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FINANCIAL RISK IN THE BIOTECHNOLOGY INDUSTRY

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ABSTRACT

The biotechnology industry has been an engine of innovation for the U.S. healthcare system and, more generally, the U.S. economy. It is by far the most research intensive industry in the U.S. In our analyses in the current paper, for example, we find that, over the past 25 years, average R&D intensity (R&D spending to total firm assets) for this industry was 38 percent. Consider that over this same period average R&D intensity for all industries was only about 3 percent.

In the current paper we examine this industry along a number of dimensions and estimate its average financial risk. Specifically, we use Compustat and Center for Research in Securities Prices (CRSP) data from 1982 to 2005 for firms defined by the North American Industry Classification System (NAICS) as biotechnology firms to estimate several Fama-French three factor return models. The finance literature has established this model as the gold standard. Single factor models like the Capital Asset Pricing Model (CAPM) do not capture all of the types of systematic risk that influence firm cost of capital. In particular, the CAPM does not reflect the empirical evidence that supports both a size-related and a book-to-market related systematic risk factor . Both of these factors, based on biotech industry characteristics, will exert a greater influence on biotech firms, on average. Another implication is, of course, that cost of capital estimates for the industry will be underestimated when a single factor model, like the CAPM, is used. This also implies that the cost estimates of bringing a new drug and/or biologic to market will be understated if financial risk and cost of capital are measured using a single-factor model.

In the current study we find that biotechnology firms are exposed to greater financial risk than other industries and are also more sensitive to policy shocks that affect, or could affect, industry profitability. Average nominal costs of capital over the 1982-2005 time period were 16.25 percent for biotechnology firms. Of course, these average estimates obscure significant variation in financial risk at the firm level, but nonetheless shed light on some interesting aggregate differences in risk. In the current paper we discuss the theoretical links between financial risk, stock prices and returns, and R&D spending. Several caveats are also discussed.

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I. Introduction

Most debates in the United States over the cost of drug development, industry profits, or current drug prices will, at one point or another, mention the risk associated with pharmaceutical research and development (R&D). Most people interpret this to mean the likelihood a potential drug will successfully advance through all the stages of development: discovery, clinical development (phases I through III), and then ultimately gain FDA approval for marketing. By some estimates, only 1 out of every 10,000 investigational new drugs (INDs), which are new molecules at the earliest stages of drug research, ever make it to the market. This type of risk is referred to as technical risk and, for pharmaceuticals, has often been compared to drilling for oil (i.e., "wildcatting") because there are many "dry holes" and only a few "gushers."

This type of risk, which is also referred to as idiosyncratic or unique risk, is not the type of risk investors typically focus on when they discuss risk in the pharmaceutical and biotechnology industries. This is because technical risk can be eliminated through diversification; specifically, it can be completely eliminated by holding a stock portfolio that mimics the stock market as a whole—the so-called market portfolio. Therefore, the type of risk investors, i.e. firm owners, care about is the risk they cannot diversify away; this is called financial, or systematic, risk. This type of risk plays an important role in firm R&D spending decisions because it, not technical risk, determines the cost of R&D finance to the firm. The higher the cost of R&D finance, the more promising an R&D project must be for it to represent a good investment for the firm's shareholder. In the current paper we study this type of risk within the pharmaceutical and biotechnology industries.

The biotechnology industry (first) and the pharmaceutical industry (second) are the two most research intensive industries in the United States[1]. We analyze and compare the financial characteristics and financial risk of these industries using contemporary models from the finance literature. To date, the relatively young biotechnology industry has not been studied as much as the pharmaceutical industry, at least with respect to financial risk and R&D spending decisions. These two industries have important structural and financial differences; yet they are often lumped together and treated as one in debates and policy formulation. Indeed, while they do share many similarities they also have important differences. For example, most large pharmaceutical companies finance their R&D projects with cash flows generated from existing product sales. Most biotechnology firms, in contrast, have yet to bring a product to market; thus, they must rely on external funding (usually equity financing via the issuance of new shares of stock) to finance their R&D projects (Vernon, 2005). Recognizing the biotech industry's unique challenges and differentiating characteristics is especially important when assessing the impact of new government polices, which we will discuss later in the paper.

