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R&D Investments, Profitability and Regulation of the Pharmaceutical Industry

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Abstract

Pharmaceutical firms are frequently in the center of political debate due to their high accounting profitability. We show that abnormal profitability in the pharmaceutical industry is a kind of optical illusion created by accounting standards for investment in research and development and their influence on reported accounting profit and book equity. Based on international financial data of 413 pharmaceutical firms between 1972 and 2012, we assess the "true" profitability of pharmaceutical firms by capitalizing R&D and amortizing it using three different methods. We find that pharmaceutical firms accounting profitability is biased and that the sign and magnitude of this bias is shaped by accounting rules and R&D intensities. After adjusting for accounting distortions, ROE of pharmaceutical firms is generally comparable in magnitude to ROE reported by firms from other industry sectors. We further show that the perception of high profitability of U.S. pharmaceutical firms triggers excessive regulatory scrutiny and increases regulation of the pharmaceutical industry. Regulators seem to fixate on reported profitability and do not adjust for accounting distortions caused by R&D accounting. We discuss the likely consequences of regulation that is largely motivated by distorted profitability.

Keywords: Pharmaceutical firms, ROE, accounting distortions, regulation

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1. Introduction

Pharmaceutical companies are frequently in the center of political debate due to their high profitability. Especially in the U.S., where drug prices are largely unregulated, the industry is blamed for "excessive profits as a result of overcharging American consumers and taxpayers" (Health Care for America Now, 2013). At first glance, accounting-based performance measures such as Return on Equity (ROE) in the pharmaceutical industry seem indeed to outperform profitability rates reported by firms in other industries. For example, the Fortune 500 list of largest companies in year 2012 reports a ROE of 9.8% for the pharmaceutical industry, which is higher than the ROE reported by firms for instance in telecommunication (2.6%) or machinery (6.5%).[1] For some NGOs and other critical observers of the health care system this high ROE shows that pharmaceutical firms benefit at the cost of the insured patients and the society at large (Angell, 2004; Public Citizen, 2002).

The high profitability of pharmaceutical firms is also documented in the academic literature. Mueller (1986) reports that pharmaceutical firms have persistently high profitability exceeding the average of other manufacturing firms by 127%. Odagiri and Yamawaki (1990) report for Japan that the profitability of pharmaceutical firms is 72% above the average of the entire economy. High profits in turn may lead policy makers to argue that drug prices are too high and must be regulated to reduce pressure on public health care expenditures. Consistent with this view, most European countries employ a variety of regulatory measures both on the demand and on the supply side (Mossialos et al., 2004; U.S. Department of Commerce, 2004; Vogler et al., 2009). In the U.K., for instance, the Pharmaceutical Price Regulation Scheme

[1] The U.S. Congressional Budget Office (2006, p. 44), using data from the Fortune magazine, documents that the median profitability of pharmaceutical firms has been persistently above the median profitability of firms from other industries over the 1986-2004 period.

(PPRS) directly caps the return rate of drug companies with a current tolerated return on capital employed of 21% (Borrell, 1999; Department of Health, 2013).

In this study, we argue that abnormal profitability in the pharmaceutical industry stems, at least in part, from an illusion created by accounting standards and their influence on reported accounting profit and book equity – the two components of ROE. The internationally accepted accounting frameworks either do not permit capitalizing R&D investments as U.S. Generally Accepted Accounting Principles (U.S. GAAP) or limit capitalizing R&D investments as International Financial Reporting Standards (IFRS) applicable in the E.U. and most countries. This treatment understates assets and equity, and can overstate reported profits because relevant cost components (amortization of R&D) are not deducted from revenues they generate. This accounting treatment biases profitability measures obtained based on reported financial statements, and can substantially increase accounting ROE relative to the true underlying economic profitability. While this argument is not new (Rajan et al., 2007; Salamon, 1982; Salmi, 1982; Taylor, 1999), our study adds to the existing evidence (i) by showing how accounting treatment affects ROE, (ii) by updating prior evidence on the extent of the accounting bias, and (iii) by using novel methods to shed new light on the true economic profitability of pharmaceutical firms in the U.S. and 6 other major economies. Importantly, we next document that accounting profitability in the pharmaceutical industry drives regulatory activity and that the regulators ignore the accounting bias when they define the number and scope of regulatory restrictions surrounding the pharmaceutical industry. To the best of our knowledge, this is the first study to establish the link between biased profitability measures and product market regulation.

We conduct our analysis in three steps using international financial data of 413 pharmaceutical firms between 1972 and 2012. First, we examine the profitability of

pharmaceutical firms and compare it to the profitability of firms from other industries. Our findings confirm results in prior literature: ROE of pharmaceutical firms in the U.S. is 19.8% or 8.7 percentage point (p.p.) higher than the average ROE reported by firms in other industries. Moreover, we find that the higher profitability of pharmaceutical firms is related to the R&D intensity in the pharmaceutical industry and shows a high and predictable variation over time. In a growing economy, pharmaceutical firms increase R&D investments, which lowers their profitability relative to firms in other industries that can capitalize their expenses (e.g., manufacturing firms capitalize investments in plant and equipment). In a contracting economy on the other hand, any cuts in pharmaceutical R&D investments have an immediate profit increasing effect. Furthermore, economic contraction triggers asset impairments in other industries, which further depresses their profit relative to pharmaceutical firms through reporting an impairment loss.

Because accounting practices distort profitability measures of pharmaceutical firms, in the second step we assess the economic or "true" profitability of pharmaceutical firms. We do so by recasting financial statements to undo the bias caused by R&D expensing and to assess the underlying economic performance of pharmaceutical firms. Particularly, we capitalize R&D and amortize it over the shelf-life of developed products, approximating the economic value creation. We use three amortization approaches, namely linear amortization, declining-balance amortization and amortization based on empirical amortization rates (see Lev and Sougiannis, 1996). Over the three proposed amortization approaches, the corrected ROE of 14.1% is comparable to profitability reported by U.S. firms from other industries (ROE = 11.1%). Non-U.S. pharmaceutical firms also have an adjusted ROE that is comparable to firms from other industries (7.6% pharma vs. 9.6% non-pharma).

We then examine whether these ROE figures are related to the degree of regulation. Similar to findings in other areas (Jones, 1991), we hypothesize that regulators will be attentive to high profitability of pharmaceutical firms leading to a greater oversight of the pharmaceutical industry. We also predict that similar to other stakeholders, regulators ignore the accounting bias due to R&D in their decision making. Given lack of systematic data in our international sample these tests are limited to the U.S., however, they indicate that higher ROE figures lead both to greater regulatory restrictions and greater scope of regulation in the pharmaceutical industry. These results provide evidence that regulators fixate on aggregate earnings and do not adjust profitability for any accounting biases.

The remaining part of the paper is structured as follows. In chapter 2 we review related literature and provide theoretical underpinnings for our analysis. Our empirical approach is presented in chapter 3. We detail the construction of our sample in chapter 4. Chapter 5 presents our results. Chapter 6 offers a brief discussion and concluding remarks.

2. Related literature and hypothesis development

Whether high accounting profits of pharmaceutical firms motivate further industry regulation has been a matter of considerable debate. In this paper we argue that a regulatory regime that ignores underlying economics of the industry is likely to distort incentives to invest in R&D. Therefore, our analysis aims at understanding the reasons for high profitability of pharmaceutical firms and whether high profitability affects regulation in the pharmaceutical industry.

