Health Care Cost Containment and Medical Innovation

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Introduction

Innovations in medical care have led to improvements in quality and quantity of life. Researchers estimated that improvements in medical care contributed to the life expectancy for newborns increasing by almost seven years from 1960 to 2000[1]. However, U.S. health spending reached an estimated 2.7 trillion dollars in 2010 and the health share of the gross domestic product is projected to increase from 17.6 percent in 2009 to 19.8 percent by 2020[2]. This creates the challenge of how to curb health care spending while continuing to enjoy the improvements in quality and quantity of life that result from innovation in medical care.

Containing the costs of care can be useful to government, employer, and household budgets, but it may have a detrimental impact on innovation, since health care costs are the main source of revenue for medical innovators. Developers seek profits and so are attracted to industries and innovate where they

[1] Cutler DM, AB Rosen, S Vijan The value of medical spending in the United States, 1960-2000. NEJM 2006; 355:920-927.

[2] Keehan SP, AM Sisko, CJ Truffer, JA Poisal, GA Cuckler, AJ Madison, JM Lizonitz, SD Smith. National health spending projections through 2020: economic recovery and reform drive faster spending growth. Health Affairs. 30:1594-1605.

believe profits can be made. Policies that reduce health care costs and, in turn, developer's profits may have a dampening impact on innovation.

Although, the overall impact of innovation in medical care is beneficial, some innovation may be wasteful from a societal perspective. Developers may spend R&D resources on protecting or expanding their market share through developing "me-too" drugs that are similar to drugs already on the market or making small changes to their existing product lines to differentiate their products. Ultimately, for a given policy, we would like to assess the impacts on health care costs for today's consumers and the impacts on innovation for future consumers and determine whether the policy makes society better off. To assess the impacts of cost containment on innovation economists have attempted to answer a number of intermediate questions, including: What is the impact of profitability and market share on innovation? How do policies affect revenues and innovation? What is the overall impact on society of innovation?

This paper explores the economics literature on cost containment and health care innovation, with most of the focus on pharmaceutical innovation. First, we discuss the market for pharmaceuticals and why it does not function as a competitive market and so does not naturally allocate an efficient level of resources to innovation. We next discuss findings from the economic literature on how profits and market size affect incentives to innovate and then explore the literature on what economists have discovered about the relationship between cost containment and innovation. We then consider the theoretical and empirical research on the relationship between cost effectiveness, price regulation, and innovation. Finally, we conclude with a discussion about the relationship between innovation and social welfare.

The cost of producing new medical products

Many innovative products in medical markets are characterized by high up-front development costs and low marginal prices for production. Goods with these characteristics will not be produced in perfectly competitive markets – once such a good was introduced, competitors would replicate it exactly and prices would fall to reflect only the marginal costs of production. Innovators would never be rewarded for their investments in research. For this reason, such products are provided with government protection (through patents) from perfect competition, at least for a period of time.

Many medical products are examples of such goods. A widely cited estimate of the cost of developing a new innovative drug in 2006 was in excess of one billion dollars, including the cost of failures and the opportunity cost of money[3]. Before a drug is marketed, the sponsor must undertake clinical trials to demonstrate that the drug is safe and effective. To provide incentives for the investment in R&D for drugs, the government protects the intellectual property of the drug developer through patents and data and marketing exclusivities. This allows the developer to sell the drug at a price that allows for profits higher than in a competitive market, if there is sufficient market demand for the drug.

[3] DiMasi and Grabowski. Managerial and Decision Economics. 2006

The impact of profits and market size on innovation

The expectation of profits leads to investment in innovation. Profits are the difference between (discounted) revenues and (discounted) costs over the life of the product. According to economic theory, all else being equal, policies that lower costs of development or production or raise revenues, through higher prices or larger quantity demanded, should result in the development of more drugs. Policies that lower costs or raise revenues stimulate R&D, while policies that raise costs or lower revenues will reduce R&D. Several studies have found that increases in profits (or related measures) for drugs leads to increases in R&D. Scherer postulates three possible links between gross profits and R&D[4]. First, R&D investment leads to new products, which if successful, increase the company's profits. Second, profits provide a cash flow for financing R&D. Third, future profit expectations will be influenced by current profitability. Scherer found that pharmaceutical industry R&D is characterized by a "virtuous rent-seeking model" in which increases in profits lead companies to increase R&D and, possibly, marketing costs until the profits are dissipated.

Acemoglu and Linn looked at the impact of market size on innovation[5]. They measure market size by looking at demographic changes in the US population. They found that the increasing average age of the population has lead to increases in availability of pharmaceuticals used by middle-aged relative to young consumers. They found that a 1 percent increase in the potential market size for a drug category leads to approximately a 4-6 percent growth in the entry of new molecular entities.

