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Research Article

The Determinants of Study Productivity in Ethical Drug Discovery

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Abstract

In 1971, the pharmaceutical producer's affiliated participants spent approximately $360 million on R&D. In 1991, they spent $8.9 billion, an increase of over 2300 percent. Although industry income has grown in step with research expenditures, there has been no full-size increase within the range of the latest tablets introduced. Why have the costs increased dramatically? Breakthroughs in pharmaceutical research can lay the foundation for qualitative improvements in the quality of existence and large discounts on the price of healthcare. However, escalating healthcare fees have focused on each factor of healthcare expenditure, which has led several observers to question the apparent decline in the productiveness of pharmaceutical studies. This bankruptcy hopes to contribute to the controversy by exploring the issue in the context of a broader examination of the determinants of study productivity in the discovery of ethical drugs. We draw upon detailed facts compiled from the internal records of the ten most important pharmaceutical companies. The statistics set allows us to distinguish between studies (or discoveries) and improvement expenses at an enormous dis aggregated stage. For instance, in the standard magnification of cardiovascular cures, we can observe distinctions among fields such as hypertension, cardio tonic, and blood-associated conditions. This study presents several descriptive facts from the sample. Our pattern corporations show a long-term decline in productivity, which is a feature of the industry as a whole. Each study and development expenditure has improved dramatically in actual terms, even as the output of important patents has fallen and the wide variety of capsules observed has remained approximately the same.

Keywords: ethics; health testing and trials; research and development; performance productivity; pharmaceutical industry

Introduction

This is an important issue for public policy because it highlights the dangers of relying on research cost per drug as a useful measure of research costs. On the one hand, if there is a significant over-investment in research, competing firms are racing to market by investing in substantially identical research, and average search costs per drug per firm substantially overstate the actual expense required to discover a new drug. On the other hand, if there are significant spillovers among firms and research projects within the same firm and if firms do not immediately dissipate anticipated returns through excess investment, research costs substantially understate the resources required to discover a new drug. Unfortunately, it is difficult to test these ideas systematically because theoretical models become fundamentally indeterminate. As a first step toward a richer understanding of the issue, we focus on exploring the assumptions on which the theoretical literature rests. The rather extreme conclusion that free entry unambiguously leads to over-investment in research is crucially dependent on at least five key assumptions: entry will occur until marginal private returns have been driven to zero, there is no spillover of knowledge among firms, there is total appropriability of consumer surplus, competing projects are perfect substitutes for each other, and there are no efficiency gains to multi-firm competition. Testing the validity of the last three assumptions is beyond the scope of this chapter, but we explore the first by examining the dynamics of investment behavior. Following the methodology pioneered by Scherer (1992) and Meron and Caves (1991), we distinguish between leaders, core followers, and fringe firms. We find weak evidence that core followers invest in response to investments by the leading firm, while fringe firms reduce their investments in research because follower firms increase their research expenditures. These effects are only marginally significant but of a very small magnitude. Our results suggest that by far the most important determinant of one year's research spending is the previous year's spending, a finding consistent with a world in which investment decisions are driven much more by heterogeneous firm capabilities, adjustment costs, and scientific opportunities than by strategic interactions. We interpret our findings as suggesting that while firms may respond strategically to each other, such reactions are probably not sufficiently important to drive marginal private returns to zero. We then investigate the nature of spillovers in the industry by studying the determinants of the output of important patents. Our results are consistent with the presence of substantial spillovers, both within and across firms, and thus, suggest that the entry of additional firms into the R&D race does not unequivocally destroy welfare. The final section presents our conclusions and explores their implications for formulating public policies. Our results suggest that the apparent decline in the pharmaceutical industry's long-term productivity is probably a function of escalating the real costs of research. There is no evidence of a shift from easier to more difficult classes or an increase in racing behavior across firms. However, our research highlights the complexity of pharmaceutical research. In the absence of good measures of returns to innovation in the industry, we cannot know whether firms, on average, make excessive expenditures on R&D. However, our results suggest that while the pharmaceutical industry sometimes holds up as a textbook example of dissipative racing behavior

