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Pharmaceutical R&D Spending and Threats of Price Regulation

Joseph Golec, Shantaram Hegde, and John A. Vernon*

Abstract

Do threats of pharmaceutical price regulation affect subsequent research and development (R&D) spending? This study uses the Clinton administration's Health Security Act (HSA) of 1993 as a natural experiment to study this issue. We link events surrounding the HSA to pharmaceutical stock price changes and then examine the cross-sectional relation between firms' stock price changes and their subsequent unexpected R&D spending changes. Results show that the HSA had significant negative effects on stock prices and firm-level R&D spending. Conservatively, the HSA reduced R&D spending by about $1 billion even though it never became law.

I. Introduction

Can proposed government policy that significantly affects the value of firms' research and development (R&D) assets affect their R&D spending decisions? The Clinton administration's Health Security Act (HSA) provides a natural experiment to study this issue because it never passed Congress but nonetheless caused significant pharmaceutical stock price declines and, presumably, R&D asset value declines. This study investigates the effects that proposed pharmaceutical price constraints had on pharmaceutical firms' R&D values (reflected in stock prices) and subsequent firm-level R&D spending.

The link from R&D to stock prices has been studied by Chan, Lakonishok, and Sougiannis (2001) and Eberhart, Maxwell, and Siddique (2004), but neither considers the link from stock prices to *subsequent* R&D spending. Durnev,

*Golec, jgolec@business.uconn.edu, Hegde, shegde@business.uconn.edu, School of Business, University of Connecticut, 2100 Hillside Rd., Unit-1041F, Storrs, CT 06269; Vernon, vernon@email.unc.edu, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, CB 7411, Chapel Hill, NC 27713 and NBER. We are grateful to the following individuals for their very helpful comments and suggestions on earlier versions of this paper: Thomas Abbott, Ernie Berndt, Martin Feldstein, Jean Paul Gagnon, Carmelo Giaccotto, Henry Grabowski, Mike Grossman, Ilan Guedj (the referee), Curt Hunter, Frank Lichtenberg, Paul Malatesta (the editor), Richard Manning, Sean Nicholson, Rexford Santerre, John M. Vernon, Y. Richard Wang, Mike Willenborg, and participants at the 2005 AEA/PEPC meetings in Philadelphia. We thank AstraZeneca, the Center for International Business and Education Research at the University of Connecticut, and the Center for Healthcare and Insurance Studies at the University of Connecticut for financial support. All errors are our own.

Morck, and Yeung (2004) find a link from stock price changes to investment spending, which suggests that there could be a link from stock prices to comparatively flexible R&D spending. Our study uses firms' stock price reactions to HSA-related events to capture investor expectations of the effects of the HSA price constraints on the profitability (value) of firms' R&D assets. If managers expect fewer profitable R&D projects, they should reduce R&D spending. Testing the cross-sectional relation between HSA-induced stock price changes and firm-level R&D spending is this paper's primary contribution.

Even though it was eventually defeated, we argue that the HSA marked a significant political shift toward monitoring and containing average drug prices.[1] In 1993 the major pharmaceutical firms pledged to keep prices low to help defeat the HSA. Indeed, we show that real pharmaceutical price inflation dropped sharply in 1993 and remained relatively low afterward. We also show that changes in the R&D pipeline around the HSA were not simply reversed after its defeat. Furthermore, firms' stock prices did not fully recover from HSA-related losses following the HSA's defeat. Investors apparently expected sustained effects from the HSA, which is consistent with the significant positive relation that we find between firms' HSA-related stock price declines and subsequent unexpectedly low R&D spending.[2]

The notion that product pricing or profitability is positively related to R&D spending seems straightforward, but there are few precise studies of this issue. Duggan and Scott Morton (2006) and Finkelstein (2004) link new government policies that boost drug profitability to increases in new clinical trials, new molecular entities, or new drugs. Acemoglu and Linn (2004) show that demographic changes that increase potential market size also attract more new drug offerings. But a positive relation between R&D spending and expected profit, as reflected in stock prices, is not a foregone conclusion. Ellison and Mullin (2001) suggest that the HSA caused a pure wealth transfer from pharmaceutical firms to consumers and that stock price declines might not lead to reduced R&D spending.

Ellison and Mullin's (2001) study links the ferocious political debate on the HSA to the extremely poor stock returns for pharmaceutical firms during 1992–1993. They find that 18 large pharmaceutical company stocks suffered an average 38% loss during the period (−52% risk-adjusted). We find similar negative returns, but for a wider variety of 111 pharmaceutical and biotechnology companies.

[1]We thank Jean Paul Gagnon of Aventis, Y. Richard Wang of AstraZeneca, and Richard Manning of Pfizer for this insight. After the HSA, examples of indirect pressure on pharmaceutical prices include discounts required on pharmaceuticals supplied to Medicaid and the Veterans Administration and the reimportation of pharmaceuticals from price-regulated countries. Tessoriero (2004) suggests that political pressure can be observed around presidential election years when pharmaceutical price increases tend to be subdued.

[2]Studies by Scherer (2001), Vernon (2002/2003), (2005), and Giaccotto, Santerre, and Vernon (2005) show that policies designed to lower average pharmaceutical prices lead to lower R&D spending at the industry level. At the company level, Lichtenberg (2004) identifies a time-series cross-sectional link between pharmaceutical stock price changes and R&D spending during 1953–1996 for a sample of 46 pharmaceutical firms. He conjectures that the HSA could have caused the significant pharmaceutical stock price declines in 1993 and the subsequent industry-level R&D spending growth declines in 1994 and 1995. But he does not measure firm-specific HSA-related returns, nor does he isolate the relation between those returns and firm-level R&D spending during these years. We focus on this relation.

We also show that the higher the R&D intensity, the larger the loss, with top quartile firms losing 60% on average (93% risk-adjusted).

We expect the most vulnerable firms to be R&D intensive, to have proportionately more leveraged R&D projects, or both. Garlappi (2004) notes that R&D projects are real options and thus equivalent to leveraged assets; hence, firms' stock betas should reflect R&D leverage. Results show that beta levels and HSA-induced beta changes help explain changes in firms' stock prices.

Ellison and Mullin (2001) suggest that the HSA might not affect R&D spending because most drug prices include large economic rents. The HSA simply reallocated rents. In other words, they believe that drug R&D options are mostly low risk and deep in-the-money. But our analysis shows that R&D-intensive, high-risk firms experience relatively large negative returns. Many of them are relatively young research-oriented firms, often referred to as biotech firms. A sharp drop in external financing available to biotech firms after the HSA documented by Lerner, Shane, and Tsai (2003) is consistent with the sharp declines in their stock prices.

Overall, we find that firms responded to the HSA by reducing their R&D expenditures below expected levels. R&D spending was lower by 7.7% in 1994, which is equivalent to a drop of $738 million ($1.48 billion) measured in 1983 (2004) dollars. Evidence shows that some of this effect was reversed in 1995 after Congress rejected the HSA in 1994, producing a net decline of about $1 billion measured in 2004 dollars.

This paper is organized as follows. Section II describes the data and the sample. Section III illustrates the HSA's effects on the stock prices of a range of pharmaceutical and biotechnology firms distinguished by R&D intensity. Section IV discusses the HSA and its potential long-term effects on R&D investment behavior. Section V proposes and tests hypotheses on the relation between HSA-related abnormal returns and firm-level R&D intensity and risk. It also tests the relation between subsequent unexpected R&D spending intensity and HSA-related abnormal returns and risk changes. Section VI concludes the paper.

II. The Data and the Sample

The study employs financial accounting data and stock market data for each sample firm around the HSA period of 1992–1993. The accounting data, such as annual R&D expenditures, are obtained from Standard and Poor's Compustat database. The stock market data, such as daily firm stock returns, are obtained from the Center for Research in Security Prices (CRSP). This limits the potential sample because both Compustat and CRSP cover few foreign firms. Nevertheless, some of the largest foreign pharmaceutical firms with significant operations in the U.S. are covered in our sample.

The sample selection process is structured to be inclusive. Unlike earlier studies, we do not focus solely on large firms. The process starts with all firms on Compustat with a North American Industry Classification System (NAICS) code of either 325412 (Pharmaceutical Preparation Manufacturing) or 325414 (Biological Product Manufacturing). Included firms must have data available for at least the years 1991–1995. This selection process results in 176 firms. Of these

176 firms, 113 also have stock returns on the CRSP database covering the period. The 63 firms eliminated are mostly small biotech firms and foreign firms that CRSP has never covered (26 firms) or started covering only after the start of the HSA event period (37 firms). Finally, of these 113, only two have less then 8 years of accounting data on Compustat. We eliminate these firms because they do not have enough data to allow us to reliably estimate their expected R&D spending using model (6). Of the remaining 111, only one has 8 years, two have 9 years, and all of the others have at least 10 years of data, including the 1991–1995 period.

This study's tests involve the effects of the HSA on companies' R&D spending decisions. This requires a standardized measure of R&D spending that allows comparisons across time and across firms of different sizes. We consider the ratio of R&D spending to a firm's total assets (RDTA) and the ratio of R&D spending to a firm's total sales (RDS). We select RDTA because it has been used in previous studies and because it gives more reasonable figures for the firms in our sample. RDS gives extreme values for those firms with little revenue. We reject excluding these firms because this would bias the sample toward more established, low R&D-intensive firms. The final sample has 64 biotech firms, 41 brand name pharmaceutical firms, and 6 generic pharmaceutical firms.

