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Mirror, Mirror on the Wall:

Medicare Part D pays needlessly high brand-name drug prices compared with other OECD countries and with U.S. government programs

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HIGHLIGHTS

1. After including rebates, brand-name drugs cost Medicare Part D 198% of the median costs for the same brand-name drugs in the 31 OECD countries.
2. Medicare Part D pays on average 73% more than Medicaid and 80% more than the Veterans Benefits Administration (VBA) for brand-name drugs.
3. Medicare Part D would save from \$15.2 billion to \$16 billion a year if it could secure the same prices that Medicaid or VBA, respectively, receives on the same brand-name drugs.
4. While Medicaid and VBA often are used as benchmarks because of the rebates or discounts they secure, even these organizations pay higher prices than many OECD countries.
5. Under current Medicare Part D pricing, non-innovative “me-too” drugs are priced as much or more than older, equally effective versions. By currently paying inflated prices for drugs that do not provide value for money, Medicare Part D artificially increases the returns and incentives for non-innovative “me-too” drugs to the detriment of new innovative medicines for unmet needs.
6. Reducing brand-name drug prices would reduce the high level of cost-related non-adherence (people not filling their prescription for financial reasons) found in Part D, by reducing beneficiaries’ premiums and co-pays. In addition, since the government pays for the majority of Medicare Part D, taxpayers’ contribution would decrease by at least \$11 billion every year.

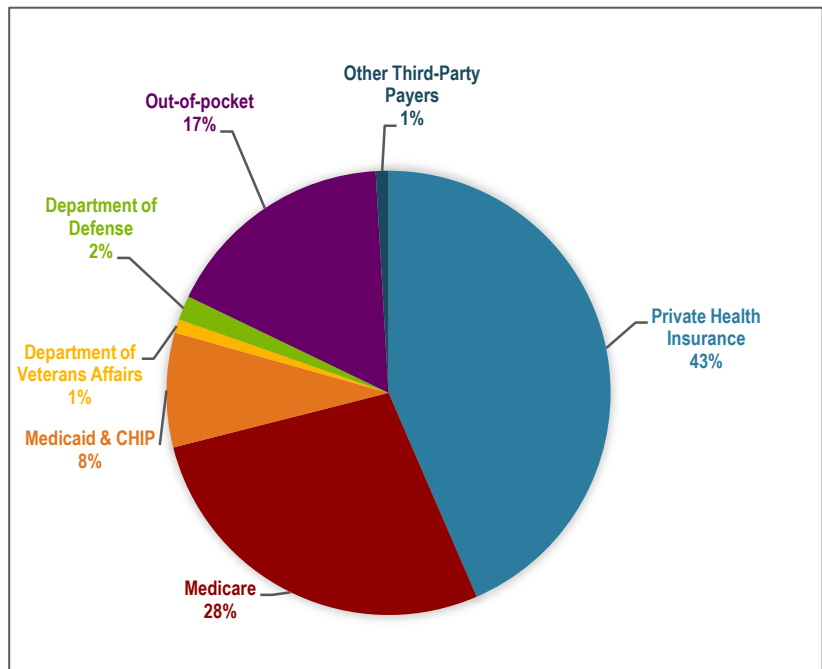
The study concludes with specific recommendations for legislation, including suggestions from current Medicaid and VBA policies, to lower Medicare Part D prices. This would thereby alleviate the current de facto rationing that occurs because so many Medicare recipients cannot afford these inordinately high prices and suffer the health consequences of cost-related non-adherence to drugs prescribed for them.

BACKGROUND

Medicare Part D was implemented in 2006 to improve drug coverage for seniors (65+) and for people with disabilities. Medicare Part D is the largest federal drug program (Figure 1), and covered 39.1 million people in the fiscal year 2013.^[1]

With \$69.3 billion in prescription drug spending in 2013,^[1] Medicare Part D alone represents approximately 7% of the \$993 billion global prescription drug market.ⁱ Around 58% of Medicare Part D spending on prescription drugs is paid to brand-name manufacturers.^[33]

FIGURE 1
U.S. retail prescription drug spending by purchaser, 2013



Source: Bloomberg L.P. (2013)

Despite its size, Medicare Part D is not allowed to “interfere with the negotiations between drug manufacturers and pharmacies and [Part D plan] sponsors” (P.L. 108-73, Section 1860D-11). Plan sponsors can obtain substantial rebates from both drug manufacturers and pharmacies, but the federal program is prohibited from leveraging its purchasing power to realize economies of scale due to this non-interference clause. Numerous reports and scientific papers have demonstrated that, after taking into account the rebates obtained by plan sponsors, prescription drugs covered under Medicare Part D are priced at much higher levels than in other federal programs.^[2-15] While the Centers for Medicare and Medicaid Services (CMS) are frequently called upon to reduce drug prices for Medicare Part D, CMS is forbidden from taking steps to secure additional rebates or discounts without action from Congress. As this policy brief will show, by using previously unavailable data comparing U.S. brand-name drug prices with those of all other countries members of the Organization for Economic Co-operation and Development (OECD), Medicare Part D needlessly pays significantly higher prices than any other comparator countries. Moreover, even in comparison to other U.S. government programs such as Medicaid and the Veterans’ Benefits Administration (VBA), significantly higher prices are paid by Medicare Part D.

ⁱ This ratio was calculated using IMS Health data for audited and unaudited markets: http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/Press%20Room/Top_line_data/2014/World%20figures%202014.pdf .