To begin, in studying the financial risk associated with the biotechnology industry, the pharmaceutical industry makes a good benchmark for comparison because it is a major competitor-partner to the biotechnology industry and because the next closest industry, in terms of research and development (R&D) spending intensity, is Computer Software. The biotech industry is the most R&D intensive major industry in the U.S., the pharmaceutical industry is next. The average R&D intensity (R&D spending to total firm assets) for the biotechnology and pharmaceutical industries was 38 percent and 25

[1] Admittedly, there are numerous issues underpinning this dichotomous classification; we discuss these in the paper.

percent respectively and computer software is third, at about 50 percent less intensive (based on R&D to total firm assets). Therefore, it makes sense to compare the biotech industry with the pharmaceutical industry, its closest rival and often-times partner. We show that these two industries are similar in many ways; however, the biotechnology industry is populated by smaller firms that spend more intensively on R&D, and for this and other reasons we will discuss, we find empirically they face greater financial risk, have higher R&D capital costs, and are more sensitive to policy shocks that affect expected future profitability—particularly with respect to government regulatory events aimed at constraining prices in the U.S.

The financial health of most biotechnology firms is more fragile because, as previously mentioned, they typically must rely on capital raised in the financial markets to fund their new and ongoing R&D projects. Pharmaceutical companies, in contrast, rely almost exclusively on internally-generated cash flows to fund R&D projects (Grabowski and Vernon, 1987; Vernon, 2003, 2005). The presence of capital market imperfections for R&D finance imparts a cost advantage to internally-generated funds over external debt and equity; thus, even holding constant financial risk and the required rate of return on new equity issues, biotech firms with no cash flows are at a financing disadvantage. This and several other significant factors affecting financial risk will be discussed and analyzed.

Our paper will proceed as follows. Section II will describe the data sample, discuss how firms are classified as pharmaceutical or biotechnology firms, and summarize a number of key financial characteristics and time series trends that distinguish biotechnology firms from their more traditional counterparts in the

pharmaceutical industry. Section III will present empirical estimates and comparisons of financial risk for these industries and discuss the cost of capital implications for firm-level investment in R&D. To do this we employ the well-known Fama-French Three Factor Model (Fama and French, 1993), which is the preferred model in the empirical finance literature. This section will also discuss the financial risk and R&D investment implications of unexpected government regulatory announcements and shocks, i.e., changes in the probability of future regulatory events or polices. A simple framework for R&D project investment decision-making will be presented to illuminate the fundamental links between policy shocks, financial risk, and R&D investment. Section IV will conclude.

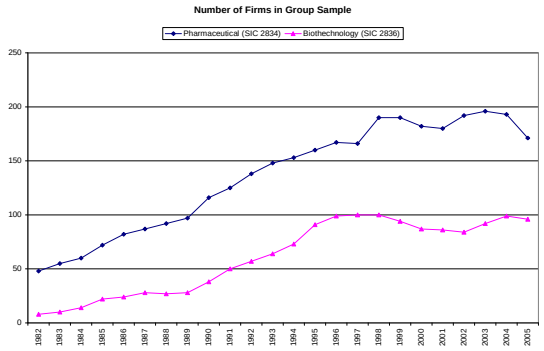
II. Data Sample and Financial Comparisons

To be included in our sample, a firm must be publicly traded and have data available on both Compustat and Center for Research on Securities Prices (CRSP) databases. Compustat contains financial statement data and CRSP contains stock return data, both are necessary for the measures estimated in this study. Therefore, the samples used to estimate all of the measures are consistent across all measures. For the pharmaceutical sample, we select all of the firms that have a Standard Industrial Classification (SIC) code of 2834, as recorded in the Compustat database. Similarly, for the biotechnology sample, we select all of the firms that have a Standard Industrial Classification (SIC) code of 2836.

For each firm in each sample, we match its Compustat data to its available CRSP data. Firms with Compustat data but no CRSP data are excluded. This means that some

small public firms that are not part of either CRSP or Compustat are excluded. This also means that many private firms (usually small) are excluded from the study. Nonetheless, most firms with a significant product under patent, in trials, or FDA approved, go public because they can sell stock to help finance their R&D. Private firms are often not this "advanced." For this reason, we believe that our results accurately represent the financial characteristics and risks of the two industries[2]. If we were able to add private firms to the sample, the most likely effect on the results would be that the average firm size would fall somewhat and the average risk level increase because private firms are typically small and have tighter financial constraints than publicly traded firms. The samples, however, are not static over time. New firms enter the industry, other firms exit, and some firms merge. As figure 1 illustrates, the number of firms in both industries has grown considerably since the early 1980s, with only a few years seeing the number of firms decline.

Figure 1



Note that the starting year is 1982. This is the first year in which there are more than a handful of biotechnology firms (there were 9 firms in 1982). The pharmaceutical industry has about 30 established firms going back further, but to make proper

[2] Personal correspondence: Ted Buckley, Ph.D., Biotechnology Industry Organization (BIO).

comparisons, the biotechnology sample must include a sufficient number of firms. To highlight some of the key differentiating financial characteristics between the two industries, we graph several financial time series. Figures 2 and 3 present average firm assets and average firm sales for both samples.