Economic theory proposes three explanations for abnormally high profitability of pharmaceutical firms relative to firms from other industries or economy in general. First, early literature in industrial economics proposes that above-average returns can be due to market

power, that is caused by market concentration and entry barriers (Comanor and Wilson, 1967; Porter, 1974). While this argument is theoretically compelling, the empirical effect of market concentration on profitability seems to be rather weak (Domowitz et al., 1986). The high risk associated with pharmaceutical R&D is sometimes put forward as a second explanation for above average returns (Schweitzer, 2006) since investors must be compensated for accepting higher risks. This explanation is plausible because investments in R&D are very high in pharmaceutical industry relative to other industries, and because investments in R&D are typically considered to be highly risky. For example, Grabowski and Vernon (1990) show that only a third of approved and marketed drugs manage to generate enough revenues to cover their development costs. At the same time, it is estimated that on average expenditures of $1 billion are needed to bring a new molecule to the market (Adams and Branter, 2010; DiMasi et al., 2003). Furthermore, as Grabowski and Mueller (1978) show, pharmaceutical firms have only few possibilities to diversify their risks. While there are some spill-over effects between the drug development projects within a firm (e.g., Cockburn and Henderson, 2001; Henderson and Cockburn, 1996), the potential to diversify investment risk at pharmaceutical firms is limited. Especially young firms of this industry face a high degree of non-diversifiable risk, which is expressed in betas of well above one (Bernardo et al., 2007; Giaccotto et al., 2011). Therefore, the higher average profitability in the pharmaceutical industry can be at least partly explained by higher risks of R&D investments.

A third and rather recent explanation of the observed high profitability of pharmaceutical firms relates to difficulties of measuring profit and invested capital (equity), as investments in intangible R&D assets are not fully reported on firms' balances. As R&D expense is the major cost component in the pharmaceutical industry, financial statements of pharmaceutical firms are strongly affected by whether R&D outlays are reported as an expense or an asset. Only a small

number of papers empirically examine whether accounting bias affects profitability in the pharmaceutical industry. In Bloch's (1974) study accounting rates of return are up to 6 p.p. higher than the calculated "true" economic rates of return. Subsequent research by Ayanian (1975), Clarkson (1977), Grabowski and Mueller (1978), Megna and Mueller (1991) and Mahlich and Yurtoglu (2011) confirm a significant accounting bias on ROE when R&D is expensed rather than capitalized. However, none of the papers elaborated on the determinants of the accounting bias as we are going to do. The sample size was small as well in most of the studies. Clarkson's (1977) analysis for instance was based on one single company.

Implementation of accounting rules generally leads to expensing a large portion of R&D outlays as incurred, while economically R&D outlays can be seen as an asset. The standard setters pursue this approach as they weigh reliability over relevance in case of R&D investments and argue that future economic benefits from R&D investments cannot be reliably measured. Thus, conditions for asset recognition are not met by investments in research or development. For example, U.S. GAAP applicable for U.S. listed pharmaceutical firms bans capitalization of R&D investments (with the exception of software manufacturers); instead R&D outlays are reported as expense.

Expensing of R&D understates the asset base of pharmaceutical firms and their shareholders' equity (e.g., Salamon, 1982; Salmi, 1982; Taylor, 1999). It also biases profit, as income statement accounts for current R&D outlays instead of economic amortization of previous R&D investments (e.g., Fisher and McGowan, 1983; Salamon, 1985, 1988). Thus, accounting for R&D can bias the nominator (earnings) or denominator (equity) of the ROE. The sign and magnitude of the bias will depend on the magnitude of R&D investments (Rajan et al., 2007). To illustrate this logic, we report in Table 1 a stylized example of two pharmaceutical firms (firm A and B) that invest each year 100 into R&D and generate 115 in annual revenues.

Both firms have a cash asset (30), some investment in R&D, and no liabilities (that is, total assets equal shareholders' equity). We use different accounting treatments for R&D in case of firm A and firm B to show how R&D accounting affects accounting profitability measures. Firm A capitalizes 100% of R&D outlays and amortizes them over the next year when they contribute to generating revenues. In this case, reported profit and equity are not biased, and accounting return is equal to the economic return. While being economically "correct", the example of firm A has also an intuitive appeal: The firm advances 100 to generate revenues of 115. Therefore, return on its investment is (115–100)/100 = 11.5%. As firm A has no liabilities, its ROE equals the Return on Assets (ROA) and hence is 11.5%.

Please insert Table 1 about here

Firm B is allowed only to capitalize 10% of its R&D investments and must expense the remaining 90% of R&D investments when incurred. Expensing of larger portion of R&D outlays leads to understatement of assets and equity. Because equity is understated, ROE of firm B is substantially overstated and equals 37.5% in years 1-3 and 262.5% in year 4. Similar, when investments increase, equity is biased downwards and ROE is biased upwards if firm expenses R&D (Lev et al., 2004; Rajan et al., 2007).

The effect of R&D expensing on earnings depends on whether current R&D expenditure exceeds amortization of previously capitalized R&D outlays. To illustrate, we next assume economic shocks and let R&D investments decrease (increase) to 90 (110) in year 3. Untabulated results reveal that when R&D is expensed as incurred, any decrease in R&D investments during an economic downturn in year 3 has an immediate income-increasing effect (ROE 60%). However, decreasing investments when those investments are capitalized produces an income-increasing effect only in subsequent years when amortization of investments affects earnings. As a result, the gap in reported performance between expensing and capitalizing firms

is expected to increase during an economic downturn (60% vs. 11.5%).[2] During the periods of economic expansion, an increase in R&D investments depresses earnings of the R&D expensing firm and lowers the magnitude of bias (15% vs. 11.5%).

Unlike firms from other industries, pharmaceutical firms are not allowed to fully capitalize their main operating asset – R&D investments. Expensing R&D when incurred understates equity and leads to overstated ROE. The magnitude of this bias depends on economic shocks: A temporary decrease in investments increases the magnitude of bias, while a temporary increase in investments lowers bias.

Hypothesis 1: Expensing R&D overstates ROE of pharmaceutical firms and the magnitude of this bias increases (decreases) when economy contracts (grows).

The example provided in Table 1 demonstrates how R&D expensing can bias ROE. In the example, this bias leads to an overstatement of accounting returns. On the other hand, one can also identify conditions under which the positive ROE bias reverts, and pharmaceutical firms report ROE that is potentially lower than ROE reported by firms from other industries. We next posit that certain combination of accounting rules and decelerating investments can negatively bias pharmaceutical firms' ROE.