Lichtenberg and Waldfogel looked at the effect of market size on pharmaceutical development by exploiting the natural experiment of the passage of the Orphan Drug Act[6]. The Orphan Drug Act provided incentives for the development of drugs in very small markets, including tax benefits and extension of exclusivity. The passage of the Orphan Drug Act resulted in an increase in the market size for previously unprofitable drugs. Lichtenberg and Waldfogel found that the Orphan Drug Act resulted in greater growth in drug consumption for less common conditions relative to more common conditions, and so concluded that greater market size is important for providing incentives for pharmaceutical development.

Finkelstein investigated the current and future impact of policies to increase utilization on development of new vaccines[7]. She found empirically that policies focused on current utilization also have an impact

[4] Scherer FM. The link between gross profitability and pharmaceutical R&D spending. Health Affairs, 20, no.5(2001):216-220.

[5] Acemoglu D and J Linn. Market size and innovation: theory and evidence from the pharmaceutical industry. Quarterly Journal of Economics. August 2004. 1049-1090.

[6] Acemoglu D and J Linn. Market size and innovation: theory and evidence from the pharmaceutical industry. Quarterly Journal of Economics. August 2004. 1049-1090.

[7] Finkelstein A. Static and dynamic impacts effects of health policy: evidence from the vaccine market. Quarterly Journal of Economics. May, 2004. 527-564.

on innovation. The economic incentives that resulted from increased utilization led to an increase in new vaccine clinical trials and new vaccines, but no increase in basic inventive activities, like preclinical trials or patent findings. Her results implied that a one dollar increase in annual expected market revenues would result in an additional 6 cents in annual present discounted value investment in that vaccine.

Although there is agreement in the literature about the empirical effect of profitability on innovation, the magnitude of the effect is still in doubt[8].

Cost Containment Strategies

Governments and private insurers use a variety of strategies to contain health care expenditures, including expenditures on medical products. In the pharmaceutical sector, these strategies include global budgets, prescribing budgets, profit controls, direct price controls, reference pricing, economic evaluations, generic substitution, and pharmaceutical reimbursement[9].

Sood et al. looked at the effect of price regulation on pharmaceutical revenues by examining the variation in pharmaceutical pricing policies across 19 developed countries[10]. They found that price regulations have a significant impact on pharmaceutical revenues with direct price controls having the largest impact, followed by economic evaluations and budgets, while reference pricing, profit controls and policies for encouraging generic use did not have statistically significant impacts on revenues. The Department of Commerce published a report, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, likewise found that pharmaceutical sector cost containment strategies lower revenues[11].

Vernon investigated the impact of price regulation on R&D by estimating several models of the determinants of R&D investment[12]. He found that expected profits and lagged cash flows are important contributors to R&D investment. He then simulated the impact of regulation lowering pharmaceutical prices in the U.S. to the average level in markets with price regulation and estimated that this would reduce industry R&D investment between 23 and 33 percent.

Cost Effectiveness Analysis and Cost Containment

[8] Scherer FM. Price controls and global pharmaceutical progress. Health Affairs.(2009) 28:no.1:w161-164.
[9] Sood N, H de Vries, I Gutierrez, DN Lakdawalla, and DP Goldman. The effect of regulation on pharmaceutical revenues: experience in nineteen countries. 28, no. 1 (2009): w125-w137.
[10] IBID
[11] U.S. Department of Commerce. Pharmaceutical price controls in OECD countries: implications for U.S. consumers, pricing research and development, and innovation. December 2004.
[12] Vernon JA. Examining the link between price regulation and pharmaceutical R&D investment. Health Econ 2005;14: 1-16

One strategy used by many countries to improve the allocation of health care dollars is cost-effectiveness analysis. Cost-effectiveness analysis typically (though not necessarily) focuses on the current costs and effectiveness of pharmaceuticals, ignoring impacts on future innovation. The use cost-effectiveness analysis in the establishment and regulation of prices may also have dynamic effects on innovation through changing developers' expectations of profits, by increasing development costs, and by better identifying the social value of innovation.

Jena and Philipson in two articles show that reducing cost effectiveness thresholds will lead to lower prices and better off consumers now but would negatively impact innovation[13][14]. Conversely, higher cost effectiveness thresholds will result in higher levels of R&D investment. They find that the most efficient allocation of resources would result from consumers paying for pharmaceuticals the maximum price they are willing to pay. This would result in very low cost-effectiveness for pharmaceuticals, but provide the best signal to developers for the most efficient level of resources to allocate to R&D. Jena and Philipson point out, however, that there are a number of factors need to be considered in determining if producers have sufficient incentives to innovate. 1) How R&D expenditures divided between public and private efforts. If the public investment is substantial then profit incentives to innovate can be smaller. 2) If health insurance leads to overuse of healthcare services due to subsidized demand, excessive profits and R&D spending could result.

