Will Putting "American Patients First" Result in Lower Drug Prices?

On May 11, 2018, the Trump Administration released American Patients First, a blueprint to lower drug costs (the blueprint). The report details four challenges with the prescription drug market, including high list prices for drugs, high and rising out-of-pocket costs for patients, government programs that overpay for drugs due to the lack of negotiation tools, and foreign governments "free-riding" off of American investment in innovation. To address these challenges, the report also lays out four key strategies for reform, including a list of more than fifty recommendations with both immediate and longer-term actions. Will this laundry list of recommendations lead to lower drug prices? This post examines the list of proposed actions, many of which will be familiar to regular readers of the Source, and discusses whether this blueprint should give Americans hope for lower drug prices.

Key Strategy for Reform 1: Improve Competition

The blueprint begins with a discussion about the complexity of the current pharmaceutical market and challenges with the way it operates and then calls for increased competition through a number of action steps including promoting the use of biosimilars. In January 2017, the Source wrote an analysis of what limits competition in the pharmaceutical market, elucidating many of the same issues described in the blueprint. The Source also described how anticompetitive contracts can significantly diminish the use of biosimilars, even after

approval by the Food and Drug Administration (FDA). In another blog post, we discussed two of the blueprint's action steps to improve competition – preventing manufacturers from gaming regulatory processes such as Risk Evaluation and Mitigation Strategies (REMS) and encouraging sample sharing for generic drug development – in its analysis of the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act). While improved competition may help decrease drug costs in cases where a brand manufacturer "games" the system to keep generic competition out of the market, the Source has examined how competition often fails among branded drugs to treat the same indication. As a result, while the Trump blueprint explores many important actions to increase competition, without action in other key areas, these proposals will likely have minimal success at containing drug expenditures.

Key Strategy for Reform 2: Encourage Better Negotiation

President Trump called fixing the "bad deal the government gets for prescriptions" his number "1 priority" and has called for allowing Medicare to negotiate with drug manufacturers since his campaign trail.[1] In remarks discussing the blueprint, Health and Human Services (HHS) Secretary Alex Azar agreed that: "I want to start with negotiation because it's so important…That is exactly what our plan brings to Medicare… We are going to make negotiation more effective than it is today in our retail drug program, Part D, and bring negotiation to where it doesn't exist, in physician administered drugs, Part B."[2] Surprisingly, however, considering previous comments from President Trump,[3] the blueprint does not call for allowing Medicare to negotiate directly with manufacturers.

Instead, the plan calls for value-based purchasing in federal

programs (including indication-based pricing and long-term financing) and allowing substitution in Medicare Part D to address price increases for single-source generics. In addition, the blueprint calls for moving coverage for drugs covered by Medicare Part B into Medicare Part D. Why is this important? Medicare Part B covers drugs that are administered in a physician's office or hospital outpatient clinic and includes expensive biologic drugs to treat autoimmune diseases and cancer. Unlike Medicare Part D, in which private insurers implement prescription drug coverage for Medicare beneficiaries and use PBMs to negotiate drug prices, Medicare Part B pays the Average Sales Price (ASP) of the drug plus 6% to the provider.[4] This payment structure gives providers a financial incentive to choose more expensive drugs. Previously, the Source covered the cancellation of a pilot program in Medicare Part B that made reimbursement for drugs administered in a doctor's office independent of the cost of the drug. Moving coverage of most prescriptions in Medicare Part B into Part D has the potential to decrease costs, as the private plans that implement Part D may be able to negotiate a better deal than the ASP plus 6% that Part B now pays. While providers are likely to oppose this change and the savings will only apply to the Medicare program, the actions proposed in this section of the blueprint may help bring down the cost of the most expensive medications covered by Medicare.

Key Strategy for Reform 3: Incentivize Lower List Prices

Under the third strategy for reform, the blueprint proposes requiring manufacturers to include list prices in advertising and updating Medicare's drug-pricing dashboard to enable greater price transparency and generic competition. Both of these suggestions seem intended to shame drug manufacturers from

listing drugs at high prices and making consumers aware of the price of their drugs, and neither directly incentivizes lower prices. In contrast, one of the proposed long-term actions in the blueprint calls for reconsideration of the safe harbor provision under the anti-kickback statute for drug rebates.[5] The Source has examined how class action lawsuits in the 1990s shaped drug pricing into a complex web of high list prices with negotiated, confidential rebates. FDA Commissioner Scott Gottlieb has also repeatedly argued that "[t]he problem is that our current system provides incentives for companies to push list prices higher, only to rebate the money later on the back end."[6] Changes to the anti-kickback statute would likely make most rebate payments between manufacturers and pharmacy benefit managers (PBMs) "illegal remuneration" and subject to criminal penalties. While the blueprint does not contain many specifics about how to reduce list prices, any actions that cause the list price to more accurately reflect the actual price paid by insurers may have significant influence on drug expenditures.

Key Strategy for Reform 4: Lower Out-of-Pockets Costs

The final strategy for reform in the blueprint calls for lowering out-of-pocket costs for patients. The Source has discussed how the growing list prices with commensurately large rebates (the gross-to-net bubble) hurt patients because they typically pay coinsurance on the list price (e.g., a 20% co-insurance for specialty medications). As the blueprint explains, the system of rebates that "had been a hidden negotiation and wealth transfer between drug manufacturers and PBMs [is] now a direct increase on consumer out-of-pocket spending that likely decreases drug adherence and health outcomes"[7] due to the high patient coinsurance. Any efforts, therefore, to make list prices

closer to the net price paid will reduce out-of-pocket costs for patients. The blueprint calls for public comment about what should be done to reduce the impact of rebates and whether PBMs should be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits. In addition, the blueprint proposes additional immediate actions such as removing pharmacist gag-clauses in Medicare Part D that prevent pharmacists from telling patients when they could pay less out-of-pocket by not using insurance and improving communication with Medicare beneficiaries about lower cost alternatives.