Figure 2

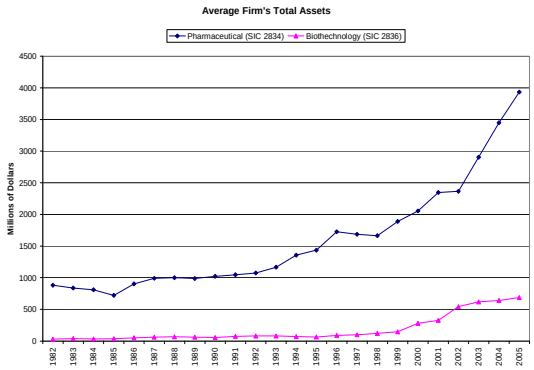
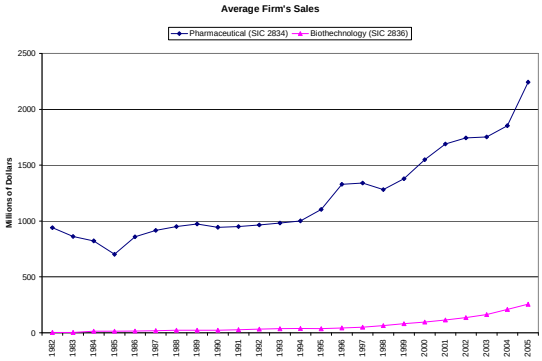


Figure 3



As seen in Figures 2 and 3, average firm total assets and average firm sales for the biotechnology sample are quite small; in fact, for many firms in this group, sales were nonexistent. This is why many biotech firms must rely on external equity markets for financing their R&D. As noted in the first section of the paper, this is in direct contrast to most large, established pharmaceutical firms, which have substantial cash flows and liquidity reserves. The academic finance and economics literatures have shown that internal and external funds in research intensive industries are not perfect substitutes: internal funds have a lower cost of capital relative to external funds when capital market

imperfections exist. This has been found to be particularly true in the pharmaceutical and biotechnology industries. Vernon (2005) discusses the capital market imperfections hypothesis with respect to these industries and provides several key references[3]. The theoretical rationale for these imperfections is grounded on arguments having to do with asymmetric information, transaction costs, principal-agent problems, financial gearing, and other factors. These issues, as will soon be seen, are not unrelated to the analyses undertaken and discussed in the following section of this paper.

Figures 4 and 5 reflect average R&D spending and total industry R&D spending for both samples, respectively. R&D spending has grown steadily overtime with biotechnology firms spending less than pharmaceutical firms.

Figure 4

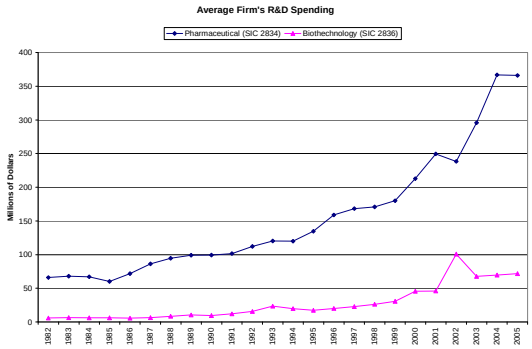
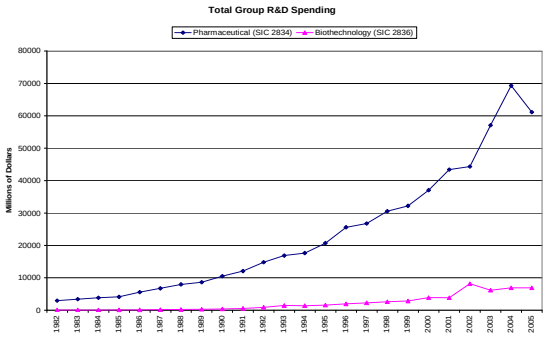


Figure 5

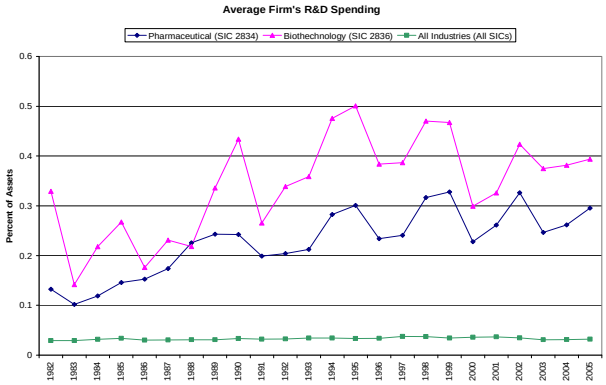


Next, we consider a standardized measure of R&D spending by firms. Figure 6 deflates average R&D spending by total firm assets. We do not standardize by sales because many biotechnology firms have little or no sales; however, they do have assets. A standardized measure is often more revealing because it measures the intensity of a