While U.S. firms follow U.S. GAAP and are required to expense R&D, accounting standards applicable in other countries allow more latitude in capitalizing some R&D outlays (Hung, 2001). Critically, IFRS applicable for listed pharmaceutical firms in Europe and in most other countries requires that research outlays are expensed as incurred, but permits capitalization of development costs. Specifically, IAS 38 requires companies to separate the research phase

[2] In the actual reporting practice, the gap is further going to increase due to reporting of impairment losses by firms that capitalize their investments. Particularly, during an economic downturn firms typically report an impairment of some investments to account for the fact that future cash flows from those investments are expected to decline. In turn, R&D expensing firms carry no (or very limited) R&D assets and thus have no assets to impair, leading to relatively higher income when economy contracts.

from the development phase of a project and to capitalize costs incurred during the development phase if capitalized costs meet a set of criteria such as ability to sell the developed product and ability to measure future economic benefits. In case of the pharmaceutical industry, these criteria are typically met when a drug is approved by the regulatory body. This leads to more development costs capitalized on balances of international firms relative to their U.S. counterparts. Also, while U.S. GAAP requires R&D purchased in the process of merger or acquisition (in-process R&D) to be expensed, IFRS allows capitalizing in-process R&D. Thus, IFRS financial statements of pharmaceutical firms may be somewhat less affected by accounting bias relative to U.S. GAAP financial statements.

Importantly, capitalization of some R&D investments increases earnings during the periods when companies grow, because larger portion of current R&D outlays are deferred into the future. However, in later years when companies mature and experience declining growth rates in R&D investments capitalization leads to lower profitability of R&D capitalizers (Aboody and Lev, 1998). This is because the amortization of previously capitalized R&D investments is higher than R&D outlays of the current period. Aboody and Lev (1998) support this prediction by showing that declining investment growth rates in software industry led to lower profits of R&D capitalizing firms. The descriptive statistics for our international sample of pharmaceutical firms indicate that our sample firms are mature (average age 36 years) and that some countries experience declining rates of R&D investments. This evidence is consistent with Cincera and Veugelers (2014) who find that U.S. has a greater number of young innovating pharmaceutical firms relative to Europe. We predict that declining growth rates may lead to lower ROE reported by international pharmaceutical firms:

Hypothesis 2: Decelerating R&D investments of pharmaceutical firms bias ROE downwards.

Anecdotal evidence suggests that the regulation of pharmaceutical industry may be motivated by high profitability of pharmaceutical firms (see e.g., Ecorys, 2009; Pear, 1993; Rapp and Lloyd, 1994). The link between accounting profits and regulation is not unique to the pharmaceutical industry. Abnormally high profits were cited in the congress request to the Federal Trade Commission to investigate possible price-fixing of gasoline by U.S. refineries[3] and were argued to cause the intervention of the Federal Trade Commission in the breakfast cereal industry (Scherer, 1982). This anecdotal evidence is supported by a theoretical literature that predicts regulators' attentiveness to firm performance as an indicator of market power (Watts and Zimmerman, 1986). The economic theory of regulation also recognizes other rationales related to firm performance such as rent distribution, revenue generation and redistribution (Posner, 1971). However, we are not aware of any empirical study that examines whether higher profits lead to regulatory actions. Furthermore, there is no prior evidence on whether in their decision making regulators rationally adjust for any bias resulting from application of accounting rules. If high profitability motivates industry regulation and regulators do not correct for this bias, the resulting regulations might distort firm R&D investments.

Accounting literature shows that users of financial statements are often limited in their understanding of how financial statements are articulated and fixate on the bottom line earnings in their evaluation of financial performance. For example, Sloan (1996) shows that investors focus on aggregate earnings and disregard information in earnings components despite those components being informative about sustainable profitability. Similar, Lev et al. (2004) find that investors do not correct for the bias caused by R&D accounting and as a result firms with abnormally high profitability are overvalued. Jones (1991) shows that firms manipulate earnings

[3] The letter asking for the investigation argued that "[a]t a time when major refiners and oil companies are making record profits and American families continue to struggle with gasoline at record prices, the idea that refiners may be manipulating the market to keep prices artificially high is offensive."

to affect regulatory outcomes and argues that regulators ignore such earnings bias in their regulatory decisions. We predict that regulators are likely to be attentive to high profitability of pharmaceutical firms leading to a greater oversight of the pharmaceutical industry. We also predict that similar to other stakeholders, regulators ignore the bias caused by R&D accounting in their decision making. That is, regulators fixate on aggregate earnings and do not adjust profitability for any accounting biases. We formulate our predictions as follows:

Hypothesis 3: High profitability of pharmaceutical firms leads to increased regulatory activity.

Hypothesis 4: Regulators fixate on aggregate earnings and do not adjust for the bias caused by R&D accounting.

3. Empirical approach

3.1. Difference in ROE between pharmaceutical and non-pharmaceutical firms and its determinants

We conduct our analysis in three steps. First, we benchmark ROE of pharmaceutical firms against ROE of firms from other industries – our proxy for "normal" profits – to examine whether accounting rules for R&D bias profitability of pharmaceutical firms. Second, we adjust ROE of pharmaceutical firms to reveal the magnitude and the sign of accounting bias. Third, we relate accounting profitability of pharmaceutical firms and accounting bias to the regulation of the pharmaceutical industry.

We use two proxies to capture effects of R&D accounting on the ROE difference between pharmaceutical and non-pharmaceutical firms. We use the difference in R&D intensity between pharmaceutical firms and non-pharmaceutical firms to proxy for the effect of R&D accounting on ROE bias. Hypothesis 1 predicts that ROE of pharmaceutical firms will be higher due to

expensing of their R&D investments. We use changes in gross domestic product ΔGDP to capture the effect of economic upturns and downturns on investments and reported ROE differences between pharmaceutical firms and firms from other industries. Hypothesis 1 predicts that economic upturns (downturns) will lead to relatively lower (higher) earnings reported by pharmaceutical firms. This leads us to the following empirical model:

$$ROE\_diff_{it} = \alpha_0 + \alpha_1 R\&D\_diff_{it} + \alpha_2 \Delta GDP_{it} + \varepsilon_{it} \quad (1)$$

where *ROE_diff* is the country's *i* difference in weighted-average ROE between the sample of pharmaceutical and non-pharmaceutical firms in year *t*. *R&D_diff* is the difference in weighted average R&D expenditure (the ratio of R&D expenditure to closing book equity) between the sample of pharmaceutical firms and the sample of non-pharmaceutical firms in a given year. Weights are set to the share of book equity in the total equity of pharmaceutical firms in each country-year. ΔGDP is the change in GDP over a year in a given country. We predict α_1 to be positive and α_2 to be negative. We estimate model (1) by means of an OLS regression. We base our inferences on robust standard errors that are adjusted for heteroscedasticity and time-series dependence.[4] Additionally, we use country fixed effects to control for country characteristics when we fit model (1) using our international sample.

We test hypothesis 2 using extended version of model (1). We add an indicator variable for declining R&D growth rates and its interaction with R&D intensity. We predict that capitalization of some R&D by international firms will depress their profitability when investment growth declines. Thus, a negative coefficient on the interaction term will provide support for hypothesis 2.

$$ROE\_diff_{it} = \alpha_0 + \alpha_1 R\&D\_diff_{it} + \alpha_2 \Delta GDP_{it} + \alpha_3 Disinvest_{it} + \alpha_4 R\&D\_diff_{it} \times Disinvest_{it} + \varepsilon_{it} \quad (2)$$

[4] Using Newey-West standard errors in time series regressions using U.S. data does not change our inferences.

where $Disinvest_{it}$ is an indicator variable that equals 1 if there is a decline in the mean growth rate of R&D in country *i* and year *t*, and 0 otherwise. Other variables are as previously defined.

