

## Comments for the Record



# Comments To CMS On Proposed International Pricing Index for Medicare Part B Drugs

TARA O'NEILL HAYES | JANUARY 7, 2019

Dear Administrator Verma,

I thank you for the opportunity to comment on the October 30, 2018, Advanced Notice of Proposed Rulemaking ([CMS-5528-ANPRM](#)) seeking to establish an International Pricing Index Model (IPI) for Medicare Part B Drugs.

The administration's objective to reduce the cost of drugs and increase Americans' access to necessary medicines is laudable. The solution that has been proposed here, however, is not likely to achieve that objective, and in fact, could result in significant undesirable repercussions.

The primary concerns with this model include:

**Restricted access to existing medicines:** The 14 countries that the Centers for Medicare & Medicaid Services (CMS) has proposed referencing in this IPI model, on average, have access to only 48 percent of the new drugs developed in the past eight years, and it took an average of 16 months after their initial global launch for those drugs to become available in those 14 countries. If the United States adopts the prices of those countries, American patients may very well face the same access restrictions as exist in those countries and lose access to existing treatment options.

**Reduced innovation for future advancements and new medicines:** If this model were adopted and applied to all Part B drugs, revenues would be reduced approximately \$9 billion per year based on the most current expenditure levels. Given that the cost to develop a new medicine is estimated to be \$2.9 billion, as many as three fewer new medicines may be developed each year as a result of this model if drug manufacturers are unable to recoup these lost revenues in other markets.

**Cost-shifting to other health insurance markets and federal programs:** Given the unlikelihood that other countries will begin to pay more for medicines as a result of this demonstration, drug manufacturers will instead attempt to shift the cost to other health care markets in the U.S., namely the employer-sponsored insurance market. To the extent that such a result occurs, American workers—not foreign countries—will bear the cost of this experiment. Further, if the average sales price in the private market increases, then Medicare will pay more for the drugs used that are not covered by the demo, potentially negating any savings that may be obtained within the demo.

The inconsistency of this model with the administration's efforts to encourage value-based pricing in the health care system: CMS has made it a priority to transition all reimbursements to a value-based payment system. Simply adopting the price set by other countries without assessing the value of the product appears to be inconsistent with this goal.

The harm this proposal will have on U.S. trade policy: For decades, American administrations, including this one, have worked hard to implement and enforce trade agreements with other countries that protect intellectual property and patent rights for U.S. products in other countries. Part of that effort includes disallowing coercion through the threat of compulsory licensing—a practice known to occur in European countries in order to force the sale of drugs at discounted prices. This demonstration, by adopting the price that other countries have obtained through coercion, undermines those efforts and sends the signal that such tactics are acceptable.

For these reasons, the administration may be better served finding a different solution.

## **Background**

The administration has identified a problem in the pharmaceutical market that warrants a solution: Americans pay significantly more, on average, for brand-name medications than people of other countries. A recent report from the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services (HHS) found that the price of 27 studied medicines was, on average, 80 percent higher in the U.S. than the average price of those medicines in 16 other countries.<sup>[1]</sup> This is largely because the price paid in those other countries is dictated by the government, most of which operate a single-payer health care system and use price controls to limit their expenditures. The higher prices paid for medicines in the U.S. contribute to Americans paying between 64 and 78 percent of worldwide pharmaceutical profits, despite the U.S. accounting for only 27 percent of global income.<sup>[2]</sup> President Trump and his administration are understandably looking for a solution to end the American subsidization of the rest of the world's health and ensure that other countries pay their "fair share." CMS states in the ANPRM that the goals of the model are to reduce government and beneficiary costs and thereby increase access and adherence, preserve the quality of care, obtain prices comparable to those paid in other countries for such drugs, reduce providers' incentive to use high-cost drugs as well as their financial burden and risk associated with furnishing drugs, and maintain stability in provider revenue.

To that end, the administration is considering launching a demonstration project through the Center for Medicare and Medicaid Innovation (CMMI) to test a new reimbursement model for physician-administered drugs covered under Medicare Part B. This demo will apply to selected drugs and all providers within the selected geographic areas; areas will be chosen to account for 50 percent of annual Medicare Part B drug spending. All providers in the demo, when using one of the drugs subject to the new reimbursement model, will be required to purchase that drug from a designated vendor. The vendor will serve as a middleman, responsible for negotiating discounts and rebates from drug manufacturers for the drugs covered by the model. CMS, rather than reimburse providers as under the [current payment system](#), will reimburse the vendors for the drugs used. The reimbursement rate will be set at a fixed percentage based on the newly developed IPI—a pricing index based on the average price of a drug in selected other countries (14 are listed in the ANPRM for consideration). Finally, CMS will use a target price multiplier to adjust the IPI factor such that the reimbursement rate under the IPI model will be 30 percent less than the reimbursement rate would be in the absence of the model.