in R&D competition, the reality is probably considerably more complex. In some cases, we find evidence consistent with the kinds of correlated patterns of investment at the research program level that we would expect to see if R&D spending decisions were dominated by strategic interaction of the kind captured by game-theoretic models. However, we also found evidence consistent with significant R&D project complementarities and other spillover benefits across firms, suggesting that correlated investment strategies may create significant externalities. While our results must be interpreted with care, they suggest that the simple characterization of R&D costs by an average dollar-per-drug figure is almost certainly incorrect.

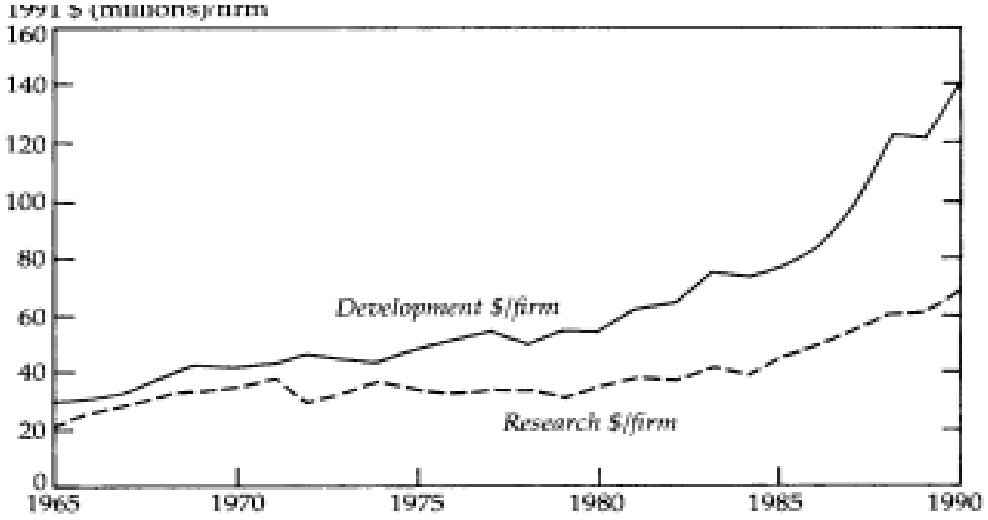

Figure 8-1 Mean R&D Spending Per Firm

Long-term trends in industry productivity

determine eight-1 plots of common spending on R&D through corporations in our sample from 1965 to 1990. While research spending has expanded in actual terms, the lion's share of the increase in pharmaceutical study fees is a function of the accelerating value of medical improvement. discern 8-2 plots R&D spending as a share of sales; at the same time, research expenditures are increasing roughly consistently with income, and development prices have outstripped them. Parent 8-3 plots the average outputs consistent with greenback from 1965 to 1990. The variety of important patents granted to the average company in our sample fell dramatically. This mirrors tendencies observed for the financial system as a whole, but even as the variety of patents, the Patent and Trademark Office workplace granted to U.S. firms fell in every industry in the Seventies, quite a number of the firms in our sample are European, and the decline in patenting prices by our sample companies are drastically higher than this more standard fashion (Griliches 1990).On average, the wide variety of investigational new drug packages and new drug packages obtained for each dollar invested in R&D with the aid of the firms in our sample has declined regularly. We must interpret this fashion with caution because corporations can take more than ten years to report a new drug's utility after the Food and Drug Administration has granted an investigational new drug license. Therefore, it is far more feasible that the acceleration in improvement spending that we consider in the overdue Nineteen Eighties could be observed by an outpouring of new drug packages over the following decade. But our data are in keeping with the combination data suggesting that the increase in spending on R&D has not been followed via a proportionate growth within the easily tracked measures of output: patents, investigational new drug packages, and new drug programs Heterogeneity throughout healing instructions Wiggins (1979) first established the importance of distinguishing healing lessons in modeling the determinants of productiveness within the pharmaceutical industry. On desk eight-1, we started the system of dis aggregating the records to expose the heterogeneity of pharmaceutical research. We show the ratio of cumulative outputs to cumulative inputs by therapeutic class for the years 1975 to 1990. These numbers must be approached with caution because they are subject to both left- and right-wing censorship. In the early years, for example, the outputs from each class were partially the result of spending before 1975, and many of the inputs to the process in the second half of the period did not yield results until after 1990. However, the numbers illustrate the variation hidden by aggregating the data. The number of important patents obtained per million dollars invested in research Examples vary from a high of 2.6 in dermatological drugs to a low of.2 in anti-infective drugs. Similarly, the ratio of investigational new drug applications obtained per billion dollars varies from twenty-five for anti-infective drugs to eighty-one for dermatological drugs, and the ratio of new drug applications to cumulative R&D spending varies from a low of six per billion in musculoskeletal research to a high of 34 per billion in dermatology.