3.2. Adjusting ROE for effects of R&D accounting

To more directly estimate the effect of R&D accounting on reported ROE, we adjust earnings and equity of pharmaceutical firms for distortions caused by the immediate expensing of R&D. This procedure requires tracking back R&D outlays, capitalizing them in periods where R&D outlays were incurred, and expensing them over subsequent years via amortization. Amortization assures that R&D outlays are matched to future revenues they help generate. Capitalizing and amortizing R&D outlays will undo distortions to earnings and equity caused by immediate R&D expensing and will result in profitability that is more descriptive of the underlying business reality (i.e. economic income) (Dechow, 1994; Dechow et al., 1998).

As a starting point of our analysis, we note that the economic rate of return (*ERR*) is given as economic profit (*EP*) divided by the employed capital (*C*). The economic profit can be stated as revenues (*Revenues*) less variable costs (*Variable costs*), less economic depreciation of tangible assets ($\lambda_{TA}\, TA$), less the portion of R&D outlays applicable to the period ($\lambda_{R\&D}\, R\&D$). The employed capital is invested into net tangible assets (*TA*) and capitalized R&D investments (*R&D*)

$$ERR = \frac{EP}{C} = \frac{Revenues - Variable\ costs - \lambda_{TA} TA - \lambda_{R\&D} R\&D}{TA + R\&D} \qquad (3)$$

The formula follows the simple intuition: Companies advance their expenses such as R&D outlays to generate revenues at the later point in time. Therefore, to determine how effective the business operates, it makes sense to relate revenues to expenses that were advanced to help generate it. Because R&D outlays have a long-term character the nominator in (3) relates

revenues only to a portion of R&D outlays that contributed to generating this revenue. This is done by employing an economic amortization rate ($\lambda_{R\&D}$). The resulting profit is then related to invested capital – the sum of R&D investments and other assets.

The accounting counterpart of the ERR is ROE measured as net income (*Income*) over equity (*Equity*). When accounting rules prescribe R&D outlays to be expensed as incurred (U.S. GAAP), the amortization parameter $\lambda_{R\&D}$ is set to zero, and current R&D outlays (*R&D outlays*) are substituted for $\lambda_{R\&D}$ *R&D*. Because R&D is expensed rather than capitalized, the R&D investment equals zero. As a result, ROE measures the economic rate of return with error:

$$ROE = \frac{Income}{Equity} = \frac{Revenues - Variable\ costs - \lambda_{TA} TA - R\&D\ outlays}{TA} \quad (4)$$

Whether accounting rules understate or overstate ROE relative to ERR in case of R&D intensive firms depends on the level of current R&D investments relative to the past R&D investments (that is, *R&D outlays* vs. $\lambda_{R\&D}$ *R&D*), and on whether the nominator effect (subtracting *R&D outlays* instead of $\lambda_{R\&D}$ *R&D*) outweighs the denominator effect (excluding *R&D* from denominator).

Thus, to account for the effects of R&D accounting we can use reported ROE and recast it using equation (3) and (4) into our estimate of ERR, that is an economic rate of return adjusted for the effects of R&D accounting. We use three accounting techniques to match R&D outlays to revenues they help generate.

First, we assume that the benefits from R&D investments accrue as a steady stream of revenues (or cost cuts) over a 10 year period after the year of initial investment. This leads to a use of straightline amortization for capitalized R&D outlays.

Second, we use a declining balance amortization, where the benefits (revenue increases or cost cuts) decline over the 10 year period. This approach follows the long tradition of using

declining balance depreciation in this line of literature (Grabowski and Mueller, 1978; Mansfield, 1968; Nerlove and Arrow, 1962; Schmalensee, 1972). Furthermore, this approach is somewhat more descriptive of the business practice in pharmaceutical industry as substitute products and expiring patents lead to declining revenues and profit margins over time. We use a constant amortization rate, because prior studies show that obtained results are not sensitive to this choice (Nadiri and Prucha, 1996). As a result, the R&D stock reported on the balance can be computed as follows:

$$R\&D_t = R\&D\ outlays_t + (1 - \lambda_{R\&D})R\&D_{t-1} \quad (5)$$

The recursive substitution leads to the following equation:

$$R\&D_t = \sum_{k=0}^{\infty}(1 - \lambda_{R\&D})^k\ R\&D\ outlays_{t-k} \quad (6)$$

We set the amortization rate $\lambda_{R\&D}$ at 10%, which is consistent with numerous previous studies (Baily, 1972; Grabowski and Mueller, 1978), and very close to the R&D amortization rate of 9.2% used by Haneda and Odagiri (1998). Finally, we set k to equal 10 years, due to data availability.

Third, we use empirically-derived amortization rates using approach proposed by Lev and Sougiannis (1996). Current R&D outlays increase future revenues or decrease future costs. The empirical approach aims at estimating the contribution of each dollar spent on R&D to future profitability. These estimates help us in the next step to reallocate R&D expenses to the periods in which they help generate revenues or lead to cost savings. In other words, we obtain empirical amortization rates. This approach does not rely on any assumptions regarding the amortization rate and amortization method (e.g., straightline, declining balance), instead the amortization rate is empirically derived using the cross-section of pharmaceutical firms. That is, the empirical approach allows for amortization rates that are adopted to firm-specific circumstances. Similar to

Lev and Sougiannis (1996), we empirically assess the relation between R&D outlays and future operating income to determine how current R&D outlays increase future sales or decrease future costs. We regress operating income on lagged R&D outlays using the following regression framework:

$$Operating\ income_{it} = \alpha_0 + \sum_{k=1}^{9} \alpha_k R\&D\ outlays_{it-k} + \varepsilon_{it} \quad (7)$$

The dependent variable *Operating income*$_{it}$ is operating income of firm *i* during year *t*. Operating income captures expected benefits from R&D – primarily revenue increases, but also cost savings. The independent variables are represented by a vector of past R&D outlays. In this set-up, the estimated regression coefficients on past R&D outlays (α_k) reveal how \$1 of past R&D outlays contributes to current operating income. We estimate regression (7) using all available data points and 9 years of past R&D outlays. We use the obtained coefficient estimates to derive amortization rates in equation (8).

$$\gamma_k = \frac{\alpha_k}{\sum_k \alpha_k} \quad (8)$$

3.3. Profitability and regulatory activity

Hypothesis 3 and 4 predict that accounting profitability of pharmaceutical firms attracts regulators attention and increases regulatory activity. To test this prediction, we employ two measures of regulatory activity as our dependent variable and use lagged ROE reported by pharmaceutical firms as independent variable. We also decompose reported ROE into adjusted ROE using empirical amortization rates as shown above and accounting bias. We are particularly interested in finding out whether regulators attach the same weights in their decision making to

the biased part of earnings as they do for the unbiased earnings. In other words, we examine whether regulators fixate on aggregate earnings:

$$\Delta Restrictions_t or\ \Delta Reg\_activity_t = \alpha_0 + \alpha_1 ROE_{t-1} + \alpha_2 Party_t + \varepsilon_t \quad (9)$$

$$\Delta Restrictions_t or\ \Delta Reg\_activity_t = \alpha_0 + \alpha_1 ROE\_adj_{t-1} + \alpha_2 ROE\_bias_{t-1} + \alpha_3 Party_t + \varepsilon_t \quad (10)$$

We limit this analysis to U.S. firms because they report abnormally high profitability and because regulatory data is only available for our U.S. sample. We include years 1997-2012 because 1997 is the first year for which regulatory data is available. We use two proxies for changes in regulation of pharmaceutical firms. $\Delta Restrictions_t$ is the log change in the number of restrictive words used in the laws pertaining to the pharmaceutical industry and issued by U.S. regulators during year *t*. $\Delta Reg\_activity_t$ is the log change in the word-length of laws in the pharmaceutical industry issued by U.S. regulators during year *t*. ROE_{t-1} is the weighted-average ROE of pharmaceutical firms in year *t–1*. Hypothesis 3 predicts a positive coefficient on lagged ROE. To control for the effects of the ruling party on the regulatory activity, we employ an indicator $Party_t$, which is set to 1 if Republicans dominate the U.S. House, and 0 otherwise. Controlling for the party of the U.S. President or the U.S. Senate majority does not change our inferences.

