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The impact of public basic research on industrial innovation: Evidence from the pharmaceutical industry

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ABSTRACT

While most economists believe that public scientific research fuels industry innovation and economic growth, systematic evidence supporting this relationship is surprisingly limited. In a recent study, Acemoglu and Linn (2004) identified market size as a significant driver of drug innovation in the pharmaceutical industry, but they did not find any evidence supporting science-driven innovation from publicly funded research. This paper uses new data on biomedical research investments by the U.S. National Institutes of Health (NIH) to examine the contribution of public research to pharmaceutical innovation. The empirical analysis finds that both market size and NIH funded basic research have economically and statistically significant effects on the entry of new drugs with the contribution of public basic research coming in the earliest stage of pharmaceutical drug discovery. The analysis also finds a positive return to public investment in basic biomedical research.

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...successful management of industrial research is dependent on rapid access to the latest discoveries in academic laboratories...

Edward M. Scolnick, M.D.

Former President of Merck Research Labs

1990 Industrial Research Institute Medalist Address

1. Introduction

In his 1990 Medalist Address to the Industrial Research Institute, Dr. Edward M. Scolnick, former President of Merck Research Laboratories, emphasized the importance of academic research as

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a source of new ideas fueling innovation in the pharmaceutical industry. In particular, he highlighted the contribution of university research funded by the U.S. National Institutes of Health (NIH) to the discovery of new drugs using a variety of specific examples such as the discovery of Captopril and Proscar.

The present paper generalizes existing case study research by examining the evidence for a systematic relationship between NIH investments into biomedical research performed in academic laboratories and pharmaceutical industry innovation. The belief that academic research creates new knowledge fueling technological opportunities has a long history in economics (Griliches, 1979, 1992; Klevorick et al., 1995). Growth theorists use the non-rivalrous nature of new knowledge to explain growth in income per capita and to introduce the possibility of increasing returns to scale (Aghion and Howitt, 2005; Jones, 2005). In the empirical literature, Jaffe (1989) analyzed the production of corporate patents by region over time and found that academic research made a significant contribution. Jaffe's findings were reinforced when applied to a single year of data on innovations by Acs et al. (1991). Adams (1990) found that academic knowledge made a

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significant contribution to manufacturing productivity growth with a lag of up to thirty years on spillovers.¹

Focusing on the pharmaceutical industry, Acemoglu and Linn (2004) built a theoretical model to explain the entry of new drugs into medical therapeutic markets. The model highlighted the influence of market size on innovation, but it also included the possibility that changes in technological opportunities from the supply-side could augment innovation. Their empirical tests found strong evidence that potential market size stimulates new drug entry, but found no evidence that NIH investments into biomedical research stimulate innovation. Moreover, Acemoglu and Linn did not control for the pharmaceutical industry's own investments in research and development (R&D).

The finding that NIH investments have no systematic relationship with pharmaceutical innovation is troubling for at least two reasons. First, it is inconsistent with existing qualitative and quantitative evidence. Among the sectors analyzed by Jaffe (1989), drugs and medical technology showed the strongest influence of academic research on corporate patenting. In two different surveys, Mansfield (1991, 1998) found the pharmaceutical industry had the highest percentage of new products based on recent academic research. Cohen et al. (2002) reported that public research influenced new project ideas in the pharmaceutical industry more than in any other manufacturing industry. Looking at science papers cited in U.S. drug and medical patents, Narin et al. (1997) found that 79% originated from public science institutions. Cockburn and Henderson (1998), using co-authorship data, showed that firmlevel "connectedness" to public research was positively related to performance in drug discovery. Second, it calls into question the contribution of public investments into biomedical research.² The NIH is the largest public enterprise supporting biomedical research. In 2010, the NIH invested over \$20 billion in biomedical research performed at universities and other not-for-profit research institutions. New drug innovation should be one of the important channels for reaping the benefits of these enormous public investments in biomedical research.