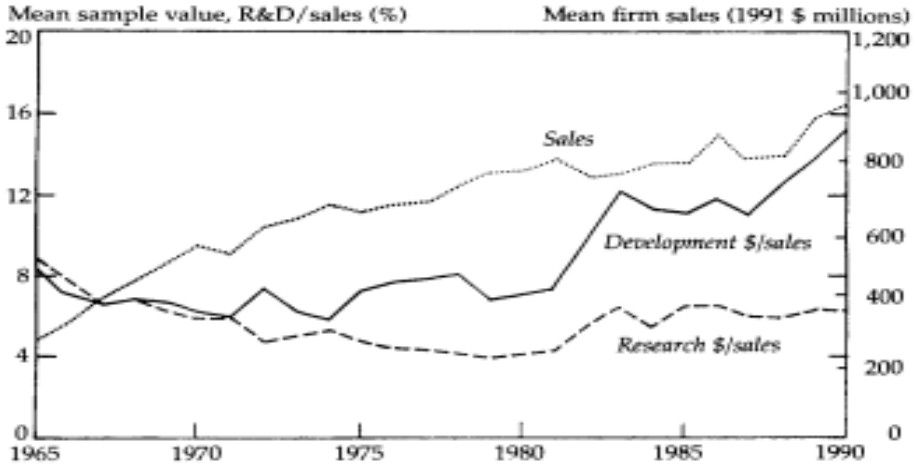

Figure 8-2: R&D As Share of Sales and Sample Average Sales

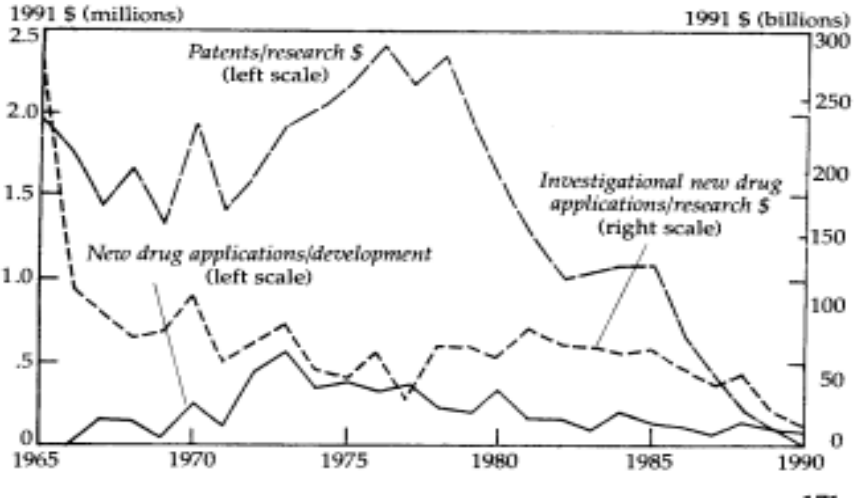

Figure 8-3: Patents, Investigational new Drug Application s, and new Drug Application per R&D Dollar

