

Determining Optimal Firm and Consumer Research and Development Spending in the Medical Technology Sector

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ABSTRACT

Many studies indicate that increasing expenditure on the development of medical technology is the main impetus behind rising health care costs. This study examines the relationship between medical technology companies' goal to maximize profit via Research and Development investments and R and D's effects on the competing factors of consumer's health benefit and health care costs. Through analysis of pharmaceutical company profits versus R and D costs, this project attempts to map out a level of optimum R and D investment spending for firms. On the consumer side, this project also attempts to map out R and D investment levels by firms that yield the best health benefit for patients of drug treatments. Finally, the project attempts to determine if an R and D optimum exists that can increase benefit to both firms and consumers.

INTRODUCTION

Health economics research indicates that a major force behind the rising costs of health care in the United States is the cost of medical technology. This is a complicated matter as these costs represent profits for medical technology companies who then proceed to reinvest these earnings into research and development spending. Thus, medical technology costs offer simultaneous costs and benefits for the consumer.

The calculation of medical technology's influence on increasing health care costs has relied on indirect measures. For instance, Cutler (2007) measured costs due to disease-specific medical technology to determine this effect. Other works, including Newhouse (1992) and Okunade and Murthy (2002) considered a residual approach (measuring other costs and declaring the residuals to be due to medical technology costs) and a proxy approach (using sample technologies to measure costs) respectively. However, while no direct measure exists to measure medical technology's impact, all reliably indicate that it one of the largest causes for the rise in health care costs.

Both the consumer and the firm seek to optimize efficiency by maximizing research and development output while minimizing costs. However, due to the high volatility of research and development's success in developing drugs and thus profits for the firm, there appears to be no clear standard across the industry in choosing an efficiency-maximizing research and development spending schedule. This study seeks to determine if firms currently operate inefficiently and to determine if an optimal research and development value can be determined.

For firms, this value must optimize profits, not maximizing drug output, but rather overall profit for

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minimal research and development input costs. However for consumers, an optimal value will maximize health benefits due to these drugs, while minimizing drug costs. Thus, this study also seeks to unite two potential optimization points, for the firm and consumer, to examine if both sides can benefit from changes in research and development spending.

THE FIRM

On the firm side, companies choose to maximize profits and are willing to set the price as high as their market power will allow. In the case of the medical technology sector, highly inelastic demand for health care represents a strong ability for companies to set their prices. However, companies have an interest in diverting a large percentage of profits towards research and development investment as this will yield future profits in the company's future. Thus the companies' profit-maximizing condition considers two effects: it must maximize profits in the current period while making an investment decision that will maximize future profits.

For example, consider a typical firm that must choose to invest in research and development spending (as an input of production). Greater investment in research and development increases the output of drugs, but may not necessarily be the most efficient, profit-maximizing solution. In a case where the company is past its drug production optimization point, there are diminishing returns to each additional level of research and development spending and the firm is barely increasing the number of drugs produced.

Additionally, consider two firms who choose two different levels of research and development spending levels. The budget constraint is the level of revenue earned from the prior period. The firms can choose to invest more in research and development spending as Firm A has done, or spend less and keep more profits from the prior period as Firm B. These indifference curves are a function of the company's willingness to take on risk by investing more heavily in research and development spending, or by choosing a more conservative route where prior revenue is more heavily kept as revenue.

Firms take on huge amounts of risk by investing in research and development and must find a suitable level of spending to maximize their profits. Also, this high level of risk leads to high prices to cover the cost of potential failures taken on by firms. Although medical technology companies have a large amount of market power, they must maintain balance to not set prices so high that they lose customers.

As further explained in the "Data" section below, this study will use pharmaceutical companies as a proxy for all medical technology companies with data from annual reports. This study will examine costs accrued by companies due to both successful and failed research and development products (listed as aggregate research and development spending in the base (current period) year's annual report. The future success and failure of spending is unobservable in the present period and thus by examining aggregate spending, "survivorship bias" of measuring only successful projects is eliminated. The study will then model medical technology costs against profits in the future period that drugs used in the model

were sold.