In the next step, we decompose reported ROE into its components in equation (10): $ROE_{t-1} = ROE\_adj_{t-1} + ROE\_bias_{t-1}$. ROE_adj_{t-1} is ROE adjusted using empirical amortization rates in year *t–1*. ROE_bias_{t-1} is the difference between observed ROE and adjusted ROE in year *t–1*. We report results for the empirical amortization rates, as we see this approach superior to using normative assumptions about the amortization rates. Hypothesis 4 predicts that regulators fixate on earnings and do not adjust for accounting bias; that is $\alpha_2 = \alpha_3$.

4. Data

Our primary sample comprises pharmaceutical firms from U.S. and 6 major pharmaceutical markets based on the number of listed pharmaceutical firms. We obtain financial data for our analysis from *Compustat North America* and *Compustat Global*. Our U.S. sample spans years 1972-2012. Due to data availability, our non-U.S. sample includes only the years 1999 to 2012. We identify pharmaceutical firms based on their SIC code (2833, 2834, 2835, and 2836), which results in a comprehensive sample of 2,281 unique firms or 26,528 firm-year observations. We delete firms with missing data for main test variables and firms with negative book equity, as calculation of ROE is meaningless when book equity is negative. To control for outliers, we delete firm-year observations in the top and bottom 1 percentile of ROE distribution. We further require that a pharmaceutical firm has at least 10 consecutive observations to model the effects of R&D accounting on ROE. Finally, we eliminate countries with less than 20 observations to obtain stable estimates of our test statistics. Our selection procedure leads to 3,000 data points or 413 unique pharmaceutical firms located in 7 countries: Australia (34), Canada (149), India (45), Japan (105), Sweden (22), U.K. (46) and U.S. (2,599). As a control group we obtain *Compustat* data for firms from all other industries and come up with 39,414 firm-years: Australia (1,327), Canada (1,929), India (1,597), Japan (1,802), Sweden (343), U.K. (1,214) and U.S. (24,585). GDP data are from OECD (2014). Regulatory data are obtained from Mercatus Center's RegData database that quantifies the federal regulations using text analysis (Al-Ubaydli and McLaughlin, 2014).

5. Results

5.1. ROE of pharmaceutical and non-pharmaceutical firms

Table 2 reports the accounting rates of return of pharmaceutical firms and non-pharmaceutical firms. We obtain a weighted average ROE for each country and year, and set weights to the share of book equity in the total equity of pharmaceutical firms in each country-year. We find that in the U.S., the average accounting ROE of pharmaceutical firms over the last 40 years is 19.8%, and is substantially higher than the accounting ROE reported by firms from other industries (11.1%). Table 2 also shows that U.S. pharmaceutical firms report 12.5 p.p. higher R&D intensity than firms from other industries.

Please insert Table 2 about here

Figure 1 further reveals that U.S. pharmaceutical firms report higher ROE in each of the sample years. The average ROE of U.S. pharmaceutical firms was in the order of 15-20% in the 1970ies and the first half of the 1980ies, ROE increased to 20-25% in the 1990ies, and then declined to 15-20% in the last decade (2000-2012). Despite this decline, U.S. pharmaceutical firms reported about 5 p.p. higher ROE in 2012 than firms from other industries. Overall, the pharmaceutical firms' ROE is between 3.3 p.p. (year 2010) and 18.4 p.p. (year 2001) higher than ROE of non-pharmaceutical firms during the second half of our sample. This descriptive evidence supports hypothesis 1 by showing that accounting for R&D investments may bias ROE.

Please insert Figure 1 about here

We find that ROE of non-U.S. pharmaceutical firms is low (4.7%) and that on average ROE of international pharmaceutical firms is 4.9 p.p. lower than ROE of firms from other industries. However, Figure 2 reveals that the country and year of analysis determine whether pharmaceutical firms "outperform" their peers from other industries. For example, Australian,

Indian and Japanese pharmaceutical firms "outperform" their peers in 2012, while pharmaceutical firms in Canada, Sweden and U.K. report lower ROE than firms from other industries. The evidence that more mature firms from our international sample report lower profitability is consistent with hypothesis 2.

Please insert Figure 2 about here

Table 3 presents the regression results for equation (2) where we explain the difference in the accounting rates of return between pharmaceutical and non-pharmaceutical firms with economic up- and downswings of business cycle and R&D intensity. We find that our model fits data well and explains about 30% of variation in ROE differences between pharmaceutical firms and firms from other industries. We find that in the U.S. the upward bias of ROE documented in our descriptive analysis is related to R&D intensity (coef. 0.431; *t*-stat. 2.51). Furthermore, we find that U.S. and international pharmaceutical firms report relatively lower ROE during economic upturns and relatively higher ROE when the economy contracts (U.S. coef. –0.399; *t*-stat. 2.19; international coef. –0.887; *t*-stat. 2.78). These results support hypothesis 1.

Please insert Table 3 about here

We employ model (2) to shed further light on what makes R&D intensity coefficient insignificant in our international sample. Recall that international pharmaceutical firms report lower ROE than their counterparts from other industries. Column (4) of Table 3 shows that decreasing investment growth is responsible for the lower ROE of international pharmaceutical firms (coef. –0.845; *t*-stat. 2.74). This evidence is consistent with hypothesis 2. In contrast, we do not observe this effect in the U.S. data where it is not predicted (coef. –0.089; *t*-stat. 0.31).

5.2. Adjusting ROE for effects of R&D accounting

We report rates of return adjusted for capitalization and amortization of R&D investments in Table 4. Again, to obtain mean values, weights are set to the share of book equity in the total equity of pharmaceutical firms in each country-year. ROE of pharmaceutical firms is adjusted for the effects of R&D accounting using three techniques: (1) Linear amortization – R&D expenditure is capitalized and amortized on a straightline basis over 10 years; (2) Declining balance – R&D expenditure is capitalized and amortized over 10 years using declining balance amortization; (3) Empirical rates – R&D expenditure is capitalized and amortized over 10 years using empirically determined amortization rates.