[3] His paper tests the capital market imperfections hypothesis using a 2SLS instrumental variable estimation procedure for a sample of pharmaceutical and biotechnology firms.

firms behavior, for example R&D spending behavior, while abstracting from the size differences across firms or industries. The standardized measures also control for inflation. Inflation reduces the real value of dollar amounts over time, making comparisons of dollar amounts across time less reliable. The ratio of two dollar amounts eliminates this problem, so the measures compared across time can be interpreted are real changes in firm behavior as opposed to simple dollar inflation. Indeed, much of the recent economics and finance literatures exploring firm investment behavior in these industries use intensity measures in their empirical work (Vernon, 2005; Golec, Hegde, and Vernon, 2006; Giaccotto, Santerre, and Vernon, 2005; and many of the earlier research cited in these recent studies). For comparative reasons, we also include average R&D spending for all industries in Figure 6. This highlights the relatively high research intensity of the biotech and pharmaceutical industries.

Figure 6



Both Biotech and pharmaceutical firms are R&D intensive, and both have become more intensive over time. Biotechnology averages 38 cents in R&D spending for each dollar of assets compared with about 25 cents for pharmaceuticals and 3 cents for all

industries. Note also biotechnology R&D intensity is most volatile, pharmaceuticals are also rather volatile, while all industries is fairly stable. Both the biotechnology and pharmaceutical industries experienced significant drops in R&D intensity around 1991-1993. It was during this time that the Clinton administration was unveiling their proposed Health Security Act, which included a major new regulation of U.S. drug prices through a Council on Breakthrough Drugs—we discuss this later as it serves as a relevant policy shock from which we can analyze and compare its effect on abnormal stock returns and subsequent R&D spending.

Finally, Figures 7 and 8 compare average net incomes in the two industries, in both absolute dollars and deflated by total firm assets.

Figure 7

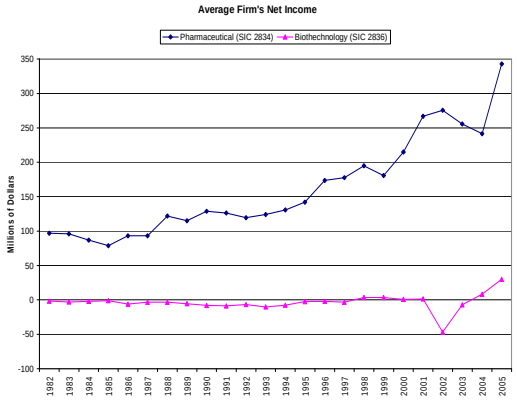
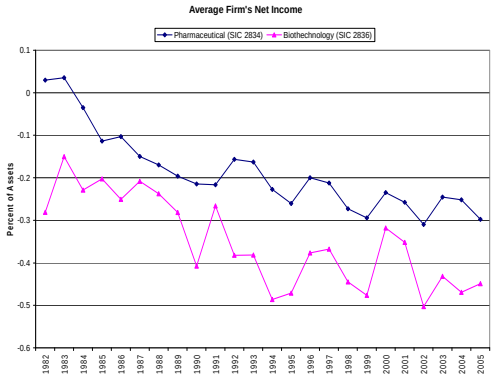


Figure 8



Because sales are sparse for most biotech firms, net income is usually low or negative. Biotechnology firms rely partly on partnerships and milestone payments, often from pharmaceutical companies for income. Our investigation of industry cash flows also reflected these patterns (cash flow equals net income plus depreciation and depletion expenses). How, then, do biotechnology firms survive under these conditions? In brief, they must raise capital in the capital markets—mostly by selling equity. By comparison,

the average pharmaceutical company has been buying back its stock and retiring its debt (hence the negative financing flows we observed in the data).

Given the existence of capital market imperfections and the higher cost of capital associated with external capital relative to internal cash flows, biotechnology firms face greater challenges in financing ongoing and new R&D projects than the average large pharmaceutical firm. As will be shown, this means that biotechnology firms face greater financial risk, and their R&D portfolios will be even more sensitive to exposure to political and regulatory risk, especially with respect to policy shocks affecting the likelihood of such events as price controls or more stringent regulation.