These variations translate into significant differences in the average "cost per drug" for each class. If we assume, for example, that investment in each program is constant across the sixteen years and that the time value of money is 9 percent, that translates into an approximate cost per new drug application of over $370 million for a musculoskeletal drug, $200 million for a cardiovascular drug, and $66 million for a million dermatological drugs were used. Thus, differences in costs across therapeutic classes are one possible explanation for the apparent decline in research productivity in the pharmaceutical industry. If firms have shifted resources away from "easy" fields such as dermatology toward "hard" fields such as anti-infective research, then research costs would rise and output would fall solely as a result of a change in portfolio composition. mean share of the increase in research costs. Firms have shifted their investment in research from anti-infective drugs to cardiovascular drugs. The results reported in Table 8-1 suggest that this shift should increase research productivity when all other factors are equal. In development, the firms in our sample have been shifting from central nervous system drugs to cardiovascular drugs, whereas the share of resources devoted to anti-infective drugs remains more or less constant. Again, the summary statistics in Table 8-1 suggest that this shift should have left research productivity approximately unchanged, all other things being equal. Thus, although research productivity differs systematically across therapeutic classes, there is little evidence to suggest that shifts among classes are at the root of the long-term "decline" in the productivity of pharmaceutical R&D. To gain insight into changes in industry productivity, we next explore the dynamics of investment behavior and differences in firm productivity. of the research portfolio by therapeutic class over time, while Figure 8-5 plots the mean share of the development portfolio. Both figures suggest that it is very unlikely that shifts in portfolio composition will drive

The Dynamics of Investment Behavior

Escalating the real costs of research in the pharmaceutical industry may reflect increasing competition and "over investment" in research. The theoretical literature exploring the relationship between competitive dynamics and investment strategy is both voluminous and inconclusive, but many of the models raise the concern that free entry into R&D competition will result in over investment relative to both private and socially optimal investment levels. Intuitively, these results are driven by the assumption that, in deciding to invest in research, firms consider only their marginal returns and do not consider the externality that they impose on other firms, reducing their chances of success. In the extreme, those models suggest that entry will occur until all expected profits are dissipated (Dasgupta and Stiglitz, 1980; Loury, 1979; Reinganum, 1982, 1989) {5,6,7,8} However, it is difficult to test these hypotheses. Models that attempt to incorporate all the relevant variables quickly become dauntingly complex, and we have, as yet, no general results on the relationship between market structure, scientific or technological regime, and the realized and optimal levels of research investment (Harris and Vickers 1987; Reinganum 1989). However, the literature highlights several factors that determine whether the entry of an additional firm into the research race raises or lowers social welfare. For example, one can show that in markets characterized by perfectly competitive behavior, complete appropriability, and research projects that are perfect substitutes for each other, there might be a giant over investment in studies (Dasgupta). and Stiglitz 1980). Conversely, in industries characterized by weak appropriability, wherein funding in studies is greater cooperative than competitive and in which studies tasks are in large part complements, there's probable to be under investment relative to the social best (Dasgupta and Maskin 1987; D Aspremont and Jacquemin 1988, 1990; Fraja 1993; Suzumura 1992) {10,11,12,13,14}

due to the fact theoretical models that try to capture simultaneously

The interactions among these elements quickly become intractable.

