Regulating Pharmaceutical Pricing: Why Is Europe More Aggressive than the US?

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ABSTRACT

Pharmaceutical prices and their rate of annual increase are a source of concern in most of the developed nations. Many mechanisms are available to regulate pharmaceutical pricing, but the US uses fewer of them than European nations. Certain European health policy considerations would appear to make European nations more aggressive, and ultimately more successful in regulating prices, than the US.

Keywords: Pharmaceutical Pricing, Pharmaceutical Regulation

INTRODUCTION

Concern over the pricing of pharmaceuticals seems to be an international issue. Consumers, patients, providers, insurance companies, and government purchasers complain about the increase in recent years in pharmaceutical prices and what they perceive to be a relatively high level of existing prices. In the U. S., prescription medications cost the U. S. healthcare systems $324.6 billion dollars in 2015, a 9% increase from 2014 (Walker, 2017, p. A4)

In his first press conference as U. S. President-elect, Donald Trump claimed that pharmaceutical companies were “getting away with murder” and he pledged to “save billions of dollars” by changing the way that the U. S. healthcare system purchases pharmaceuticals (ibid). The President-elect went on to indicate “we’re going to start bidding and we are going to save billions of dollars over a period of time.”

According to the Kaiser Family Foundation Health Tracking Poll, 77% of people surveyed believed that drug costs are too high. (Economist, December 10, 2016, p. 34) However, in the same survey 75% of those people surveyed said that they could afford the cost of the pharmaceuticals which they are taking.

Higher drug prices accounted for most of the 11% increase in U. S. hospital pharmacy costs in 2015 according to The Wall Street Journal (December 19, 2016P., B1). The newspaper reported that hospitals are attempting to reduce their use of certain pharmaceutical agents in response to increasing drug prices. The Organization for Economic Cooperation and Development (OECD) indicated that pharmaceutical expenditures per capita in the United States in 2012 were more than double the OECD average for the same period of time (OECD 2014 p.3).

Differences between pricing levels and regulatory schemes in Europe versus the United States lead to the question as to why Europe appears to have been more successful and more aggressive in regulating pharmaceutical prices. If European nations have been more successful in implementing regulatory measures to control the relative price level and rate of increase in pharmaceuticals, why is it that the United States has not adopted similar measures?
Pharmaceutical Pricing in the United States

It is not accurate to say that pharmaceutical companies can charge whatever they wish for drugs in the United States. In fact, there are several mechanisms in place which serve to reduce the purchase price of pharmaceuticals from drug company list prices. For instance, Medicare Advantage Plans are managed care organizations which provide contracted services to Medicare beneficiaries. These private managed care organizations negotiate pharmaceutical prices with drug manufacturers. Medicaid, the US system for lower income individuals, receives rebates for each drug the program purchases on behalf of Medicaid beneficiaries (Feldstein, 2015, p. 467). The federal government’s 340B program enables specified entities to purchase pharmaceuticals at discounted prices from manufacturers (HRSA, 2017). Purchasing entities eligible to receive the more favorable 340B pricing are defined by federal statute and include health centers and look-alikes, Ryan White Clinic and state aid assistance programs, Medicare/Medicaid disproportionate share hospitals, children’s hospitals, and other safety net providers (ibid). Pharmacy Benefit Managers (PBMs) are firms that manage health plans’ and drug benefits for pharmaceuticals sold in retail pharmacies. These firms can promote brand name substitution and receive larger discounts from drug manufacturers for the purchasing which they direct (Feldstein, 2015, p. 416).