Implementation of a two-period model will be necessary to gauge the effects of research and development spending in terms of input costs and output profits. Research and development is unique in that the largest costs occur up-front and the benefits are not realized until subsequent periods. Thus, costs need to be measured in the period before the drug's release and as it is being produced (operational costs) in the period after its release along with profits post-release. According to Keyhani, Diener-West, and Powe (2006), average drug development time, post acceptance of the Investigational New Drug application (IND) is 6.3 years. During this time, many of the overall research and development costs are spent in trying to develop the new drug. Thus, this study uses this length of time to calculate aggregate research and development spending costs for the development of new drugs in a 2 year period that immediately follows.

Profit-cost analysis will lead to a cost-efficiency measure to determine how successful (in terms of maximizing profits) various research and development strategies have worked by analyzing profits in the subsequent period. The overall purpose of this part of the study is to determine a potential optimal value of research and development spending by firms that is the most efficient compared to current investment decisions. In addition, methods for companies to expand profits will also be examined to determine if a more-efficient, optimal decision exists.

THE CONSUMER

The study will then proceed to examine the consumer's side of the equation. The product of research and development is medical technology. Consumers desire to maximize the benefit of medical technology while at the same time minimize its costs that add to the increased spending on aggregate health care. Thus, it is important to find methods to measure both the health benefit and the cost associated with increased expenditure on health care for each level of research and development spending from different firms.

The problem of health benefit can be calculated by approximating the cost of an extended year of life by using a similar approach to the work of Cutler and McClellan (2001). In this study, various health conditions were examined by comparing the technology used to treat the condition and the average health benefit yielded by using the technology. The authors used \$100,000 as the value for each year extended by the technology, using a quality-adjusted life year (QALY) method (see "Quality-Adjusted Life Year" section for a more in-depth explanation). The study will attempt to measure not only the years of life extended by the treatment, but also the quality of life rendered by the treatment as well (using any available data that can be found from other research studies of medical treatments, such as clinical trial studies) and create a series of QALY values for various drugs associated with different firm research and development spending schedules.

The quality of life/years of life extended variable will thus provide the backbone of the potential health benefits offered to consumers. It may be assumed that the more spending on research and development

that occurs, the higher the value of welfare benefit for the consumer. However, this study would like to test whether this is the case and hypothesizes that at a certain level, additional spending on research and development has a minimal health benefit and in fact increases associated costs for the consumer. For example, on a graph drawn with increasing return approaching a plateau, the point of the beginning of the plateau results in minimal benefits of additional research and development spending for the firm; likewise a similar graph can be drawn where a similar point will have minimal health benefits for the consumer with increased research and development spending.

Using the calculated values of technologies' benefits and costs, the study will attempt to find the most efficient technological output for cost (or the most cost-efficient solution). There is a possibility that the most cost efficient solution occurs far below current research and development expenditure levels, indicating that this efficient solution fails to provide enough utility for consumers to make up for the benefits of decreased costs. Thus, current data must be analyzed to determine if a more cost-efficient solution is also feasible when taking into account consumer utility for health benefits (that is, consumers demand a high amount of health benefit and low values will not occur due to the necessity of medical technologies).

The final goal of this project is to compare the optimal values facing the firm and facing the consumer of research and development spending. Firms may currently operate in an inefficient manner, spending far more than is necessary to maximize profits in the next period. In addition, the consumer health benefit may actually occur at a lower amount of research and development spending than would be predicted. Thus, this study will attempt to find such opportunities for Pareto Improvements in terms of an optimized research and development spending value for both sides, benefiting both consumers and producers.

UNIQUE FEATURES OF THIS STUDY

Many studies have attempted to map out optimality on both the firm and consumer sides. However, this study will attempt to match both sides to determine if there is a spending level that will benefit both groups. In addition, previous studies have not done a very thorough job in examining additional "quality of life" factors that are a byproduct of medical technology's health benefit, which this study will attempt to solve using clinical trial studies.