Rather, we discover the validity of the core assumptions on which the models of hire dissipation depend. First, under the loose entry, companies will respond strategically to every difference and could invest in search until marginal returns fall to zero. Second, there are no spillovers of information either across initiatives inside the company or among corporations. A greater dialogue of the theoretical troubles involved and the relationship between our studies and the prevailing literature is given in our look at "Racing to make investments? The Dynamics of Opposition in Moral Drug Discovery" (Cockburn and Henderson 1995) 15 As is well known, the literature shows that the two workable styles of investment conduct are steady and dissipating. Reinganum (1982) offers a model in which symmetric oligopolistic corporations race for a well-defined prize. In these situations, the companies' reaction functions slope upward, and one company's marginal increase in spending is met by an increase in its opponents' spending. On the other hand, Harris and Vickers (1987) broaden a model of contention among asymmetric firms in which expanded spending via the leader

Inspired a submissive reaction using fans.

The difference between the two behaviors builds on Scherer (1967) advanced work and is confirmed through previous empirical work. Grabowski and Baxter (1973), for instance, observed that in the chemical industry, the two largest companies responded quickly to adjustments in every different Meron and Caves (1991) observed that in a sample of twenty-eight U.S. production industries, leaders and followers reacted positively to every company's increase in R&D fees, while fringe corporations' investments decreased with their larger rivals' funding. Scherer (1992) discovered that firms with extra domestic income in more concentrated U.S. markets are likely to react more aggressively to increasing import competition than smaller firms or companies in less

focused markets. In Tables 8-2, 8-3, and 8.4, we present our evaluation of the investment dynamics that symbolize our pattern. Desk 8-2 contains the results of regressing investment on the control variables suggested by the qualitative analysis. They include the stock of research, which is intended to capture, among other things, unobserved differences in the quality of the program; firm and therapeutic class dummies; a time trend, and variables intended to capture shocks to scientific opportunity—news—in their own patents and important papers. We define news as the excess of the current year's flow over the amount necessary to maintain the stock given a depreciation rate of B: This formulation is intended to capture activities above normal levels.7 Of all the control variables, only news about patents is significant. We use three specifications for the dependent variables. In model (1) the dependent variable is just the level of research spending, and

The explanatory variables include lagged research to capture adjustment costs. This variable dominates the regression and its coefficients are indistinguishable. In Model (2), we constrain it to one by using the first difference of R as the dependent variable. We include a lag difference of R in this specification, but this is insignificant. Model Equation (3) uses a new version of R and lagged news on the right-hand side. Lagged news is strongly significant, suggesting that changes in research strategies are correlated from year to year. In Table 8-3, we introduce competitor expenditures into the regression to test for the presence of strategic interactions.8 We reproduce model (3) from Table 8-2 for purposes of comparison. Model 4 tests the hypothesis that every firm responds to every other firm by including news in competitor research as an independent variable. It is insignificant. Model (5) tests the hypotheses that the leading firm responds only to core followers, while core followers respond both to each other and to the leading firm, and fringe firms respond both to the leader and the core followers.9 All the coefficients except that of the leader's response to the core followers have the expected sign, but Only one is significant: fringe firms appear to react submissively to investments by their core followers. Moreover, the standard test for the significance of additional variables cannot reject the hypothesis that competitive spending adds no additional explanatory power to either Model (4) or Model (5). While we must temper our interpretation of this result because our firms together comprise only about 28 percent of the industry, the result provides only very limited support for the

presence of strategic interactions among firms

In Table 8-4, we test for the idea that racing behavior may have increased over time, even if it was not present in the sample as a whole. Model (6) is run using the data from 1961 to 1974, while model (7) tests for the significance of competitive investment from 1975 to 1988.10 Competitive investment is insignificant in both specifications, and a Chow test cannot reject the hypothesis that there is no difference in the dynamics of the two periods. Thus, we find limited evidence of strategic interactions in investment behavior. Moreover, the magnitude of these reactions is very small; together, in the most successful specification, they add only.1 percent to the explanatory power of the regression, and our results suggest that the most important determinant of a period's investment is the preceding period's investment. These results are consistent with qualitative findings. Highly trained personnel are expensive to hire and let go of, and dramatic increases in the size of a program are unlikely to lead to equally dramatic increases in its productivity. l1 Discovery research is a highly uncertain process, and our quantitative finding that investments are highly serially correlated is consistent with a world in which investment decisions are driven by heterogeneous firm capabilities, adjustment costs, and the evolution of scientific opportunity.

