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Spiraling Drug Costs - Proposed Solutions
(Part Two of a Two-Part Series)

As stated in the first installment of this two-part series on rising pharmaceutical drug costs,[1] healthcare expenditures constitute approximately 17 percent of the U.S. *gross domestic product* (GDP), more than any other country in the world per capita.[2] However, the U.S. realizes poorer health outcomes than other developed countries on numerous measures.[3] One of the main factors for high healthcare expenditures is the rising cost of prescription drugs,[4] with drug net spending increasing by 20 percent from 2014.[5] Overall, pharmaceuticals expenditures comprises an estimated 16.7 percent of all healthcare costs in the U.S.[6] As discussed in the first installment of this two-part series, causes for these increased costs include: (1) the pharmaceutical industry's protection from competition; and, (2) uneven negotiating power among both government and private payors.[7] In the second installment of this two-part series, three proposed solutions for lowering costs will be discussed. These three proposed solutions include: (1) increasing marketplace competition among pharmaceutical companies; (2) expanding government flexibility with pharmaceutical price negotiations; and, (3) implementation of VBR programs on the provider level.[8]

Increasing competition in the pharmaceutical industry has been cited as a means to combat rising drug costs.[9] Several business practices, such as *evergreening* and *pay-for-delay* deals, can block or delay market entry of generic drugs, subsequently decreasing competition and increasing prices.[10] With *evergreening*, clinically irrelevant changes are made to a drug in order for the pharmaceutical company to extend the patent and maintain exclusivity rights on that product.[11] If the *U.S. Patent and Trademark Office* were to change their definition of what constitutes "*novelty*" when issuing patents, these insignificant changes, and their corresponding price increases, could potentially be avoided.[12] In recent years, several U.S. Supreme Court decisions have altered regulations on what products can be patented, such as those for DNA sequences, combination products, and diagnostic tests, among other pharmaceutical products.[13] Other countries, such as India, require pharmaceutical companies to show that a modified drug has increased effectiveness in order to receive a patent for it.[14] Implementation of a similar law in the U.S. may reduce drug costs significantly. Further, stronger government oversight and enforcement of existing laws, such as antitrust regulations against *pay-for-del*ay arrangements,[15] i.e., deals between two pharmaceutical companies to delay the release of a generic drug into the market, may greatly reduce drug costs by stifling anticompetitive business practices of pharmaceutical companies, consequently decreasing drug prices.[16]

Increasing the federal government's ability to negotiate drug prices with pharmaceutical companies may significantly reduce federal drug expenditures. The *Medicare Prescription Drug, Improvement and Modernization Act* of 2003 (MMA) established Medicare Part D, in which the federal government covers the cost of prescription drugs, but prohibits the Secretary of *Health and Human Services* (HHS) from "*interfer[ing] with the negotiations*" or "*institut[ing] a price structure*" for Medicare Part D drugs.[17] Because the federal government cannot negotiate for lower prices with pharmaceutical companies under Medicare Part D, a significant amount of Medicare benefit payments is spent on drug expenditures (approximately 14 percent of Medicare benefit payments were spent on drug expenditures in 2016, an increase from 9 percent in 2006).[18] A simple solution may be to remove this interference clause; however, with many private payors managing Medicare Part D, there are complex administrative and logistical obstacles to overcome before such a price negotiation can take place.[19] Unlike Medicare Part D, Medicaid has mandatory federal rebates and state-negotiated supplemental rebates, which grant significant discounts on drugs.[20] If Medicaid mandatory rebates are applied to Medicare Part D, then a 15 percent rebate could lead to a $110 million reduction in federal expenditures between the years 2010 and 2019.[21] Further, when the MMA was passed, individuals who were dual-eligible for both Medicare and Medicaid were assigned to have drug costs covered by Medicare Part D, instead of Medicaid.[22] Switching dual-eligible individuals back to Medicaid, and taking advantage of those mandatory rebates, could lead to savings of up to $2.8 billion annually.[23]

Changes at the provider-level may also serve to reduce drug prices, including physician education[24] and *value-based reimbursement* (VBR).[25] For example, information regarding drug costs and VBR models could be integrated into the medical school curriculum.[26] Additionally, *academic detailing*, or educational

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outreach programs facilitated by pharmacists, nurses, and physicians, which uses pharmaceutical sales techniques in an academic, evidence-based manner to inform physicians about recent trends in drug advancements.[27] These programs have been shown to assist physicians in making more appropriate medication decisions in relation to cost and effectiveness, and are currently being implemented in numerous states and hospital systems.[28] Further, incentivizing physicians to make optimal decisions when prescribing medications through VBR models may help reduce drug expenditures. Two VBR models have been proposed, including the *clinical pathways* approach and the *bundled payment* approach.[29] In the *clinical pathways* approach, a board of physicians utilize evidence-based medicine to determine the least costly procedural regimen, and physicians are rewarded for compliance with this regimen through higher reimbursement rates and bonus payments.[30] This type of payment model led to a 35 percent reduction in drug costs when treatments established by the *U.S. Oncology Network*, a national oncology management organization, were adopted for lung cancer patients undergoing chemotherapy.[31] In the *bundled payment* approach, payors can bundle drug costs with other procedures performed during an *episode of care*, which may force pharmaceutical drug companies to lower prices to align with lower reimbursement rates.[32]

As described above, drug costs may be significantly lowered through enhanced market competition; increased government involvement in the price negotiation process; physician education; and, VBR. Attempts to decrease drug prices may have a significant impact on U.S. healthcare spending, given that almost half of pharmaceutical drugs are purchased by the government.[33] Reductions in drug expenditures may have major implications not only for drug consumers, who are burdened by out-of-pocket costs, but also for taxpayers, who fund federal government healthcare programs. Despite many of the potential solutions proposed for decreasing pharmaceutical drug costs, one of the most significant hurdles to the execution of these solutions is the lobbying power of the pharmaceutical industry, which spends more on lobbying efforts than any other industry.[34] Their lobbying power, however, may wane as an increasing number of politicians, including senators Bernie Sanders (D-NH) and Elizabeth Warren (D-MA), have publically criticized the industry.[35] President Donald Trump has also taken a public stance against rising pharmaceutical drug costs, stating that pharmaceutical companies are "*getting away with murder*."[36] To date, however, the Trump Administration has not taken any action against the industry, other than revealing a draft of an Executive Order that may enhance, rather than stifle the industry's efforts to increase drug costs.[37]

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