On the consumer side, Cutler and McClellan's (2001) work examining health benefits due to medical technology provides many key methodologies for this project. The study extended Newhouse's (1992) study examining the technological costs and health benefits for heart attacks. Their findings concluded that the between the years 1984 and 1998, heart attack technology provided a net social benefit of \$70,000 for consumers. To reach this value, they took the average cost of treatments associated with heart attack patients and subtracted this value from the number of years that this treatment added to a patients' life on average. The conversion for a year of life was taken to be \$100,000 per life year extended. This value was calculated from a quality-adjusted life year (QALY) approach that will be taken as a fact for the purposes of this project.

QUALITY-ADJUSTED LIFE YEAR APPROACH

Sassi explains the calculation of the QALY in his 2006 work. This paper will provide the conversions necessary to express the conditions stated in clinical trial studies of specific prescription drugs caused by their use to numerical values for easier drug health benefit evaluation. Quality of life extended is measured on a scale of 0-1 with 1 measuring someone in perfect health who has added a year to his or her original life expectancy. Those whose lives are extended, but live with some side-effect, have a positive QALY that is less than 1. Generally, this is determined through surveys involving people rating their quality of life with a certain illness (generating the Disability-Adjusted Life Year). This value is then subtracted from 1 to form the QALY. However, without the ability to survey thousands of participants with various conditions, this paper will generate a novel scale applying fixed values for certain problems associated with prescription drugs. This is an effective and simple way of measuring health benefit added by the prescription drug (the benefit – the side effects or risks). As with Cutler and McClellan (2001), these values can then be converted into dollar figures.

The Australian Productivity Commission (2005) performed an in-depth study to determine the benefits of medical technology innovations in addition to Cutler and McClellan (2001). The Commission broke down different ways in which technology affects consumers, although the material is rather dense. This paper will provide a resource to compare to Cutler's methodology. In addition Cutler (2007) performed a detailed examination of costs and benefits due to medical technology over an entire lifetime for the consumer following a myocardial infarction. While these and other studies approximate both benefits and costs well, they fail to examine an optimal value of research and development spending that would maximize consumer health benefits while at the same time minimize costs.

Cutler and McClellan's (2001) framework will be utilized for this study's methodology to calculate net social benefits for the consumer. However, as mentioned above I must add conditions that will take into account quality of life and other factors (using the QALY approach) that are not well-examined by current studies, which only indicate only how many years of life a technology adds on average for a patient of a disease. I will however follow their basic design on taking a certain market basket of drugs/conditions and analyze both the cost and benefit associated with treatments for patients with this specific disease.

FIRM RESEARCH AND DEVELOPMENT SPENDING

Kort's (1998) model takes the uncertainty of the success or failure into account of the firm's decision to invest in research and development. In addition, the model utilizes a two period system that takes into account the initial investment in period one and the rewards gained in the subsequent period. Firms must maximize their profits in both periods not based on research and development spending for the future and current profits from prior works. While this equation is rather complex, it nicely derives a value of K^* , or optimal research and development investment. However, it seems firms do not seem to operate strictly to maximize profits and are constantly increasing their research and development budget due to competition

and the desire to capture as much market share as possible with new drug treatments. Thus, they operate to constantly increase production of new drugs and rarely consider other R and D spending schedules.

Data regarding pharmaceutical firm behavior will be taken from company annual reports and other information available on the internet. Other works, including Carlton and Perloff (2005) and Chakravarty (1995) helped with the methodology regarding the measurement of the net social benefit value for consumers and the basic implementation of models in calculating the firm research and development optimal condition. All of these works have helped to develop this paper's goal to compare both sides of the spending decision to try and develop an optimal condition that satisfies both sides.