III. Estimates of Financial Risk: Fama-French Three Factor Model

We now turn to the measures of financial risk as reflected in the stock prices and returns of the firms in each sample. The most widely-used finance model of risk and return was developed by Fama and French (1993). The characteristics of the stocks are measured by estimating the following three-factor return model for each stock over its available CRSP stock return data.

$$(R_{it} - R_{ft}) = \alpha_i + \beta_{im}(R_{mt} - R_{ft}) + \beta_{is} SML_t + \beta_{ih} HML_t + \varepsilon_{it}, \qquad (1)$$

where for each trading day t, R_{it} is stock i's return, R_{ft} is the risk-free return, R_{mt} is the CRSP value-weighted stock index return, SML_t is the size factor, and HML_t is the book-to-market factor, α is the alpha, β_m is the beta (market factor loading), β_s is the size factor loading, β_h is the book-to-market factor loading, and ε_t is a residual error term. The

parameters are measured separately for each firm i. and then averaged over the particular sample. The factor data are taken from Kenneth French's (2007) website.

Note that this model measures three sources of systematic risk for each firm. β_m measures a firm's general stock market-related risk (more risk implies firm's return moves closely with the market), β_s measures a firm's size-related risk (smaller firms typically have more risk), and β_h measures a firm's risk due to a stock price premium over equity book value (larger premium, more risk). Unsystematic, or idiosyncratic, risk is measured by the standard deviation of ε_t.

The levels of systematic risks for a firm are important because they determine the firm's cost of capital. All else equal, the larger a firm's factor loadings, the larger its systematic risks and cost of capital. β_m measures a firm's market-related risk. One can think of this as the degree to which a firm's stock returns vary with the return of the general stock market. The general stock market return is driven by general economic conditions such as growth in gross national product, hence, β_m measures how sensitive a firm's business is to the general economy.

β_s measures a firm's size-related risk. This is the degree to which a firm's stock returns vary with the difference in returns between a portfolio of small stocks and large stocks. This is thought to measure risk typically faced by small companies. But note that not all small (large) companies will have a large (small) β_s. Some large companies may actually have some of the financial characteristics of small companies. For example, small companies often have high growth rates and this could be one reason they are risky. Occasionally, a large firm will grow fast too, so it may have a large β_s.

β_h measures a firm's book-to-market-related risk. This is the degree to which a firm's stock returns vary with the difference in returns between a portfolio of high book-to-market ratios and low book-to-market ratios. The book-to-market ratio is the ratio of a firm's book value of equity to stock market value of equity. This is thought to measure financial distress risk. A high book-to-market ratio implies that although the firm has significant common equity listed in its financial statements, the stock market value of the equity is relatively low. This is a signal that stock market investors believe the firm's assets have little value, and the firm has a greater probability of experiencing financial distress.

Tables 1 reports results from our estimation of the Fama and French three-factor model for the pharmaceutical and biotechnology firms in our two samples. For comparison, we list the statistics for the risk factor loadings for all industries, the computer industry, and the automobile industry as estimated by Fama and French (1997) in their analysis of costs of capital for 48 different industries. Note that Fama and French's data covered an earlier period of time (1963-1994) and used wider definitions of industries than our definitions for pharmaceuticals and biotechnology. Nevertheless, their estimates offer reasonable benchmarks with which to compare our estimates.

Table 1: Average Risk Measure Using the Fama and French Three Factor Model

Sample	**Average Risk Measures for Sample Firms**				
	Total Return Volatility	**Market Related β_m**	**Size-Related β_s**	**Price-Book-Related β_h**	**Residual Return Volatility**
All Industries (Fama & French,1997)	-	1.04	0.39	0.02	-
Computers (Fama & French,1997)	-	0.90	0.17	-0.49	-
Automobiles (Fama & French,1997)	-	1.10	0.17	0.60	-

Pharmaceutical	0.1807	0.92	0.80	0.02	0.0472
Biotechnology	0.2129	1.06	1.13	-0.10	0.0549

On average, as the results in Table 1 show, biotechnology firms are riskier than pharmaceutical firms on all measures. For example, the size-related factor loadings differ (0.80 vs. 1.13) because biotech firms are smaller, on average, than pharmaceutical firms. This implies that biotech firms should have to pay a 1.3 percent higher cost of equity capital than pharmaceutical firms, holding everything else constant. When all factors are considered simultaneously and using average factor values from the entire 1927-2005 time period, the nominal cost of capital for the average pharmaceutical firms is 14.5 percent compared to 16.25 percent for biotech companies. These reflect industry averages, but individual firms within each industry will have significantly different costs of capital.

