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Policy Brief: The International Pricing Index for Medicare Part B Drugs

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In announcing its proposed Medicare pricing model for Part B drugs, the administration has promised to "cut down on foreign freeloading." Actually, the proposed plan does nothing to affect the prices of drugs paid by countries abroad, and it actually may lead those countries to further reduce the prices they pay. Furthermore, implementing this plan would leave Americans, and people everywhere, worse off over time. The economic incentives that make investments in new cures and treatments possible would decline, and fewer new valuable therapies would be introduced. Of course, this is not a popular perception, but it is a reality.

PROBLEMS WITH THE PROPOSAL'S FACTUAL BASIS

As described in the October 25 Health and Human Services (HHS) press release,[1] the plan envisions reimbursing drug manufacturers at a level pegged to prices set in other countries. Undergirding the proposal is a study[2] by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE) that compares prices paid in the United States to those paid in 16 foreign countries. Economists have studied international variation in prescription drug prices over many years, and important lessons have been learned, few of which were applied in the ASPE study. Any policy built on the basis of analysis like this should concern Americans as they consider the implications for their access to cures both today and in the future.

Of immediate concern is the fact that the countries included have vastly different healthcare systems and standards of living than the United States. Are prices in Greece (with a per capita GDP[3] only 47%[4] of the United States') a reasonable benchmark to what American prices should be? Economic principles suggest that higher incomes imply greater willingness and ability to pay for high-quality care. Pegging prices to countries with substantially lower standards of living will result in lower-quality care. This is already the reality in other countries; many of the drugs included in the ASPE study are not available in all the countries studied, including therapies for cancer and other serious conditions.[5]

Another major concern is that the ASPE study does not adequately correct for differences in patent protection and other forms of intellectual property across countries. The result is price differences that are affected by the availability of biosimilars and generics abroad.

1 US Health and Human Services, "What You Need to Know about President Trump Cutting Down on Foreign Freeloading," press release, Oct. 25, 2018, https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html.

2 US Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Comparison of US and International Prices for Top Medicare Part B Drugs by Total Expenditures," Oct. 25, 2018, https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf.

3 International Monetary Fund, "GDP per Capita, Current Prices," https://www.imf.org/external/datamapper/NGDPDPC@WEO/OEMDC/ADVEC/WEOWORLD/GRC/USA?year=2018.

4 The 47% figure uses Purchasing Power Parity-adjusted International Dollars. Absent this adjustment, Greece's per capita GDP is 32% of the US level.

5 PhRMA analysis of IQVIA Analytics Link and FDA, EMA, and PMDA data, November 2018, https://www.phrma.org/fact-sheet/the-united-states-vs-other-countries-availability-of-cancer-medicines-varies. See also PhRMA, "Biopharmaceuticals in Perspective (Chart Pack)," Summer 2018, 148–49. https://www.phrma.org/report/chart-pack-biopharmaceuticals-in-perspective-summer-2018.

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In the case of biologics, the study uses originator biologic prices both here and abroad. However, because there are more biosimilars available abroad, the study compares domestic prices for biologics that currently face no biosimilar competition to those abroad that do face such competition. Competitive pressures from biosimilar availability tend to reduce the prices of innovative products. The ASPE study makes no attempt to compensate for the resulting bias in the price differences.

In the case of small molecule drugs, the study's methods are even more problematic. ASPE directly compares the prices of drugs in the United States that face no generic competition to a mix of brand and generic prices abroad. As the report explains, "We exclude all US products with generic competition as of July 1, 2018, from our analysis. However, single-source status may be related to US-only patent or other exclusivity terms, so our main analysis combines the generic sales with brand sales, outside the US, if generics are available in another country." The gap between brand and generic prices is typically large both in the United States and abroad. Comparing brand-only prices in this country to a mix of brand and generic prices other countries is certain to lead to an overstatement of actual price differences.

INCENTIVES FOR INNOVATION

The quality of its methodological underpinnings aside, far more important are the impacts this policy would have on incentives for innovation. The US market for medicines provides a large share of the revenues that enable companies to invest in drug discovery and development. Imposing price controls, or ceding pricing power for the domestic market to governments abroad that bear a relatively small share of the impact of their choices, will leave consumers with fewer solutions to future health concerns.

Market-based prices for new products lead investors to support the development of products that solve problems for consumers. Less investment will occur if investors know that prices will be set lower than the market would dictate. This is true both in this country and abroad. If foreign countries were to allow market forces to dictate prices, more investment would occur and we would be more likely to see cures to diseases like Alzheimer's and cancer than we are with the price interference that exists today.

Although it seems cliché to say, *it is true* that the search for new, valuable medicines is long and costly, with low probabilities of success. Because of the economics of drug discovery, innovators must find ways to finance the effort. Whether that process begins in large companies or small start-ups, investors weigh the returns promised from drug discovery against those promised in other sectors of the economy. If investments in new medical devices, web-based applications, new and improved energy sources and transportation methods, communications devices and software, and many other competing opportunities exceed those of drug discovery, then that investment will flow elsewhere. Hence, the further prices for new drugs are pushed below market level, the more likely it is that investors will find better returns elsewhere.