DATA SOURCES

The study uses pharmaceutical companies as a proxy for all medical technology companies. Pharmaceutical companies publish a wealth of information through their annual reports, such as aggregate research and development spending as well as revenue information. Prescription drug costs and drug clinical trial reports can also be easily accessed over the internet. In addition, pharmaceutical companies' research and development decisions are often times quite dynamic and provide a good indicator of the effects influencing firm decision making. Finally, limiting the scope of technologies to just pharmaceuticals allows for greater simplicity and flexibility in data manipulation.

FIRM RESEARCH AND DEVELOPMENT SPENDING REVISTED

On the firm side, the key to this project is to accumulate the necessary data regarding firm research and development spending to test the model on optimal firm R and D spending. According to Keyhani, Diener-West, and Powe (2006), the average drug development time (for clinical trials and regulatory review) was 6.3 years between 1992-2002. Thus, this study uses R and D spending values from 2000-2006 and then examines what drugs entered the market between 2007-2008. This provides the success rate (number of drugs entering market/costs during drug development period) for firms to examine potential optimums.

Drug development also appears to be cyclical, thus the study also examines the number of drugs that were accepted by the FDA between 2000-2006 as well. This will be compared to the drugs approved between 2007-2008 to determine how realistic this window is compared to a longer period.

MEASURING HEALTH BENEFIT

On the consumer side, the most difficult step will be to analyze additional variables characterizing health benefit that go beyond the standard years of life extended value. All of these variables, currently grouped under the title "quality of life" will likely be difficult to observe. However, this project uses prescribing information on drugs to determine the how beneficial treatments are for patients compared to the risks from taking these drugs. This data is manipulated into a numeric value using the QALY that

provides an easier analysis for the quality of life under this treatment option.

PAIRING CONSUMER NET SOCIAL BENEFIT TO FIRM RESEARCH AND DEVELOPMENT

Finally, the study takes both the consumer optimal research and development value in terms of health benefit and compares it with the optimal research and development spending value (in terms of profit maximization) for the firm. The drugs which have been examined for consumer's health benefits will be the same drugs that entered the market between 2007-2008, thus pairing the firm's research and development strategy to the net social benefit of these same drugs for the consumer. It will be evident what research and development strategy taken on by the firm yields the highest value of net social benefit to yield an optimal research and development value for the consumer. The study will then examine if it is possible for both sides to choose a different R and D spending level that will provide benefits for both, or a Pareto Improvement.

FIRM RESEARCH AND DEMAND OPTIMUM

Using the FDA New and Original Drug Approvals search engine, I searched for new drugs approved between 2006-2007. I limited the drug companies I was searching for to the top 10 companies using PharmExec.com's list of the top 10 companies by U.S. market share. The data was puzzling because Pfizer, the leading pharmaceutical company in the world has only produced 1 drug for the market within this 2-year period compared to 8 each with Novartis and GlaxoSmithKline. This seemed to indicate that companies developed drugs in cycles. Thus, I decided to examine drugs produced within a wider window, from 2000-2008. This data is more representative of the current leaders by U.S. market share, although Novartis stands out as a clear outlier, producing far more drugs within this period than its current position in U.S. sales indicate.

Since 2000-2008 drug approval data seems to be more accurate, representing the perceived cyclical nature of drug development, I decided to graph this data versus aggregate research and development spending to determine if diminishing marginal returns to research and development spending occurs and if a possible optimum value can be determined. The data from this chart includes all research and development costs accrued by the company from the years 2000-2006, which represents the 6.3 year estimated average period to create a successful drug entrant into the market.

The data indicates that increasing spending in research and development leads to increased drug output. I removed the outliers of Novartis and GlaxoSmithKline and found that the R-squared of the linear trend line was more representative than the logarithmic R-squared with values of .8178 and .6952 respectively. Thus, it does not appear as though diminishing returns to R and D spending occur. Companies should strive to increase R and D spending and the yearly data from 2000-2006 indicated that almost always, companies increased their R and D expenditure.