Advocates for price reductions argue that reductions in Part D prices would produce significant savings for the Medicare program itself and reduce beneficiary premiums, thereby aligning Medicare Part D with these other programs. Advocates for price reductions often argue that Medicare Part D was designed less as a system for social protection for the sick than as a system of corporate welfare for brand-name drug companies.^[3,16-17] Price reduction opponents argue that a rebate policy would be compensated by reduced incentives for manufacturers to offer favorable rebates to private payers, that it would undermine the competitive system used in Part D and that it would lead to higher beneficiary premiums. While contending that it would increase costs for payers, opponents also argue that it would reduce revenue available for private investment in research and development for new drugs and thereby harm innovation.^[18-20]

This policy brief assesses the price reduction issue by:

1. Comparing domestic and international prices for patented drugs;
2. Analyzing price levels for brand-name drugs obtained by different U.S. government programs;
3. Looking at the correlation between price levels and research and development spending; and
4. Examining the potential impacts of policy reforms.

ANALYSES

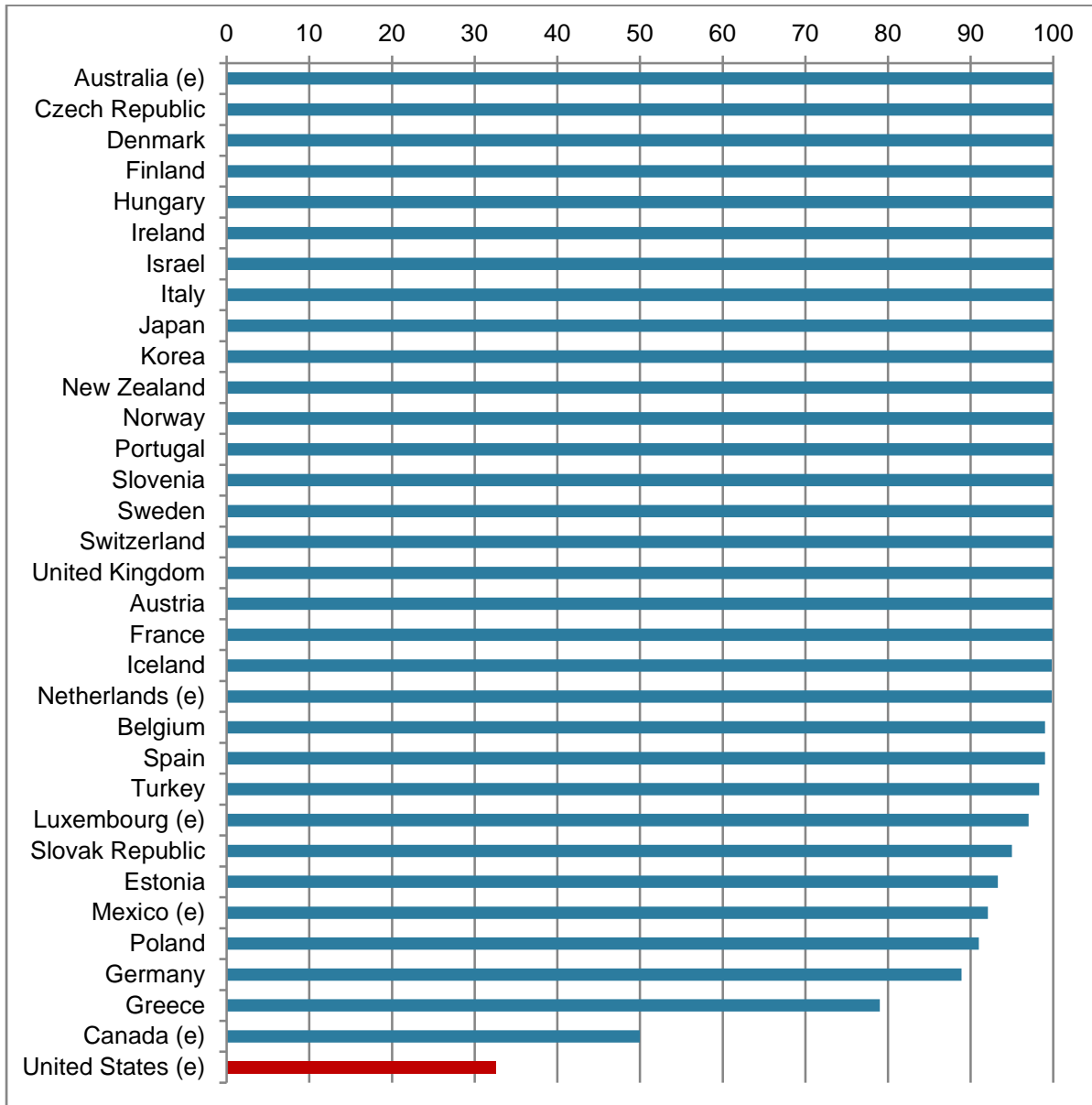
1 – How the United States compares to other countries

The U.S. system for the provision of prescription drugs is characterized by the predominance of private drug plans. Among all OECD countries, the U.S. ranks last in terms of the proportion of its population covered by a public drug plan, with the majority of OECD countries having 100% of the population covered by a public drug plan (Figure 2).