To get a better feel for the data and the sample, consider the averages for the study variables reported in Table 1. Averages are reported for the full sample and subsamples of firms grouped by R&D-to-asset quartiles. Note that the accounting variables such as R&D and total assets are measured for each firm with annual data averaged over 1989–1991. The returns-based variables are measured using daily stock returns. Beta is measured using the market model with the CRSP value-weighted index. Beta and return volatility for each firm are measured over the pre-event period covering April 24, 1990 to January 10, 1992. The pre-event period directly precedes the event period (January 13, 1992–September 29, 1993) and is selected so that it has the same number of trading days as the event period. The event period consists of 434 trading days starting 5 trading days before the first HSA-related event (see Table 2) and ends 5 trading days after the last HSA-related event. Beta change (volatility change) is measured as the difference between the event period beta (volatility) and the pre-event period beta (volatility).

Table 1 also reports tests for the difference between the averages for quartiles 1 and 4, unless that difference is statistically insignificant and there exists another difference between large and small firm quartiles that is statistically significant. Quartiles 1 and 2 mostly contain the large established firms, and quartiles 3 and 4 mostly contain the small young firms. Other differences may be significant as well, but if the statistic reported is insignificant, none of the other quartile differences is significant. For example, quartile 2 firms spend the most on R&D on average because the larger pharmaceutical firms mostly fall into that quartile. The difference in the average dollar amount of R&D spending between quartiles 1 and 4 is not significant, but the difference between quartiles 2 and 4 is significant.

Garlappi (2004) shows that because R&D is equivalent to a leveraged investment, R&D-intensive firms could have relatively large betas. Table 1 shows that the average pre-event betas increase across R&D intensity quartiles. Quartile 4 firms are about 50% more risky on average than the lowest R&D-intensive

TABLE 1

Averages of the Study Variables for the Full Sample and by R&D-to-Assets Quartiles

Each firm observation for R&D, total assets, R&D-to-assets, working capital-to-assets, capital expense-to-assets, advertising-to-assets, and debt-to-assets is measured as an average using annual Compustat data over 1989–1991, the 3-year period preceding the HSA event period. Dollar figures are adjusted for consumer price inflation (All Urban Consumers-All Items, base period 1982–1984 = 100). Beta and return volatility for each firm are measured using daily CRSP value-weighted index returns over the pre-event period covering April 24, 1990 to January 10, 1992. Beta change and volatility change are measured as differences between betas and volatilities measured over the event period (January 13, 1992–September 29, 1993) and the pre-event period. The event period consists of 434 trading days starting 5 trading days before the first HSA-related event (see Table 2) and ends 5 trading days after the last HSA-related event. The pre-event period consists of the 434 trading days preceding the event period. Firms are ranked by R&D-to-assets and grouped into quartiles. Except for advertising, the full sample includes 111 firms, and quartiles 1, 2, and 4 include 28 firms. Quartile 3 includes 27 firms. For advertising-to-assets the sample is limited to 51 firms, with quartiles 1, 2, 3, and 4 having 17, 20, 11, and 3 firms, respectively. The difference between averages for quartiles 1 and 4 is tested unless that difference is statistically insignificant and another quartile difference is statistically significant. ***, **, and * denote estimate significance at the 1%, 5%, and 10% levels, respectively, in a two-tailed test.

Variable	Full Sample	Quartile 1	Quartile 2	Quartile 3	Quartile 4	Quartile Difference Tested	*t*-Stat. for Quartile Difference
R&D (millions)	60.1482	47.3005	181.3749	5.8609	4.1176	Q2 – Q4	3.77***
Total assets (millions)	661.3324	743.8590	1,833.1300	31.7168	14.1359	Q1 – Q4	2.10**
R&D-to-assets	0.2494	0.0393	0.1104	0.2571	0.5910	Q1 – Q4	–10.50***
Working capital-to-assets	0.4391	0.3324	0.3669	0.6004	0.4626	Q1 – Q3	–2.92***
Capital expense-to-assets	0.0682	0.0568	0.0938	0.0521	0.0694	Q1 – Q4	–0.81
Advertising-to-assets	0.0451	0.0534	0.0585	0.0115	0.0132	Q2 – Q4	2.38**
Debt-to-assets	0.1583	0.2180	0.1744	0.0900	0.1120	Q1 – Q4	2.68***
Pre-event period beta	1.2763	0.9883	1.2667	1.3697	1.4841	Q1 – Q4	–2.69***
Beta change	0.1003	0.1527	0.0916	0.1190	0.0388	Q1 – Q4	0.57
Pre-event period return volatility	0.0420	0.0347	0.0325	0.0500	0.0512	Q1 – Q4	–4.57*** (F = 1.52***)
Return volatility change	–0.0016	–0.0001	–0.0005	–0.0056	–0.0014	Q1 – Q4	0.72

firms in quartile 1. A similar pattern is observed for average pre-event return volatilities.

The average beta changes are not statistically different across quartiles, mostly because of the relatively large variation in beta changes within each quartile. This could indicate that there is considerable variation in firms' R&D leverage within each quartile. Similarly, average return volatility change differences between quartiles are statistically insignificant.

The quartiles also do not differ much with respect to capital expenditure intensity, measured by the ratio of capital expense to assets, although the average capital expenditure intensity of quartile 2 is the largest, perhaps because it contains many large pharmaceutical firms that must spend heavily on production and office facilities. Those firms also spend heavily on advertising; hence, quartile 2 firms are the most advertising intensive on average. Unlike capital expenditure intensity differences, however, some advertising intensity differences between quartiles are significantly different.

Finally, financial leverage, measured by the ratio of total debt to assets, shows that the firms in the first two quartiles are more leveraged than the firms in the second two quartiles. Firms in quartiles 1 and 2 generate relatively more sales and cash flow with which they can service debt. Nevertheless, none of the quartiles shows high average leverage. Overall, Table 1 illustrates that the R&D-to-assets quartiles 1 and 2 are composed of similar firms. The same is true for quartiles 3 and 4. Significant differences often appear when comparing across these quartile pairs.

III. The HSA's Effects on Pharmaceutical Stock Prices

Ellison and Mullin (2001) provide a detailed analysis of the events surrounding the HSA and describe its major provisions. They, as well as Abbott (1995), contend that the most significant provision for pharmaceutical firms was price limits on new breakthrough drugs.[3] Grabowski and Vernon (1990) show that breakthrough drugs must earn large profits in order to cover the combined R&D costs of many drugs that are never marketed. For the purposes of our study, this means that the proposed price limits on breakthrough drugs would likely cut the value of firms' R&D assets, particularly for R&D-intensive firms such as small biotechnology firms.

To get a general idea of the magnitude of the possible stock price effects of the HSA on our sample, we examine the cumulative abnormal returns (CARs) one would have earned on the stocks in our sample during the period when President Clinton's health care and pharmaceutical reform proposals became known to investors.

Table 2 lists the major events that we believe were at least partial surprises to investors and that can be tied to President Clinton. Ellison and Mullin (2001) provide a more detailed description of these events in their chronology of health care reform. We include 11 events, starting with Clinton's January 19, 1992 announcement of a vague health care plan just prior to the New Hampshire primary and ending with his official release of the specific plan on September 22, 1993. One can argue about which events to include. We searched for significant events Ellison and Mullin (2001) might have missed and found none. But they include Clinton's July 16, 1992 acceptance of the Democratic presidential nomination and the October 3, 1993 presentation of the plan to Congress. Because neither event was a surprise, we exclude them.

We do not exclude events based on realized CARs.[4] For example, we include Clinton's New York primary win because we believe investors could have been surprised by it, even though the CAR for that event was positive.

[3]The HSA proposed extended prescription coverage; hence, R&D-intensive firms could have benefitted from greater expected unit sales. But it also proposed purchasing groups, restrictive formularies, drug utilization reviews, and generic substitution, which could have offset the effects of extended coverage. Furthermore, Coulson and Stuart (1995) show that the demand for pharmaceuticals is price inelastic, making it unlikely that the decrease in profit per unit could be made up in larger volumes. Heavy lobbying by pharmaceutical firms against the HSA implies that they expected significant negative effects.

[4]The market model is

$$R_{it} = \alpha_i + \beta_i R_{mt} + \varepsilon_{it},$$

where R_{it} is firm i's daily stock return on day t, R_{mt} is the market return on day t represented by the CRSP value-weighted index, α_i and β_i are ordinary least squares coefficients for firm i, and ε_{it} is the error term for firm i at time t. The coefficients are estimated over the 255 trading days before the event period and used to calculate A_{it}, the risk-adjusted return on a particular day t for firm i, as

$$A_{it} = R_{it} - \hat{\alpha}_i - \hat{\beta}_i R_{mt}.$$

We calculate the compound sum of risk-adjusted daily returns during the event period for each firm, and we weight that sum by each firm's total market value as a proportion of the total market value of all 111 firms. The risk-adjusted portfolio return is the sum of the 111 weighted returns.

TABLE 2

Value-Weighted Cumulative Abnormal Returns for a Portfolio of 111 Pharmaceutical and Biotechnology Companies

Cumulative abnormal returns (CARs) for each of the following events are calculated using the market model with the CRSP value-weighted index return as the market return. CARs cover 11 trading days: 5 trading days before the event, the event day, and 5 trading days after the event. Each of these events was considered to be a potentially important political event that could have made pharmaceutical price controls more likely. HSA-related return, used in the study tests, includes only the CARs for the last four events. These events are most closely linked to the HSA and occurred after Clinton was elected president. The *t*-statistic is based on a time-series standard deviation of the portfolio mean abnormal returns during the market model estimation, as suggested in Brown and Warner (1980) to avoid bias from cross-sectional correlation of returns. *** and * indicate that CARs are significant at the 1% and 10% levels, respectively, in a one-tailed test.

