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Liability risk in the pharmaceutical industry: Tort law in the US and UK

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ABSTRACT

This paper examines the extent to which product liability risk contributes to the high costs of pharmaceuticals in the United States relative to prices in the United Kingdom. Research on pharmaceutical prices rarely accounts for the impact of liability risk, and none that we are aware of compares the United States and United Kingdom. Drawing on a dataset of 77 brand name drugs sold in both the U.S. and the U.K., we analyze relative manufacturers' factory prices in each nation. We utilize several proxies for liability risk including drug litigation history, the percentage of plaintiff wins, and controlled substance classification. Importantly, under U.S. law there are no caps on the amount that can be awarded to a plaintiff claiming economic losses in the U.S. However, payouts in the U.K. are limited. Accounting for market differences and regulatory environments, we find liability risk can account for a portion of the price differential that exists between the U.S. and U.K., warranting further investigation.

1. Introduction

Pharmaceutical prices in the United States are frequently compared to drug prices in other industrialized nations. Compared to U.S. consumers, Europeans spend less than two-thirds as much on biopharmaceuticals per capita, though much of this gap is generated by use of more costly drugs in the United States (Lakdawalla et al., 2009). Differences in government regulations and market structures explain most of the price differences between the U.S. and the rest of the world. International drug price comparisons are complicated by availability across countries and differences across drugs: active ingredient, route of administration, dosage strength and form, manufacturer, and package size. Accordingly, it is only possible to compare a subgroup of drugs which leads to varying conclusions. Not surprisingly, this contributes to the tremendous controversy surrounding pharmaceutical pricing studies and results. There is general consensus that U.S. drug prices are among the highest in the world, but striking disagreement on how large the international price differences are and for what reasons. The existing literature argues a wide range of reasons for drug price differences, including price controls, profit controls, lower income levels, differences in disposable income, lower manufacturing and distribution costs, differences in product approval, private versus public healthcare systems, the impact of a market for generic substitutes, dissimilar patent protection laws, different demand levels, and different levels of drug discounts.

The majority of the literature detailing international price differences overlooks the effects of tort law on these price differences. The difference in the products' liability environments across countries is an important, though usually omitted, component. Following Manning (1997), this study analyzes how tort law contributes to the

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comparatively high costs of pharmaceuticals in the United States relative to the United Kingdom. As a former British colony, many American legal traditions and policies originated in English Common law and English Statute law, which were exported by England to most parts of the British Empire. Many aspects of that system continue to influence U.S. law. This study probes whether and in what ways U.S. law has evolved away from British Common Law as it currently exists in the U.K. The historic legal similarities provide a backdrop for the examination of the importance of tort law, an aspect of the legal code that significantly differs between the U.S. and the U.K. Tort law in the U.S. is not only different from English tort law on a fundamental level, including the impact of the jury, class actions, the allocation of contingency fees, punitive damages, the allocation of litigation costs, and the pressure to settle, but also in practice (Magnus, 2010). In the U.S., juries usually award the damages to plaintiffs in product liability lawsuits while judges make the awards in the U.K. Juries are much harder to predict and often award much larger compensatory damages than judges (Magnus, 2010). Thus, U.K. tortfeasors – one who commits a tort – are generally less vulnerable than their U.S. counterparts. The different legal systems assess the costs and benefits of pharmaceuticals differently, which leads to differential estimates of liability risk and thus different prices. The greater litigation risk in the United States potentially contributes to higher drug prices. That is, drugs considered to be riskier have potentially higher litigation costs in the United States, and this may translate into higher prices for those drugs.

In January 1994, the U.S. General Accounting Office (U.S. GAO) released a study comparing prescription drug prices between the United States and the United Kingdom. Of the 200 drugs frequently used in the U.S., the GAO was able to match 77 drugs by name, manufacturer, dosage strength, and form in the U.K. The GAO report found that the market basket of these 77 common drugs cost 60% more in the U.S. than in the U.K. That finding warrants further examination and is the basis for this study. Following Manning's (1997) methodology, this study draws on the 77 common drug pricing data from the GAO in conjunction with drug litigation history to investigate the role of liability costs in drug pricing differentials. Integrating the liability risk into the price ratios between the U.S. and the U.K. will likely decrease the price differential range between the two countries.