Vernon et al. explore the impact of cost-effectiveness on innovation by considering the impact of signaling of future profits to innovators[15]. If regulators set cost effectiveness thresholds too low developers under-invest in R&D. Alternatively, if regulators set cost effectiveness thresholds too high developers will over-invest in R&D.

Vernon, in another paper, also explores the impact of greater requirements for cost-effectiveness on innovation due to the impact on development costs[16]. Vernon asserts the increase in clinical trial size to reach the necessary power to demonstrate effectiveness relative to a comparator rather than a placebo would significantly increase development costs. This increase in development costs would be likely to decrease profits and, in turn, innovation.

Other economists have suggested that greater use of cost effectiveness could lead to more socially valuable innovation. Jayadev and Stiglitz suggest that we could increase innovation and decrease costs

[13] Jena AB and Philipson TJ Cost Effectiveness analysis as a price control Health Affairs, 26, no. 3 (2007):696-703.

[14] Jena AB and Philipson TJ Cost Effectiveness analysis and innovation, Journal of Health Economics 27 2008 1224-1236.

[15] Vernon JA, Goldberg, and JS Stevens. Economic evaluation and cost effectiveness thresholds: signals to firms and implications for R&D investment and innovation. *Pharmacoeconomics.* 2010; 28 (10): 877-887.

[16] Vernon JA, JH Golec, and JS Stevens.Comparative Effectiveness Regulations and Pharmaceutical Innovation. *Pharmacoeconomics*. 2010; 28 (10): 877-887.

by using value based pricing, which would link the price to the marginal value of the innovation[17]. This would discourage innovation in pharmaceuticals with little social value.

How valuable is innovation?

Additional innovation may not be an efficient use of resources. In the health care market, where consumers frequently do not directly pay for their health care, products may be purchased whose price exceeds the consumer's true willingness to pay leading to over-investment in innovation. Also, developers may innovate by developing pharmaceuticals that do not offer benefits beyond what is already on the market to gain market share. This innovation for "business stealing" may make society worse off, as the fixed costs of development are incurred, but there is no improvement in health outcomes.

On average, research suggests that additional innovation is welfare enhancing. Lakdawalla et al. looked at the welfare impacts (health and medical spending) of lowering U.S. prices to E.U. levels[18]. They constructed a 5 step microsimulation model that 1) calculated new drugs introductions based on new molecular entities mapped to seven diseases, 2) identified the "top-selling drugs", 3) estimated health effects of top-selling drugs based on clinical trial results, 4) estimated effects of changes in revenue on innovation, and 5) mapped health status and health care use. They found that price controls have modest benefits in the short run and substantial costs in the long run. Alternatively, reductions in co-payments increased utilization, increased revenues, and innovation benefitting current and future generations. Scherer critiqued their model on several points[19]. One, the estimate for the impact of changes in revenues on innovation was based on Acemoglu and Linn's estimate, which Scherer believes is too high and was calculated based on population counts, not revenues. Two, the authors limited the model to blockbuster drugs which earn extraordinary profits and so would still be likely to be developed even with lower revenue expectations.

If innovation is welfare improving on average, there may be considerable variation between pharmaceuticals. For example, Finkelstein found that for most of the diseases studied, the increased R&D induced by changes incentives was in socially wasteful investment for business stealing[20].

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[17] Jayadev A and J Stiglitz. Two Ideas To Increase Innovation And Reduce Pharmaceutical Costs And Prices. *Health Affairs*, 28, no.1 (2009):w165-w168.

[18] Lakdawalla D, DP Goldman, PC Michaud, N Sood, R Lempert, Ze Cong, H de Vries and I Gutierrez. U.S. Pharmaceutical policy in a global marketplace. *Health Affairs*. 28, no.1 (2009):w138-w150

[19] Scherer FM. Price controls and global pharmaceutical progress. Health Affairs.(2009) 28:no.1:w161-164.

[20] Finkelstein A. Static and dynamic impacts effects of health policy: evidence from the vaccine market. Quarterly Journal of Economics. May, 2004. 527-564.

Conclusion

The economics literature generally indicates that innovation in medical products has produced tremendous benefits for U.S. consumer in longer and healthier lives. Also, in little dispute is that developers respond to incentives and when the profitability or size of a market increases, they respond by offering more products. However, there is little agreement of the size of the effect of changes in profitability on innovation and how to ensure that the innovation that takes place is welfare-enhancing.