The empirical rate of amortization was obtained by estimating equation (7) and inserting the estimated coefficients into equation (8). We find that the most recent three years have the strongest impact on current year's operating income with estimated regression coefficients equal 1.500, 0.849, and 0.526 for year *t–1*, *t–2*, and *t–3*, respectively. The coefficients are significantly different from zero at the conventional level using robust standard errors clustered at firm ($p < 0.01$). The coefficients on other past R&D outlays range from 0.047 to 0.356. We estimate that on average $1 spent on R&D generates $3.88 in operating income over the next 10 years. Due to data availability, we report results using this approach only for our U.S. sample. Rather than assuming how the benefits from R&D accrue, this approach aims to match R&D outlays to future benefits they help generate using observed relationship between R&D outlays and future benefits. To illustrate the use of the approach, we estimate that in the U.S. the amortization rate on *t–1* and *t–2* R&D investment is 1.500/3.883 = 38.6% and 0.849/3.883 = 21.9%, respectively.

Please insert Table 4 about here

Looking at the U.S. sample in Table 4, we find that adjusting for accounting distortions leads to lower ROE regardless of the approach used to adjust ROE. We find that over all methods adjusted ROE equals 14.1%, which is about 6 p.p. lower than reported ROE of 19.8%. This decrease is economically and statistically pronounced (*t*-stat. 18.44). Similar, the difference between ROE of pharmaceutical firms and ROE of firms from other industries declines from 8.7 p.p. to 2.9 p.p. after adjusting for accounting distortions caused by immediate R&D expensing. Thus, ROE of U.S. pharmaceutical and non-pharmaceutical firms converge after eliminating accounting distortions. Our international sample provides further support for this conjecture. Particularly, we find that the difference in ROE declines from –4.9 p.p. to –2.0 p.p. after adjusting ROE of pharmaceutical firms for accounting distortions caused by immediate R&D expensing.

5.3. ROE and regulatory activity

Our previous tests show that U.S. firms' ROE is overstated. Do regulators base their laws on this overstated ROE? Table 5 tests this prediction. We find that despite the low number of data points, our models fit the data well and explain up to 50% of variation in regulatory outcomes. Supporting hypothesis 3, Panel A reports that higher profitability levels lead to greater restrictions (coef. 0.795; *t*-stat. 3.54) and greater scope of regulation (coef. 0.385; *t*-stat. 2.53) in the pharmaceutical industry. We also find that the ruling party affects restrictiveness of issued regulations, but not their scope. As a robustness test we control for lagged R&D investments. However, we do not find that R&D investments affect regulation. Importantly, controlling for R&D intensity does not affect our inferences in respect to our main test variables. To assess the economic significance of these results, we reestimate models (9) and (10) after substituting raw changes in the number of words and restrictions for the log changes of these variables as our

dependent variable. Untabulated results reveal that a 1 p.p. increase in ROE leads to an increase in the law text of 74,000 words and 483 restrictions per year.

Please insert Table 5 about here

We next test hypothesis 4 and examine whether regulators fixate on earnings and ignore accounting bias. To provide some preliminary support for hypothesis 4, we run a regression of regulatory changes on one of the two ROE measures: reported ROE and ROE adjusted using empirical amortization rates as above (results are not tabulated). Looking at the explanatory power of two regressions will reveal which earnings measure is more relevant for the regulators' decision-making. Despite high correlation between the two performance measures (0.54), we find that reported ROE explains about 9 p.p. more of the variation in the restrictiveness of issued laws (35% vs. 26%). This evidence is in line with hypothesis 4. While reported ROE better explains changes in the scope of regulation than adjusted ROE, the difference in adjusted R^2s is economically small (1 p.p.).

To provide a formal test of hypothesis 4, we next decompose reported ROE into adjusted ROE (not affected by accounting distortions) and the component of ROE that represents accounting bias. This analysis is reported in Panel B of Table 5. Functional fixation on aggregate earnings predicts that regulators attach similar weights to adjusted ROE and the bias component. That is, they do not distinguish between the two components. We find that the magnitude of the accounting bias predicts the number of issued restrictions (coef. 0.671; *t*-stat. 1.83). Critically, we find that the coefficient on the accounting-bias component of ROE (0.671) is similar to the coefficient on adjusted ROE (0.931) and is similar to the coefficient of reported ROE (0.795). The *F*-test reported at the bottom of Panel B shows that regulators attach similar weights to the true and biased ROE in their decoction about the amount and restrictiveness of newly issued laws

(*F*-stat. 0.79 and 0.21, respectively). These results support hypothesis 4 and suggest that regulators fixate on aggregate earnings and do not adjust for the accounting bias.

6. Discussion and concluding remarks

Overall, we find that pharmaceutical firms report higher ROE than firms from other industries in the U.S. but not in our international sample. Consistent with the effects of R&D accounting on reported ROE, we find that pharmaceutical firms report relatively lower ROE during economic upturns, and relatively higher ROE when the economy contracts. We also find that ROE differences are significantly related to the higher R&D intensity of pharmaceutical firms. While higher R&D intensity increases the ROE of pharmaceutical firms in the U.S., international R&D-intensive pharmaceutical firms report lower ROE. This result can be explained by the composition of our international sample that includes less mature firms compared to the U.S. Young firms have high R&D outlays relative to sales, which depresses their reported ROE. However, the difference between U.S. and non-U.S. samples may be also due to the difference in accounting for R&D in the U.S. relative to other countries. While U.S. GAAP prohibits capitalization of R&D outlays, accounting standards in other countries allow or even require capitalization of some R&D outlays. For example, under IFRS non-pharmaceutical firms can capitalize development costs, and the implementation of IFRS requirements also leads to some development costs capitalized on the balances of pharmaceutical firms.

When we adjust ROE for accounting distortions we observe consistently lower ROE in all three different adjustment approaches used. After adjusting for accounting distortions, ROE of pharmaceutical firms is generally comparable in magnitude to the ROE reported by firms from other industries. These results tentatively suggest that high profitability of pharmaceutical firms may be at least partly a kind of "optical illusion" created by the expensing of R&D investments.

Our final set of tests reveals that high profitability of pharmaceutical firms leads to greater scope and restrictiveness of regulation. Furthermore, similar to other stakeholders, pharmaceutical regulators focus on reported profitability and do not adjust for an upward bias caused by R&D accounting.

One policy implication of our study is that price regulation or rate of return regulation in the pharmaceutical market should be reviewed and applied with caution when it is solely motivated by the allegedly high profitability of the industry. This is especially true since such a policy also impedes R&D investments and innovation in the long run because profits serve as a major source of R&D investments (Civan and Maloney, 2009; Grabowski and Vernon, 2000; Mahlich and Roediger-Schluga, 2006; Scherer, 2001) and signal to pharmaceutical firms to assess which products provide consumers the highest value. If profits accurately reflect that value, they will induce the pharmaceutical industry to invest in R&D at the optimal level. A regulatory regime which deviates from this optimality condition is likely to distort incentives to invest in R&D, which might either induce firms to over- or underinvest in R&D. While overinvestment will destroy shareholder value (Saad and Zantout, 2014), underinvestment is more likely to have far reaching economic costs induced by a future absence of new drugs and consecutive lost life years (Abbott and Vernon, 2007; Lichtenberg, 2007).

