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Understanding Incentives in Health Care

Anna A. Levine

First I empirically show how market structure influences the split of producer surplus innovators receive for successful innovation in the biotechnology pharmaceutical industry. After identifying the drivers of firms' values for adding a new drug to their product portfolio, I show that when the distribution of marketing rights for products in a physician specialty are concentrated in a single firm, the bargaining position of the innovator is weakened and this effect becomes more severe as the size of the physician specialty increases. Next, I examine the effect of state legislation restricting physician investment in magnetic resonance imaging (MRI) facilities on the usage and availability of MRI technology. I find this legislation decreases the number of MRI machines available by 12% and shifts where procedures are performed from hospital to non-hospital based facilities.

Understanding Incentives in Health Care: Executive Summary

Anna A. Levine*

Introduction

With health care costs spiraling out of control, understanding how to design effective regulation to provide incentives for both the efficient innovation and usage of new health care technology is more important than ever. In chapters one and two I explore how market structure is driving the expected returns innovators receive in the biotechnology pharmaceutical industry and in turn provide incentives for future innovation. In chapter 3 I examine how regulation which is aimed at preventing physician moral hazard when ordering and referring patients for magnetic resonance imaging procedures has impacts impacts not only on the availability of new technology but also in the types of facilities available. Understanding how regulatory policy not only effects the short term market incentives for firms but also how the markets are fundamentally organized is important when trying to predict the impact of any proposed regulation.

Incentives for Innovation in the Biotechnology Pharmaceutical Industry: Chapter 1 and 2

Over $19.8 billion was invested in biotechnology research in 2007. Venture capital firms and large pharmaceutical firms both make huge investments in startup firms in this area. In addition, there is a very active licensing market in this industry; less that one third of approved biotechnology pharmaceuticals are marketed by the firms that brought the drug into phase 1 FDA trials. Therefore return on investment in this area depends not only on the probability of successful innovation and the market potential of any successful new innovation but also on the split of rents the innovator will receive from licensing the marketing rights of a product to another firm. The split of rents will depend on how the new product "fits into" the current portfolios of potential acquirers, and on the costs associated with the innovator marketing the product themselves.

Consolidation of marketing impacts the level of competition in licensing markets and the return an innovator will receive from successful innovation. The structural model of licensors' profits I estimate in Chapter 2 allows me to quantify how the split of overall producer surplus an innovator receives varies with the characteristics of the product and the distribution of the domestic marketing rights for other pharmaceutical products across firms. I find that when marketers' values for adding a given product to their portfolio vary widely, particularly at the top of the value distribution, the return an innovator receives upon successful innovation is depressed. The problem is more severe when the innovator does not have the capabilities to market their product themselves. This lack of competition

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for the marketing rights of a product allows large marketing firms to extract value leaving a smaller proportion of overall producer surplus for innovators.In the first chapter, I provide motivation for the empirical model I use in my estimation and also provide additional contextual information about the biotechnology pharmaceutical industry.

Chapter 1: Biotechnology Pharmaceutical Industry: An Overview

Biotechnology pharmaceuticals differ from traditional small molecule drugs both in the type of markets these drugs serve and in the technology used in innovation. Many of the new biotech drugs are high cost drugs that serve specialty markets. They provide treatments for patients with conditions such as cancer, HIV, and Gaucher disease. Biotechnology innovation relies heavily on the tools of molecular biology. Biotechnology drugs are produced using living organisms, making process innovations an important part of biotechnology research. [1]

The market for prescription drugs accounted for $216.7 billion in 2006, accounting for roughly 10% of overall US health care expenditures.[2] As drugs move from the manufacturers to patients, the drugs themselves pass through several types of firms, and the flow of funds move through along a somewhat different pathway. Understanding how pricing in this industry operates is important when trying to understand the strategic forces at play.

Typically, drugs themselves move from the manufacturers to wholesalers to retail pharmacies to the patient. While money moves in a somewhat more complicated way as shown in Figure 1. Rebates are typically negotiated between each pair of firms and vary significantly across the different pairs of firms. These rebates may be for the speed of service (in the case of wholesalers and manufacturers) or dependent on market share (in the case of Pharmacy Benefit Managers (PBMs) and manufactures). The types of relationships range from being very strategic, complicated, and open to lots of negotiation (PBM and manufacturers) to being fairly standard and simple (manufacturers and wholesalers).

According the PhRMA, the major pharmaceutical trade association, pharmaceutical companies spent over $12 billion on sales and marketing in 2007. Promotional activities include providing free samples of medication to physicians, direct to consumer advertising, physician detailing, arranging speaking events for health care experts, as well as advertising in physician professional journals.