Date of Event	Description of HSA-Related Event	CAR (%)	*t*-Statistic
January 19, 1992	Clinton issues health care reform proposals before New Hampshire primary.	–8.41	–4.49***
February 18, 1992	Clinton unexpectedly finishes second in the New Hampshire primary.	–3.79	–2.02***
March 10, 1992	Clinton does well in the Super Tuesday primaries.	–3.04	–1.62*
April 7, 1992	Clinton wins New York primary and becomes the favorite to win the Democratic nomination.	1.01	0.54
June 4, 1992	Republicans in the House of Representatives offer their health care reform proposal.	–5.10	–2.72***
September 24, 1992	Clinton speaks at Merck on health care reform.	–6.31	–3.37***
November 3, 1992	Clinton wins presidential election.	–0.85	–0.45
January 25, 1993	Clinton names Hillary Clinton to head his Health Care Task Force.	–8.35	–4.45***
February 12, 1993	Clinton says drug prices are too high.	–7.70	–4.10***
September 11, 1993	*New York Times* describes probable regulations based upon a leaked copy of the plan.	0.31	0.17
September 22, 1993	Clinton officially announces his health care reform plan.	–3.27	–1.74*
	Total for the 11 events.	–45.50	–5.19***
	Total for the 4 events in 1993.	–19.01	–8.14***

The event period starts on January 10, 1992, 5 trading days before Clinton first announced his health care reform plan. We include 5 days before the announcement because there is often leakage of news before a formal announcement, especially with regard to political proposals. The event period ends on September 29, 1993, 5 trading days after Clinton publicly announced the specific health plan to be sent to Congress.

Table 2 reports 11-day value-weighted CARs, covering 5 days before and 5 days after for each of the 11 major events. The sum of the CARs over the 11 events is −45.50%, significant at the 1% level after accounting for cross-sectional correlation. In most cases, Ellison and Mullin (2001) report smaller magnitude CARs around these events (their Table II). The difference is due to our wider window around the events and our sample, which includes many high R&D-intensive firms that we show suffered larger price declines.

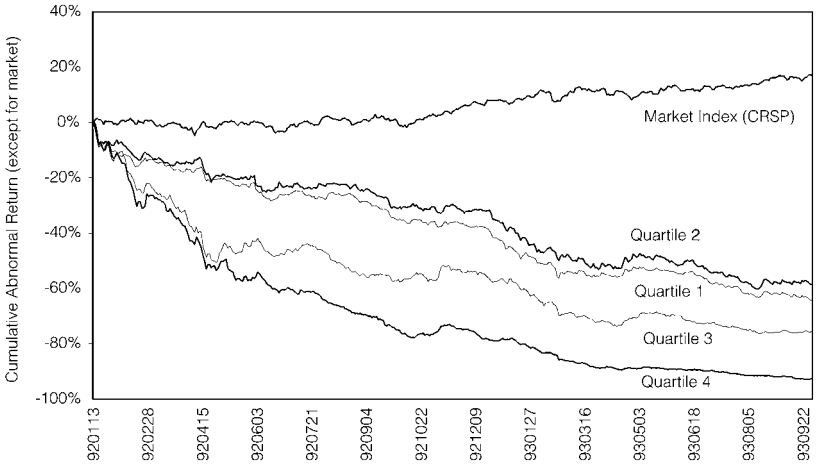
To illustrate this point, Figure 1 plots value-weighted CARs for the 111 firms stratified by RDTA into quartiles. Quartiles 1 and 3 are plotted with thin lines, and quartiles 2 and 4 with thick lines. Graph A of Figure 1 shows that quartiles 1 and 2 experience similar CARs over the period. Quartiles 3 and 4 start out similar but diverge somewhat later on. This is consistent with the averages in Table 1, which show that these quartile pairs are comprised of firms with some similar characteristics. Graph B shows that all of the quartiles rallied briefly after the HSA lost political support in late 1993, but losses continued for quartiles 3 and 4 at least into June of 1995.

FIGURE 1

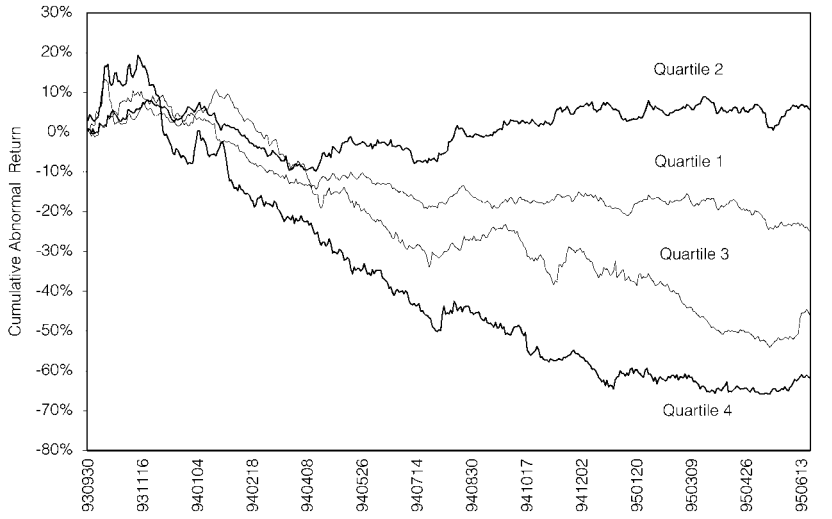
Cumulative Abnormal Returns during the HSA Event Period and Afterward

Graph A of Figure 1 plots value-weighted cumulative abnormal returns (CARs) during the HSA event period from January 13, 1992 to September 29, 1993 for 111 pharmaceutical and biotechnology stocks sorted into quartiles by R&D-to-assets. Market index cumulative returns are actual unadjusted returns. Graph B plots abnormal returns for the same sample for an equal length period (September 30, 1993–June 20, 1995) following the HSA event period.

Graph A. CARs during the HSA Event Period



Graph B. CARs after the HSA Event Period



By the end of the event period, CARs in quartiles 1 through 4 are −64.31%, −58.49%, −75.51%, and −92.63%, respectively. Except for the fact that quartile 2 CARs slightly exceed quartile 1 CARs, higher R&D intensity is associated with lower CARs across the quartiles. One reason why quartile 2 CARs could exceed quartile 1 CARs is that quartile 2 firms experienced an average beta increase of 0.09 compared to 0.15 for quartile 1. The larger beta change could indicate that quartile 1 firms' R&D projects were more marginal, and hence their values were

more negatively affected by the HSA. The large negative returns cannot be due to increased betas coupled with a bear market. The thick line for the cumulative total return for the CRSP value-weighted index shows that the market earned about 18% during the event period.[5]

Ellison and Mullin (2001) argue that news about the probability of price control legislation leaked out gradually over the full event period, and they use an isotonic regression method to try to capture the full effects. But using isotonic regression, or the full period CAR in our study, requires one to assume that there were no persistent events unrelated to the HSA during this 434 trading-day period (about 1.75 years). Such confounding events could reduce the validity of our measure of the effects of price controls proposed in the HSA. Indeed, even using the CARs from all 11 events could be problematic because some are not directly tied to pharmaceutical price controls in the HSA.[6]

Fortunately, our empirical tests do not require an accurate measure of the full effect of the HSA. We require a reasonable measure of the relative cross-sectional effects of the HSA on our sample of firms. Therefore, we use only the last 4 events, which are more closely tied to the HSA and occur in 1993, after Clinton took office. The first event is the appointment of Hillary Clinton to head the group charged with writing the HSA. She was known to be predisposed to pharmaceutical price constraints. The second event is a speech by Clinton in which he directly stated that pharmaceutical prices were too high. The third event is the *New York Times* story reporting the specific regulations from a leaked preliminary copy of the HSA. The fourth event is the formal release of the plan. The sum of the 4 events' CARs for the full 111 stock portfolio is −19.01%. A particular firm's HSA-related CAR is simply the sum of its CARs for the 4 events.[7]

IV. The HSA's Long-Term Effects

A. Drug Price Inflation

Before we propose and test some specific hypotheses concerning the effects of the HSA on firms' R&D spending, we explain why the HSA represented a substantial long-term industry change. Ellison and Mullin (2001) argue convincingly that the HSA posed a serious threat to the pharmaceutical industry. Indeed, the industry believed that the HSA could be so ruinous that 21 large firms pledged to keep their price increases below consumer inflation starting in 1993 in order to convince Congress that the legislation was not necessary.

[5]The CARs for the 111 firms together are excluded from Figure 1 to make it easier to read. Such a line would plot between quartiles 1 and 2 and end up at a −62% CAR. The total cumulative return of the 111 stock portfolio, unadjusted for risk, ends up with a loss of 32% during the period, clearly poor performance given that the market earned 18% and the portfolio has an average beta greater than 1.

[6]Using CARs measured over all 11 events listed in Table 2 or the full event period in the empirical models produces qualitatively similar results.

[7]Each firm's model parameters are estimated over the 255-day trading period following the end of the event period (September 29, 1993). We do not use the trading period before the events because this would entail using data from 1992, when the other seven events occurred and during which Table 1 shows that firm betas were changing. Using the pre-event period betas gives qualitatively similar results, however.

