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Perpetual Motion – Pharma Cost Spiral Persists

Approximately 17 percent of the U.S. *gross domestic product* (GDP) is comprised of healthcare, more than any other country in the world per capita. The U.S., however, realizes poorer health outcomes than other developed countries on numerous measures.[1] One of the main factors for high healthcare expenditures is the rising price of prescription drugs.[2] Between the years of 2013 and 2015, prescription drug net spending increased by 20 percent,[3] which currently comprises an estimated 16.7 percent of all healthcare costs.[4] These rising costs do not affect prescription drug consumers exclusively, as 40 percent of prescription drug expenditures are covered by government payors, increasing the national budget and burdening taxpayers.[5] Two reasons are cited as the main factors for rising drug costs: (1) protection from competition; and, (2) uneven negotiating power.[6] In this first installment of a two-part series on rising prescription drug costs, these two reasons for rising drug costs are explored.

Patents for pharmaceutical drugs block generic drugs from entering the market for several years, protecting brand name drugs from the threat of new market entrants that may increase competition and lower prices.[7] Pharmaceutical companies can further delay the entry of generic drugs into the market through a process called *evergreening*, in which slight modifications are made to the existing brand name drug, such as new forms of release, different dosages, or new combinations, so that the life of the original patent can be extended.[8] For example, although EpiPen has been around since 1977, pharmaceutical company Mylan holds a virtual monopoly over the drug after acquiring the patent for the autoinjector, the drug's delivery system, in 2007, allowing Mylan to raise the cost of the drug by over 400 percent.[9] Moreover, *"pay-for-delay"* deals are often made between a pharmaceutical company nearing expiration of a drug patent and a pharmaceutical company with an available generic drug, in order to postpone the release of the generic that would otherwise decrease the price of the brand name drug once introduced into the market.[10] For example, pharmaceutical company Novartis was able to extend a patent for Gleevec, a drug used to treat chronic myelogenous leukemia, from July 2015 to February 2016, after making a deal with a subsidiary of Sun Pharmaceutical Industries, to withhold the release of a generic substitute.[11] The trend of delaying generic drug entry has become an issue for the healthcare industry because, although brand name drugs only make up ten (10) percent of all drugs prescribed, they account for 72 percent of drug expenditures, which has subsequently increased overall healthcare costs.[12]

The introduction of a generic drug into the market may not always result in lower costs, as the prices for many generic drugs have risen exponentially in recent years.[13] Although more than half of the 21,000 generic drugs analyzed by *Connecture*, a health insurance information technology firm, showed no price change from 2008 to 2015, approximately 400 generic drugs showed increases of more than 1,000 percent within the same time period.[14] One of the most notable examples of this phenomenon is when Turing Pharmaceuticals raised the price of Daraprim, a drug used to treat toxoplasmosis and malaria, from $13.50 to $750 a pill, causing outrage among infectious disease specialists, other providers, and patient advocate groups.[15] Because of the lack of a comparable substitute within the pharmaceutical market, Turing Pharmaceuticals was able to increase the price of Daraprim by over 5,500 percent, despite the lack of any patent protection on the drug.[16] Other reasons cited as contributing factors for rising generic drug costs include consolidation among pharmaceutical companies and a 2014 ban on some Indian-imported drugs by the *Food and Drug Administration* (FDA).[17]

As noted above, a second factor attributed to rising drug prices is the discrepancy in negotiating power between the U.S. and other developed countries.[18] Unlike the U.S., the healthcare system in most other developed countries operates under a single-payor framework, e.g., Germany, Canada, France and the United Kingdom, giving the government greater leverage over pharmaceutical companies to negotiate lower drug prices because of their larger patient base.[19] As a result, the post-rebate prices for drugs were 10 to 15 percent higher in the U.S. than countries such as Canada, Germany, and France.[20]

Variations in negotiating power also exist among health insurance payors within the U.S.[21] For example, under the *Medicare Modernization Act of 2013* (MMA), Medicare Part D is banned from negotiating the prices of drugs with pharmaceutical companies.[22] Conversely, Medicaid may rebate discounts of at least 23.1 percent of the average manufacturer's prices for most brand name drugs,[23] granting it more flexibility in negotiating and consequently lowering costs. For private insurers, the level of negotiating power is more varied due to the

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existence of *prescription benefit management* (PBM) companies,[24] which claim to reduce prescription drugs costs by negotiating rebates with drug manufacturers and discounts with drugstores, among other activities.[25] However, many experts argue that the presence of these entities could instead be increasing costs and reducing access to prescription drugs, especially in the case of cancer care.[26] Reasons for this include the consolidation of many PBM companies in recent years and the lack of transparency in their price negotiation strategies.[27]

Overall, regulatory protections against competition and the inability of certain payors to negotiate prices have caused both brand name and generic drugs to rapidly increase in price over the past several years. This has consequently created a significant financial strain on the U.S. healthcare system, burdening both U.S. tax payors and drug consumers. In subsequent years, policy changes will most likely need to be made in order to close regulatory loopholes and curb drug costs. In part two of this two-part series, proposed solutions to rising pharmaceutical drug costs will be examined.

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(Continued on next page)

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