Direct financial payments to health care providers account for a small percentage of overall sales and marketing expenditures for pharmaceutical firms. In Chapte 1 I provide a summary of these direct payments to physicians in Minnesota from 2002-2004 using data collected from pharmaceutical firm payment disclosures in Minnesota to the State Board of Pharmacy. This information was taken from paper records and transferred into electronic form by Ross et.al. and is described in detail in their 2007 JAMA article. The data set includes information regarding payment date, recipient identity including address and professional degree, payment purpose and value, and the company disclosing the payment. According to Minnesota law, disclosures are required for payments of $100 and greater, excluding pharmaceutical samples, publications, and educational materials. Gifts of $50 or greater are prohibited.As explained in Ross et al. 2007, the amounts reported are likely underestimates of the actual payment from pharmaceutical firms directly to physicians in Minnesota as some very large companies only appear in one out of three years.

Figure **??** show the magnitude of the total direct payments reported by each pharmaceutical firm made to health care providers during this time period. GlaxoSmithKline with a total of $5,776,305

[1] Robbins-Roth provides an excellent industry overview

[2] These are estimates from the the 2006 National Health Expenditure Accounts estimates by the Center for Medicare and Medicaid Services

made the most payments during the time period, while Amgen with $1,502,808 was the biotech firm with the largest reported payments.

This data demonstrates pharmaceutical firms frequent financial contact with health care providers even in a state where explicit financial gifts of great than $50 are illegal and these direct financial payments are subject to public reporting requirements. Some of these relationships involve large transfers of financial resources and these relationships often involve repeated interactions. We also see that multiple firms contact the same individuals for assistance and therefore maybe implicitly competing for these physicians attention.

Finally, I in this chapter I discuss how these features of the industry relate to the returns innovators receive for successful innovation in this industry and how well these returns are aligned with social welfare.

Chapter 2: Licensing and Scale Economies in the Biotechnology Pharmaceutical Industry

In many innovative industries the majority of innovation occurs in a large number of small firms while marketing and commercialization are done by a smaller number of large firms. This is particularly true in biotechnology. Most marketing rights in this industry are transferred from the innovating firm either through a license or acquisition to another firm that markets the product. The size distribution of innovators is shown in Figure 2 while the size distribution of marketers is show in Figure 3. In Chapter 2 I develop and estimate an econometric model that quantifies the forces driving the consolidation of products across firms.

My estimates use data on the current distribution of domestic marketing rights and assumptions about how this distribution relates to firms' underlying profit functions. Specifically I assume the distribution of products across firms is a pairwise stable allocation. An allocation is pairwise stable if there do not exist two firms that jointly benefit by trading some part of their product portfolios while allowing an accompanying monetary transfer between the two firms. Using the revealed preference inequalities implied by pairwise stability, I proceed with estimation using a matching estimator developed recently by Fox (2007).

Throughout the paper, I refer to physician class/specialty and disease/indication class. Drugs in the same indication/disease class compete with one another to be prescribed by a physician when a patient has a particular disease or disorder. However, drugs in the same physician class/specialty (but not in the same indication class) do not compete with each other to be prescribed for a given patient. For example, if one drug treats Rheumatoid Arthritis and another drug treats Multiple Sclerosis, these drugs do not directly compete against each other to be prescribed for a particular patient (i.e. they are not in the same indication class), but they are in the same physician class - Rheumatology.

In my analysis I find that the economies of scale firms realize from marketing multiple drugs in the same physician specialty and the diseconomies of scale firms encounter when growing the overall size of their product portfolio are important factors in explaining differences in firms' valuations for licensing a particular product. An incumbent firm's return from deterring entry of new firms into a product market or a physician class, is also important. Additionally, I find that innovators are more likely to keep products they innovate particularly when the innovator already has cash flow from another successful product.

Using my parameter estimates I calculate each potential marketing firm's value for adding a product to their portfolio. My estimates show that when the marketing rights of products in a physician specialty are concentrated in a single firm, the bargaining position of the innovator of a new

drug in this physician class is weakened. This effect becomes more severe as the size of the physician specialty increases. An increase of 10,000 physicians in a specialty increases the difference between the firm with the highest valuation and the firm with the second highest valuation by an average of 2%.

My results have important implications for merger analysis. Preserving competition in the licensing market is important to ensure innovation incentives. Therefore, when considering the effect of a merger, policy makers should consider the effects on competition in the licensing market in addition to traditional considerations about the downstream market. This is a particularly important force to consider in physician specialities where the concentration of marketing rights across firms is high even when these products do not compete in the downstream market.