There are more than 500 drugs covered under Medicare Part B, but spending is highly concentrated on a small number of those drugs. The top 50 drugs in terms of total spending under Part B are primarily biologics and single source drugs—accounting for nearly 80 percent of those expenditures. Accordingly, CMS is planning to

apply this model, at least initially, to single source drugs, biologics, biosimilars, and multiple source drugs with a single manufacturer.

## **Concerns with the IPI Model**

### *Lost Revenue and the Harm to Innovation and Economic Growth*

Analysis of the top 10 drugs covered by Part B in terms of total spending shows that in 2016 these drugs accounted for 48 percent (\$12 billion) of all Part B drug expenditures but only 13 percent of all claims. While the average sales price of these drugs was only \$602, these drugs must be taken many times during treatment. The average annual spending for these drugs for each beneficiary using them was \$15,849 in 2016. These drugs were provided to more than 5 million beneficiaries, roughly 9 percent of all Medicare enrollees. Sales of these drugs in the U.S. accounted for 62 percent of their worldwide revenues, but only one-third of worldwide sales by volume, highlighting the price disparity between the U.S. and foreign markets. Nearly half (47 percent) of U.S. revenues and 29 percent of worldwide revenues for these drugs are covered by Medicare Part B. With the demonstration applying to half of Part B drug spending, it is estimated that if this demo had been applied in 2016, roughly 15 percent (or nearly \$8 billion) of worldwide sales of these medicines would have been subject to the 30 percent price reduction under this model. This would amount to nearly \$2.5 billion in reduced revenues in a single year just for these 10 medicines. If the demo were applied to all Part B drugs, expenditures for which now equal nearly \$30 billion, revenues would be reduced approximately \$9 billion per year.

Reduced revenues have a significant effect on future investments and development, as the probability of earning a worthwhile profit is critical to enticing potential investors to finance an endeavor with such high costs and such low probabilities of success. In 1986, research and development (R&D) investments by pharmaceutical firms in Europe exceeded R&D in the U.S. by roughly 24 percent.<sup>[3]</sup> Following the imposition of government price controls in many European countries, and consequently the reduced return on investment, R&D spending by pharmaceutical companies grew at an annual rate of just 5.4 percent in the European Union, compared with 8.8 percent growth in the U.S. As such, more than half of the world's pharmaceutical R&D investments have been made in the U.S. since the turn of the century, whereas less than 30 percent is invested in Europe.<sup>[4]</sup> Research estimates that this lack of investment came at a cost of 46 fewer new medicines being introduced and nearly 1,700 fewer jobs over a 19-year period.<sup>[5]</sup> Research by the Organisation for Economic Cooperation and Development (OECD) and IQVIA indicates the need for R&D investments is even greater now as the target populations for each new drug grows smaller with the development of treatments for less common diseases: 95 percent of the 7,000 known rare diseases are still without any therapeutic option.<sup>[6]</sup> Further, the amount of spending per new drug approved has been growing for decades.<sup>[7]</sup> It is well known that innovation is the primary factor that drives economic growth and improves people's standard of living. Pharmaceutical companies have historically invested 10-15 percent of revenues in R&D.<sup>[8]</sup> Declining revenues will reduce innovation and lead to lower economic growth.

Given that the cost to develop a new medicine was recently estimated to be \$2.87 billion, after accounting for the costs of failed attempts for each successful one, the lost revenue expected from this demonstration is nearly equivalent to the cost of a new medicine *each* year.<sup>[9]</sup> And as the cost to develop a new medicine is increasing each year, the significance of this lost revenue will as well. If this reimbursement model were adopted for all Part B medicines, an estimated three fewer new medicines would be developed each year; unless, of course, these lost revenues in the U.S. market can be replaced by increased revenues in other markets.