2. Literature review

2.1. Pricing differentials

The controversy surrounding pharmaceutical prices is of special interest due to increasing expenditures on U.S. healthcare. According to the 2009 National Health Expenditures (NHE) fact sheet, national healthcare expenditures rose to $2.5 trillion in the United States, a 4.0% increase from the previous year. This accounts for 17.6% of the U.S. Gross Domestic Product (GDP). Given the increasing proportion of healthcare expenditures on pharmaceuticals, an understanding of global drug price differentials is more important and policy-relevant than ever.

An extensive literature discusses the differences in drug prices both domestically and internationally with a wide variety of results.[1] The U.S. GAO 1994 study selected the 200 most frequently distributed drugs in the U.S., which represented 54.9% of all prescriptions. Their principal findings were that 66 drugs (86%) cost more in the United States than in the U.K., and 47 drugs costs more than twice as much in the U.S. Prescription drugs in the United States cost, on average, 60% more than in the United Kingdom. The pricing differentials ranged from 62% lower in the U.K. to 1712% higher in the U.S. Although the GAO study examined the extent to which pharmaceutical manufacturers charge more in the U.S., the GAO study also points to some contributing factors, such as the regulatory constraints levied on pharmaceutical manufacturers in the U.K. market and the lack of similar constraints in U.S. markets.

Another study on price differentials, conducted by the Committee on Government Reform and Oversight of the U.S. House of Representatives, found that U.S. drug prices were 102% higher than in Mexico and 72% higher than in Canada (U.S. H.O.R., 1998). The GAO (1992) also analyzed prescription drug prices in the United States and Canada, finding that U.S. pharmaceutical prices averaged 32% more than in Canada. Typical of many studies on pharmaceutical price differentials, these studies were heavily criticized, mostly stemming from the small or unrepresentative data sets, the exclusion of generic drugs in samples, or the use of price indices (Jacobson, 2007).

To accurately measure price differences across countries, Danzon and Chao (2000) address many of the usual criticisms, their study reports price indices for Canada, France, Italy, Germany, Japan, and the U.K., relative to the U.S., using an inclusive data set for all outpatient pharmaceutical sales in 1992. Danzon and Chao analyze U.S. quantity-weighted price indexes, finding average price differentials that are much smaller than most previous studies using smaller samples based on leading brand drugs. Relative to U.S. prices, Canada was 2.1 lower, Germany 24.7%, France 32%, Italy 13%, Japan 12%, and the U.K. 17% lower, demonstrating that relative drug prices in the U.S. are not as high as most studies have indicated.

Unlike most studies, Danzon and Kim (1998) find that 1992 drug prices in the U.S. were far from highest in the world. Their results show the U.S. consumer would have to pay 3% more in Canada, 27% more than in Germany, 30% less in France, 9% less in Italy, 8% less in Japan, 44% more in Switzerland, 9% more in Sweden, and 24% less in the U.K. The authors attribute their results to heavy reliance on generic substitutes for branded drugs.

[1] A vast literature considers the nature and causes of pricing differentials across countries. A comprehensive summary of this literature is beyond the scope of this paper, though interested readers may want to consult Danzon and Furukawa (2006), Danzon and Chao (2000), Danzon and Kim (1998), Szuba (1986), Schut and Van Bergeijk (1986), Reekie (1984), Lakdawalla et al. (2009), Sood, de Vries, Gutierrez, Lakdawalla, and Goldman (2009), Andersson (1995), Jacobson (2007), Scherer (1993), U.S. GAO (1992), U.S. GAO (1994a, 1994b), Kanavos et al. (2005), Pita Barros and Martinez-Giralt (2008), Bhattacharya and Vogt (2003), Ekelund and Persson (2003), and Pirson et al. (2013), among other studies.