Historically, large traditional pharmaceutical firms were highly involved in the research and development of new pharmaceutical products. Today the bulk of research occurs in small venture capital backed firms (Cockburn 2004). At the same time, the direction of drug development has shifted towards drugs treating niche diseases prescribed by specialists with few if any other treatments. Possible explanations for this shift include changes in the nature of research and an increase in capital available to support start-up firms. My paper suggests a third contributing factor: as research has shifted towards niche markets, startup innovators no longer face the threat of hold up in the licensing markets. In niche markets large marketing firms are not able to extract value from new innovators and therefore these innovators receive a larger proportion of total producer surplus.

Maybe cut this part?

Several related studies analyze licensing, mergers and acquisitions in the biotechnology pharmaceutical industry (Lerner, Merges 1999, Danzon et al. 2004). In Danzon, Epstein, and Nicholson (2004), the authors look at the predictors of merger activity and the subsequent impact of mergers on firm growth. Consistent with my results, they identify the importance of established distribution networks, and financial distress of small firms as important drivers for merger activity. My analysis also reveals how the importance of these forces may vary across different disease markets in this industry.

Restrictions on Referrals: Application to Magnetic Resonance Imaging

Experts many times have an informational advantage over the clients they serve. In a market where experts provide both diagnostic and referral services the service providing companies would like to compensate the expert for their referrals in order to secure demand. However this compensation may cause a moral hazard problem for the expert, as instead of sending the patients who need the service to the best service provider, they may instead refer too many patients to the suboptimal (from the point of view of the clients) service provider. In this paper I quantify the effect of restrictions on the types of contracts allowed between experts and service providers in the market for magnetic resonance imaging (MRI) services.

In this market as in other health care markets, search costs are high, the informational advantage of the expert is large, and patients do not directly face the prices of the goods they consume. Physicians determine when a patient needs an MRI procedure. In addition, the physician typically refers the patient to the specific MRI facility where the MRI will be performed. MRI services are often covered by health insurance, hence patients are not price elastic and pay a fixed fee independent of where they receive their MRI. Most consumers have no way of ascertaining the quality of an MRI facility and hence rely on their physicians for this information. Therefore understanding the impact of revenue

sharing between experts and service providers is of utmost importance as other forces which we may normally expect to discipline markets are weaker.

If an MRI provider wants to increase their market share they must find a way to get physicians to refer more patients to their facilities. One way to try to increase market share would be to give physicians a financial incentive to refer their patients to a particular center. When physicians have partial or full ownership of the machines to which they refer patients they have financial incentives for sending their patients to their own MRI facility.

As medical equipment becomes more important for medical care, providing these MRI services has become more lucrative. Medicare spending for imaging services paid as part of the physician fee schedule rose from 5.2 billion to 9.3 billion from 1999-2003 (Miller 2005).[3]

This study examines the effect of state laws regulating physician investment in MRI facilities on the number of MRI machines available and the number of MRI procedures performed. MRIs entered general clinical use in 1983. During the sample period 1992-1998, there were state laws governing physician investment in 29 states as described in Table X. These laws take various forms; some require physicians to reveal their investment interest in any facility they refer their patients to, some restrict all referrals for patients on state Medicaid, while others restrict referrals for all patients. Today Stark II legislation (which was written in 1994, but not enacted fully until 2002) regulates the investment interests physicians can have in MRI facilities they refer their Medicare and Medicaid patients to. The Stark Laws as well as many state laws do not prohibit physicians from referring their patients to MRI machines they or other member of their group practice own if the machine is located in their offices.

If doctors increase the number of patients they refer for MRIs when they make a profit from these referrals, then we would expect to see relatively fewer MRI procedures performed in states with laws restricting physician investment. In addition, if doctors have a comparative advantage as investors in MRI facilities, even if there is no moral hazard problem we would expect to see fewer MRI machines in states with referral laws. This decrease in the supply of MRI machines may also induce fewer MRI procedures in these states.

If find that laws restricting physician investment in MRI facilities decreases the number of MRI machines available by an average of 12%. I find that the decrease in machines mainly comes from a decrease in the number of hospital machines rather from a decrease in the number of non-hospital machines. I do not find conclusive evidence that these laws decrease the number of MRI procedures performed in these states, however my results suggest that one effect of the law is to shift where procedures are performed from hospital settings to non hospital settings. One possible explanation for the change in where procedures are performed is that when physicians are unable to invest in larger free-standing facilities or in hospital based facilities, they instead purchase machines for their offices or group practices, an arrangement still considered legal even in the presence of legislation restricting physician investment in MRI facilities located outside of the physicians office.