The large negative pharmaceutical stock returns in 1992–1993 imply that investors also expected the HSA to have substantial effects. Indeed, we argue that the HSA marked a significant and sustained political shift toward monitoring and containing average drug prices. One indirect way to see this is to examine changes in news flows concerning drug price inflation around the HSA. Our search of *The Wall Street Journal* found that average drug price inflation is discussed in only three articles from 1984 until 1992. During the HSA event period of 1992–1993, 12 such articles appeared, and from 1994 through 2005, 42 such articles appeared. Therefore, the 1992–1993 HSA event period can be viewed as a time when the industry and stock investors realized that pharmaceutical pricing would be more politicized if not federally regulated.

The Wall Street Journal articles did not simply report drug price inflation; they typically compared it to general consumer price inflation. A second way to illustrate the HSA's long-term effects is to consider real pharmaceutical price inflation over time. After all, health care prices, and particularly high drug price inflation, were a potent political issue that Clinton leveraged to win the presidency. If the industry's self-imposed price constraints stifled drug inflation in 1993 and the HSA's defeat in 1994 fully removed political pressure on drug pricing, then one should see a decline in real drug price inflation in 1993 and a rebound in 1994.

Figure 2 illustrates the annual rates of real pharmaceutical price inflation from 1985 to 2006. Real pharmaceutical price inflation is measured as 1 plus the annual pharmaceutical inflation rate divided by 1 plus the general consumer price inflation rate (all items price 1982–1984 = 100) minus 1. For comparison, European Union (EU) real pharmaceutical inflation is computed and plotted as well.[8] As described in Vernon (2003), EU countries have different methods of pharmaceutical price regulation, but most set an objective of 0 real price inflation. Indeed, the Clinton administration modeled its HSA price constraints after those of some EU countries.

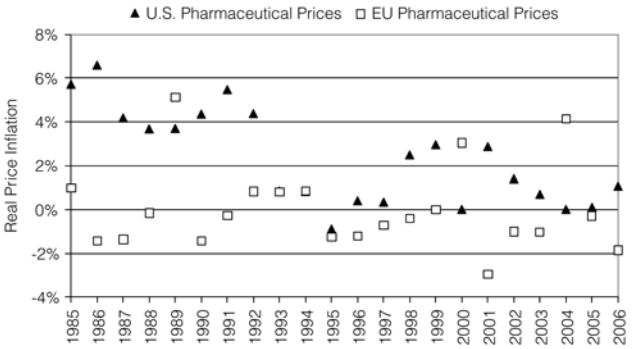
Figure 2 shows that the EU has been effective in limiting average pharmaceutical price inflation to approximately 0 from 1985 to 2006. In contrast, U.S. prices increased at rates well above inflation until 1993, when they dropped sharply. But U.S. real price inflation does not revert to high rates after the HSA's defeat in 1994. In fact, real pharmaceutical price inflation is essentially identical in the U.S. and EU in 1993, 1994, and 1995. Because the bulk of large pharmaceutical firms' sales come from the U.S. and EU, they are clearly aware of pricing practices in both markets. But firms do not change EU pricing in 1993. Real pharmaceutical price inflation in the EU averaged 0.3% both before and after 1993, while in the U.S. it averaged 4.8% before 1993 and 1% afterward (U.S. change is significant at 0.001% level). The U.S. rates start to exceed EU rates somewhat after 1993 but remain subdued compared to pre-1993 rates. Note that the U.S. rate falls back to 0 in the election years of 2000 and 2004. Tessoriero (2004) suggests that this

[8]U.S. pharmaceutical and consumer price index (CPI) (all items price 1982–1984 = 100) indexes are from the Bureau of Labor Statistics (www.bls.gov/cpi/home.htm#data). EU CPI is from Eurostat Harmonized Indices of Consumer Prices (all items) (epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home). The EU pharmaceutical price index is from Eurostat starting in 2001 and compiled from Organisation for Economic Co-Operation and Development (OECD) Health Data 2003 for the years before 2001.

FIGURE 2

Annual Real Pharmaceutical Price Inflation for the U.S. and EU (European Union) from 1985 to 2006

Figure 2 illustrates that in 1993 there was a sharp drop in real pharmaceutical price inflation in the U.S. but not the EU. Nevertheless, in most years, real U.S. pharmaceutical price inflation exceeded or equaled that of the EU (in 1993 and 1994 they were equal).



reflects the industry's strategy of keeping real inflation low in presidential election years in order to limit political support for drug price controls.

B. Pharmaceutical Stock Price Performance Following the HSA's Defeat

If rejection of the HSA effectively eliminated political pressure to limit drug prices, pharmaceutical stock prices should recover from their short-term HSA-related decline. Graph B of Figure 1 plots the cumulative value-weighted CARs of the stocks in each RDTA quartile over a post-HSA period. Like the HSA event period, it includes 434 trading days, but it starts on September 30, 1993 (the day after the HSA event period ends) and ends on June 20, 1995. The CARs are based on the market model using the CRSP value-weighted index return as the market return. Each firm's model parameters are estimated over the 255 trading days following June 20, 1995.

Figure 1 illustrates an interesting dynamic. As Ellison and Mullin (2001) note, the HSA lost political momentum shortly after it was released. The figure shows that each quartile of stocks rallied as the HSA lost its support, outperforming the market through the beginning of February 1994. But by the time Sen. Bob Dole pronounced the HSA "dead" on March 2, 1994, all of the quartiles had lost their gains.

By the time Congress officially shelved the HSA on July 21, 1994, a clear dichotomy had emerged in the industry. The high R&D intensity quartiles 3 and 4 plunged. Low R&D intensity quartile 1 fell to a lesser extent. But quartile 2, which contains most of the largest brand name firms, started to outperform the market and partially regained its losses. Of course these firms did not fully regain their losses, at least during this post-HSA period.

A full explanation of this dichotomy is beyond the scope of this paper. But high real rates of pharmaceutical price increases became a thing of the past (e.g., Figure 2). Large brand name firms could perhaps fare comparatively well under these conditions through increased advertising to support the value of their

marketed drugs. But generic firms' values depend on price competition with high-price drugs, and biotech firms' values depend on their R&D project values, each of which could fare relatively poorly. If the HSA marked the beginning of implicit pricing limitations, brand names could have become more valuable, while R&D became less valuable. Hence, we will tangentially consider evidence that firms changed their investment behavior with respect to advertising and capital expenditures. The data are limited for advertising expenditures, however, because firms are not required to report them separately from general expenses.

C. The HSA's Effects on the Pharmaceutical R&D Pipeline

Firms must report R&D expenses separately in their financial reports; hence, we rely on these data to test the HSA's effects on R&D in the next section. One weakness of these data is that firms have some flexibility in reporting R&D, subject to auditor review. Firms could have understated R&D spending when the HSA was proposed in order to pressure politicians to reject it. Analysis of more tangible measures of R&D like the types, costs, and progress of each firm's individual projects would be preferable. But until the last 10 years or so, comprehensive data on firm-level R&D pharmaceutical projects have been limited. This is particularly true for the small firms that make up the bulk of our sample.[9] Some comprehensive aggregate data are available from the Food and Drug Administration (FDA) and industry organizations, however, and we use it to examine aggregate R&D behavior around the time of the HSA.

The progress of a pharmaceutical R&D project is often described with reference to its stage in the drug development "pipeline." Major stages include chemical development, synthesis, testing on animals, three stages of human clinical trials, and submission of results to the FDA for possible drug marketing approval. In all, the pipeline covers 12 to 15 years on average. Data are relatively scarce at the start of the project pipeline, even for larger firms, because they try to avoid alerting competitors earlier than necessary. Unfortunately, beginning-stage projects could also be most affected by the HSA compared to those in clinical trials, which are difficult to stop once they start. The closer to the end of the pipeline, the smaller the remaining cost until final marketing and the less likely that price constraints would affect the decision to continue the project.

The FDA compiles some aggregate beginning-stage data on regulatory filings, but individual firm project data are treated as proprietary and not released. Nevertheless, trends in the FDA's aggregate data should reflect the experience of our sample of firms because our sample includes all of the firms traded on major markets during the period, and their filings likely comprise most of the

[9]For competitive reasons, many firms do not publicly release at least some of their data. Therefore, private data sources, which aggregate data from various public sources, are unlikely to be comprehensive. We contacted the major compilers of pharmaceutical project data including Pharmaprojects, NERAC, Thomson's Investigational Drug Database, Thomson-Derwent, Recombinant Capital, What's in the Pipeline, and NDA Pipeline (now part of Inteleos), and none had comprehensive data for our sample of firms for the early 1990s. Indeed, Manheimer and Anderson (2002) show that the private sources that they examined are incomplete.

commercial filings around the HSA. We will miss some small private firms' filings, but they do not make many filings.[10]

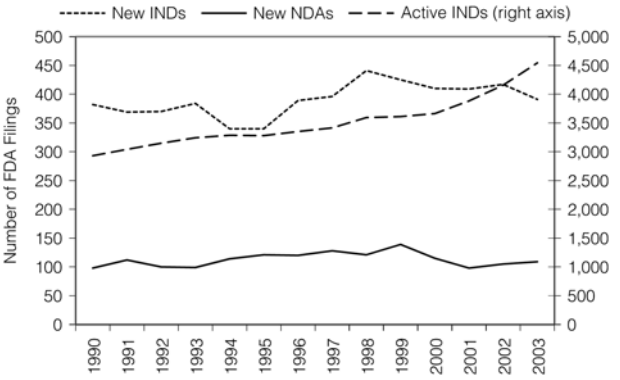
Graph A of Figure 3 shows the aggregate number of investigational new drug (INDs) filings and new drug applications (NDAs) filed at the FDA by year for commercial drugs between 1990 and 2003.[11] An IND is filed at the beginning of human testing and contains a firm's early lab data along with a step-by-step plan for the phases of human clinical trials. An NDA is filed at the end of the trials when a firm requests FDA approval to sell a drug.

