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Similar Products at Different Prices: Can Biopharmaceutical Companies Segment Markets?

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ABSTRACT *New data on Medicare Part B payments show provider-level utilization of two similar but distinct biologic medications used to treat wet age-related macular degeneration. Their interaction provides insight into the ability of manufacturers to effectively segment markets and suggests some analogies for the future interplay between originator biologics and biosimilars. In particular, most ophthalmologists administer a mix of Avastin (used off-label), Lucentis, and other drugs; only a small share exclusively choose Lucentis. This is inconsistent with the hypotheses that (1) the manufacturer is able to effectively segment the market, and (2) the major factor driving physicians' product choice is the financial motivation. The data are consistent with the notion that physicians typically exercise medical judgment on a patient-by-patient basis and that product choice is driven largely by factors other than simple financial interests. This raises important dynamic efficiency considerations regarding incentives for future biologic competition.*

Key Words: Pricing; Biotechnology; Physician; Prescription; Firm Behavior.

JEL classifications: L110, D4, L650, I11, L2.

Background

The biopharmaceutical industry has been studied extensively by scholars in industrial organization and public policy because its structure, regulatory environment, and pricing are unique among modern industries. Early articles exploring the dynamics of this industry include Comanor (1964, 1986).

Among the most fundamental aspects of the modern biopharmaceutical industry are the discovery and development of new medicines and the interplay between alternative treatments. In the most common case, when a

The following product names referenced throughout the article are registered trademarks of the indicated companies: Lucentis, Genentech, Inc.; Avastin, Genentech, Inc.; Eylea, Regeneron Pharmaceuticals, Inc.; Visudyne, Novartis, AG; Macugen, Eyetech, Inc.

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new therapy is introduced, that therapy typically enjoys patent protection (or in some cases another form of regulatory exclusivity) from immediate copying for some period, during which it may compete with previously developed alternative (nonchemically identical) therapies. After patent protection (or regulatory exclusivity) ends, small-molecule branded drugs are subject to intense competition. This competition comes from generic entrants who face low manufacturing costs, typically charge far lower prices, and take advantage of institutional pressures that encourage the use of generics. Key early contributions to the literature on the effects of patent expiration and the impact of generic entry are Caves et al. (1991) and Grabowski and Vernon (1992).

An interesting development currently unfolding in the United States – one that has been unfolding in Europe for nearly a decade – is the competitive interplay between innovative large-molecule biologic medications and their "generic" counterparts, or "biosimilars." A regulatory pathway for the review of biosimilars was authorized under the Biologics Price Competition and Innovation Act of 2009 (BPCIA; part of the Affordable Care Act), but the exact details of what it takes to gain Food and Drug Administration (FDA) marketing authorization are still evolving. An important step in that process, however, is an FDA review committee's recommendation for approval of the first biosimilar in the United States (see Novartis 2015). Going forward, the interplay between competing similar but distinct biologic medications will be an issue of intense interest for policy makers, biopharmaceutical company management, patients, and academics.

There is a substantial literature that attempts to forecast how competition will unfold between originator biologics and the biosimilars that reference them. The primary view is that the competition confronting originator biologics from biosimilars will bear only faint similarities to the brand-generic experience. A partial list of articles discussing the potential outcome of biosimilar entry includes the following: Grabowski, Guha, and Salgado (2014); Trusheim, Aitken, and Berndt (2010); US Federal Trade Commission (2009); Grabowski and Kyle (2007); Grabowski, Ridley, and Schulman (2007); and Trusheim, Berndt, and Douglas (2007).

We may not see the equivalent of the patent cliff that occurs in the small-molecule sector for three reasons: (1) the manufacturing of biologics is far more complex and costly than the manufacturing of small-molecule drugs; (2) the regulatory approval process is and will likely remain far more involved, keeping the number of potential competitors down; and (3) physicians and patients may not be quick to adopt unproven biosimilars. Meaningful utilization of originator molecules is likely to persist beyond patent (or data exclusivity) expiration, and prices may not fall dramatically over short periods of time. Over the coming years, as biologic therapies come to play an increasingly important role in medical care, the industrial organization of the biopharmaceutical industry is likely to change as well. It is useful to look into current market dynamics to get a sense of the direction and degree of those changes.

As suggested above, an important question will be what happens when two similar but distinct medications can be substituted for each other in a high-value medical application. Although, as indicated, biosimilar entry in the United States is only on the verge of becoming a reality, there are examples of competition between different branded versions of biologics employing similar mechanisms

Here, we focus on one particular example of the interplay between similar biologic therapies that are used for the prevention of blindness as a result of wet age-related macular degeneration (AMD). These products are Genentech's Lucentis and Avastin. The chemical names of Avastin and Lucentis are, respectively, bevacizumab and ranibizumab. The brand names will be used for ease of discussion.

Avastin was approved by the FDA in February 2004 with an indication for the treatment, in combination with certain chemotherapy agents, of metastatic colon and rectal cancer. It has since been approved for treatment of a wider range of cancers. Lucentis received FDA approval in June 2006 to treat wet AMD and has also received FDA approval for two additional indications, but our focus here will be on wet AMD treatment.