While all other OECD countries provide public coverage for at least three-quarters or, more often, all of its population, the U.S. and Canada remain anomalies. These two countries rely mostly on private plans, and they are both characterized by very high drug costs, lack of cost-efficiency, significant waste, and a large proportion of their populations not being able to fill prescriptions due to financial reasons.^[21] Countries with universal public drug coverage have significantly lower costs per capita for prescription drugs, and their population has better access to medicines.^[22]

FIGURE 2

Percentage of the population covered by a public drug insurance plan in all OECD countries (%), 2013 (or latest year)



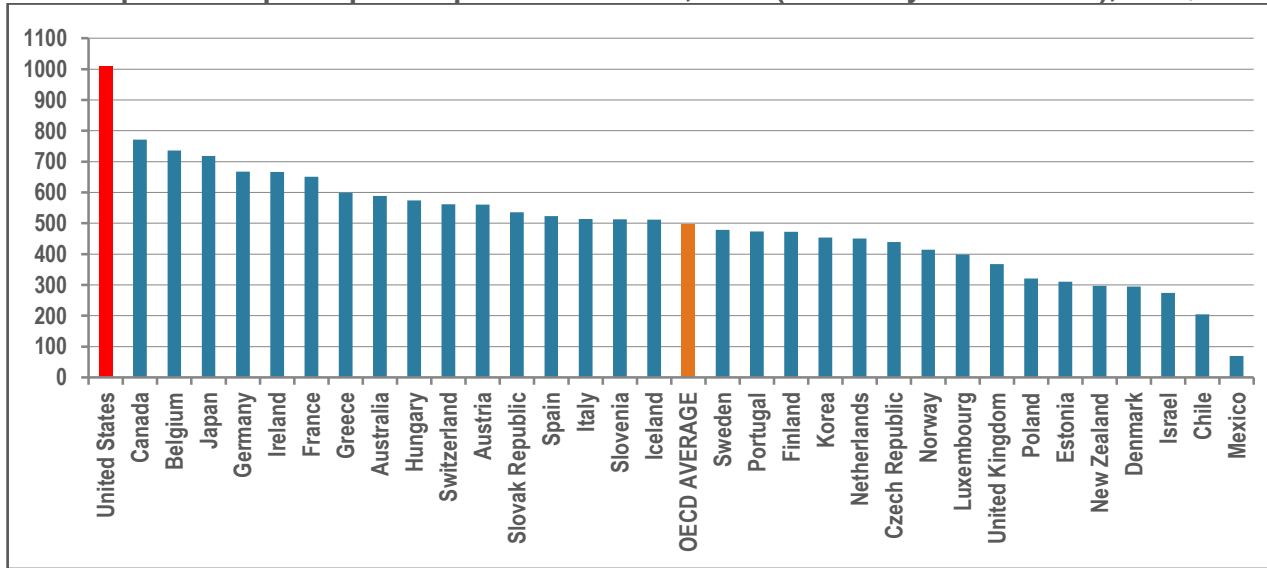
(e): estimate

Source: OECD Health Data: Social Protection (Extracted from OECD iLibrary)

Studies comparing international prices consistently show that average U.S. retail or manufacturer prices for prescription drugs are much higher than in other OECD countries.^[22-24] The U.S. is characterized by the highest cost per capita for pharmaceuticals among all OECD countries. Figure 3 shows that U.S. costs per capita for pharmaceuticals (\$1,010) are in fact more than twice as much as the OECD average (\$498).

FIGURE 3

Total expenditure per capita on pharmaceuticals, 2012 (or latest year available), U.S.\$ PPP



Source: OECD Health Statistics (2014).

Even with high per capita spending, Americans have poor access to prescription drugs with a high ratio of cost related non-adherence (CRNA): 19% of Americans did not fill their prescriptions for financial reasons in 2014,^[25] a much higher ratio than other comparable OECD countries in which CRNA ratio varies from 2% to 13%.^[26] While the introduction of the Affordable Care Act reduced CRNA since 2010 (from 26% to 19%), the high prices of drugs in the U.S., coupled with the high levels of deductibles and out-of-pocket co-payments required from patients, are the main reasons why so many Americans still cannot afford to fill prescribed drug treatments.^[25] Medicare Part D participants similarly report high levels of CRNA. For example, 16% of diabetes patients covered under Medicare Part D do not fill at least one of their prescriptions every year for financial reasons.^[27] Improving the efficiency of social protection provided under Medicare Part D requires reducing co-payment and deductible expenditures by patients by lowering the rates of co-payments and deductibles, or by reducing the price of prescription drugs. A higher CRNA ratio entails more visits to clinics or to the emergency room, which might explain in part why the implementation of Medicare Part D was not successful in improving health outcomes for Medicare enrollees.^[28]

Medicare Part D enrollees normally pay the official price for brand-name drugs. However, their plan sponsors can negotiate rebates with manufacturers, and these rebates are passed on to beneficiaries by offering them lower premiums.ⁱⁱ The Congressional Budget Office (CBO) calculated that the average rebatesⁱⁱⁱ obtained under Medicare Part D by plan sponsors from