FIGURE 3

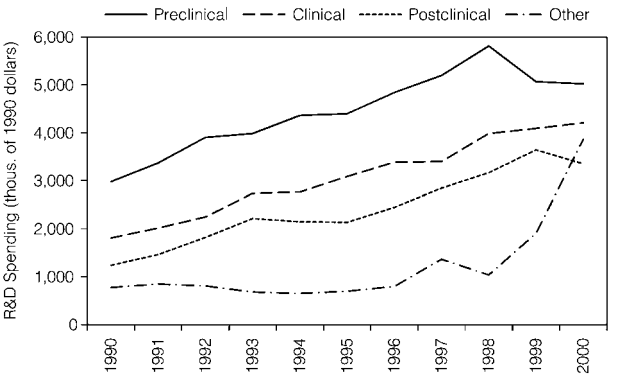
The Number and Progress of R&D Projects for the Years Surrounding the HSA

Graph A of Figure 3 shows the number of FDA filings for all commercial investigational new drugs (INDs) or new drug applications (NDAs), and Graph B shows R&D spending by members of Pharmaceutical Researchers and Manufacturers of America (PhRMA) broken down by development stage.

Graph A. FDA Filings for INDs and NDAs



Graph B. R&D Spending by PhRMA Members



The HSA events occur during 1992–1993, and Congress rejects the HSA in July 1994. Effects on IND filings could lag these events because of budget cycles

[10]We thank Clark Nardinelli at the FDA for this suggestion.

[11]For the number of INDs per year and the number of NDAs per year, see http://www.fda.gov/Drugs/InformationOnDrugs/default.htm

and time between preclinical lab work and IND filing. The figure clearly shows a dip in new INDs filed in 1994 and 1995. The number of active INDs captures the net effects of new filings and withdrawals. INDs can be withdrawn when a drug's development is abandoned. Active INDs grow in each year except for 1995 and increase by only 43 in 1994. This implies that withdrawals were high in 1994 and 1995 because there were over 300 new INDs in those years. Note that INDs rise back to their trend in 1996, but they do not rise above trend to recoup the declines in 1994 and 1995.

DiMasi, Hansen, and Grabowski (2003) show that approximately 6 to 8 years separate an IND and NDA, on average. Hence, drops in INDs in 1994 and 1995 are followed by drops in NDAs in 2000 and 2001. This illustrates how even short-term effects on early-stage projects have long-term effects that ripple through the pipeline over many years.

More detailed evidence of what was happening at various stages of the R&D pipeline is obtained from the Pharmaceutical Researchers and Manufacturers of America (PhRMA). They report R&D spending by their members, broken down into various development stages.[12] Like the FDA, they report aggregate figures and do not divulge individual company information. Because PhRMA includes most large pharmaceutical and biotech firms, its figures probably accurately represent the pattern of aggregate R&D spending by the development stage, although most small firms' spending is excluded.

The PhRMA figures appear in Graph B of Figure 3 and are adjusted for CPI inflation to real 1990 dollars. Note that real total R&D spending grows on average throughout the period. Nevertheless, preclinical spending growth slows in 1993, and this is followed by slower growth in clinical and postclinical spending in 1994 and in postclinical spending in 1995. The pattern is consistent with a 1993 event that caused some firms to cut early-stage spending (before INDs are filed). This effect then carries through to the other stages. A cutback in early-stage spending by some firms is also consistent with the sharp drop in IND filings in 1994. Overall, these figures suggest that the effects of the HSA on firm-level R&D spending could be spread across 1993, 1994, and 1995.

Although the largest HSA effects show up in the total filings of INDs, some effects could show up in the NDA data if firms expect some marginal drugs to be unprofitable at constrained prices. Starting with 1993, the FDA has compiled the number of NDAs that firms submit to the FDA but that are not filed for detailed FDA review. The FDA often provides some limited feedback to firms about its submission before it decides whether to file it. Table 3 presents this data. Column 3 shows that about 25% (15%) of NDAs submitted in 1993 (1994) were rejected by the FDA because they were incomplete or because firms withdrew them, significantly more than in any other year. This could indicate that firms cut corners when preparing their NDAs or that they changed their appraisals of the

[12] See the 1990–2000 issues of the PhRMA Annual Profile. Note that in 1999, PhRMA redefined the "Other" R&D category, apparently accounting for the increase in that category and the drop in the preclinical category. In 2001, it completely revised how it reports the various R&D categories; hence, figures after 2000 are not comparable and are excluded from Figure 3.

value of some drugs and withdrew them from FDA consideration. Withdrawals allow firms that have paid FDA filing fees to obtain at least partial refunds.

TABLE 3

Number of Drug-Related Submissions to the FDA for End-of-Pipeline or Post-Approval Regulatory Reviews by Year

New drug applications (NDAs) are submissions of clinical data for FDA review and possible approval for sale of a new drug. NDA supplements are submissions of new clinical data to support a new or expanded use of an already approved drug. Manufacturing supplements are supplements to original or supplemental NDAs that describe proposed changes to a drug's manufacturing process, typically to improve the cost efficiency of the process. Drug marketing launch reviews are reviews of new marketing and promotional materials for approved drugs. Each approved drug may have multiple marketing campaigns during its life, with different marketing campaigns for physicians and consumers. Similarly, each approved drug may have multiple changes in its manufacturing process. The FDA will refuse to consider an NDA, supplemental NDA, or manufacturing supplement submission if it is incomplete, if the sponsor withdraws it before the review process starts, or if the sponsor fails to pay the filing fees. The decision to consider a submission must be made within 60 days after the sponsor delivers the submission to the FDA. The FDA sets new filing fees each year. NDA fees are always twice as much as supplemental NDA and manufacturing supplement fees. During 1993–2000, NDA fees averaged about $240,000 ($120,000 for supplemental NDAs and manufacturing supplementals). There are no fees for marketing launch reviews.

	NDAs			NDA Supplements			Manufacturing Supplements			Drug Marketing
Year	No. of Subm.	Incompl. or Withdrawn	Refused for Failure to Pay Filing Fees	No. of Subm.	Incompl. or Withdrawn	Refused for Failure to Pay Filing Fees	No. of Subm.	Incompl. or Withdrawn	Refused for Failure to Pay Filing Fees	Campaign Launch Reviews
1993	116	29	3	97	4	1	1,059	14	0	159
1994	127	19	16	106	6	14	884	11	2	221
1995	140	6	23	94	4	13	1,285	34	2	417
1996	123	5	9	117	3	9	1,238	20	0	558
1997	128	2	5	158	2	10	1,267	5	0	539
1998	132	8	10	140	5	8	1,477	11	3	399
1999	136	6	4	153	8	8	1,480	20	1	350
2000	133	7	5	196	7	14	1,466	23	5	276

The FDA does not report separate figures of incomplete submissions and withdrawn submissions; however, they do report the number of complete submissions that they refuse to consider because firms fail to pay filing fees. Those fees averaged about $240,000 during the period. Column 4 shows that about 13% (16%) of NDAs submitted in 1994 (1995) were rejected by the FDA because firms failed to pay their fees, significantly more than in other years. This could indicate that in 1994 and 1995, firms reassessed their projects and found more for which it was not worth paying the filing fee.

Columns 5, 6, and 7 contain similar data for NDA supplements. NDA supplements are submissions of new clinical data to support a new or expanded use of an already approved drug; hence, firms typically spend much less compiling data for supplemental NDAs. Furthermore, filing fees are halved, averaging $120,000 during the period. Column 6 shows that the numbers of rejected or withdrawn supplement NDAs were not unusually large in 1993 or 1994, although the proportion failing to pay filing fees was larger in 1994 and 1995. Firms did not change their assessments of drugs covered by supplemental NDAs to the same degree as those covered by first-time NDAs, perhaps because more supplemental drugs remained profitable even under the expected price constraints. Nevertheless, it appears that some marginal supplemental drugs were reassessed as not worth paying the fees for.

Columns 8, 9, and 10 contain similar data for manufacturing supplements. These are supplements to original or supplemental NDAs that propose changes to

a drug's manufacturing process, typically to improve production cost efficiency. Except for a slight increase in 1995, a very small proportion of these are rejected as incomplete or withdrawn, and almost none are rejected because firms fail to pay filing fees (average of $120,000). Because manufacturing supplements cover drugs already being profitably sold, expected price constraints could have less impact on firms' decisions to improve their manufacturing processes.

Column 11 in Table 3 shows the number of new marketing campaigns reviewed by the FDA. These are reviews of new marketing and promotional materials for approved drugs. Each drug may have multiple new campaigns during its life cycle, including different campaigns for physicians and consumers. The number of new campaigns increases significantly from 1993 through 1996, particularly in 1995. Firms appear to have put more resources into marketing already approved drugs during this time.