Even though the data from 2007-2008 of new drugs approved by the FDA is not an accurate representation of R and D output for firms, I decided to examine the cost-profit ratio from R and D spending by firms from 2000-2006 versus the profit of drugs created in 2007-2008 using profit data from

2009 to see if I could still find an optimum spending level for firms. I subtracted the profit of 2006 from the profits of 2009 to get a rough estimate of profit from drugs entering the market in 2007 and 2008. I also added costs of advertising and selling the drug, as increases in expenditure in this category has the potential to increase sales of drugs for firms. Note that Wyeth was acquired by Pfizer in 2009 and thus 2009 Wyeth data is not available. I then determined the cost/revenue ratio. I sorted the data to reveal who had the lowest cost/revenue ratio and compared it to the companies who spent the least on research and development. Unsurprisingly, the data is inconclusive, likely representing the cyclical nature of drug development and the misleading number of drugs developed by companies in the period 2007-2008.

While the data is inconclusive, it suggests that medium spending on R and D tends to yield the best results. Even when the problem of cyclical drug development is considered, Novartis seems to have the most-efficient drug production. Novartis produced the most drugs between 2007-2007 and 2000-2008 and had only the third-highest aggregate R and D spending amount. The two ends of R and D spending, Pfizer and Amgen, had the highest cost/revenue ratio, although this is likely a function of cyclical drug production for Pfizer. In general, higher expenditure on R and D yields higher drug output, but medium spending appears to be the best and optimal strategy.

CONSUMER RESEARCH AND DEVELOPMENT OPTIMUM

To determine optimal consumer research and development spending, I decided to limit my data set to drugs produced between 2007-2008 for the 4 firms at both ends of the R and D spending spectrum. The highest spender was Pfizer, and the lowest spender was Amgen. I also included Novartis, which was the most efficient spender using the 2007-2008 data and 3rd highest spender overall, and Wyeth, which was the second lowest spender on R and D.

I used each of the government-mandated "Prescribing Information" to weight their adverse reactions. I also characterized the drug's environment (what other drugs treat the same condition) and then developed my own QALY-like scale of values.

Amgen seems to have the most beneficial drug for consumers with a value of .85. It is possible that Amgen's research and development spending is aimed for blockbuster drugs that could arise from treatment of a previously untreated condition. However, it is likely this sort of targeted research and development approach is unlikely as companies do not have tight grip on when and how treatments can be developed. Novartis has the second most beneficial drug series, but also developed more drugs than any of its competitors. Thus, Novartis's research and development spending yields the best package for consumers. It is important to note again that this two year window does not adequately represent the makeup of drug production as it appears as though some companies go through a cyclical wave of high and low development throughout various years. Nevertheless, Novartis seems to have the best package for consumers.

CONCLUSION

While overall the results of this study are inconclusive due to the perceived cyclical nature of drug development, it appears as though increased spending on research and development generally yields in higher drug output. Drug output may be the best way to judge R and D because firms may not be able to steer their development into higher-earning opportunities, such as developing treatments for currently poorly-treated conditions. Diminishing returns to R and D spending were noticed, but this could be because companies have yet not reached the plateau of spending which could eventually result in less drug production for increased expenditure.

In all data sets, Novartis appears to have the best results in terms of drugs developed. The company's spending is also 3rd highest; while on the higher side, it also shows that companies do not need to spend exquisite amounts to produce many drugs (as in the case of Pfizer). This efficient production could be due to a hidden variable in Novartis' operational management that cannot be elucidated here.

On the consumer side, Novartis again appears to be the leader in producing the optimum research and development spending leading to maximum number of useful drugs approved. Pfizer's high spending only resulted in 1 average-benefit drug. The low spending Amgen did better, producing 1 high-benefit drug. Wyeth did better, spending on the low side and producing 3 moderately beneficial drugs. However Novartis produced the highest amount of drugs with the second highest average benefit for consumers while being only the third highest spender on research and development.