Note that both the pharmaceutical and biotechnology industries have considerably more size-related risk than the average of all industries, the computer industry, and the automobile industry. Conversely, the automobile industry has a larger price-to-book factor loading, making them more risky on that dimension. Therefore, the cost of capital for the average computer firm is only about 9.18 percent, while for the average automobile firm it is 16.10 percent. For the average firm across all industries, the cost of capital is 14.05 percent. If we had data on private biotechnology firms, adding them to our biotechnology sample would likely increase average cost of capital for the

biotechnology sample because private firms are typically small and they would have large size risk (β_s).

Effects of Clinton's Health Security Act (HSA) on Biotechnology Firms Compared to Pharmaceutical Firms

We have shown that the theoretical risk measures for biotechnology firms are larger than for pharmaceutical firms. Now we test to see if, when a risk appears, biotechnology firm stock valuations (reflecting their underlying intangible assets' values) suffer even more than pharmaceutical stock prices. Data necessary to estimate individual firm's factor risks in the factor model come from 1991 and the abnormal returns illustrated, which are returns after adjusting for firm risk levels, come from the 1992-1993 period. Figures 9 and 10 below show the returns for the portfolios of pharmaceutical and biotechnology stocks; hence, they illustrate the return one would have earned during the period if one held an equally-weighted portfolio of either the two portfolios of firms' stocks.

Figure 9

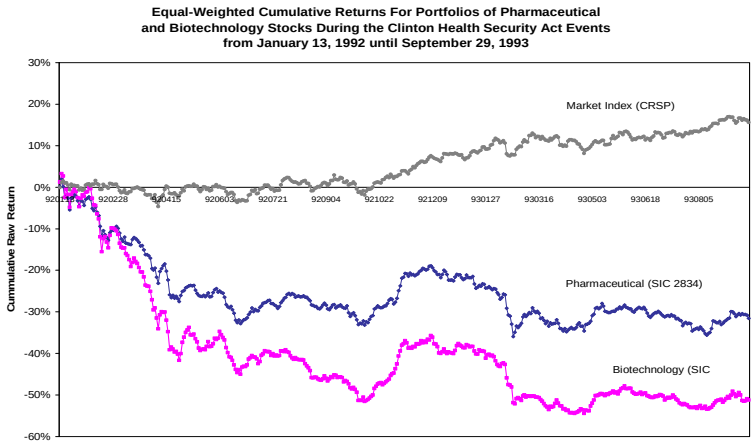
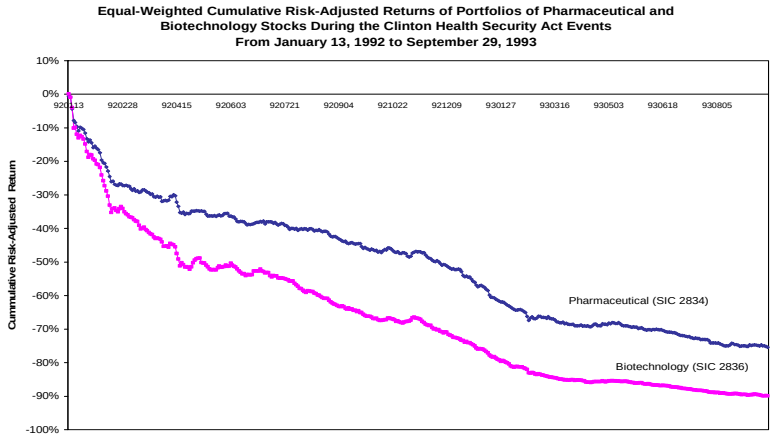


Figure 9 shows that, even before adjusting for the risk one bears in holding pharmaceutical or biotechnology companies, both samples of companies significantly underperformed the general market during the period when the HSA was being developed and debated. Pharmaceutical firms' stocks lost about 32 percent and biotechnology firms' stock lost much more, about twice 51 percent.

Figure 10



After adjusting for risk, pharmaceutical stocks suffered 70 percent losses and biotechnology stocks suffered 90 percent losses. Over the sample period 1982-2006, about 30 percent of the biotechnology firms were delisted because of mergers or takeovers, and about 18 percent were delisted because their financial condition had deteriorated to the point that they did not satisfy exchange minimum financial requirements. By comparison, about 32 percent of the pharmaceutical firms were delisted because of mergers or takeovers, and about 14 percent were delisted because their financial condition had deteriorated to the point that they did not satisfy exchange minimum financial requirements. This shows that biotechnology firms were probably more financially vulnerable than pharmaceutical firms because they were somewhat more

likely to exhibit financial conditions that deteriorated to the extent that they were not attractive takeover candidates. A theoretical model and argument for expecting these results is presented in the appendix and relies on real options theory.