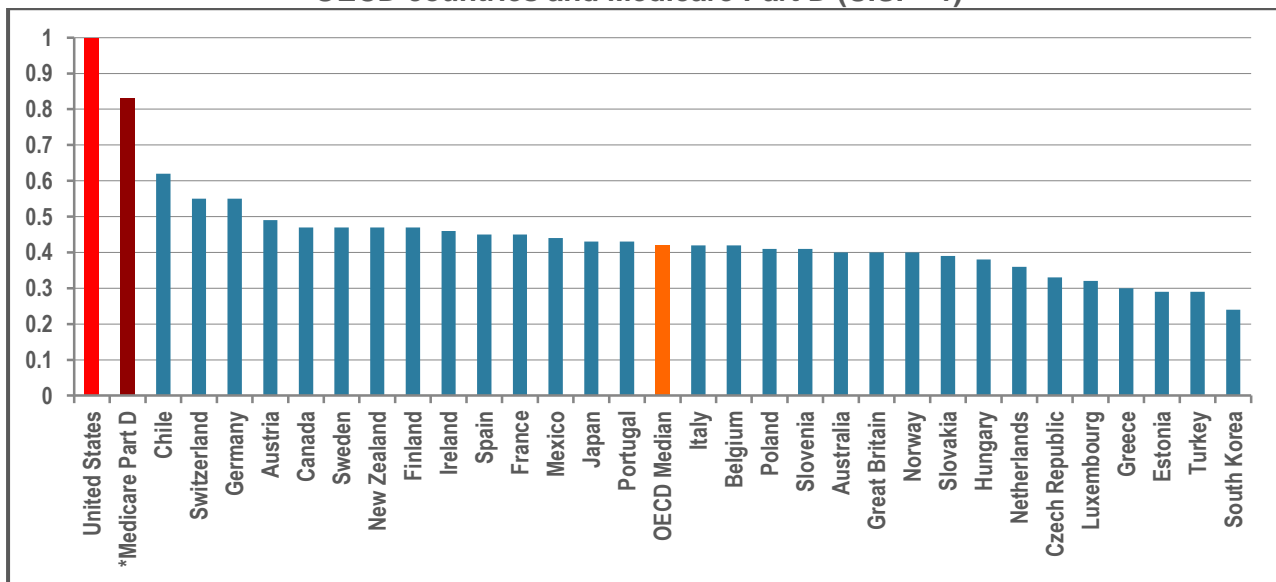
ⁱⁱ Some plan sponsors pass rebates on to beneficiaries at the point of sale so beneficiaries end up paying lower prices, which allows them to pay lower deductibles and co-payments. This way of transferring rebates is unusual and concerns less than 1% of beneficiaries.^[32]

ⁱⁱⁱ Rebates are normally price concessions obtained through different agreements between the plan sponsors and the manufacturers. Rebates are normally set in a way that artificially inflates official prices.

brand-name manufacturers represented 15% of retail prices in 2010.^[10] However, retail prices of brand-name products include a markup of about 13% by pharmacies and wholesalers over manufacturer prices.^[29] A 15% rebate on retail prices thus represents a 17% rebate on manufacturer prices.^{iv}

By using previously unavailable data comparing international brand-name drugs at ex-factory prices (prices obtained by manufacturers), we find a striking discrepancy with drug prices in the U.S. as compared to all other OECD countries (Figure 4). The Patented Medicine Prices Review Board (PMPRB)^v provided the authors comprehensive data on American sales-weighted averages for 640 patented drug products' price in all OECD countries. Figure 4 compares average foreign prices of patented drugs to average prices in the U.S. The median OECD price was only 42% of the U.S. price. Note that these OECD data compare official prices for patented drugs but exclude any rebates or discounts obtained from brand-name drug manufacturers. Most countries, including the U.S., use confidential agreements to obtain additional rebates and discounts.^[30] After-rebate prices for Medicare Part D were included in Figure 4 for comparison purposes.

FIGURE 4
Average foreign-to-U.S. price ratio for patented drugs in 2014 at ex-factory price:
OECD countries and Medicare Part D (U.S. = 1)



*: Medicare Part D prices are the U.S. official prices minus the average rebate of 17%.
Source: IMS AG's MIDAS™; CBO^[10].

Brand-name drugs are thus normally paid at artificially inflated official prices, and the manufacturers then reimburse the plan sponsors based on the details of the respective agreements.^[32]

^{iv} For example, if the manufacturer price is \$100 with a markup of \$13 for wholesalers and pharmacies, a manufacturer rebate of 15% of retail price represents 15% of \$113, or a rebate of \$16.95, which rounds off to 17% of the manufacturer price.

^v The Patented Medicine Prices Review Board is a Canadian independent quasi-judicial body monitoring against excessive drug prices in Canada. Because excessive drug prices are determined by comparing international prices, the organization has developed expertise in comparing international patented-drug prices.

IMS Health estimates that global off-invoice rebates and discounts represented approximately 25% of global sales growth in recent years.^[31] Due to the importance of off-invoice rebates and discounts and their variations in different countries, any comparison of international drug prices must be interpreted with caution. However, since Medicare Part D does not benefit from additional rebates, one can safely conclude that Medicare Part D, as shown in Figure 4, pays at least twice as much as the OECD median for patented drugs.

While rebates have existed in the U.S. since the 1980s, other OECD countries typically negotiated or regulated transparent list prices. Since the mid-2000s, however, almost all OECD countries started obtaining off-invoice rebates depending on their bargaining capacity with brand-name drug manufacturers. The increasing use of confidential rebates at the global level appears to be driven largely by manufacturers' desire to circumvent existing price regulations.^[30] Many countries use external benchmarking (regulation using foreign official prices as an index) to cap domestic prices. Confidential rebates defuse such regulation by artificially inflating official prices. In the same way, mandatory rebates set as a percentage of official prices, as is the case in some programs in the U.S., are rendered inefficient at containing drug prices due to the artificial accompanying increase of official prices. While rebates are passed on to Medicare Part D enrollees through lower premiums, artificially inflated prices still result in artificially inflated co-pays and deductibles for the same enrollees, which induce an increase in CRNA.

2 – How Medicare Part D compares to other U.S. programs

This section compares the rebates received from brand-name manufacturers by Medicare Part D with both rebates received by Medicaid and discounts for Veterans' Benefits Administration (VBA), and shows the subsequent average manufacturer price of brand-name prescription drugs in these three programs.