### *Cost-shifting*

Unfortunately, because drug prices in most other countries, including those being considered for this IPI model, are dictated by their governments rather than the market, it is unlikely manufacturers will gain enough leverage to convince other countries to pay them more. This is underscored by the fact that other countries have already proven their willingness to deny access to medicines if the price is above what they are willing to pay, as shown by the average availability of new medicines standing at only 48 percent in the 14 countries being considered. To the extent this is true and drug manufacturers are indeed unable to shift the cost of reduced revenues overseas, they will likely shift costs to the private market in the United States. The primary holders of private market insurance are American workers. But only so much cost-shifting to American workers is possible. In order to make up for a 30 percent price reduction on nearly a quarter of their sales, prices in the private market would have to rise by 13 percent to keep the average sales price (ASP) roughly equal to what it currently is. The remaining lost revenue will be seen in less innovation and fewer new medicines in the future with a high probability of restricted access to existing medicines once the model goes into effect.

### *Undermining Trade Policy*

Adopting the failed and unfair practices of other countries will not solve the problem, it will simply import it while simultaneously undermining other efforts by the administration. For years, U.S. trade negotiators have been fighting the exact unfair trade practices the administration addresses in this proposal. Foreign governments prohibit drug manufacturers from selling their product at a price above that set by the government and threaten American drug manufacturers with compulsory licensing if they do not provide the medicine at the government's dictated price. The Drug Pricing Blueprint—the initial document outlining the administration's ideas for reducing drug prices—was released by HHS in May 2018. It states: “Every time one country demands a lowers price, it leads to a lower reference price used by other countries. Such price controls, combined with the threat of market lockout or intellectual property infringement, prevent drug companies from charging market rates for their products, while delaying the availability of new cures to patients living in countries implementing these policies.”<sup>[10]</sup> In February 2018, a report from President Trump's Council of Economic Advisors noted the importance of “preserving incentives for biopharmaceutical innovation” as a key to “better health in the future,” and recognized that the prices set by foreign governments “erode the returns to innovation.”<sup>[11]</sup> Adopting the prices set in these other countries is an indirect adoption of the policies and practices they use to obtain those prices. Doing so undermines the Trump Administration's own trade policy and erroneously sends the signal to other countries that the U.S. supports their tactics and price controls.

Rather than adopt the ill-advised and punitive practices of foreign countries, a more appropriate solution would be to fight those unfair practices and encourage countries to instead pay prices truly representative of a drugs' value and cost to develop. Doing so would have significant positive effects worldwide in the long-term. A recent study found that if other nations lifted their price controls on pharmaceuticals, there would be 9 percent more medicines available by 2030 and the life expectancy of a 15-year old today in America would increase by more than a year.<sup>[12]</sup> Another study found that if European prices for medicines increased 20 percent, the resulting increased innovation would generate welfare gains over the next 50 years worth \$10 trillion in the U.S. and \$7.5 trillion for Europeans.<sup>[13]</sup>

Ultimately, without the adoption of appropriate trade enforcement mechanisms, it is unlikely that other countries will willingly agree to pay more simply because the U.S. is paying less. Other countries have already proven their willingness to deny access to medicines if the price is more than they're willing to pay.

### *Savings Estimate*

CMS estimates that if this demonstration is implemented, the federal government could save \$17.2 billion

between 2020 and 2025. This estimate, though, assumes the prices in the referenced countries will remain the same. But the objective of this policy as stated by President Trump is for other countries to pay more. If they do, the amount of savings gained in the U.S. will be diminished. In other words, the only way to achieve that level of savings is for the policy objective to fail to be met. If the objective is not achieved (and it is not likely to be), we will have saved \$17 billion, but likely at the expense of the advancement of science and the development of new medicines along with potentially restricted access to existing medicines.

The savings estimate also assumes utilization rates for these products will remain unchanged; but six of the top 10 drugs by total spending in Part B have biosimilars available now and the other four have biosimilars in development. It is likely that between now and 2025—the end of the demonstration period—utilization of many brand name drugs is expected to decrease as biosimilar use increases. Some savings would be gained simply from differences in utilization. It is possible, though, that this model will reduce revenues for biosimilars beyond a sustainable level, having the undesirable effect of suppressing their availability and thus their expected savings.