Financial Risk, Stock Price Changes, and R&D Spending: A Brief Overview

Given (i) biotech firms' reliance on external capital markets to fund their R&D, and the fact that they face a higher cost of equity capital than pharmaceutical firms, as the empirical results in Table 1 show, and (ii) the greater sensitivity of biotechnology firm stock prices to the HSA, a brief discussion of the implications these characteristics and observations have for R&D spending is warranted.

Per point (i), the implication is clear: biotechnology firms, on average, face a higher hurdle rate, or required rate of return, on their R&D projects. All things held constant, biotechnology firms will spend less on R&D than traditional pharmaceutical firms because fewer projects will meet investors (the firm owners) required rate of return. This is illustrated below in Figure 11.

Figure 11: An Economic Model of Equilibrium R&D Spending

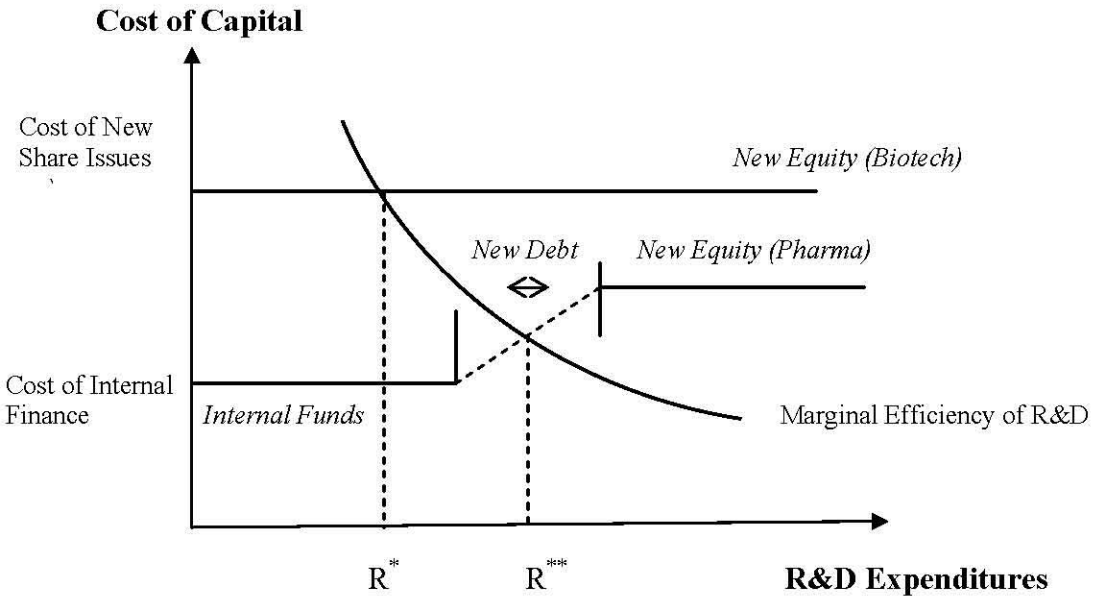

Cost of Capital
Cost of New Share Issues
New Equity (Biotech)
New Debt
New Equity (Pharma)
Cost of Internal Finance
Internal Funds
Marginal Efficiency of R&D
R*
R**
R&D Expenditures

Figure 11 contains a single demand curve for R&D investment. It is appropriate to think of this downward-sloping curve as reflecting the expected rates of return on all potential R&D projects ordered from the highest expected return to the lowest. Firms will continue to undertake R&D projects (and move down the demand curve) as long as the expected rate of return on the next project exceeds the firms cost of capital. This supply and demand model contains two equilibrium R&D expenditure levels: one for a biotechnology firm with no cash flows (e.g., a firm with no sales) and one for a pharmaceutical firm with positive cash flows, as well as access to external debt and equity, like the biotech firm. If these two firms face identical investment opportunities, as reflected by the single demand curve (i.e., the marginal efficiency of R&D), then the equilibrium level of R&D spending for the biotech firm, R^{**}, will be less than the equilibrium level of R&D spending for the pharmaceutical firm, R^{*}, because of greater financial risk, limited access to internal funds, and higher cost of R&D capital. Furthermore, within this simple but useful model it is easy to see how a policy that reduces expected returns to R&D (causing a leftward shift in the demand curve) will result in lower equilibrium R&D spending for both pharmaceutical and biotechnology firms.