In general, it appears that moderately high expenditure on research and development yields the most optimal solution in terms of profit for firms and health benefit for consumers. As a whole higher spending seems to be better than lower spending as it increase profit and benefit for both firms and consumers as well. Thus, it is no surprise that firms constantly strive to increase their research and development spending levels yearly as it benefits not only them, but the consumer as well.

ENDNOTES

1. The following websites provided brief summaries classifying the prescription drugs used in this study: www.associatedcontent.com (Exforge), www.centerwatch.com (Tekturna), www.drugs.com (Toviaz), www.guide4living.com (Exelon), www.healthcentral.com (Reclast)
2. Pharmaceutical company websites provided the "Prescribing Information" used to classify drugs
3. The Federal Drug Administration's Investigational New Drug Application website (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu>) provided the data for drugs approved by year
4. The Security and Exchange Commission's EDGAR Database (<http://www.sec.gov/edgar.shtml>) provided annual report information when annual reports were not available on pharmaceutical company's websites.
5. The list for the top 10 drug companies by market share was provided by www.pharmexec.com
6. Data and graphs available on request.

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REFERENCES

- Bessen, James E. 2007. "Estimates of Patent Rent from Firm Market Value." Boston University School of Law Working Paper No. 06-14.
- Carlton, Dennis W. and Jeffrey M. Perloff. 2005. *Modern Industrial Organization*. Pearson Addison-Wesley: Boston, MA.
- Chakravarty, Satya R. (1995): *Issues in Industrial Economics*. Avebury: Aldershot, England.
- Congressional Budget Office. 2006. "Research and Development in the Pharmaceutical Industry."
- Cutler, David M. and Mark McClellan. 2001. "Is Technological Change In Medicine Worth It?" *Health Affairs*, Volume 20:11-29.
- Cutler, David M. 2007. "The Lifetime Costs and Benefits of Medical Technology." NBER Working Paper Series.
- DiMasi, Joseph A., Ronald Hansen, and Henry Grabowski. 2003. "The price of innovation: new estimates of drug development costs." *Journal of Health Economics*, Volume 22:151-185.
- Eli Lilly and Company. 2008. "2008 Annual Report and Proxy Statement."
- Getzen, Thomas E. 2007. "Modelling Long Term Healthcare Cost Trends." The Society of Actuaries.
- Kaiser Family Foundation. 2007a. "Trends in Health Care Costs and Spending." Menlo Park, CA.
- Kaiser Family Foundation. 2007b. "How Changes in Medical Technology Affect Health Care Costs." <<http://www.kff.org/insurance/snapshot/chcm030807oth.cfm>>.
- Keyhani, Salomeh, Marie Diener-West, and Neil Powe. 2006. "Are Development Times For Pharmaceuticals Increasing or Decreasing?" *Health Affairs*, Volume 25:461-468.
- Kort, Peter M. 1998. "Optimal R & D Investments of the Firm." *Or Spektrum* (Netherlands), Volume 20: 155-164.
- Newhouse, Joseph P. 1992. "Medical Care Costs: How Much Welfare Loss?" *Journal of Economic Perspectives*, Volume 6(3): 3-21.
- Okunde, Albert A. and Vasudeva N.R. Murthy. 2002. "Technology as a "Major Driver" of Health Care Costs: a Cointegration Analysis of the Newhouse Conjecture." *Journal of Health Economics*, Volume 21: 147-159.
- Perloff, Jeffrey M. 2008: *Microeconomics: Theory & Applications with Calculus*. Pearson Education: Boston, MA.
- PriceWaterhouseCoopers. 2006. "The Factors Fueling Rising Healthcare Costs."
- Productivity Commission of Australia. 2005. "Impacts of Advances in Medical Technology in Australia." Research Report, Melbourne.
- Ringel, Jeanne S., Susan Hosek, Ben Vollard, and Sergej Mahnovski. 2001. "The Elasticity of Demand for Health Care." National Defense Research Institute (RAND).
- Sassi, Franco. 2006. "Calculating QALYs, comparing QALY and DALY calculations." Oxford University Press: London, UK.