Medicare Part D

Even though the government Medicare Part D program cannot directly negotiate rebates with brand-name manufacturers due to the non-interference clause, plan sponsors can, and the savings are purportedly redistributed to beneficiaries through lower premiums. However, the Office of Inspector General (OIG) at the Department of Health and Human Services has raised serious concerns that the rebates are not always passed on to beneficiaries.^[32] According to the OIG, sponsors underestimated the beneficiary rebates in 69% of their bids for plan year 2008, which resulted in artificially inflated premiums for Medicare Part D enrollees. As mentioned, the plan sponsors' rebates obtained under Medicare Part D from brand-name manufacturers represented 17% of the manufacturers' price in 2010. This represents a total amount of \$6.1 billion in rebates, while a total of \$36 billion was paid to brand-name manufacturers during that year.^[33]

By design, beneficiaries of Medicare Part D receive different types of rebates depending on amount of their spending. The basic drug benefits under Medicare Part D in 2014 were as follows^[10]:

1. No coverage for the first \$310 per year (no rebate obtained).
2. Coverage for 75% of spending between the deductible and an initial coverage limit of \$2,850 (average rebate of 17% on brand-name drugs).
3. “Doughnut hole”: Limited coverage for generic and brand-name drugs when spending is between the initial coverage limit and a catastrophic limit on out-of-pocket costs of \$4,550. While in the “doughnut hole”, beneficiaries receive a mandatory discount^{vi} of 50% for brand-name drugs.
4. Coverage for 95% of spending above the catastrophic limit (average rebate of 17% on brand-name drugs).

Medicaid

Medicaid benefits from two separate statutory rebates from brand-name manufacturers:^[10]

1. The “basic rebate”: Brand-name manufacturers offer a mandatory rebate of at least 23.1% of the average manufacturer’s price. If the manufacturer offers any “qualified” purchaser (hospital, mail-order pharmacy, HMO) a rebate in excess of 23.1%, then the rebate received by Medicaid is increased to match that larger private rebate.
2. The “inflation rebate”: This rebate is imposed if the average manufacturer’s price for a brand-name drug rises faster than general inflation.

The “inflation rebate” represents more than half of the rebates obtained on brand-name drugs.^[11] Such a rebate seems necessary because many brand-name and generic drugs increase their prices at a pace significantly higher than inflation.^[11,35] In 2010, Medicaid spent \$27.4 billion on prescription drugs including 11.4 billion in rebates^[34]. Of the remaining \$16 billion, 76% was spent on brand-name drugs (\$12.2 billion), including \$1.8 billion (15%) to wholesalers and pharmacies.^[33] In the end, Medicaid paid \$10.4 billion to brand-name manufacturers after benefiting from rebates totaling \$11.4 billion.^{vii} Medicaid thereby benefited from rebates of 52% (11.4 billion / 21.8 billion) on brand-name drugs. Note that while a mandatory “basic rebate” on official prices can achieve some savings, it also creates an adverse effect by encouraging brand-name manufacturers to artificially increase the initial official prices of brand-name drugs.^[36] The “inflation rebate” does not produce such an adverse effect because an artificial increase of prices over inflation would be countered by an automatically greater inflation rebate. However, if the

^{vi} Note that discounts are different from rebates. Rebates are normally reimbursed by manufacturers after the drug was paid at its full price. Discounts are price reductions at the point of sale, which allow buyers not to pay for drugs at their full price.

^{vii} Note that the federal rebates totaled \$10.4 billion while some states benefited from additional rebates obtained at the state level. Additional rebates by these states totaled \$1 billion. It is important, however, to emphasize that only some states obtained additional rebates of various magnitudes and that the analysis of average prices or average rebates masks diversity between states.

price rises faster than inflation, the inflation rebates do not compensate beneficiaries on their co-pays based on inflated drug prices at the point of sale, which might increase CRNA.

Veterans' Benefits Administration (Department of Veterans Affairs)

VBA utilizes four contracting mechanisms to acquire its prescription drugs at discounted prices:^[2]

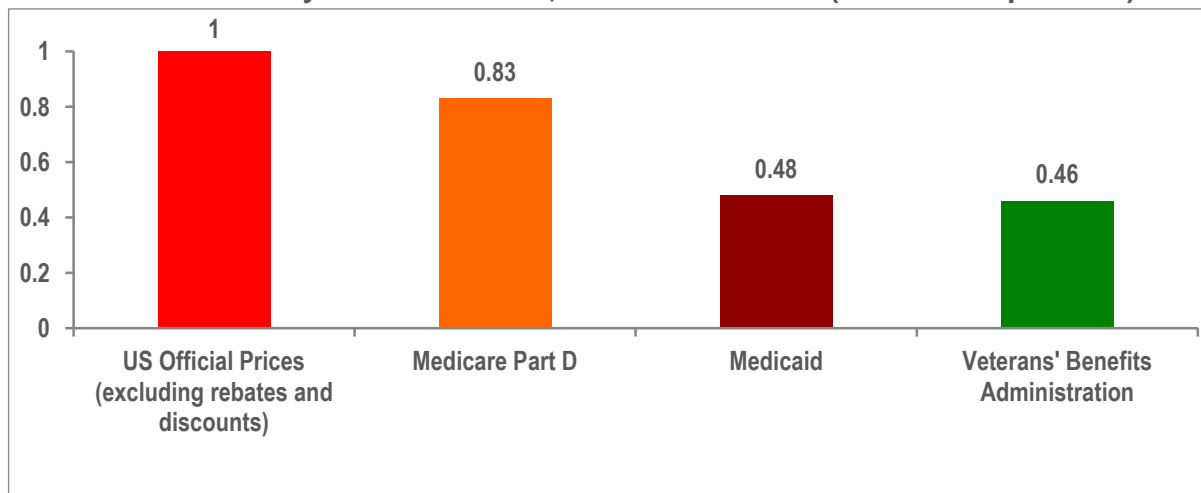
1. The Federal Supply Schedule (FSS): VBA uses the FSS, which is a catalog of discounted prices obtained through federal procurement policy. FSS prices for brand-name drugs must be no greater than the prices manufacturers charge their "most favored customers" under comparable terms and conditions.
2. Performance-based incentive agreements, or Blanket Purchase Agreements (BPAs): The most common BPA revolves around market share agreements in which VBA commits to purchase a specific volume of drugs in exchange for additional discounts.
3. Pricing under the Veterans Health Care Act of 1992 (P.L. 102-585): Under this law, pharmaceutical manufacturers agree to sell VBA drugs at no more than 76% of the non-federal average manufacturers price (non-FAMP) minus any additional discounts, including mandatory discounts to counter price increase over the inflation rate. Note that the "inflation discounts," contrary to "inflation rebates," reduce drug prices at the point of sale. There is impact on co-pays, however, since VBA beneficiaries pay flat co-pays whatever the price of the drugs they buy.
4. National standardization contracts: VBA seeks competitive bids from manufacturers for products that are therapeutically equivalent within specific drug classes, and contracts with those manufacturers whose products it believes provide the best value based on medical effectiveness, safety and price, in exchange for including their products on VBA's national formulary and committing to use products throughout the VBA health care system. Such bids can be considered a rational use of market forces which allows the price reduction of patented brand-name drugs by putting them in competition with other brand-name drugs of equivalent therapeutic value.

