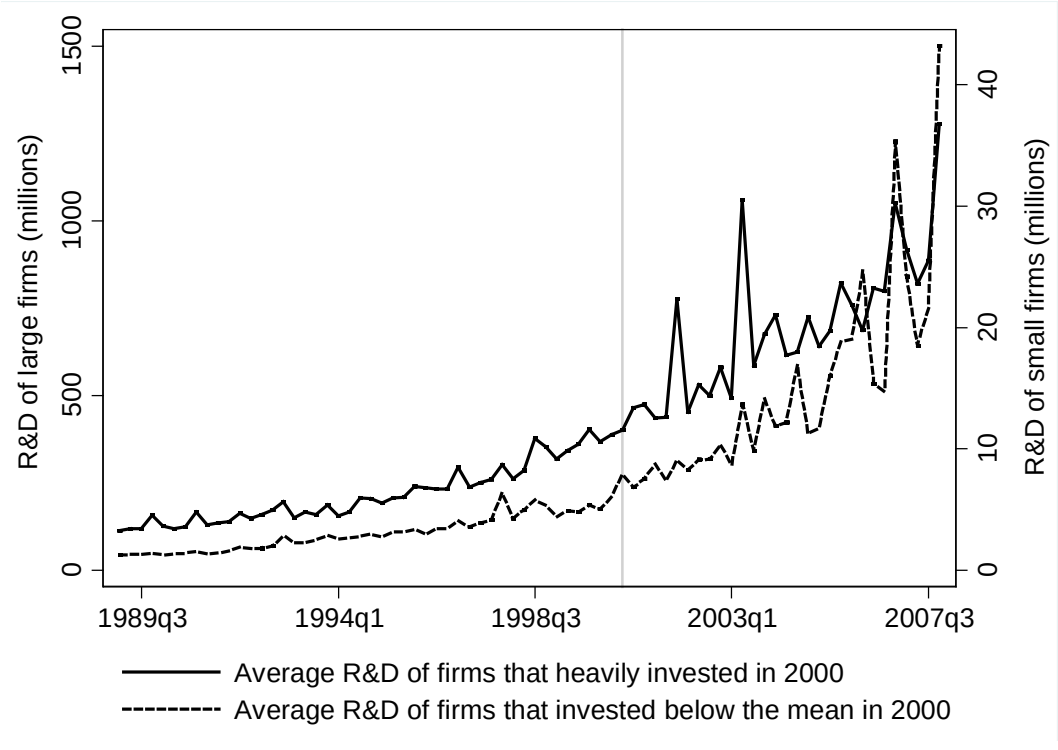
Note: Vertical line marks 1993 threat of price controls. The dashed lines show 95% confidence interval for the interaction term. To estimate the pre-trend, I substitute *Post1993* variable with a dummy variable which equals 1 for all periods post 1990.

Figure 7. Average R&D of firms with large vs. small R&D investments in 1993.



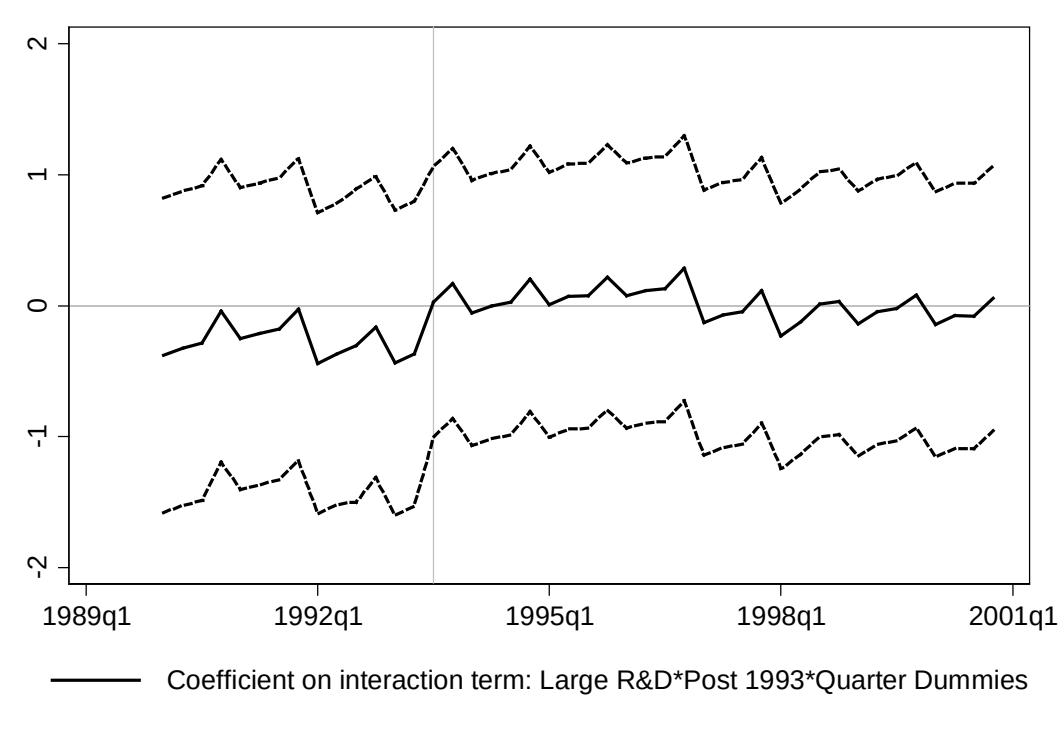
Note: Vertical line shows 1993 threat of price controls.

Figure 8. Average R&D of firms with large vs. small R&D investments in 2000.



Note: Vertical line shows 2000 threat of price controls.

Figure 9. Comparing pharmaceutical companies via R&D spending: time-specific treatment effect after 1993 threat.



Note: Vertical line marks 1993 threat of price controls. The dashed lines show 95% confidence interval for the interaction term. To estimate the pre-trend, I substitute *Post1993* variable with a dummy variable which equals 1 for all periods post 1990.

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