Finally, we were able to obtain one measure of preclinical activity available for all firms in our sample: patent applications filed at the United States Patent and Trademark Office (USPTO). We searched the USPTO Web site for the number of patents filed by each firm in each year from 1990 to 1997. Table 4 reports the number of patents filed each year for the full sample and for each R&D-intensity quartile. For the full sample, patent activity increases in 1994 (27%) and 1995 (62%), and the increases are significant at least at the 3% level. Note that patent activity increases proportionately more for higher R&D intensity quartiles, with the lowest R&D intensity quartile (quartile 1) exhibiting relatively small increases. The 1994 (1995) patent change for quartile 1 is significant at only the 9% level (insignificant), while the other quartiles exhibit patent changes in 1994 or 1995 (or both) that are significant at the 3% level or better.

TABLE 4

Numbers of Patent Applications Filed for the Full Sample of Firms and for Each R&D-Intensity Quartile of Firms for Each Year from 1990 to 1997

The number of patent applications filed by sample firms in each year is obtained by searching the United States Patent and Trademark Office Web site (http://patft.uspto.gov/netahtml/PTO/search-adv.htm). The number of patents filed is summed across firms each year for the full sample of 111 firms as well as across firms in each R&D-intensity quartile.

	Year of Patent Application							
Sample	1990	1991	1992	1993	1994	1995	1996	1997
Quartile 1	289	246	276	277	324	367	258	407
Quartile 2	1,035	1,021	1,151	1,167	1,465	2,367	1,475	1,997
Quartile 3	50	56	53	90	135	342	77	112
Quartile 4	25	28	37	66	112	227	87	81
Full sample	1,399	1,351	1,517	1,600	2,036	3,303	1,897	2,597

One interpretation of the patent figures is that firms could have directed relatively more effort and resources into patenting and relatively less into clinical trials in 1994 and 1995 in response to the HSA (Figure 3 shows fewer new INDs in these years). This behavior is consistent with Schwartz (2004), who characterizes pharmaceutical patents as real options. A substantial portion of patent option value is the right to abandon drug development relatively early in the face of catastrophic events such as price regulation. Patents are relatively inexpensive to file (between $5,000 and $10,000 in legal costs) and are flexible indicators of firms'

research activity. Firms that cut back on clinical trials could use patents to assure their investors that they continue to make progress elsewhere.[13]

Overall, the FDA and PhRMA data depict an industry reallocating resources to develop new uses and marketing for already approved drugs. Firms started fewer clinical trials around the time of the HSA (fewer INDs filed in 1994 and 1995 and reduced clinical R&D spending), perhaps because trials are the most costly part of the drug development pipeline. In a price-constrained environment, cheaper-to-develop supplemental new drugs and improved manufacturing could be more economical. Quartile 3 and 4 firms have few already approved drugs; hence, redirecting resources to them is a less available option. Instead, these firms appear to have increased patent activity, which could help convince investors that they are creating potentially valuable new drugs without spending heavily on clinical trials.

V. Testing for Expected Effects of the HSA on R&D Spending

In this section, we study firm-level R&D spending data, which are available for all the firms in our sample. R&D spending can be modeled to provide a measure of a firm's expected and unexpected annual spending. This is difficult to do for the number of projects or for project staging, even if complete project-level data were available. A measure of unexpected R&D is required to test if firms changed their behavior due to the HSA, because total R&D spending increased for each quartile during the period, although the rate of growth declined around the time of the HSA.

Firms in the pharmaceutical industry are traditionally characterized as generic, brand name, or biotech. This study, however, characterizes firms by how intensively they invest in R&D and the leverage of the R&D. The greater a firm's R&D intensity and leverage, the greater the impact of the HSA on firm value and stock price. To see this, let firm value be V and the net present value of future firm cash flows under (no) price controls be (V_N) V_H. If the probability of price controls is p, then the value of the firm is

$$V = pV_H + (1-p)V_N. \tag{1}$$

Firms developing breakthrough drugs will invest heavily in R&D and have $V_H < V_N$ (i.e., expected future cash flows from breakthrough drugs under price controls will be smaller than under no price controls). News that causes p to increase will reduce the value of the firm, and the greater the difference between V_H and V_N, the greater the reduction in value.[14]

The value of firms in quartiles 3 and 4 are likely to be most affected because most of their sales are expected to come well in the future. Between 1989 and

[13] Lerner et al. (2003) and Hall (2005) provide evidence that firms use patents to satisfy investors or partners, and Hall, Jaffe, and Trajtenberg (2005) find a significant positive relation between patents and firms' market values. An example of a firm reallocating resources from clinical trials to patenting when it raised new capital can be found in Somatix Therapy's 1996 10K report.

[14] We thank the referee for suggesting this line of argument.

1996, quartiles 3 and 4 sales averaged only \$17 and \$5.5 million, respectively (quartiles 1 and 2 averaged \$747 million). The decrease in real drug price inflation compounds over time, so that the values of drugs to be sold far in the future are likely to be more negatively affected than currently marketed products.

A. The Relation between HSA-Related CARs and Firms' R&D Exposures

We will use each firm's four-event CAR (described above) to measure the relative effect of the HSA on its stock price. We do not need to measure the aggregate effect of all 11 events that might have impacted p. Our cross-sectional analysis only requires a measure of the relative effect across firms. This leads to our first hypothesis:

Hypothesis 1. All else being equal, a firm's stock price response to HSA-related news releases will be negatively related to its R&D intensity.

Because a firm's true R&D intensity is not observable, we will use an accounting (historical) variable to capture a firm's R&D intensity. Following Chan et al. (2001), we will construct a proxy by capitalizing a firm's R&D spending over 5 years[15] and then divide that by total assets.

Of course, accounting figures provide a crude measure of a firm's R&D intensity. To obtain supplemental measures of R&D intensity and R&D leverage, we follow the real options literature that describes R&D projects as real options. For example, Garlappi (2004) and Schwartz (2004) model an R&D project as a call option, and Schwartz shows how government regulation can affect its value. The expected HSA effects can be measured by the effects of price limits for future drugs on the expected value and risk of a call option.

For simplicity, assume that the firm's R&D portfolio is a single project, which can be described as a call option. If it chooses to, the firm can spend E dollars on R&D and receive a call option on the production of a new drug. The value of the project under price controls, V_H, is

$$V_H = c(S_H, \sigma_H, X, T, r) - E, \tag{2}$$

and the value of the project under no price controls, V_N, is

$$V_N = c(S_N, \sigma_N, X, T, r) - E, \tag{3}$$

where $c(\cdot)$ is a function defining the value of a call option on a new drug with an expected net present value of future cash flows of $S_j, j = H, N$, a percent volatility for S_j of σ_j, and a fixed investment cost to build a production plant of X at time T in the future. The risk-free rate of return is r.

Drug price constraints will reduce a drug's future cash flows, but not the expected production costs, X (X is equivalent to financial leverage). This will

[15] Their specification for capitalized R&D (CRD) for company i in year t is

$$\mathrm{CRD}_{i,t} = \mathrm{RD}_{i,t} + 0.8\,\mathrm{RD}_{i,t-1} + 0.6\,\mathrm{RD}_{i,t-2} + 0.4\,\mathrm{RD}_{i,t-3} + 0.2\,\mathrm{RD}_{i,t-4},$$

where $\mathrm{RD}_{i,t-i}$ is the R&D expense for year $t - i$, $i = 0$ to 4.

reduce the option's in-the-moneyness $(S-X)$ and hence its value. From Galai and Masulis (1976), $(S-X)$ is negatively related to asset beta (β). A firm composed of mostly at-the-money or out-of-the-money R&D projects should have a relatively large β and be relatively sensitive to price controls. That is, the value of out-of-the-money projects will fall proportionately more, and they are more likely to be abandoned because their values are more likely to fall below E.

On the other hand, option value is positively related to σ_j. Therefore, we expect the stock price response of firms with large pre-event σ_j to be less sensitive to the HSA news and positively related to the event-induced change in volatility, all else being equal.

Although the moneyness, β_j, and σ_j of a firm's R&D options are not observable, the R&D sensitivity can be partly inferred from a firm's pre-event stock β_i and σ_i, as well as their changes during the HSA event period. All else being equal, price regulation is likely to increase a firm's β_i and decrease its σ_i, as is common for price-regulated utilities. Of course, the size of the changes will vary across firms depending upon the sensitivity of the firms' R&D assets to price controls. This leads to the following hypothesis:

Hypothesis 2. All else being equal, the stock price response to HSA-related news events will be negatively (positively) related to a firm's pre-event β_i (σ_i) and the event-induced β_i (σ_i) change.

Hypothesis 2 simply observes that marginal R&D projects, like out-of-the-money options, have larger β_i (are more leveraged), making their values more sensitive to the negative HSA effects. The reverse is true for firms with large σ_i, all else being equal.

Our first empirical model tests Hypotheses 1 and 2 using cross-sectional data measured around the HSA.

$$(4)\quad \mathrm{CAR}_i = b_0 + b_1(\mathrm{CRDTA}_i) + b_2(\beta_i) + b_3(\Delta\beta_i) + b_4(\sigma_i) + b_5(\Delta\sigma_i) + \varepsilon_i.$$

CAR_i measures firm i's stock market value reaction to surprise announcements associated with the HSA. Following Chan et al. (2001), R&D intensity (CRDTA_i) is the capitalized value of firm i's R&D spending divided by its total assets. β_i and σ_i are firm i's beta and return volatility, respectively, measured before the HSA. $\Delta\beta_i$ and $\Delta\sigma_i$ are changes in these variables during the HSA event period. Hypothesis 1 implies $b_i < 0$. Hypothesis 2 implies $b_2 < 0$, $b_3 < 0$, $b_4 > 0$, and $b_5 > 0$.