Spillovers and Research Productivity In an industry characterized by straightforward duplicative racing behavior, one firm's success is another's loss, since each firm invests in identical research programs and there are no spillovers of knowledge across firms. However, if there are significant spillovers of knowledge across firms, research productivity may be correlated with competitive investment and additional entry into the R&D race may enhance welfare.

We test for the presence of spillovers in our data by regressing important patents for a variety of control variables and a set of measures designed to capture competitive activity in the field. We can use these equations as a production function for important patents that competitors' research successes enter as inputs to each other's R&D.

Table 8-5 sets out our results. Models (9) and (0) use the full sample. Model (9) suggests that one's output and the success of rival firms' efforts are positively and significantly correlated. Using competitors' discovery spending instead of their patents gives very similar results: competitors' investment has a positive and significant impact on their research productivity; however.12 The model fails to control for changes in scientific opportunity, thus raising the possibility that the observed correlations across firms merely reflect exogenous shifts in opportunity that make it easier to obtain patents in any given class. Model (10) included key papers as a measure of scientific opportunity. There is no significant correlation between these measures and own output, and important competitive patents remain a significant predictor of own patents. Models (11) and (12) repeat those analyses using cardiovascular data alone; model (12) uses more detailed measures of scientific opportunity.14 Patent output is not significantly correlated with key papers in the public sector, which suggests that major shifts in the stock of public knowledge are not immediately translated into patents. However, patent output is significantly correlated with the flow of key papers published by private-sector researchers. Nonetheless, controlling for that effect

strengthens the correlation between research productivity and competitor output.

Thus, our results are consistent with the idea that knowledge spillovers across firms are significant. Important patents per discovery dollar are likely to be significantly higher if competitors have recently obtained several important patents in the area, and far from leading to a "mining out" of opportunities, competitors' research appears to be a complementary activity to their R&D. Thus, the entry of additional firms into a therapeutic area may enhance welfare. We must qualify that result by observing that not all patents are equally important. If, for example, a major discovery in an area makes it easier to obtain patents in the area, and if our measures of scientific opportunity do not capture that effect, then correlation in output across firms may reflect no more than the generation of "me-too" patents for "me-too" drugs. Two factors moderate this problem. The first is that so-called me-too drugs may offer important additional therapeutic benefits such as reductions in side effects or improved efficacy with different segments of the population. The second is our finding that output is positively associated with a competitive investment as well as with competitive output, which suggests that we are capturing the effect of genuine spillovers of knowledge.

Research Method:

The research methodology section describes the approach taken to conduct the study. It outlines the study's design, information collection strategies, and sample selection criteria. The primary facts series concerned surveys and interviews with researchers, industry specialists, and key stakeholders inside the ethical drug discovery area. The gathered statistics have then been analyzed with the use of statistical strategies, including regression evaluation and correlation analysis, to discover the determinants of the studies' productiveness.

Results:

The results section presents the findings obtained from the statistical analysis. It highlights the huge determinants that affect research productivity in moral drug discovery. The results may additionally consist of statistical values, which include regression coefficients, p-values, and effect sizes, to quantify the impact of every determinant. The segment may additionally include visible representations, together with graphs or tables, to beautify the presentation of the consequences.

Discussion:

The dialogue phase translates and explains the results in the context of the study's goals. It delves into the implications of the diagnosed determinants on research productivity in moral drug discovery. The discussion can also explore the relationships between special determinants and their combined

impact on productivity. It also considers ability obstacles of the study and suggests areas for future studies

limitations and recommendations for further investigation:

pattern length and Generalizability: The study's findings can be restricted by the pattern size and the precise context in which information changes and accumulates. To improve generalizability, future studies ought to include a larger and more diverse group of drug discovery researchers from numerous agencies and geographic locations. Subjectivity in data series: The qualitative facts amassed via interviews may be challenged by individual biases and views. To mitigate this drawback, destiny research should take into account employing more than one interviewer and accomplishing member checking to enhance the credibility and reliability of the qualitative findings.