AN INSIGNIFICANT IMPACT ON R&D?

HHS suggests that the reduction in prices contemplated is small enough as a percentage of total R&D spending to be tolerable, and that it will not have a meaningful effect on the finances and thus the R&D investments of innovative drug companies. However, this view is short sighted, and there are several reasons why the impact on R&D is likely to be larger than estimated by the Administration, potentially significantly so. In particular, there are a number of secondary effects that the Administration has not considered in its estimate that are likely to increase the adverse revenue impact of this plan. One is the spillover of discounted prices outside of the

demonstration, as the demonstration forces down the official "average sales price" paid in the rest of Part B and influences prices for other public and private payers.

Another is the downward pricing spiral international reference pricing often leads to. The other countries targeted for price comparison in the proposal do not exist in a vacuum. Many of them employ their own international reference pricing schemes, some of which include the United States in their set of reference countries. Setting domestic prices in comparison to prices in those countries may well change the calculated prices abroad, which would then feed back into further price reductions here. Even beyond this type of formulaic downward price spiral, politicians in other countries would likely see reduced US prices as an opportunity to reduce their prices even further, again leading to a spiral that reduces prices under the proposed program. In either of these two scenarios, "foreign freeloading" is not addressed, but likely exacerbated.

Other dynamic international pricing effects will also undoubtedly come into play, exposing as a misplaced hope the assumption that US companies can mitigate the effects of this plan by simply bargaining harder with foreign governments. As Grabowski and I have pointed out elsewhere,[6] and as was recently explained in the *New York Times*,[7] the purchasing situation in many countries imposes severe restrictions on pricing that are unlikely to be broken. With no alternative purchasers in these systems, bargaining in the true sense is not a realistic option. For negotiations to be meaningful, one party must be able to walk away from conditions that it finds unacceptable. In the business of life-saving and enhancing medicines, companies find it very difficult to exercise the walk-away option. On the one hand, companies face a serious public relations backlash if they refuse to supply a critical medicine in a country, and on the other hand, if a company does refuse to supply a product in a country, the country may simply award a license to another competitor to produce the product. Most simply, at the end of the day, getting something is better than getting nothing, so companies agree to price concessions.

Back-of-the-envelope calculations—based on reasonable assumptions and an understanding of the market dynamics described above—suggest that the reduction in investment that occurs as a result of this proposal could reduce the number of new drugs introduced in the coming decade by between 20 and 40. The impact would likely fall disproportionately on physician-administered medicines used by Part B beneficiaries. The number of new Part B medicines, which treat serious and life-threatening diseases including cancer and multiple sclerosis, could be reduced by a third. Of course, no one knows precisely what drugs will not be discovered in the future, but that is actually a serious problem. There are many important medical conditions that are likely to be addressed with novel therapies. Which ones will not be developed? No one knows. But without knowing the value of the missing or foregone treatments, one cannot know whether or not the cost of those missed opportunities is worth the reduction in spending that is promised by the policy.

CAN WE AFFORD TO HAVE LOWER PRICES?

Some people believe that drug companies are excessively profitable and that they can afford to take the hit implied by this proposed price reduction. It is helpful in that regard to bear in mind that the financial prospects of the biopharmaceutical industry are not impervious to the economic forces of supply and demand. Indeed, there is good evidence that the returns to investment in drug discovery have plateaued and fallen for many companies, calling into question their ability to continue developing new cures.[8] There is also solid evidence that

6 Henry Grabowski and Richard Manning, "Drug Prices and Medical Innovation: A Response to Yu, Helms, and Bach," *Health Affairs* (blog, June 2, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170602.060369/full/.