We also control for some potentially confounding issues by adding 2 variables to model (4). First, cross-sectional variation in firms' financing constraints could account for variation in CAR. We measure financial constraints with the "KZ" index developed by Kaplan and Zingales (1997) and implemented in Lamont, Polk, and Saa-Requejo (2001), which depends upon cash, cash flow, debt, dividends, and Tobin's q. Second, some brand name drug firms voluntarily constrained their price increases prior to the HSA. The HSA passage could have forced them to make their pledge more permanent than the market expected. In this case, CAR and a binary variable identifying price-constrained firms should be negatively related. Alternatively, because the firms constrained prices before the HSA events, the effect of those events on them could be diluted.

Table 5 reports the results for tests of Hypotheses 1 and 2 using empirical model (4). The first regression shows that CARs and CRDTA are significantly negatively related. This supports Hypothesis 1 as well as Figure 1, which showed that the more R&D-intensive firms experienced larger negative HSA-related CARs.

TABLE 5

Regression Estimates for the Cross-Sectional Relation between Sample Firms' HSA-Related Returns and their R&D Asset Intensity and R&D Leverage

The basic regression is

$$(4) \qquad CAR_i = b_0 + b_1(CRDTA_i) + b_2(\beta_i) + b_3(\Delta\beta_i) + b_4(\sigma_i) + b_5(\Delta\sigma_i) + \varepsilon_i.$$

HSA-related stock return for firm i (CAR) is the firm's cumulative abnormal return for the four 1993 HSA-related events listed in Table 2. The sample includes 111 brand name pharmaceutical, generic, and biotech firms. Capitalized R&D assets (CRDTA) are measured by capitalized R&D spending over the 5 years preceding 1993, divided by total assets at year-end 1992. Beta (β_i) and return volatility (σ_i) are measured for each sample firm i over the pre-event period (April 24, 1990–January 10, 1992). Beta change ($\Delta\beta_i$) and return volatility change ($\Delta\sigma_i$) are measured as differences for firm betas or return volatilities between the event period (January 13, 1992–September 29, 1993) and the pre-event period. The event period consists of 434 trading days starting 5 trading days before the first HSA-related event (see Table 2) and ends 5 trading days after the last HSA-related event. The pre-event period consists of the 434 trading days preceding the event period. Extended versions of the model include financial constraint effects and a variable to identify firms that voluntarily constrained their drug prices. Financial constraint is measured with the KZ index. Price constraint dummy$_i$ (PCD) variable equals 1 if firm i pledged to keep its price increases below the inflation rate and equals 0 otherwise. Regressions are estimated using ordinary least squares with t-statistics based on White's (1980) heteroskedasticity-consistent standard errors in parentheses. ***, **, and * denote estimate significance at the 1%, 5%, and 10% levels, respectively, in a two-tailed test.

Intercept	CRDTA	β	$\Delta\beta$	σ	$\Delta\sigma$	KZ	PCD	R^2	F-Stat.
–0.01	–0.13**	–0.20***	–0.12**	7.22*	3.15			0.19	4.78***
(–0.11)	(–2.44)	(–2.75)	(–2.57)	(1.95)	(0.83)				
0.01	–0.13**	–0.21***	–0.13**	7.11*	3.00	0.01		0.19	4.00***
(0.09)	(–2.35)	(–2.70)	(–2.81)	(1.85)	(0.78)	(0.56)			
–0.02	–0.13**	–0.21***	–0.13***	7.61*	3.33	0.01	0.04	0.19	3.42***
(–0.21)	(–2.25)	(–2.71)	(–2.81)	(1.83)	(0.77)	(0.48)	(0.58)		

The first regression also shows that both β_i and $\Delta\beta_i$ are significantly negatively related to CAR as predicted by Hypothesis 2. Assuming that β_i and $\Delta\beta_i$ measure R&D leverage, this means that firms with more marginal R&D assets experienced larger negative HSA-related returns. For example, the first and fourth RDTA quartile firms have average betas of 0.99 and 1.49, respectively. The -0.20 estimate on β_i implies that quartile 4 firms' stocks declined by 10% more than quartile 1 firms' stocks on average, all else being equal. The negative relation between CAR and $\Delta\beta_i$ helps to explain why quartile 1 firms suffered somewhat larger losses on average than quartile 2 firms. Quartile 1 firms had larger $\Delta\beta_i$ on average.

Also consistent with Hypothesis 2, CAR and σ_i and $\Delta\sigma_i$ are positively related, although only the relation between CAR and σ_i is statistically significant. Given that first and fourth RDTA quartile firms have average σ_i of 0.035 and 0.051, respectively, the 7.22 estimate on σ_i implies that quartile 4 firms' stocks declined by about 12% less than quartile 1 firms' stock on average, all else being equal. These results imply that the stock price of a firm with a 1.49 beta and a 0.035 volatility would decline by about 22% more than a stock with a 0.99 beta and a 0.051 volatility, all else being equal.

The third regression includes the KZ index measure of financial constraints. The estimate on KZ is statistically insignificant. Furthermore, none of the other

estimates change much. This means that none of the other variables in the regression is picking up the effects of financial constraints as opposed to R&D leverage.

Finally, the last regression includes a variable to test whether firms that pledged to keep price increases low experienced relatively low CARs. Twenty-one established firms pledged by mid-1993 to keep their drug price increases below the general consumer price inflation. Of the 21 firms listed in Ellison and Wolfram (2001), 10 are part of our sample.[16] The estimate on the price constraint dummy (PCD_i) variable is not statistically significant; hence, these firms did not suffer greater losses than the others, all else being equal.

B. The Relation between Firms' Subsequent R&D Spending and the HSA Price Threats

Model (4) establishes the drivers of firms' stock price reactions to the HSA. Our next model tests whether firm managers reduced their R&D spending in response to the HSA. CAR_i, $\Delta\beta_i$, and $\Delta\sigma_i$ measure the HSA-induced changes facing management. To the extent that these changes imply that the values of some of a firm's R&D projects fall below their expenses, managers should reduce R&D spending from what it would have been otherwise. A large negative CAR_i or positive $\Delta\beta_i$ implies that a firm has more marginal R&D projects, so that managers should cut R&D more. Conversely, a large $\Delta\sigma_i$ implies larger R&D options values, and managers should cut less or increase spending. These arguments lead to:

Hypothesis 3. All else being equal, unexpected R&D spending is positively related to CAR_i and $\Delta\sigma_i$, but negatively related to $\Delta\beta_i$.

Empirical model (5) tests this hypothesis.

$$(5) \qquad URDTA_{i,t+1} = b_0 + b_1(CAR_{i,t}) + b_2(\Delta\beta_{i,t}) + b_3(\Delta\sigma_{i,t}) + \varepsilon_{i,t+1}.$$

Unexpected R&D ($URDTA_i$) is firm i's unexpected R&D spending as a proportion of its total assets. It is a residual from a model that estimates normal or expected R&D spending intensity. Hypothesis 3 implies $b_1 > 0$, $b_2 < 0$, and $b_3 > 0$.

Model (5) calls for a measure of unexpected R&D spending. R&D-to-assets (RDTA) is a standardized measure of actual R&D spending intensity used in earlier studies such as Eberhart et al. (2004) (henceforth, we use RDTA and "R&D spending" interchangeably). We follow earlier studies to model expected and unexpected RDTA.

Because the HSA did not become law, it did not directly reduce firms' product prices, sales, cash flows, etc. Therefore, these accounting variables can be

[16] Our sample includes Abbott Labs, Bristol-Meyers Squibb, Eli Lilly, Glaxo, Johnson & Johnson, Merck, Pfizer, SmithKline Beecham, Warner-Lambert, and Wyeth-Ayerst (American Home Products). The other firms are Ciba-Geigy, Dupont-Merck, G.D. Searle, Genentech, Hoechst-Roussel, Hoffmann-La Roche, Knoll, Marion Merrell Dow, Syntex, Upjon, and Zeneca. These 11 firms do not have the necessary data.

used to estimate a firm's expected RDTA in a particular year in the absence of the HSA. Grabowski (1968), Lichtenberg (2004), and Himmelberg and Petersen (1994) used lagged R&D, contemporaneous or lagged sales, and cash flows. Large firms may rely on sales and cash flows, but Hall (2002) shows that small firms rely on investor financing. As they raise capital in a particular year, their current assets, working capital, and R&D increase in that year. Mikkelson and Partch (2003) document the positive contemporaneous relation between liquidity and R&D expenditures. Guedj and Scharfstein (2004) show that liquidity levels impact biotech firms' decisions about whether to continue developing marginal drugs. Therefore, we use the following model that combines these major drivers of R&D spending:

$$\begin{aligned}(6)\quad \text{RDTA}_{i,t} &= a_0 + a_{i,1}(\text{RDTA}_{i,t-1}) + a_{i,2}(\text{SALES}_{i,t}) \\ &\quad + a_{i,3}(\text{CASH\_FLOW}_{i,t}) + a_{i,4}(\text{CURRENT\_ASSETS}_{i,t}) \\ &\quad + a_{i,5}(\text{WORKING\_CAPITAL}_{i,t}) + \mu_{i,t}.\end{aligned}$$

Unexpected RDTA (URDTA) for each firm i in year t is measured as the error term ($\mu_{i,t}$) from model (6). The purpose of the model is to get an accurate prediction of R&D based on accounting variables but not stock price changes. Sales and cash flow are measures of liquidity flows, and current assets and working capital are measures of a firm's current pool of liquidity. We estimate the regression separately for each firm over the years for which it has annual Compustat data during 1980–2000. Most firms have at least 10 years of data during this period (one firm has 8 and two have 9 years). Only 22 firms have data before 1980, and 25 firms have no data after 2000.