## **Responses to Specific Questions Included in the ANPRM**

### **III. Model Concept Designs**

#### **Countries to include in the International Pricing Index**

CMS should carefully review the pricing standards and mechanisms used to set prices in each of the countries under consideration for inclusion in the IPI. CMS should only select countries that it believes appropriately assess and price covered drugs; such an evaluation and corresponding price should accurately reflect a drug's value. This is particularly important given CMS's commitment to transitioning all Medicare reimbursements to value-based payments; this goal can only be achieved with this payment policy if CMS determines the prices set in these other countries accurately reflect a drug's value. Setting a fixed price for a given product based on nothing more than the price paid in other countries means the reimbursement rate is devoid of any value-assessment by CMS. To the extent that the price set in other countries is based on the country's assessed value of the product, we are simply adopting their value metrics. CMS should consider whether this is appropriate and consistent with our own goals and value metrics.

For example, if a country's evaluation protocols use a specified value for a year of life to calculate the drug's value, CMS should determine if it matches the value that CMS places on an additional year of life. CMS in the past several years has used a median quality-adjusted life year (QALY) value of \$293,000.<sup>[14]</sup> The National Institute on Cost Effectiveness (NICE)—the organization responsible for determining the price of covered health care goods and services in the United Kingdom—on the other hand, uses a cost-effectiveness threshold that is 30 percent lower than what the standards of the World Health Organization would dictate.<sup>[15]</sup> Evaluations of the top 10 Part B drugs have found that six of the top 10 drugs are cost-effective for the treatment they provide at their U.S. market price<sup>[16]</sup>; two were found to not be cost-effective<sup>[17]</sup>; and two lacked studies on their cost-effectiveness. Evaluations conducted with too strict a cost-effectiveness threshold, such as that used by NICE, will not yield the same results and access to these medicines may be denied, which largely explains why the U.K. only provides access to 60 percent of new medicines launched within the past eight years.<sup>[18]</sup>

To that point, CMS should also analyze the level of access to drugs in each country it plans to include in the model, particularly new drugs that improve current treatment options. In the United States, 89 percent of all 290 new medicines and 96 percent of the 82 new cancer medicines launched between 2011 and 2018 were available



within three months; in the 14 countries being considered by CMS for the IPI, only 48 percent of all new medicines and 57.1 percent of new cancer medicines are available, and it takes an average of 16 months and 17.8 months, respectively, for access to those medicines to be gained.<sup>[19]</sup> When adjusting for population, the figures improve just slightly: 51.5 percent of all new medicines and 59.7 percent of new cancer drugs are available in these 14 countries within 17.4 months. Still, this level of access to new medicines significantly lags behind the availability of new drugs in the United States. Of the 54 new medicines launched during this period covered under Medicare Part B, only 28, on average, are available in these other countries, and it took an average of 18 months for access to be granted after their initial launch. In fact, only 11 of the 27 medicines studied in the ASPE report were available in each of the 16 other countries analyzed, despite all 27 being available in the U.S. and covered by Medicare Part B. Basing the target price on a study for which nearly 60 percent of the medicines (and thus their prices) were not universally available for comparison makes it more likely that the price will not be truly reflective of a drug's value.

The lack of access to new medicines seems to be highly correlated with a country's use of price control mechanisms. Japan, the world's second largest pharmaceutical market, has a highly protectionist policy intended to bolster its domestic pharmaceutical industry and does not adequately reward innovation.<sup>[20]</sup> Only 49 percent of new medicines launched since 2011 are available in Japan. In France, a committee is tasked with evaluating a medicine's therapeutic value relative to existing treatments, and this is used as the primary basis for determining a drug's reimbursement rate.<sup>[21]</sup> The committee tends to undervalue products during its assessment because a higher rating dictates a higher price. Further, if expenditures grow faster than a target rate, pharmaceutical companies are required to pay rebates. Only 48 percent of new medicines are available to the French as a result of these policies. As noted in a report by the U.S. Department of Commerce International Trade Administration, Canada's Patented Medicines Prices Review Board sets a maximum price for pharmaceuticals and any price increase is punishable by fine; further, price cuts and freezes are used to prevent prices from rising faster than inflation.<sup>[22]</sup> The U.K., as mentioned, uses a cost-effectiveness threshold that is so low, only 60 percent of all new medicines since 2011 are available there. Of particular concern among the countries being considered is the inclusion of Greece: only 14 percent of all new medicines since 2011 are available to the people of Greece, and it took an average of 30 months for those 41 medicines to become available.