However, the United States faces two significant regulatory barriers which limit the ability of the government to negotiate pharmaceutical prices. The Medicare Modernization Act created the Medicare Part D Prescription Drug Benefit in 2008. Under the provisions of the statute, the federal government is prohibited from negotiating drug prices directly with pharmaceutical firms (Feldstein 2015, p. 462). In a similar vein, the Patient Protection and Affordable Care Act, enacted in 2010, allocated $1.1 billion dollars for comparative effectiveness research (CER) in order to determine the most effective means of treatment for many medical conditions. However, the U. S. Congress prohibited the use of research information from CER for “mandating coverage, reimbursement or treatment decisions for public and private payers” (Feldstein 2015, p.347). As a result, public and commercial payers are prohibited from using CER data in negotiating pharmaceutical prices or making decisions on the use of pharmaceuticals for certain treatment modals.

Pharmaceutical Price Regulation

There are several recognized mechanisms for regulating pharmaceutical prices at a national level. To date, European nations appear to be more aggressive in pursuing several of these policy options as a way of regulating pharmaceutical prices. F. M. Scherer of Harvard University identified five pricing mechanisms that have been used internationally as a means of restraining the growth of pharmaceutical prices (Scherer 2000, p. 1329). Those mechanisms are: reference pricing, item-by-item negotiation and control, formula pricing, profit or rate of return regulation, and capping or budgetary constraint controls.

Reference pricing occurs when somewhat comparable pharmaceuticals are placed into specific reference groups and the reimbursement provided under governmental or private insurance plans is fixed at the lowest price within that reference group. While individuals are free to purchase higher priced medications listed within the group, they are expected to pay the difference between the price of the lowest priced drug and the more expensive medication which they desire to purchase. Danzon (2000, p. 1) expanded on the concept of reference pricing by specifying that countries, other than the United States, had used this methodology to either “directly through controls on prices, or indirectly through limits on reimbursement under social insurance schemes” use reference pricing to include governmental setting of prices for pharmaceutical purchase, based upon the lowest prices within the reference group.

Item-by-item negotiation and control. Under this mechanism, the prices of pharmaceuticals covered by national health insurance plans are specifically set by administrative proceedings. This means
that the government establishes the acquisition price at which the medication must be sold for use in national programs.

**Formula pricing.** Under this methodology, new pharmaceuticals being introduced into a market are priced at a relatively high level compared to existing pharmaceuticals. The government then reduces the price of those new drugs in subsequent time periods as the use of those drugs in the market place declines. This method has a history of use in Japan and was found to encourage physician prescribing of new medications by allowing the physicians higher margins on drug acquisitions for new medications. However, as the drug remains on the market for an extended period of time, that price which the physician is allowed to charge declines.

**Profit or rate-of-return regulation.** This methodology is somewhat comparable to the approach taken in regulating public utility rates. On an annual basis, the assets of individual pharmaceutical companies are measured to include capitalized value of research and development expenditures. Each pharmaceutical company then negotiates with the regulatory authority a specified pre-tax rate of return, usually in the range of 17 to 21%. Drug revenues are set, or adjusted, so that after the operating research and development and sales promotion costs are deducted, the pharmaceutical company is left with a profit sufficient to yield the agreed upon rate of returns on assets. The United Kingdom is the only nation known to have set a rate-of-return method such as this.

**Aggregate budget restraints.** Under this mechanism, national budgets for pharmaceutical acquisitions are set. The government provides reimbursement for prescribed pharmaceuticals up to a specified level, beyond which any additional amounts are subsequently deducted from the incomes of physicians. At a higher level of increased costs, the excess expenditures were to be deducted from pharmaceutical manufacturer reimbursements. According to Scherer, this methodology was utilized in Germany until the late 1990’s. As might be imagined, the administrative implementation of such a system can become greatly complicated.

Vernon (2003, p. 22) has identified three predominant means of pharmaceutical price regulation: direct price controls as utilized in France and Italy, indirect price controls through limits on reimbursement under governmental insurance programs (Germany & Japan), and indirectly through profit controls on manufacturers (United Kingdom).