We again account for financial constraints and the brand name drug firms that voluntarily constrained price increases around the HSA. These firms may have cut R&D more than other firms in response to the HSA. Therefore, the KZ index and a variable identifying price-constrained firms are added to model (6) and should be negatively related to URDTA_i. Alternatively, because the firms pledged to constrain their prices before the HSA-related events, the effect on post-HSA R&D could be negligible.

Table 6 reports the regression tests of empirical model (5) for the relations between URDTA and CAR, $\Delta\beta_i$, and $\Delta\sigma_i$. Because CAR is measured in 1993 and managers might not respond immediately by changing current R&D budgets, results are presented for 1993, 1994, and 1995. Section IV showed that the effects may indeed be spread out over one or more of these years.

Results for the first three regressions show that URDTA and CAR are significantly positively related only in 1994. Given that most firms had negative CARs, this implies that they cut their R&D intensity in the year following the HSA-related events. Because the last HSA event occurs late in 1993, one might expect to observe the strongest effect on R&D budgets for the following year. The prediction of a significant negative (positive) relation between CAR and $\Delta\beta_i$ ($\Delta\sigma_i$) is not observed. In fact, the 1993 and 1995 regressions produce some contradictory results (although the F-statistics show that both regressions are quite weak). The negative estimate on CAR in the 1995 regression could indicate that some firms,

TABLE 6

Regression Estimates for the Cross-Sectional Relations between Sample Firms' Unexpected R&D Spending and their HSA-Related Return and R&D Leverage Change

The basic regression is

$$\text{URDTA}_{i,t+1} = b_0 + b_1(\text{CAR}_{i,t}) + b_2(\Delta\beta_{i,t}) + b_3(\Delta\sigma_{i,t}) + \varepsilon_{i,t+1}. \quad (5)$$

Unexpected R&D-to-assets (URDTA) is measured for years 1993–1995 as the residual values from the regression in equation (6) for each firm estimated over the years for which it has annual Compustat data during 1980–2000. All 111 sample firms have at least 8 years of data including 1991–1995. HSA-related stock return for firm i (CAR_i) is the firm's cumulative abnormal return for the four 1993 HSA-related events listed in Table 2. Beta change ($\Delta\beta_i$) and return volatility change ($\Delta\sigma_i$) are measured as differences for firm betas or return volatilities between the event period (January 13, 1992–September 29, 1993) and the pre-event period (April 24, 1990–January 10, 1992). The event period consists of 434 trading days starting 5 trading days before the first HSA-related event and ends 5 trading days after the last HSA-related event. The pre-event period consists of the 434 trading days preceding the event period. Extended versions of the model include financial constraint effects (measured by the KZ index) and a variable to identify firms that voluntarily constrained their drug prices. Price constraint dummy_i (PCD) variable equals 1 if firm i pledged to keep its price increases below the inflation rate, and 0 otherwise. Regressions are estimated using ordinary least squares with t-statistics based on White's (1980) heteroskedasticity-consistent standard errors in parentheses. ***, **, and * denote estimate significance at the 1%, 5%, and 10% levels, respectively, in a two-tailed test.

Sample	Intercept	CAR	$\Delta\beta$	$\Delta\sigma$	KZ	PCD	R^2	F-Stat.
1993	–0.01	0.01	0.05***	–0.49			0.08	3.30**
	(–0.86)	(0.32)	(2.58)	(–0.63)				
1994	0.01	0.13***	0.02	–2.20			0.16	6.64***
	(0.15)	(4.19)	(1.19)	(–1.62)				
1995	0.01	–0.05*	–0.02	1.01			0.05	1.75
	(0.72)	(–1.86)	(–0.82)	(1.46)				
1994	–0.02	0.13***	0.02	–2.77**	0.01		0.19	6.30***
	(–1.05)	(4.46)	(0.94)	(–2.07)	(0.98)			
1994	–0.02	0.13***	0.02	–2.80**	0.01	0.02	0.19	5.03***
	(–1.11)	(4.44)	(0.95)	(–2.06)	(0.99)	(1.07)		

after cutting R&D in 1994, restored some of it in 1995 after the HSA was rejected by Congress in 1994.[17]

The fourth regression in Table 6 includes the KZ index, and the fifth regression includes both the KZ index and the price constraint dummy (PCD) variable to test whether firms' financing constraints or their pledge to constrain price increases affected their R&D spending. Neither KZ nor PCD has a significant effect on firms' unexpected R&D spending. The significant negative estimate on $\Delta\sigma_i$ could reflect manager risk aversion. Managers could respond to an increase in $\Delta\sigma_i$ conservatively, by investing less in risky R&D projects, even though their option values increase with $\Delta\sigma_i$.

The insignificant effect of PCD could be explained by the fact that self-imposed pricing constraints likely reduced these firms' sales, cash flows, etc., from what they would have been. Because model (6) strips the influence of these variables from URDTA, it is not surprising that URDTA and PCD are unrelated. A better regression test of whether self-imposed price constraints affected firms' R&D spending uses ERDTA in place of URDTA, where ERDTA is the predicted value from equation (6). When we reestimate the last regression in Table 5 using

[17] To further support the claim that the significant estimates on CAR imply a response to the HSA events of 1993, we also ran the models in Table 6 for 1992 and 1996, a year before and a year after the 1993–1995 period that we think could be affected. Neither is significant. For the regression using 1992 (1996) URDTA, the estimate on CAR is 0.008 (−0.008) with a t-statistic of 0.30 (−0.25).

ERDTA as the dependent variable, the estimate on PCD equals −0.239 (*t*-stat. = 6.61). If we use ERDTA measured in 1993 or 1995, the estimates are −0.190 (*t*-stat. = 4.44) and −0.189 (*t*-stat. = 4.65), respectively. All of these estimates are highly significant, and the differences between the 1994 estimate and the other two are also significant. This is consistent with Ellison and Wolfram (2001), who show that the firms' self-imposed price restrictions were most evident in their 1994 drug prices.

Finally, we estimate the magnitude of the effect that the HSA had on firm R&D. The average firm experienced a −17.81% HSA-related return. Given the 1994 estimate of 0.13 for the relation between URDTA and CAR, the average firm decreased its RDTA by about 0.023 below its expected level. With the average RDTA of about 0.30 in 1994, this is about a 7.7% decline, or about $738 million ($1.48 billion) in 1983 (2004) dollars. If we account for the reversal of some of this effect using the 1995 regression estimate of −0.05, the net effect is about $1 billion in 2004 dollars. This probably underestimates the effect because it excludes the effects of self-imposed price constraints.

C. The HSA Effects on Capital Expenditures and Advertising

The HSA apparently affected firms' R&D spending decisions. Spending on related items could also be affected if the items are complements or substitutes for R&D. Two relevant items are capital expenditure and advertising. We reran the regressions in Table 6 using unexpected capital expenditure intensity (UCAPEXTA) and unexpected advertising intensity (UADVTA) in place of URDTA. UCAPEXTA and UADVTA were estimated using the same approach as URDTA. Given the limited statistical significance or sample sizes for these regressions, we only summarize the results here.

All of the sample firms report capital expenditure in each year, so the regression sample size is 111 firms. After reestimating the regressions in Table 6, we find that none of the estimates of the relations between UCAPEXTA and CAR is statistically significant at conventional levels, although all of the point estimates are positive.

Unlike capital expenditure (CAPEX) and R&D, firms are not required to report advertising as a separate item; consequently, only 51 sample firms report advertising expense. We again reestimated the regressions in Table 6 and find that none of the estimates of the relations between UCAPEXTA and CAR is statistically significant at conventional levels, although the point estimates are negative.

Taken together, the results for UCAPEXTA and UADVTA indicate that firms did not respond to the HSA by changing capital expenditure or advertising in the same way they did for R&D. This strategy makes sense, because capital expenditure and advertising mostly support currently marketed drugs whose prices are already set, while R&D supports future drugs whose prices could be constrained.

VI. Conclusion

Recent research shows that R&D spending creates R&D assets that investors impound into stock prices. This study considers whether an increased likelihood of price regulation reduced R&D asset values (and stock prices), leading to reduced R&D spending. We use the Clinton administration's Health Security Act (HSA) as a natural experiment to test this proposition and show that pharmaceutical firms cut their R&D spending by about $1 billion (in 2004 dollars) in response to the HSA price controls.

The HSA's main provision was a cap on new drug prices. As a way to limit political support for the HSA, the major pharmaceutical firms agreed to keep drug price inflation low. Indeed, we show that real drug price inflation fell sharply in 1993 and remained relatively low afterward. We also find evidence of negative changes in firms' drug research pipelines in the years 1993–1995. Conversely, the number of new marketing campaigns and drug patent filings rose sharply in those years.

Events leading up to the formal presentation of the HSA to Congress in late 1993 could be traced as far back as the Democratic primaries in early 1992. We show that pharmaceutical company stocks sustained significant price declines from then until late 1993. The average firm experienced a −38% return during the period (−62% risk-adjusted), while the market index earned 18%. But relatively R&D-intensive firms suffered much larger losses on average. After the HSA was defeated in Congress, the industry as a whole rallied for a few months, but soon after, the R&D-intensive firms again suffered large stock price losses. Only brand name firms enjoyed risk-adjusted gains, perhaps because brand name capital became more valuable compared to R&D capital.

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