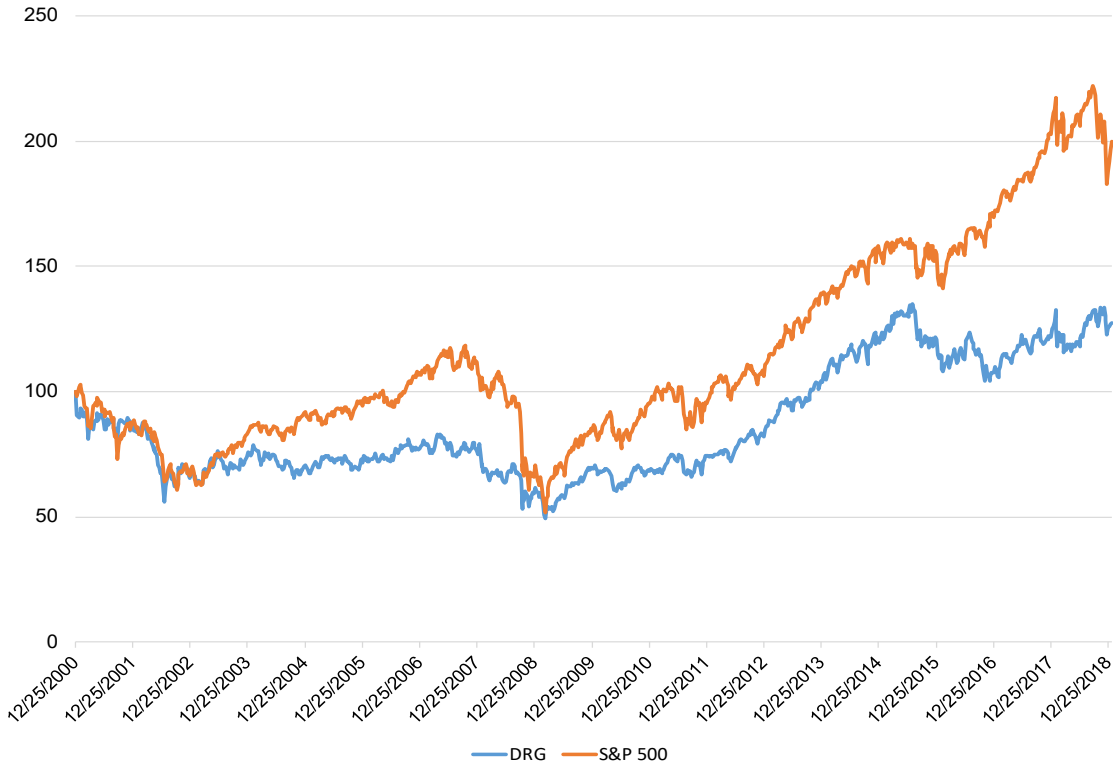
7 Robert Pear, "Fact Check: Trump Officials Say Drug Prices Are Inflated. So Are Some of Their Claims on a Solution," *New York Times*, Dec 16, 2018.

8 See Ernst R. Berndt, D. Nass, M. Kleinrock, and M. Aitken, "Decline in Economic Returns from New Drugs Raises Questions about Sustaining Innovations," *Health Affairs* 34, no. 2 (2015): 245–52.

after accounting for its extraordinary cost of capital and the level of capital investment involved in drug discovery and development, the biopharmaceutical industry has economic profit rates that fall in the middle relative to all US industries.[9]

Recent trends in the financial returns of new drug development are illustrated by the performance of the stock prices of highly capitalized drug companies. Since the economic downturn just after the turn of the century, the NYSE DRG[10] index has underperformed the market overall as measured by the S&P 500. The DRG index was created during a time that many new and valuable drugs, such as statins, non-sedating antihistamines, and new antidepressants, were being developed. Through the end of the 1990s, driven by the success of those new drug introductions, the DRG index substantially outperformed the S&P 500. However, things have changed. Since late in 2000, and particularly since the financial crisis of 2008 and 2009, the DRG index has consistently lagged the overall market, as illustrated in the graph below. Most interestingly, the pharmaceutical index has not participated in the overall market growth that has occurred in the past three years. While the S&P 500 index has doubled since December 2000, the DRG index has increased by only about 27%. Blithe statements that the imposition/importation of price controls will have no real effect on the industry should be carefully evaluated in light of this evidence.

Figure 1 – Index of weekly closing prices since DRG peak: Dec. 25, 2000



9 See Richard Manning and Saurav Karki, "Policy Brief: Economic Profitability of the Biopharmaceutical Industry," September 2018, https://www.bateswhite.com/media/publication/167_Economic%20profitability%20of%20the%20drug%20industry.pdf.

10 NYSE ARCA, "The NYSE Arca Pharmaceutical Index," 2014, https://www.nyse.com/publicdocs/nyse/indices/nyse_arca_pharmaceutical_index.pdf.

WHAT DO PEOPLE WANT AND HOW WILL THEY GET IT?

It may seem obvious that people want lower drug prices. While economic theory would tell you that people *do* prefer lower prices for everything they buy, all else the same, there is an important qualifier in the economists' common refrain: all else is not the same over time. In addition to wanting lower prices on the things they buy today, people also want new and better solutions to problems they currently have or anticipate having in the future.

People want better treatments and ultimately a cure for cancer; they want effective treatments or even a cure for Alzheimer's disease. They want to live healthier lives. The way for them to get those things is to allow market forces to dictate the prices of new medicines. Of course, people need to be able to afford new therapies. Well-designed health insurance should make that possible. But if everyone knew that the cure for cancer, or Alzheimer's, or any number of other conditions would be priced like aspirin if and when it's discovered, it would never be discovered.

Despite the apparent simplicity and asserted effectiveness of an international reference pricing regime, there is a real danger lurking in it. If this idea were to spread to other programs, we could soon have prices throughout the US healthcare system for drugs and other components of care that are divorced from the market forces that signal value to patients. If we allow prices to be set by a collection of foreign governments that have no connection to us as patients, now and in the future, we stand to see serious damage done to the future of care. Ironically, people abroad would feel that pain, eventually, as well. Legitimate debates can be had about coverage and payment for medicines in the United States, but adopting the approach taken by foreign countries whose systems do not themselves support the current level of innovation is dangerous and misguided.

Let's not start down that path.