The main data set used in this study is from an MRI census performed in 1992, 1996 and 1998. The MRI census collects a large amount of data including data on the number of MRI magnets (number of magnets is closely related to number of machines as usually there is one magnet per machine), the number MRI procedures performed, as well as information about the type of site (hospital or non hospital). I use Metropolitian Statistical Area (MSA) level data that is disaggregated by facility type.

In my analysis I also control for the presence of state laws requiring a certificate of need to operate MRI equipment. These laws require facilities to apply to state health planning agencies and

[3]This increase in Medicare spending was not accompanied by a notable decrease in imaging services in other settings (Miller 2005)

demonstrate a genuine need in the community to either increase in size of an existing MRI facility or to opening a new MRI facility. If find that the presence of this legislation also decreases the number of MRI machines available but that the effect of this law is largely on non-hospital based facilities. This is consistent with certificate of need legislation imposing higher costs on non-hospital based facilities. I do not find conclusive evidence that certificate of need legislation decreases the overall number of MRI procedures performed, but I do find that it shifts where these procedures are performed from non hospital facilities to hospital facilities. As there were no changes in certificate of need legislation governing MRI facilities during my sample period these results are based on cross sectional variation in the presence of certificate of need legislation.

Figure 1: Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain

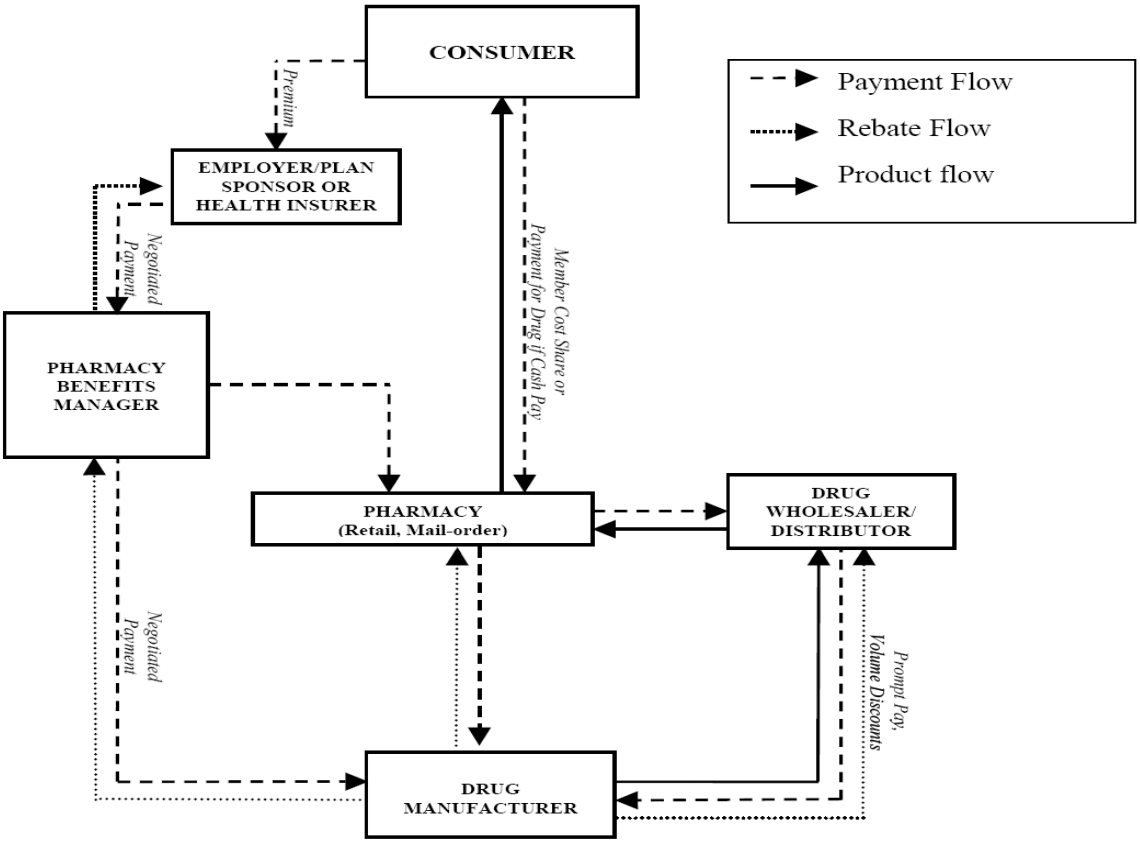

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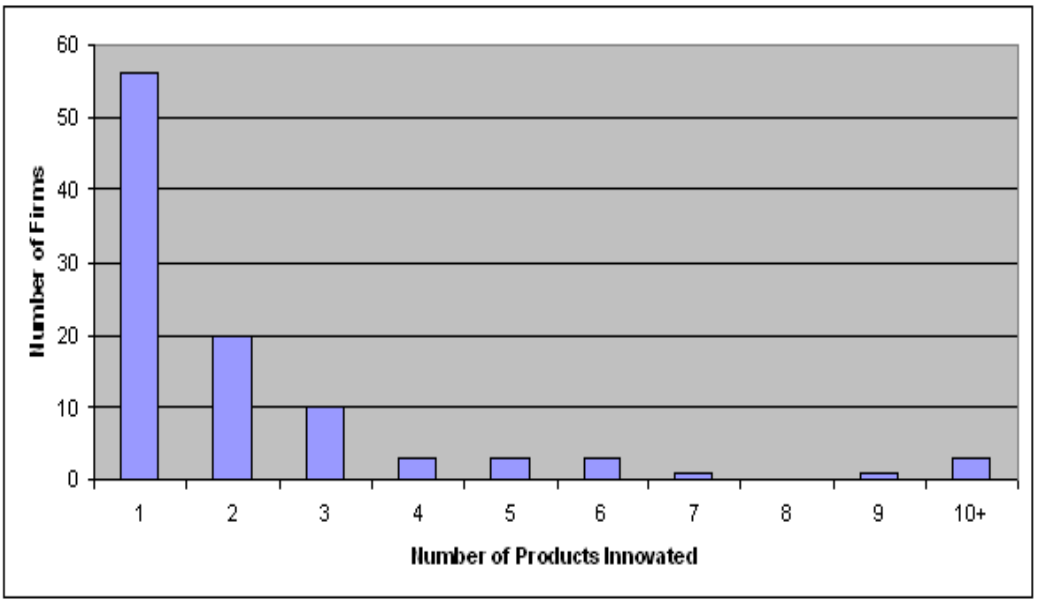
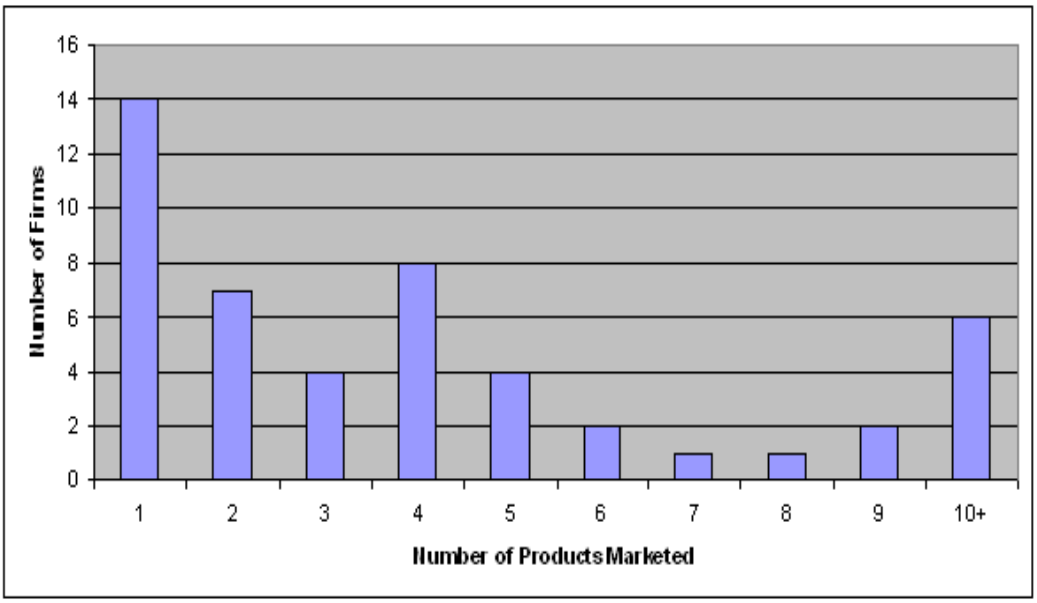
Figure 2: Size Distribution of Innovators



Data comes from company websites, and Recombinant Capital database. A product is defined as a current marketer, tradename, indication class combination. The innovator is defined as the firm which had control of marketing rights when the product entered phase 1 FDA trial.

Figure 3: Product Portfolio size of Marketing Firm: *Excluding large traditional pharmaceutical firms*



Data comes from company websites, and Recombinant Capital database. A product is defined as a current marketer, tradename, indication class combination. A marketing firm is defined as a firm who had control of US marketing rights in July 2006 of at least one biotech product. Their product portfolio is all of the products they market in the US in July 2006.