On a drug-by-drug basis, VBA selects the mechanism that offers the lowest price. By actively managing its drug formulary, VBA ensures the maximization of value for money without producing incentives for manufacturers to artificially inflate their official prices. The exact amount of discounts and rebates obtained by VBA is not known because VBA normally does not disclose publicly the prices it pays. The studies by Austin B. Frakt,^[4,37] an health economist associated with VBA, synthesize existing literature analyzing discounts obtained by VBA and estimate that VBA paid brand-name drugs at an average retail price of 60% of what was paid by Medicare Part D. For this brief, however, our calculations are based on manufacturer prices, not on retail prices. Considering that the price reductions applied only to the manufacturers' prices, and considering that retail prices include a markup of 13% for wholesalers and pharmacies,^[29] the retail price difference means in fact that VBA paid an average manufacturer price of 54% of what was paid

by Medicare Part D. Since Medicare Part D itself paid on average 83% of the official manufacturer price, VBA thus paid about 46% of the official manufacturer prices.^{viii}

By synthesizing what is known about Medicare Part D, Medicaid and VBA (as explained above), it is possible to compare real manufacturer prices paid on average for brand-name drugs by Medicare Part D, Medicaid, and VBA.

FIGURE 5
Comparison of the estimated average price paid to brand-name prescription drug manufacturers by Medicare Part D, Medicaid and VBA (U.S. official price = 1).



Source: CBO^[10,15], Avalere Health^[33], CMS^[34], Frakt^[4,37]

Figure 5 shows that Medicare Part D pays a significantly higher price for the same brand-name drugs than Medicaid or VBA. On average, a brand-name drug that costs \$83 under Medicare Part D would cost \$48 under Medicaid and \$46 under VBA. Medicare Part D paid \$36 billion to brand-name manufacturers in 2010.^[33] If Medicare Part D benefited from the same rebates over brand-name drugs as Medicaid, the program would have saved \$15.2 billion a year on the price of brand-name drugs. If Medicare Part D benefited from the same discounts as VBA, it would have saved \$16 billion a year.^{ix} Note that Medicare Part D beneficiaries in the doughnut hole, who pay for their drugs out-of-pocket while receiving a 50% rebate, still pay more for brand-name drugs than the real prices paid by Medicaid and VBA. Overall, Medicare Part D pays on average 73%

^{viii} For example, if a brand-name drug costs under Part D \$113 at retail price, it costs \$100 at manufacturer price once the 13% markups for pharmacies and wholesalers are deduced. If the drug costs for VBA 60% of the retail price, its retail price is \$67.80 for VBA, which means a price difference of \$45.20. Considering that this price difference is due to rebates or discounts by brand-name manufacturers, VBA thus pay \$45.20 less on the manufacturer price (\$100) paid by Part D, or \$54.80. In percentage, it means that VBA pays a manufacturer price equivalent to 55% (after rounding) of the manufacturer price paid by Part D. Since Part D pays manufacturer prices that are on average 83% of the official U.S. manufacturer price, VBA thus pays manufacturer prices that are on average 46% (after rounding) of the U.S. official manufacturer prices ($100 \times 0.83 \times 0.55 = 0.4565$).

^{ix} For Medicaid, the result is obtained by calculating $36 \text{ bn} - (48/83 \times 36 \text{ bn}) = 15.2 \text{ bn}$. For VBA, the result is obtained by calculating $36 \text{ bn} - (46/83 \times 36 \text{ bn}) = 16 \text{ bn}$.

more than Medicaid and 80% more than VBA in terms of manufacturer price for the same brand-name drugs.

Of similarly great concern is the comparison between Figure 4 and 5. Medicare Part D pays significantly higher prices for brand-name drugs than any other OECD countries. It pays 34% more than Chile's official prices (Chile is the second-highest-priced OECD country). It pays 98% more than the OECD median of official prices.