What is the likely impact of these strategies?

Many experts have called the blueprint "incomplete"[8] and Wall Street analysts said the plan did not pose a threat to the industry.[9] In fact, the stocks of Pfizer, Merck, Gilead Sciences, and Amgen all jumped after President Trump's speech detailing the plan. Even the stocks of Express Scripts and CVS, two of the largest PBMs – middlemen that Trump pledged "wouldn't be so rich anymore" – rose 2% after the speech.[4] If Wall Street isn't worried about the changes proposed by the blueprint, is there any reason to hope that the plan will help bring down drug prices?

At first review, the answer may be "no". The blueprint does not suggest any immediate or comprehensive changes to the way drugs are distributed or paid for. It avoids proposals that have been considered in the past, like importing drugs from overseas and allowing Medicare to set the price it will pay for drugs. Many of the actions proposed in the blueprint, in isolation, are unlikely to substantially affect drug prices. Nonetheless, if the blueprint represents only the first step toward a comprehensive change in the pharmaceutical market and the

Administration's request for feedback reflects a desire to begin an open dialogue, there may be reason for hope. Other indications suggest reason for optimism. For example, under Commissioner Gottlieb, the FDA implemented a Drug Competition Action Plan and approved a record number of generics in 2017.[10] The Source explored how a few draft guidances issued by the FDA should speed up approval of generic equivalents for complex drug and drug-device combination products. In light of the actions at the FDA, the blueprint may reflect growing momentum in the federal government to target drug industry practices that do not add value to patients. As Adam Fein, CEO of Drug Channels Institute, warned in a Drug Channels Post, although "[d]rug channel companies and their investors were relieved that the administration didn't impose harsh and immediate changes to the system[, …] it would be unwise to assume that the danger has passed."

Attempts to regulate the pharmaceutical industry have sometimes felt like an on-going game of wack-a-mole. Every time pharmaceutical manufacturers and supply chain companies find what appears to be a loop-hole and make profits without adding value, Congress considers legislation to fill that hole.[11] Once a solution is implemented, however, new tactics to increase profits emerge. Meaningful action to address rising drug expenditures and out-of-pocket costs requires legislative action and a concerted effort among agencies, including the FDA, the Federal Trade Commission (FTC), the Centers for Medicare and Medicaid Services (CMS), and the United States Patent and Trade Organization (USPTO). If the Trump blueprint reflects an honest desire to create systemic changes across many agencies and spark dialogue with the American people, it represents a meaningful first step in controlling drug prices.

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[1] Baker S. **Trump: Azar will bring drug prices "way down"**. January 29, 2018. *Axios*. Available from:

https://www.axios.com/trump-azar-drug-prices-way-down-1517250647-2e81ca5f-f608-4184-ad97-ccaaf20cb460.html.

[2] Azar A. **Remarks on Drug Pricing Blueprint**. May 14, 2018. Available from: https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html.

[3] Minchillo J. **Donald Trump says Medicare should negotiate drug prices**. January 26, 2016. *STAT*. Available from: https://www.statnews.com/2016/01/26/trump-negotiate-drug-prices/.

[4] MedPac. **June 2017 Report to the Congress: Medicare and the Health Care Delivery System. Chapter 2: Medicare Part B drug payment policy issues**. June 15, 2017. Available from: http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

[5] 42 CFR § 1001.952(h).

[6] Scott Gottlieb. "EpiPen Price Increases: How Regulatory Barriers Inhibit Pharmaceutical Competition." *Statement before the Senate Committee on Health, Education, Labor, and Pensions; Subcommittee on Children and Families*. October 7, 2016. Available at: http://www.aei.org/wp-content/uploads/2016/10/HELP-Written-Testimony-FINAL-10-7-16.pdf.

[7] The U.S. Department of Health and Human Services. **American Patients First**. May 2018. Available from: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pd

f.

[8] Sarpatwari A, Avorn J, Kesselheim AS. **An Incomplete Prescription: President Trump's Plan to Address High Drug Prices**. *JAMA.* Published online May 17, 2018. Available from: https://jamanetwork.com/journals/jama/fullarticle/2681947?utm_source=silverchair&utm_medium=email&utm_campaign=article_alert-jama&utm_content=olf&utm_term=051718.

[9] Feuerstein A and Garde D. **Trump promised to bring pharma to justice. His speech sent drug stocks soaring.** May 11, 2018. *STAT.* Available from: https://www.statnews.com/2018/05/11/trump-drug-pricing-speech-stocks/

[10] Uhl K. **2017 Was Another Record-Setting Year for Generic Drugs**. February 7, 2018. *FDA Blog.* Available from: https://blogs.fda.gov/fdavoice/index.php/2018/02/2017-was-another-record-setting-year-for-generic-drugs/

[11] See e.g., The Improving Access to Affordable Prescription Drugs Act H.R. 1776 and S. 771 – 115th Congress, The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act S. 974 and H.R. 2212 – 115th Congress.