Using novel data on NIH biomedical research awards from 1955 through 1996, this analysis examines the possibility that changes in technological opportunities from public investments in basic biomedical research contribute to pharmaceutical industry innovation. The NIH data are combined with the pharmaceutical industry's own R&D investment and a market size proxy to estimate a panel data model of pharmaceutical innovation by therapeutic market over time. The statistical analysis shows that NIH funded basic research, potential market size, and industry R&D all have economically and statistically significant effects on the entry of new drugs. The elasticity estimate in the preferred model implies that a 1% increase in the stock of public basic research ultimately leads to a 1.8% increase in the number new molecular entities (NMEs), an important category of new drug therapies defined by the U.S. Food and Drug Administration (FDA). For an average NME, the results also indicate the lag between public investment and NME applications to the FDA is seventeen to twenty-four years. The primary contribution of public basic research to new technological opportunities seems to occur in the years preceding private drug discovery.

The analysis also finds a positive return to public investment in basic biomedical research. Using market sales data for an average NME, the direct return for the six therapeutic markets analyzed is about forty-three percent. One must interpret the magnitude of this estimate cautiously. The estimate does not reflect the plurality or totality of channels through which basic biomedical research is likely to impact social outcomes. It is limited to the contribution of basic research to NME innovation.³ Even for NME innovation, the rate of return calculation is based on estimates of sales revenue that do not capture consumer surplus, intergenerational improvements in health, or indirect returns acting through industry R&D. So, while the return is positive, the calculations represent only a fraction of the social return to public basic research investment.

The rest of the paper is organized into the following sections. Section 2 outlines the pharmaceutical innovative process and reviews the research relationships within this process. Section 3 presents the empirical model used in the analysis. This is followed by a description of the data sources and measures in Section 4. Section 5 presents the empirical results and discussion. Concluding remarks are found in Section 6.

2. Pharmaceutical product innovation and public basic research

Innovation in the pharmaceutical industry takes place when private firms introduce new drug therapies into the marketplace. Before a new drug therapy can be marketed in the United States, it must receive approval from the U.S. Food and Drug Administration (FDA). As such, FDA policies and requirements fundamentally impact the nature and structure of the pharmaceutical innovative process. The FDA also classifies new pharmaceutical products. The pharmaceutical innovations analyzed in this paper come from their group of new molecular entities (NMEs), which is the category of new products with the greatest therapeutic and economic potential.⁴ One should not confuse NMEs with other pharmaceutical products that are discovered through long-term experience or post-market clinical observation. While these other products, such as Upiohn's Rogaine cream for hair growth, may be therapeutically and economically important, new indications or uses of approved drugs do not qualify as new molecular entities. For this reason, the analysis focuses on NIH investments into basic research, although public clinical research investments were included in some of the robustness checks.

The nature and structure of the pharmaceutical innovative process determines how and when public basic research influences new drug innovation. This process is typically described as beginning with drug discovery, moving to pre-clinical studies, human clinical development, and eventually to application for approval from the FDA. It is relatively structured and sequential compared to most other industries due to the regulatory requirements imposed by the FDA. Case study evidence suggests that public basic research has its primary influence on industry drug discovery. Public basic research provides a foundation of knowledge which creates both new opportunities for addressing therapeutic outcomes and new information for chemical screening. The new opportunities stem mainly from advances in our understanding of metabolic processes in normal and disease states while, in the chemical screening

¹ There are a number of other contributions to this literature including Mansfield (1991, 1998), Narin et al. (1997), Beise and Stahl (1999), and Arundel and Geuna (2004). Salter and Martin (2001) provide a survey.

² The contribution of public research to drug innovation is an important part of the debate on pharmaceutical profits and drug pricing. Based mostly on case study evidence in reports such as NIH (2000), advocates on both sides of the debate acknowledge a positive NIH contribution, but they interpret the evidence differently. For further background, refer to Sampat and Lichtenberg (2011) and Reichert and Milne (2002).

³ Salter and Martin (2001) survey and classify the variety of ways that public investment in basic research can have economic benefits. Also refer to McMillan and Hamilton (2003), Cockburn and Henderson (2001), and Malo (2009).

⁴ Even within this group of potentially important innovations, there are significant differences in actual or realized therapeutic and economic impact. See Scherer and Harhoff (2000) and Grabowski and Vernon (1994, 1996) for an analysis of the distribution of sales revenue for NMEs. Cockburn (2006) provides a good overview of the issues.

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