Following the early emergence of evidence that Avastin injections might be beneficial in the treatment of wet AMD, ophthalmologists began using Avastin for this unapproved (off-label) use. There is clinical trial evidence suggesting that patients receiving Lucentis and Avastin for AMD have comparable outcomes (US National Institutes of Health 2012), but the FDA has also issued an alert to healthcare professionals indicating concern about potential safety risk from using inappropriately repackaged use of Avastin in its off-label use in treating wet AMD (US Food and Drug Administration 2011a).

While the price per treatment of Avastin in its approved use (cancer) is not terribly different from the price of Lucentis in its approved use (wet AMD), the quantities needed in each use differ dramatically. For example, the dose of Avastin used in clinical trials for cancer is 500 times the dose used to treat wet AMD (US National Institutes of Health 2012). As a result of the dramatically different demand structures for these two drugs, the off-label use of Avastin to treat wet AMD results in much lower expenditures (see, e.g., Pershing et al. 2015). Lucentis sells for about $2,000 per injection, while the dose of Avastin typically administered by ophthalmologists for the treatment of wet AMD sells for approximately $50 per injection (see Whoriskey and Keating 2013). Hence, it may be in the manufacturer's economic interest to attempt to separate the markets for Lucentis and Avastin in their respective approved uses.

A key question in the industrial organization of the biopharmaceutical industry is whether the owner of two apparently substitutable products with two distinct uses is able to segregate markets and sustain different prices that correspond to the value of the products in those distinct uses. While it might seem obvious that in an open market, price sensitive buyers would select the lower-priced product that suits their needs, there are questions about how patients and physicians perceive and respond to products that may or may not seem identical. There are also issues of dynamic efficiency and the incentive to develop new therapies. If a prospective innovator is unable to earn financial rewards for developing products that provide valuable treatment for serious conditions, less than optimal investment will be called into the search for such innovations. The appropriate balance between the static efficiency gains associated with allowing physicians and patients to choose Avastin for wet AMD treatment and the dynamic efficiency gains associated with the development of new treatments is an important question that is beyond the scope of this article, but it deserves careful attention as the market for biosimilars evolves.

Another important question is the degree to which biopharmaceutical

Clearly, if manufacturers attempted and were able to exert substantial influence in cases such as this, one would expect to observe substantial use of the higher-priced Lucentis and minimal use of the lower-priced alternative. A recent change in Medicare policy provides some insight into the utilization patterns of these two products for the treatment of wet AMD. What we find is that despite economic incentives to segment the market for these two products, the market is in fact not segregated very completely. As indicated in recently released Medicare Part B data, a large share of the potential demand for wet AMD treatment is filled with Avastin. In addition, the physician-level patterns of use between these two products are consistent with conditions that might reasonably be expected if physicians are acting in their patients' interests.

Insight from a New Data Source

Lucentis versus Avastin

Recently, the Centers for Medicare and Medicaid Services made available to the public for the first time detailed data regarding the Medicare Part B program. The data cover all of 2012 and contain a wealth of information – more than nine million records of data for more than 880,000 healthcare providers. For the first time, one can look up a participating physician by name in a publicly available data set and observe a great deal of information, including the services provided, the drugs administered, and the amounts paid by the Medicare Part B program for those services and drugs. Medicare Part B covers doctors' services and outpatient care (US Centers for Medicare and Medicaid Services 2012). A brief article discussing the reaction to this data release and the issues discussed here was recently published in the online magazine Pharmaceutical Executive (2014) by three of our co-authors, Scher, Twigg and Huson.

The choice physicians make between Lucentis and Avastin has been a common topic in the health policy literature (see, e.g., Hutton et al. 2014). The release of the Medicare data attracted a great deal of attention in the popular press, with prominent articles appearing in many of the country's most widely read newspapers, websites, and other periodicals (see, e.g., Abelson and Cohen 2014; Chen and Pearson 2014; Luhby 2014). Many of these articles focused on high-billing physicians, highlighting the amounts they have been paid by Medicare, and in some cases questioning the medical practices in which these physicians have engaged. Ophthalmologists specifically received scrutiny as a result of the data's public release; several articles in the press identified these physicians as frequent high billers.

Several articles focused on ophthalmologists' prescribing behavior with respect to Avastin and Lucentis for the treatment of wet AMD. Medicare Part B payment to doctors when they inject these drugs is set at a 6% markup over the drug's Average Sales Price (ASP), and hence doctors receive higher Medicare payments when they use a drug that costs more to acquire.

The difference in the Medicare Part B payment between these two products has been cited in articles to suggest that financial incentives may be motivating ophthalmologists to use Lucentis instead of Avastin. Of course, one needs to be cautious about what inferences can and cannot be drawn based on these data alone – for example, the data do not provide information on the reasons for the physician's product choice, the severity of patients' medical conditions

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