Vogler and Habimana (2014, p. 8) have identified Managed Entry Agreements (MEA) as another method European governments have used in an attempt to control the pricing of high cost pharmaceuticals. An (MEA) is “an arrangement between a manufacturer and payer/provider that enables access to a new health technology subject to specified conditions”. The authors indicate that these contractual arrangements can be designed in different ways and are either considered financial schemes “(e.g. discounts, price volume agreements or capping) or health outcome related schemes (e.g. risk-sharing schemes, coverage with evidence (CED) or conditional reimbursement)”. According to the authors, the World Health Organization Collaborating Center for Pharmaceutical Pricing and Reimbursement Policies determined that the most frequently utilized policy measure for pharmaceutical pricing and reimbursement was price cuts. They indicate that the number of cuts was much higher than the changes related to “wholesale and pharmacy remuneration and the value-added tax on medicines.”

**The Differences in Europe**

When one compares the policy approaches of European nations to the United States, it becomes apparent that European nations are much more willing to engage in stronger regulatory mechanisms to restrain pharmaceutical price growth. Some reasons for stronger price regulation are listed below.
Europeans seem to value healthcare as a public good. Europeans value healthcare as a legal right, whereas the United States has no recognition of healthcare as a legally enforceable right for its citizens. The recognition of healthcare as a legally enforceable right leads to the recognition of healthcare as a public good meant to benefit all citizens. The concept of healthcare as a public good has been recognized by both Csizmazia (2013 p.16), and Mohammed (2015 p.2). In writing of pharmaceuticals as a public good, Csizmazia states:

“These arguments (against price regulation) blur in the case of public interest, such as health (Palley, 2005). In this case actually the public goods are meant to be available for everybody at an affordable price. For that reason governments attempt to negotiate with suppliers of pharmaceuticals in order to reach a consensus related to the state subsidized pharmaceuticals (e.g., reimbursements schemes).”

The European Union allows for reimportation. The European Union allows for the reimportation of pharmaceuticals from one nation to another, also known as “parallel trade” in Europe.

“Exporters buy the authorized pharmaceutical products in countries, where the price is significantly lower than in the target country, then they repack the products if necessary, and supply to the countries with higher prices. They simply undercut the prices of the target countries. This activity is not new in the EU. Exporters have certain advantages besides simply the cost advantage; they usually do not need to go through a second marketing authorization procedure” (Csizmazia, 213, p 10).

Such reimportation is not legally permissible in the United States. Although the U.S. Congress had authorized the use of reimportation, the U.S. Food & Drug Administration said that it was unable to develop sufficient regulations to insure the quality of pharmaceuticals reimported into the United States from other countries. As a result, U.S. law does not allow for the reimportation of pharmaceutical from other nations.

Europeans make greater use of effectiveness studies in pharmaceutical purchasing. As was indicated above, U.S. federal regulation prohibits the use of government generated effectiveness information in making pharmaceutical purchasing decisions. But such limitations are not the situation in Europe, where effectiveness information is used in deciding which pharmaceuticals will be place into formularies and which will be allowed to be purchased for use in individual countries. Engelberg (2015, p 2) writes that “U.S. Government efforts to conduct and use comparative effectiveness research to hold down drug costs have been a failure.” Costello (2016, p. 8) has also written of the value of effectiveness studies in determining which pharmaceutical products will be approved for purchase in a given nation. He writes: “The introduction of effectiveness studies, and their use for pharmaceutical purchasing decisions, can demonstrate the value of certain pharmaceutical purchases compared with others.” An easing of the federal restrictions on the use of effectiveness studies in the United States could be very beneficial in providing additional resources to be used in determining pharmaceutical prices.

CONCLUSION

Pharmaceutical prices are lower in Europe because European nations are more willing to engage in aggressive regulatory measures designed to restrain pharmaceutical price growth. The United States has been unwilling to adopt measures that would emulate what has been done in Europe. As a result, pharmaceutical prices in the U.S. remain among the most expensive in the world. If U.S. policy makers are to get serious about restraining the growth of pharmaceutical prices, they would seem well informed to adopt many of the measures that are proving to be successful in Europe.
REFERENCES


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