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Figure 1: ROE of pharmaceutical firms vs. ROE of firms in other industries in U.S. (1972-2012)

Figure 1 compares the ROE of pharmaceutical firms (with SIC codes 2833, 2834, 2835, and 2836) to the ROE of non-pharmaceutical firms in the U.S. Firms with missing data for main test variables and firms with negative book equity are excluded from the sample. Firm-year observations in the top and bottom 1 percentile of ROE distribution are deleted to minimize the impact of outliers.

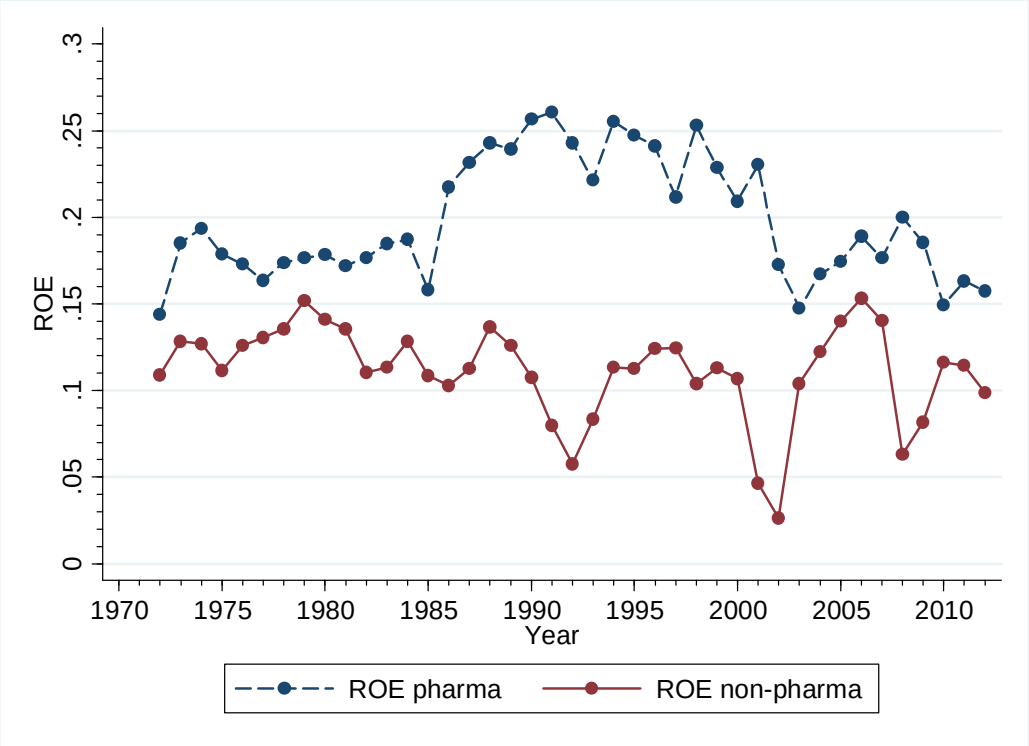

Figure 2: Difference in ROE between pharmaceutical firms and firms in other industries for international sample (1999-2012)

The sample comprises 6 countries: Australia (AUS), Canada (CAN), India (IND), Japan (JAP), Sweden (SWE), and U.K. (GBR) over the period 1999-2012. *ROE difference* is the difference in weighted-average ROE between the sample of pharmaceutical and non-pharmaceutical firms in a given year and country. Weights are set to the share of book equity in the total equity of pharmaceutical or non-pharmaceutical firms in each country-year.

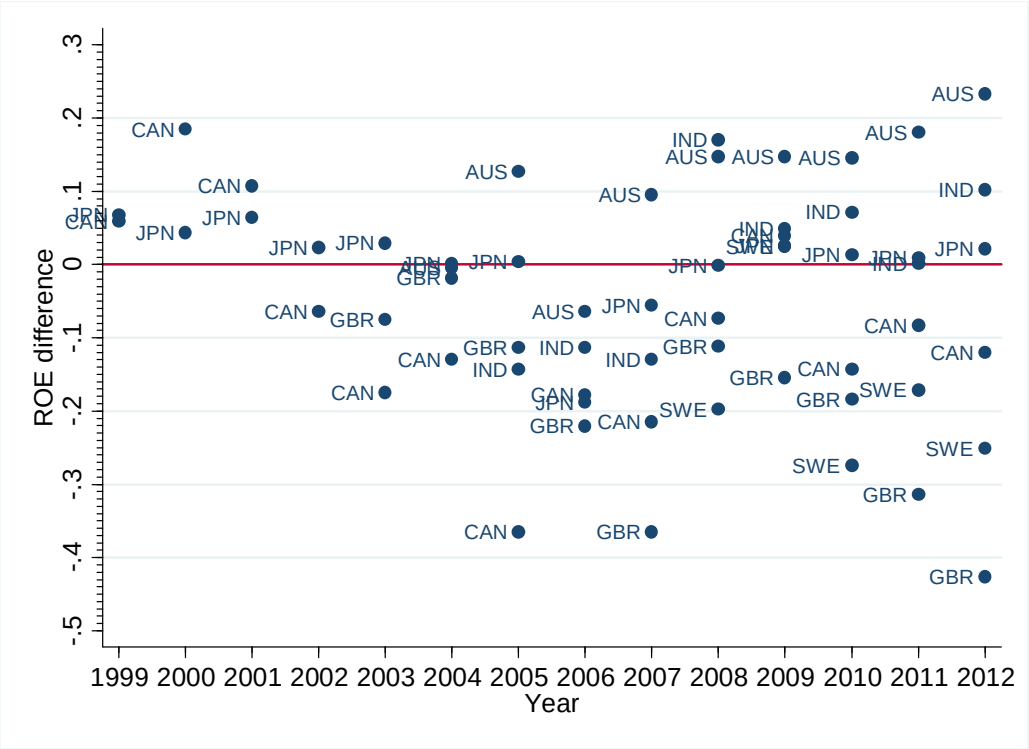

Table 1: **Effects of R&D accounting on ROE**

Table 1 compares two hypothetical pharmaceutical firms, A and B, with different accounting treatments for R&D. Both invest each year 100 into R&D and generate 115 in annual revenues. Both firms have a cash asset (30), some investment in R&D, and no liabilities. Firm A capitalizes 100% of R&D outlays and amortizes them over the next year. Firm B is allowed only to capitalize 10% of its R&D investments and must expense the remaining 90% of R&D investments when incurred.

Company A capitalizes **100%** of R&D outlays

	Year				
	1	**2**	**3**	**4**	**5**
R&D outlays	100	100	100	100	0
Balance:					
Capitalized R&D (intangible asset)	100	100	100	100	0
Cash	30	30	30	30	30
Assets = Shareholders' equity	**130**	**130**	**130**	**130**	**30**
Income statement:					
Revenues	0	115	115	115	115
– Amortization of capitalized R&D	0	–100	–100	–100	–100
= Net income	**0**	**15**	**15**	**15**	**15**
ROE		**11.5%**	**11.5%**	**11.5%**	**11.5%**

Company B capitalizes **10%** of R&D outlays

	Year				
	1	**2**	**3**	**4**	**5**
R&D outlays	100	100	100	100	0
Balance:					
Capitalized R&D (intangible asset)	10	10	10	10	0
Cash	30	30	30	30	30
Assets = Shareholders' equity	40	40	40	40	30
Income statement:					
Revenues	0	115	115	115	115
– R&D expense	–90	–90	–90	–90	0
– Amortization of capitalized R&D	0	–10	–10	–10	–10
= Net income	**–90**	**15**	**15**	**15**	**105**
ROE		**37.5%**	**37.5%**	**37.5%**	**262.5%**

Table 2: **Accounting profitability of pharmaceutical and non-pharmaceutical firms**

Table 2 reports summary statistics on the accounting rates of return of pharmaceutical firms and non-pharmaceutical firms for firms in the U.S. (Panel A) and international sample (Panel B). We obtain a weighted average *ROE* (the ratio of net income to closing book equity) for each country and year, and set weights to the share of book equity in the total equity of pharmaceutical firms in each country-year. *ROE_diff* is the difference in weighted-average ROE between the sample of pharmaceutical and non-pharmaceutical firms in a given year and country. *R&D_diff* is the difference in weighted-average R&D expenditure between the sample of pharmaceutical and non-pharmaceutical firms in a given year and country.