Longitudinal Research: This study presents an image of the determinants of productiveness in ethical drug discovery. Completing longitudinal studies over an extended period ought to offer insights into how these determinants evolve and their long-term effects on studies' productivity. cross-disciplinary analysis: at the same time as this examination acknowledges the importance of interdisciplinary collaboration, further research may want to delve deeper into the precise mechanisms and procedures that maximize productivity in one-of-a-kind interdisciplinary settings. Comparisons between single-discipline and multi-disciplinary groups may also be explored.

Metrics for productiveness: The have look broadly speaking is based on productiveness metrics as a degree of studies output. but, productiveness on my own won't capture the entire effect and excellent drug discovery studies. future investigations should contain extra measures, such as medical achievement quotes, patent filings, and quotation counts, to offer an extra comprehensive knowledge of research productiveness.

Comparative evaluation: A comparative evaluation between exceptional research organizations, educational establishments, and enterprise settings ought to shed mild on the elements that differentiate enormously effective drug discovery packages from much less productive ones. examining first-class practices and achievement memories ought to **provide treasured insights and tell** techniques to decorate productivity throughout the sector. outside elements: The study focuses primarily on internal determinants of productivity in ethical drug discovery. destiny research ought to keep in mind the impact of external elements, along with regulatory frameworks, market dynamics, and public funding guidelines, on research productivity. expertise those external influences can assist identify additional regions for development. Fee-effectiveness analysis: Investigating the price-effectiveness of different studies strategies and practices should provide insights into how assets may be allocated greater correctly to maximize productiveness in moral drug discovery. This evaluation could recollect factors that include studies funding, failure prices, and time-to-market for new pills.

Conclusions

Over the past twenty years, the pharmaceutical industry appears to have suffered a dramatic decline in productivity. We have used dis aggregated data at the research program level to explore that decline in the context of the drivers of productivity in drug discovery. Our results suggest that the decline is probably not a function either of a shift to research in more difficult areas or of an increase in racing behavior in

the industry. Rather, our results are consistent with the hypothesis that rising real costs of research in the industry reflect decreasing returns. The switch to more science-intensive methods of drug research appears to be a major contributor to increasing costs, but the most important driver of cost escalation appears to be the rocketing costs of developing clinical drugs. We speculate that this probably reflects both a shift to the treatment of conditions that require more complex clinical trials and increasing regulatory stringency, but we have no data about those issues.15 In general, our results must be interpreted with caution. Our analysis of investment behavior and spillover effects applies only to competition in research or drug discovery; we plan to explore the determinants of productivity in development in later work. Moreover, the validity of our spillover analysis is crucially dependent on our use of important patents as a measure of output. We plan to extend our analysis by using alternative measures of output. We also hope to enrich our understanding of how the dynamics of the industry have evolved. Those results have potentially important implications for public policy. Most importantly, they suggest that the presence of several competitors in any given area may increase social welfare. While it may be tempting to think that one could rationalize the amount of R&D conducted by the industry or set prices based on the research expenditures of a single firm, our analysis suggests that it may be dangerous to think of research costs in terms of some measure of "dollars. per drug" deduced from the spending of any single firm. A reduction in the number of firms conducting research in any given area may have significant negative externalities if R&D spending complements rather than substitutes for rivals' investment. Intuitively, the true cost of a drug may include the costs of those programs in rival firms that failed but contributed to the industry's common pool of knowledge by spilling information across the boundaries of the firm.

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Conflict of Interest

The authors declare no conflict of interest

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