To: United States Department of Health and Human Services

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RE: High Costs of Cancer Drugs in the US

Executive Summary

This policy memo focuses on the high cost of cancer drugs in the United States. It compares approaches to control the prices of cancer drugs between the United States and European Union countries, especially Germany. It suggests two major strategies: promoting the use of generic drugs and introducing governmental intervention in the drug pricing stage. Possible resistance from pharmaceutical companies and policy adjustments are also discussed.

Background on Policy Challenge

The financial burden of healthcare is a universal problem across the world. While preoccupied by the idea that if they can be cured, patients also need to figure out how to afford all the treatments they have received. Some patients would even be so intimidated by the high costs of health care that they decide to not receive any treatments. How much the health care burdens each patient is highly dependent on their countries' policies on health coverage as well as the prices of various treatments in their nations. As a country without universal health care, the U.S. stands out on the above health issue. The per-capita spending on health care is most salient in the US relative to other developed countries (Tikkanen & Abrams, 2020). What is more eye-catching is the fact that there is no difference on the public spending from the government side among these developed countries, which indicates that how much patients' pay out of pocket is the driver of the gap (Tikkanen & Abrams, 2020). Therefore, how to lower the price of healthcare is the key issue that the federal government needs to tackle to ensure the health care

rights for the citizens. Considering that prescription cancer drugs take about 12% of total spending on healthcare in the United States (Lauenroth et al., 2020), this policy memo will shed light on high costs of cancer drugs for the following discussion.

Call for Lesson Drawing

European Union (EU) member countries, specifically Germany, are likely to provide valuable lessons for the US federal government in terms of controlling the price of anticancer drugs. The price of cancer drugs in most EU countries presents to be more friendly and more affordable for people (Chow et al., 2022; Goldstein et al., 2017). One factor that could explain the low price in the EU is the abundant availability of generic drugs to enhance the market competition (Kesselheim et al., 2016; Wouters et al., 2017). In addition to the relatively low cost of oncology drugs, the cancer mortality rate of some EU countries is even lower, Iceland and Switzerland, for example, compared to that of the US (Chow et al., 2022). Even though there are several factors that account for the low cancer mortality rate of these EU countries, the data indicates that the effectiveness of anticancer drugs has not been compromised by the relatively low price. While reducing the price of cancer drugs is one big chunk of the goal, maintaining the quality of cancer drugs should not be neglected. Therefore, Germany deserves an even greater level of attention for the lesson drawing. Of all these EU countries, Germany used to be on top of the list of drug retail prices (Schlette & Hess, 2013). With the implementation of the German Drug Market Restructuring Act (AMNOG) in 2011, price negotiations through benefit analysis have resulted in an average price reduction of 24.5% for anticancer drugs, while clinical benefits for patients are still guaranteed (Lauenroth et al., 2020). In sum, this policy memo argues that the substantial availability of generic alternatives and government price intervention are viable solutions to the high costs of cancer drugs issue in the United States.

Core Arguments

Promoting generic drugs is a very promising strategy for reducing the price of anticancer drugs. The underlying reason for the high drug prices in the US stems from the low market competition, which allows leading pharmaceutical companies to set prices at any levels without worrying about losing customers (Chow et al., 2022; Kesselheim et al., 2016). Initially was invented for innovation encouragement, legal protections for drugs has been ruled out other manufactures to enter the market for a long time, leaving the one or two who are already obtained the approval from the Food and Drug Administration (FDA) to monopolize a certain drug market (Kesselheim et al., 2016). Without alternatives, patients have to accept the only available option regardless of their insurance coverage. What is even worse is that the research and development of cancer drugs is always both time and financially intensive, leading manufacturers to share the high investment burden with patients by imposing terribly inflated prices. Therefore, the key to approaching the problem in the drug market is to encourage competition through supporting generic drugs in the pharmaceutical industry. In EU countries, the availability of generic medicines contributes significantly to savings of up to 97% on original prices (Godman et al., 2019). And one major difference is that offering generic drug substitution is mandatory in 13 EU countries whereas this policy is all voluntary in 50 states of the US (Wouters et al., 2017). Therefore, it is foreseeable that once the federal government starts to mandate the generic policy substitution in the nation, drug manufacturers will sense the pressure and involuntarily adjust their cancer drugs prices to stay attractive in the market.

Another lesson that the US federal government can learn from Germany is to start getting involved in the drug pricing process. Noticeably, when granting approvals to new drugs, the FDA dismisses pricing in the process and solely relies on unvalidated preliminary results as the

criterion (Chow et al., 2022). As a result, the price is not being assessed and the newly added benefits associated with cancer drugs are always unclear (Chow et al., 2022). Serious issues have been aroused here, including that drug manufactures are free to determine prices without any restrictions and new drugs, which are greatly advertised and widely used right after commercialization in the US, cannot bring additional new benefits to patients (Chow et al., 2022). As the trade-off between price reductions and the dynamism of drug productions is commonly shared in industrialized countries, Germany has set a good example for the lesson borrowing (Lauenroth et al., 2020). Instead of stepping in the process of price setting at the outset, the German government assesses the benefits of new drugs offered to patients in the first year and renegotiates the price with manufacturers accordingly under the AMONG (Schlette & Hess, 2013). This act has succeeded in reducing the price of anticancer drugs and matching the price of anticancer drugs to their clinical efficacy (Lauenroth et al., 2020). Therefore, it is very necessary for the federal agency, FDA, for example, to participate in drug pricing. Related federal agencies in the US should keep granting drug companies autonomy in price setting at the start but keep an eye on drugs' clinical benefits to ensure the rationality of prices as well as the interests of patients.

Considering Adjustments and Rebutting likely critiques

Nevertheless, policies from EU countries cannot be adopted immediately in the USA since there are conditions in the nation that need more attention. In terms of genetic anticancer drugs, how to advertise them and allow more physicians and patients to choose them over brand-name drugs after being approved by FDA are concerning issues. Streamlining the generic drugs approval is a very powerful leverage against drug companies with patent rights. But if such generic anticancer drugs remain silent in the market, the strength of this leverage would be

largely diminished, failing to achieve the goal of price reduction. Therefore, it has been suggested that government should play a role to force doctors to choose generic drugs (Wouters et al., 2017). However, the healthcare in the US is decentralized, indicating that each state owns autonomy to formulate drug policies. In regions where drug patent holders are located, the backlash against generics is foreseen to be very robust, especially considering cancer drugs are economically lucrative. Therefore, how to compensate pharmaceutical manufacturers and encourage doctors also need to be included in policy making.

Also, the US government never takes part in drug pricing, which adds an additional step if the German AMONG is being borrowed. It requires to create a department that evaluates the health outcomes of brand-name drugs, especially cancer drugs, and negotiates prices with drug manufacturers. Fortunately, the Patient Centered Outcomes Research Institute (PCORI), established in 2010, can fill part of the gap through its clinical effectiveness research (Schlette & Hess, 2013). However, it is highly questionable whether drug manufacturers (especially those of anti-cancer drugs) would support a similar AMONG act, as it would largely jeopardize their profits. Therefore, it requires the Congress to introduce new legislation that incentives pharmaceutical companies to engage in price negotiating (Rodwin et al., 2021).

Final Recommendation

In light of the high cancer drug prices, this policy memo suggests the US government to prompt generic drugs and intervene in drug pricing. Policy change is complex, especially given the strength of the major stakeholders, the cancer drug manufacturers. Despite the fact that health care is very decentralized in the nation, a top-down strategy will have to be adopted in countering the forces of resistance, which whicwill require Congress to pass the relevant drug price control bill.

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