While Medicaid and VBA are often used as benchmarks, it is important to remember that, in spite of the significantly lower prices they manage to secure as compared with the U.S. official prices, even these organizations still pay much higher prices than the official prices of most OECD countries. Furthermore, other OECD countries rarely pay the actual official price, since they also manage to obtain rebates through different types of confidential agreements.^[30]

3 – Correlation between price level and research and development expenditures

Medicare Part D alone represents around 7% of sales in the global pharmaceutical market. Opponents of Medicare Part D price reductions argue that such reductions would decrease incentives for brand-name drug companies to invest in research and development (R&D). These claims are inconsistent with data showing that the introduction of rebates for Medicaid had no impact on research and development for antipsychotics, drugs disproportionately used by Medicaid recipients.^[8] In all cases, the concern that lower revenues would impede the arrival of new drug products is somewhat misplaced.

The main issue is: The current pricing scheme incentivizes pharmaceutical companies to invest in R&D for which kind of drugs? If drug plans continue to allow setting the prices of new medicines at similar levels for similar drugs, manufacturers can continue to bring drugs with similar molecular structures, often called me-too drugs, to the market with little or no innovation while still obtaining considerable returns. Manufacturers are then incentivized to develop non-innovative and less risky "me-too" drugs instead of new innovative medicines for unmet needs, and to invest in marketing instead of R&D.^[38,41] The more drug plans demand value for money — for example, by refusing to pay for new, expensive patented drugs that do not provide additional therapeutic value as compared to existing, lower-priced alternatives — the more drug plans provide incentives for greater therapeutic innovation. This type of incentive system would send the message that we will pay only for new drugs that provide additional therapeutic value as compared with existing alternatives.

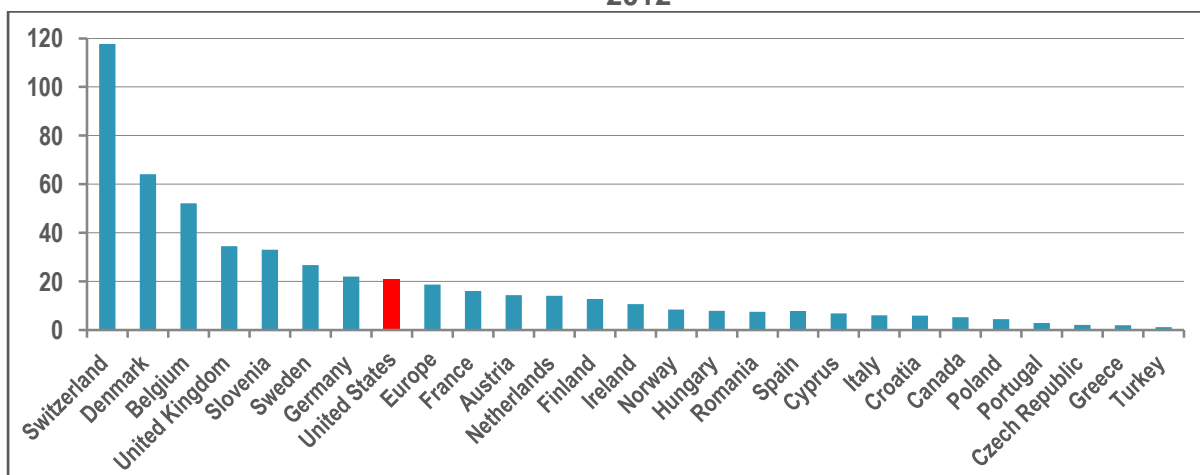
Current systems of drug pricing and reimbursement may foster spending on R&D, but this too often leads to new medicines that are not innovative, which in turn does not play a significant role in improving the health of patients. It is estimated that around 80% of new patented drugs entering the market provide no significant additional therapeutic benefits as compared with existing alternatives.^[39] When drug plans are willing to pay high prices for drugs with low therapeutic value, or when generics cannot adequately penetrate the market once the originator goes off-patent, the need to invest in the development of new innovative products declines

accordingly.^[40] In fact, by agreeing to pay inflated prices even for me-too drugs, drug plans like Medicare Part D artificially increases the returns on me-too drugs and thus reduces incentives for breakthrough innovation.^[41]

An increase in profits does not necessarily lead to increased investment in research. Profits are generally distributed to shareholders, through dividends and share buybacks. They also can be used to buy competitors through mergers and acquisitions, often resulting in the closure of research laboratories. An accounting study based on the annual reports of 10 of the largest global pharmaceutical firms over the 10-year period from 1996 to 2005 revealed net operating profits after tax of \$413 billion and a net return on shareholders' invested capital of 29%.^[42] Compared with other industrial sectors, this is an exceptionally high return. These firms distributed 77% of net earnings (\$317 billion) to their shareholders as dividends or share buybacks, they used 16% (\$65 billion) of their net earnings to build provisions for future mergers and acquisitions, and they invested only 10% of net earnings (\$43 billion) in tangible fixed assets. The pharmaceutical industry generated higher profit margins than any other major industrial sector in 2013 and 2014.^[43] 2014 was a record year in terms of share buybacks^[44] and mergers and acquisitions in the pharmaceutical sector.^[45] For these reasons, the connection between net revenues and R&D spending is not clear.

Another concern often raised is that if a country reduces its prices, pharmaceutical R&D investments will flee abroad. For many years, higher price levels often were cited as an important policy lever for attracting R&D investment. Drug companies argued that if they could not obtain high prices in a country, they would move their R&D out of that country. Domestic and international data have not supported this link. In fact, several countries that have patented drug prices which are, on average, substantially lower than in the U.S. have achieved domestic R&D-to-sales ratios (a standard index to measure R&D intensity) well above those in the U.S. (Figure 6).