Panel A. U.S. sample (1972-2012)

Variable	N	Mean	Std. Dev.	Percentile		
				25th	50th	75th
ROE pharma	41	0.198	0.035	0.173	0.186	0.231
ROE non-pharma	41	0.111	0.027	0.104	0.113	0.129
ROE_diff	41	0.087	0.049	0.043	0.067	0.119
R&D_diff	41	0.125	0.043	0.083	0.127	0.163

Panel B. International sample (1999-2012)

Variable	N	Mean	Std. Dev.	Percentile		
				25th	50th	75th
ROE pharma	60	0.047	0.138	–0.038	0.056	0.128
ROE non-pharma	60	0.096	0.044	0.065	0.099	0.127
ROE_diff	60	–0.049	0.149	–0.148	–0.011	0.054
R&D_diff	60	0.120	0.078	0.072	0.107	0.156

Table 3: Effect of R&D accounting on ROE

Table 3 reports the estimated coefficients of equations (1) and (2). The dependent variable, ROE_diff_{it} is the country's i difference in weighted-average ROE between the sample of pharmaceutical and non-pharmaceutical firms in year t. $R\&D\_diff_{it}$ is the difference in weighted average R&D expenditure (the ratio of R&D expenditure to closing book equity) between the sample of pharmaceutical firms and the sample of non-pharmaceutical firms in year t. ΔGDP_{it} is the annual change in GDP in country i and year t. The sample comprises U.S. firms over the period 1972-2012 and the international firms (Australia, Canada, India, Japan, Sweden, U.K.) over the period 1999-2012. Columns (1) and (2) are OLS regressions, while columns (3) and (4) are estimated using country fixed effects. t-statistics use robust standard errors adjusted for heteroscedasticity and time series dependence and are reported in parentheses below coefficient estimates. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Dependent variable	ROE_diff_{it}			
Sample	**U.S.**		**International**	
	(1)	(2)	(3)	(4)
$R\&D\_diff_{it}$	0.431**	0.450**	–0.825	–0.316
	(2.51)	(2.37)	(1.58)	(0.61)
ΔGDP_{it}	–0.399**	–0.400*	–0.887**	–1.178**
	(2.19)	(1.95)	(2.78)	(2.98)
$Disinvest_{it}$		0.018		0.102*
		(0.63)		(2.18)
$R\&D\_diff_{it} \times Disinvest_{it}$		–0.089		–0.845**
		(0.31)		(2.74)
Intercept	0.059*	0.054*	0.094	0.049
	(1.97)	(1.81)	(1.58)	(0.83)
Country fixed effects?	No	No	Yes	Yes
Adj./Overall R^2	0.304	0.272	0.332	0.294
N	41	41	60	60

Table 4: ROE adjusted for the influence of R&D accounting

Table 4 reports the rates of return (ROE) after adjusting earnings and equity for capitalization and amortization of R&D investments. ROE of pharmaceutical firms is adjusted for the effects of R&D accounting using three techniques: (i) linear amortization, (ii) declining balance, and (iii) empirical amortization rates. The lower part of the table reports ROE_diff_{it}, the difference in weighted-average ROE between the sample of pharmaceutical and non-pharmaceutical firms as a result of the three types of adjustments.

	Sample	
Pharmaceutical companies	U.S.	International
ROE, as reported	0.198	0.047
ROE, linear amortization over 10 years	0.167	0.069
ROE, declining balance over 10 years	0.174	0.083
ROE, empirical amortization rates	0.082	–
Average *ROE* for three amortization methods	0.141	0.076
ROE_diff	0.087	–0.049
ROE_diff, linear amortization over 10 years	0.055	–0.026
ROE_diff, declining balance over 10 years	0.062	–0.013
ROE_diff, empirical amortization rates	–0.030	–
Average *ROE_diff* for three amortization methods	0.029	–0.020

Table 5: Profitability and regulation of pharmaceutical firms

Table 5 reports the estimated coefficients of equations (9) and (10). The dependent variable is a proxy for regulation of pharmaceutical industry in the U.S. The sample comprises U.S. firms over the period 1998-2012. $\Delta Restrictions_t$ is the log change in the number of restrictions in the pharmaceutical industry issued by U.S. regulators during year *t*. $\Delta Reg\_activity_t$ is the log change in the word-length of laws in the pharmaceutical industry issued by U.S. regulators during year *t*. ROE_{t-1} is weighted-average ROE of pharmaceutical firms in year *t–1*. $Party_t$ is an indicator variable for the ruling party of the U.S. House of Representatives in year *t* (1 if Republican, and 0 if Democrats). Estimation method is OLS. Panel A reports results for aggregate ROE. Panel B reports results for ROE components: $ROE_{t-1} = ROE\_adj_{t-1} + ROE\_bias_{t-1}$. ROE_adj_{t-1} is reported ROE in year *t–1* adjusted using empirical amortization rates. ROE_bias_{t-1} is the difference between observed ROE and adjusted ROE in year *t–1*. The last row of panel B reports the value of the *F*-test that compares the coefficient of ROE_adj_{t-1} and the coefficient of ROE_bias_{t-1}. *t*-statistics use robust standard errors adjusted for heteroscedasticity and time series dependence and are reported in parentheses below coefficient estimates. ***, **, and * indicate statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A: Aggregate reported ROE

Dependent variable	$\Delta Restrictions_t$	$\Delta Reg\_activity_t$
	(1)	(2)
ROE_{t-1}	0.795***	0.385**
	(3.54)	(2.53)
$Party_t$	0.036**	0.007
	(3.01)	(0.72)
Intercept	–0.132***	–0.053*
	(3.12)	(1.78)
Adj. R^2	0.482	0.276
N	15	15

Panel B: ROE components

Dependent variable	$\Delta Restrictions_t$	$\Delta Reg\_activity_t$
	(1)	(2)
ROE_adj_{t-1}	0.931**	0.556*
	(2.62)	(2.10)
ROE_bias_{t-1}	0.671*	0.230
	(1.83)	(1.12)
$Party_t$	0.036**	0.007
	(3.06)	(0.70)
Intercept	–0.124**	–0.042
	(2.57)	(1.48)
Adj. R^2	0.441	0.250
N	15	15
Test $ROE\_adj_{t-1} = ROE\_bias_{t-1}$	0.21 (p = 0.65)	0.79 (p = 0.39)