Also of concern are the indirect effects and implications of adopting a reference pricing model. Of the 14 countries under consideration for this reference pricing model, 11 use reference pricing themselves to control their prices. The average number of countries referenced is 17. Between four and six of these 11 countries reference each of the following countries in determining their own price: Cyprus, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia, and Spain. By referencing the price of drugs in countries that reference the prices in other countries, we would indirectly be referencing the prices of those other countries. The average gross domestic product (GDP) per capita in these countries listed was \$18,685 in 2017, while the GDP per capita in the U.S. was \$59,532—more than three times greater. The estimated age-standardized mortality rate for all cancers in these countries is 123.47, compared with a rate of 91 in the U.S. The average life expectancy in these countries is nearly a year shorter than that of the U.S. It is not appropriate for the U.S. to reference the prices paid in countries whose GDP per capita is less than a third of ours. Further, given the poor health outcomes in these countries, CMS should carefully consider the implications of modeling our health care programs on the policies of these countries.

Given the evidence that prices paid are strongly correlated with the availability of medicines, CMS should consider the impact that such a reduction in reimbursements will have on the availability of medicines in the U.S. and determine the degree to which such a trade-off between reduced costs and access to medicines is in the public's interest.

### **III. A. Model Vendors**

#### **Opportunities for model vendors and participants to enhance quality and reduce costs**

CMS seems to be looking for ways to encourage use of high-value products while avoiding incentives that have plagued the [Medicare Part D](#) program and led to the increased use of high-cost/high-rebate drugs. In this ANPRM, CMS states its interest in vendors' use of indication-based pricing and outcomes-based contracts. CMS also states that vendors will be prohibited from paying rebates or volume-based incentive payments to physicians and hospitals. One potential pitfall here, though, is that CMS has not indicated its intention to prohibit vendors from receiving rebates from drug manufacturers. In Part D, such rebates are often provided to plan sponsors as a reward for preferential formulary placement which is known to increase sales for a product relative to competitors with less favorable placement. If vendors' primary negotiating leverage in this model is similarly drawn from its ability to increase sales volume for a given product, it is likely that a rebate structure similar to that currently used in Part D may develop. Vendors may establish a fee schedule with providers that offers preferential fees for drugs for which they have negotiated the best deals, which may not be the lowest cost drugs in the rest of the market.

Despite concerns regarding the potential rise of perverse incentives, the ability to utilize indication-based pricing and outcomes-based contracts will likely yield positive results. This is especially important given the development of biosimilars for many of the top 10 Part B drugs with the highest total program spending. Currently, many biosimilars have difficulty gaining market share because they may not share all of the indications of a reference product and manufacturers of the original biologic may threaten to stop providing significant rebates for their drug if a biosimilar is added to the formulary. Because the biosimilar does not cover all the same indications, the reference product is still needed and losing access to its rebates is not worth the benefit gained from having access to the biosimilar. To the degree that indication-based pricing in Medicare may allow for that obstacle to be overcome elsewhere, significant savings may be achieved, as the effects will reach beyond the Medicare market.

### **III. B. Model Participants, Compensation and Selected Geographic Areas**

#### **Model Geographic Areas**

CMS should consider the extent to which spending on particular drugs is concentrated inside or outside the selected geographic areas and take caution to ensure the model does not disproportionately impact a particular drug. Further, CMS should not just consider overall spending, but spending across classes of drugs so as not to place an undue burden on any particular sector of the drug industry.

#### **Increased administrative burden for providers**

Providers in the demo are likely to face an increased administrative burden as a result of the new payment and drug acquisition mechanisms that must be established to run this model. While the demo will be mandatory for all providers in a selected geographic area, not all drugs will be included in the model. Thus, providers in the

demo will be forced to utilize two different payment and acquisition systems. This increased administrative burden may need to be accounted for in the add-on payment.

## **Drug Add-on Payment**

CMS, noting that the current add-on payment made to providers may unintentionally encourage use of high-cost drugs over potential lower-cost alternatives, is looking to replace the current method for calculating the add-on payment. CMS is considering alternatives, such as payments based on a drug's class, the physician's specialty, or the physician's practice. CMS is right in its identification of the potential undesirable outcome of the current add-on payment method to encourage use of high-cost drugs (though evidence of this occurring does not exist). Whether a perverse incentive is being exploited or not, the current methodology for determining the amount of the add-on payment does not seem to match its intent. The add-on payment should reimburse providers for the cost of their labor in administering the drug as well as any costs associated with acquiring the drug, such that the provider is financially neutral with regard to which drug to use, allowing them to make the best decision for their patient. In order to achieve this goal, the most appropriate basis for such payments is likely drug class and administration mechanism. CMS should further evaluate the amount of time required to administer the drug as well as any necessary monitoring that must be conducted; this evaluation should also consider the type of provider administering the drug and performing any monitoring to allow payments to appropriately reflect differences in labor costs across provider types.