Per point (ii), the link between stock prices, expected returns, and R&D needs first to be discussed first. Consider a biotechnology firm that has no marketed products and several ongoing early-stage R&D projects. Because firm stock prices reflect investors expectations of this firm' future financial prospects, as is the case with all publicly traded companies, a proposed policy or a new regulation that diminishes these prospects (i.e. the

HSA), will simultaneously reduce this firm's stock prices and lower its demand for R&D, all else considered[4]. The effect of a decline in the demand for R&D, ceteris paribus, is a lower equilibrium R&D level, as described within the context of point (i). More important, perhaps, is the sensitivity of R&D to stock price changes resulting from new policy proposals or regulations. This story is somewhat more complex, and the appendix provides technical details. Basically, when R&D projects are modeled as real options, it is straight-forward to show that biotech firms have characteristics that predispose them to having a higher degree of stock price sensitivity to policy shocks than pharmaceutical firms. And this in turn will make their R&D spending more sensitive to policy shocks. Golec, Hegde, and Vernon (2006) show this empirically in their study of the HSA effects on the pharmaceutical industry.

III. Conclusions

The data and empirical results presented in this paper document numerous important and significant differences in firm characteristics, financial risk, and sensitivities to regulatory policy shocks between firms in the biotech industry and firms in the pharmaceutical industry, as defined by NAICS SIC Codes. While there are indeed challenges to defining the appropriate participants in these two industries for comparative analyses, the thrust of this research is nevertheless clear: while pharmaceutical firms face considerable financial risk and are vulnerable to policy shocks, biotechnology firms face

[4] Deviating from this hypothetical biotechnology firm example raises important issues because firms with marketed products will experience stock price declines due to the policy's impact on current and future products; moreover, firms may have business operations outside of the biotechnology industry (say consumer products). The point we wish to convey is that establishing the link between stock prices and the demand for R&D is more complicated that that suggested by our example.

more financial risk and are more vulnerable, on average, to policy shocks affecting expected future profitability[5]. Given the biotechnology industry's rapidly expanding role and contribution to the discovery and development of new drugs and biologics, it is important for policy makers to be cognizant of the fact that this industry, as a result of its dependence on external capital and the heightened sensitivity it has to policy shocks and new regulations, is more fragile with respect to its R&D projects and programs than the more established pharmaceutical industry. This is particular true for smallest biotechnology companies.

[5] We also ran analyses using the Biotechnology Industry Organization's (BIO) membership to define biotechs, both with and without its largest members that fall under the NACIS coding for pharmaceutical firms. When these large companies were excluded the BIO sample and the biotechnology NACIS sample produced nearly identical results.

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Appendix: Financial Risk and R&D Projects as Real Options

A more formal way to relate financial risk, leverage, and the cost of capital to R&D expenditures comes from modern finance theory and uses a real options framework. We briefly present this next and discuss some recent empirical evidence on these links within the context of the aforementioned Clinton administration HSA.

We begin by characterizing firms based on how intensively they invest in R&D, and the leverage of the R&D. As shown and discussed in the paper, this is a key differentiating feature of the two samples. Biotechnology firms are, as shown in Figure 6, more R&D intensive, on average, than pharmaceutical firms, and the greater a firm's R&D intensity and leverage, the greater the impact of the HSA on firm value and stock price. This is what we observed and summarized in Figures 9 and 10 with respect to biotechnologies more negative stock price reactions to HSA events and shocks.

To see this more formally consider the following simple model (see Golec, Hegde, and Vernon, 2006 for a more nuanced discussion and presentation). 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:

$$V = p\, V_H + (1 - p)V_N \,. \qquad (2)$$

Expected future cash flows from new drug sales 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. This is, of course, all very intuitive. Assume for simplicity that the firm's R&D

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

$$V_H = c(S_H, \sigma_H, X, T, r) - E \quad (3)$$

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

$$V_N = c(S_N, \sigma_N, X, T, r) - E \quad (4)$$

The function $c(\bullet)$ defines 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, as outlined in the Clinton HSA, will reduce a drug's future cash flows, but not the expected production costs, X (X is equivalent to financial leverage). This will reduce the option's in-the-moneyness (S – X), and hence its value. Galai and Masulis (1976) have show why (S – X) is negatively related to asset beta (β). Therefore, 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 (or other regulatory events and or shocks that have a similar effect). That is, the value of out-of-the-money projects will fall proportionately more, and are more likely to be abandoned because their values are more likely to fall below E.

Option value is also 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 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 equal, price regulation is likely to increase a firm's β_i and decrease its σ_i. Of course, the size of the changes will vary across firms depending upon the sensitivity of the firms' R&D assets to price controls. Thus, external policy shocks such as proposed price regulations will reduce the option value of firms' R&D projects by simultaneously reducing expected future cash flows and future cash flow volatilities. Golec, Hegde, and Vernon (2006) study these links carefully and estimate the impact of the HSA events on subsequent R&D spending, which declined relative to expected/predicted levels.