FIGURE 6
Country-specific ratio of domestic pharmaceutical R&D to domestic patented drug sales, 2012



Source: Pharmaceutical Research and Manufacturers of America (PhRMA),^[46] European Federation of Pharmaceutical Industries and Associations (EFPIA),^[47] PMPRB^[48]

Increasingly, analyses show that the impact of drug prices on companies' decisions on where to invest and conduct research are, at best, of marginal importance. Other factors — such as where companies can find the best science base at reasonable cost, taxation incentives, flexible labor markets and economic stability — are seen as having greater importance in companies' decisions than drug prices.^[48-49] There is no reason to believe that Medicare Part D price reductions would cause a flight of pharmaceutical R&D investment outside the country.

4 – Conclusions and policy considerations

The after-rebate prices Medicare Part D plan sponsors pay for brand-name drugs remain significantly higher than the current market prices found in other countries or in other programs such as Medicaid or VBA. Medicare Part D would save between \$15.2 billion and \$16 billion a year if it could obtain the same manufacturer prices that Medicaid or VBA, respectively, obtains for the same brand-name drugs. Lower brand-name drug prices for Medicare Part D not only would generate savings, but, by increasing patient access to prescribed drugs, it also could improve adherence to treatments by reducing the high level of cost-related non-adherence found in Medicare Part D.

One of the arguments invoked against price reductions asserts that public interference in drug negotiations would undermine the plan sponsors' competitive system used in Medicare Part D and lead to higher costs for beneficiaries.^[20] This argument should not be an obstacle against reducing prices. Part D is designed based on a model of “managed competition” among private insurers. The same model is active in countries such as Switzerland and the Netherlands that offer universal drug coverage for their populations through regulated private insurers. Competition among private insurers in these countries is not undermined by lower brand-name prices, and beneficiaries pay significantly lower premiums. In fact, these countries often are cited as models in terms of “managed competition” for drug coverage.^[50] According to Figure 4, average brand-name drug prices in Switzerland (excluding rebates) are 34% less than after-rebate prices in Medicare Part D, while average brand-name drug prices in the Netherlands (excluding rebates) are 57% less than in Medicare Part D.

Because Medicare Part D represents 7% of global pharmaceutical sales, there is also concern that reducing brand-name drug prices would reduce spending in R&D. As discussed in Section 3, pricing schemes and the amount of revenues are factors in terms of R&D investment decisions. They are especially important factors in determining the types of R&D that will be fostered. Because of the design of their pricing schemes, Medicare Part D and Medicaid do not mainly emphasize paying for valuable products. They foster, instead, a pharmaceutical business model with few incentives for developing innovative products. They provide incentives for developing less risky me-too products that do not lead to improvements in the health of patients. In fact, because of its high price level, Medicare Part D acts as an indirect subsidy for me-too products, to the detriment of more innovative research.

Proposed modifications to Medicare Part D's pricing scheme create an opportunity to provide not more but better incentives for R&D. A purchasing system emphasizing therapeutic value — for example through value-based pricing —not only would decrease prices but also would provide greater incentives for R&D investment in drugs that represent improvements on existing therapies.^[41,51]

A managed formulary, such as the Veterans' Benefits Administration National Formulary, weighs the additional therapeutic value of a drug to determine the amount of reimbursement. It is based on the capacity to refuse reimbursement of a drug if its low therapeutic value does not justify its price. For example, such formularies normally implement mandatory generic substitution to avoid paying for higher-priced brand-name drugs when the same clinical results can be obtained with generics. While a managed formulary often is considered a tool to reduce costs, it also is, in fact, an important tool to eliminate waste by reducing opportunity costs so that maximum therapeutic value for every dollar spent can be realized. Large scale savings could thus be obtained with managed formularies and price negotiations, even within the constraints imposed by a monopoly-supported private R&D system, through a better use of market competition for similar products.

While Medicaid and VBA obtain almost equivalent brand-name price levels, they create completely different incentives for pharmaceutical R&D. The unconditional "basic rebates" of Medicaid foster the current business of developing me-too drugs while creating an incentive to artificially inflate official prices. The proactive drug formulary management of VBA maximizes therapeutic value for every dollar spent and thus provides greater incentives for producing more innovative products.

The main argument against managed formularies is that such formularies restrict patients' choices. Indeed, managed formularies do not reimburse all new drugs, only those that provide value for money. However, freedom of choice is never at stake, since patients can decide to pay out of pocket for the drugs or treatments they desire, even if clinical evidence shows that these treatments do not provide therapeutic value for money. A managed formulary for prescription drugs does not reduce freedom of choice; it only reduces the freedom to needlessly waste taxpayers' money.

5 – Recommendations

Based on the analysis provided by this policy brief, the following is recommended for inclusion in legislation to significantly lower Medicare Part D drug costs:

1. Medicare Part D should reduce brand-name drug prices to at least the level of Medicaid or VBA.
2. Mandatory rebates on official prices (i.e., Medicaid's "basic rebate") should be avoided, but mandatory discounts for drug prices that increase over the rate of inflation (i.e., VBA's "inflation discounts") should be introduced for both brand-name and generic drugs.
3. Mandatory generic substitution for all plans under Medicare Part D should be introduced.

4. A managed formulary applicable to all plans under Medicare Part D should be introduced.
5. Price reductions should be used to reduce co-payments and deductibles in order to reduce cost-related non-adherence.
6. To preserve freedom of choice, patients wanting access to treatments that are more expensive than equivalent, equally safe and effective treatments covered under Medicare Part D should have the opportunity to access these treatments, but they should have to pay the price difference out-of-pocket.

Given the complex nature of this issue, it is recommended that members of Congress create a joint working group to investigate the ways and means of implementing the recommended reforms. The mandate of this working group should not be *if* the structure and pricing for Medicare Part D drugs should be reformed, but *how* they should be reformed to ensure the greatest benefit to the American people.

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