CMS should implement such a change immediately. Given that providers under this model will no longer be responsible for the cost of the drug itself, they are not at risk of any financial loss on the cost of the drug. Thus, recognizing the inappropriateness of the current payment structure, CMS should act to correct it as soon as possible. Further, the notion that providers should be financially held harmless seems unjustified. CMS has already made the case that providers have likely been overpaid for years as a result of the inappropriateness of the current add-on payment structure. If that's the case, then there should be no reason to ensure they continue to be overpaid. Establishing a payment metric and formula that adequately compensates providers for their work can and should be established without regard to an arbitrary and inappropriate baseline.

## **III. C. Included Drugs**

Given CMS's objective to reduce overall program expenditures, the drugs CMS intends to target with this model seem to be the most appropriate for achieving that result, with the exception of biosimilars. Single-source drugs, biologics, and multiple-source drugs with a single manufacturer tend to be the highest cost drugs and benefit from a lack of competitive pressures to naturally bring prices down. The 27 drugs included in the ASPE report fall into these categories and represent more than 50 percent of Part B drug expenditures. Biosimilars, though, are the market-based solution to high prices for biologics; biosimilars create competition and—like generics for small molecule drugs—are less expensive than the innovator drug and place downward pressure on the price of the reference product. Biosimilar development and use should be encouraged and applying this model to biosimilars will likely stifle their creation and adoption.



Also of great concern is how CMS will reimburse for new drugs that are not yet available elsewhere, which, as the evidence has shown, is quite common. In the ANPRM, CMS notes it is considering simply applying to new drugs the average price differential established by the IPI. This could significantly undervalue new drugs, enough so that it could very likely have a chilling effect on the development of new medicines. As discussed before, the promise of a return on investments is vital to incentivizing an investment to be made in the first place. If a drug manufacturer cannot expect to recoup the costs of their investments, they have no incentive to spend the money and take the risk of not earning it back.

Finally, as mentioned before, including some drugs used by a provider but not all will create additional administrative burdens for providers in the demo.

## **H. Interaction with Other Federal Programs**

CMS states in the ANPRM that the reimbursement rate provided in the IPI model will be included in the calculation of metrics used in reimbursement formulas for other federal programs, including the Medicaid Drug Rebate Program, 340B, and Medicare itself. Such a policy expands the impact of the model far beyond its direct scope, exponentially increasing the potential impacts of the model.

Regarding Medicare Fee-for-Service and ASP: The average sales price (ASP), which is currently used to determine the reimbursement rate for Part B drugs outside the model, will be impacted by this model because sales to vendors will be included in the calculation of ASP. Given that CMS is only going to reimburse vendors at 126 percent of the average international price, manufacturers will need to provide their drug for no more than that, or else the vendors will lose money. If manufacturers sell their drugs to providers in the demo for a lower price than currently available, this will have the impact of lowering the ASP. However, to the degree that manufacturers account for such price reductions in the demo by increasing their prices in the private market in the U.S., as discussed earlier, the ASP may increase, and thus the reimbursement rate for drugs used by Medicare providers outside the demo would increase, potentially negating any savings obtained by the IPI model.

## **Conclusion**

The Trump Administration has properly identified a significant problem with the international pricing of pharmaceuticals. The proposed solution, however, is misguided and likely to backfire. Adopting the non-market prices of other countries, and thus the punitive and authoritative policies used to obtain those prices, will likely also mean adopting for American patients the same level of restricted access to new medicines as experienced in other countries. Worse yet, this demo may result in new medicines never being developed in the first place. Americans highly value their access to and choice of new treatment options. The reduced innovation that will occur as a consequence of the reduced revenues that will result from this model will have significant ramifications. Further, referencing the prices paid for drugs in countries that do not adequately reflect the value of medicines is inconsistent with the administration's goal of adopting a value-based payment system. Finally, this model will undermine American trade policy which may have repercussions far beyond the pharmaceutical industry. The Administration should not adopt this policy and should instead look for other means to reduce Americans' health care costs.

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