NATIONAL ACADEMY OF SOCIAL INSURANCE

Reining in Prescription Drug Prices

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Americans pay higher prices and spend more per person for prescription drugs than any other developed country in the world,[1] and spending is growing at a rapid and unsustainable rate. Unlike other nations, our laws and regulations – and the way they are enforced – permit pharmaceutical manufacturers to set their own prices with little government oversight. Retail prescription drug spending rose nine percent in 2015, reaching $325 billion and outpacing the rate of spending growth on all other health services.[2] According to the Centers for Medicare & Medicaid Services (CMS), the increase in spending "is attributed to the increased spending on new medicines, price growth for existing brand name drugs, increased spending on generics, and fewer expensive blockbuster drugs going off-patent."[3] Some of the key challenges for reining in prescription drug prices are discussed below, followed by a menu of policy options for addressing these challenges.

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Policy Challenges

Lack of competition for existing branded drugs

One of the key drivers of prescription drug spending has been the steady rise in spending on brand-name prescription drugs. Pharmaceutical companies lack incentives to rein in pricing; in fact, they are often incentivized to do just the opposite. Price protections for pharmaceutical companies through federally conferred monopolies such as patents prevent robust free market competition and reduce the capacity for negotiations between payers (i.e., public or private insurers) and pharmaceutical manufacturers.[4] Both new and existing branded drugs drive up costs. According to a recent study by the IMS Institute for Healthcare Informatics, over half of the total spending growth in 2015 was from new branded products, which accounted for $24.2 billion of new spending growth; generic medicines contributed $7.9 billion and protected brand[5] medicines $2.7 billion to growth, respectively.[6]

[1] A.S. Kesselheim, J. Avorn, and A. Sarpatwari, 2016, The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform, JAMA, 316(8):858-71, http://bit.ly/2drTfrN.
[2] CMS, National Health Expenditures 2015 Highlights, http://go.cms.gov/2hB0tcB.
[3] Ibid.
[4] Kesselheim, Avorn, and Sarpatwari, 2016.
[5] Protected brand medicines are those that are over two years old and have not yet faced generic competition.
[6] IMS Institute for Healthcare Informatics, 2016, Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020, http://bit.ly/2i2ij97.

Monopoly power – Specialty drugs, orphan drugs, and evergreening

Innovation requires investments in research and development that pharmaceutical developers need to recoup when products go to market. There is, however, little to no transparency on the true costs of research and development for innovative products. Another factor driving high prices for many prescription drugs is monopoly power for specialty drugs,[7] orphan drugs,[8] and the evergreening of old prescription drugs.[9] In 2015, specialty drugs accounted for 37.7 percent of drug spending and 11 percent of drug spending growth.[10] Usage of these specialty drugs – and therefore spending – is projected to grow even faster in future years. Similarly, pharmaceutical companies can charge exceedingly high prices for orphan drugs that treat conditions affecting relatively small populations (under 200,000) of people in the U.S. For instance, treatment for a condition affecting fewer than 10,000 individuals costs, on average, upwards of $200,000 per year.[11] The process of evergreening also results in higher prices by extending patent protections, which restrict or prevent competition (with only minor modifications of drugs that do not necessarily provide additional benefit for patients).[12]

Medicare cannot negotiate prices

One particular factor driving the American health care system's high costs, without improving quality, is a law passed by Congress which forbids the Secretary of Health and Human Services from negotiating prices directly between Medicare, the largest single purchaser of drugs, and pharmaceutical manufacturers.[13] In contrast, other government health programs such as those administered by the Veterans Administration, the Department of Defense, and Medicaid have negotiating mechanisms in place to achieve lower drug prices.[14] In total, federal programs cover over one-third of all Americans,[15] and combining the forces of the various public insurers would provide the federal government with substantial negotiating leverage to lower drug prices.

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[7] There is no standard definition for a specialty medication, but they are generally considered to be high-cost prescription medications used to treat complex, chronic conditions. Medicare's definition of specialty drugs is based on price; pharmaceuticals costing $600 or more per month are considered specialty. See: Centers for Medicare and Medicaid Services, 2015, Medicare Part D Specialty Tier, http://go.cms.gov/2jcziFx.

[8] An orphan drug a pharmaceutical that remains commercially undeveloped owing to limited potential for profitability.

[9] The term "evergreening" describes the practice of making incremental, patentable innovations for medicines, thereby preserving market exclusivity, without significantly bettering the standard of care.

[10] Express Scripts, 2016, 2015 Drug Trend Report, https://lab.express-scripts.com/lab/drug-trend-report.

[11] Jerry Isaacson, 2016, Analysis of Orphan Drug Market, LifeSci Capital, http://bit.ly/2hNyNBM.

[12] Reed F. Beall, Jason W. Nickerson, Warren A. Kaplan, and Amir Attaran, 2016, Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products? PloS one, 11(2):e0148939, http://bit.ly/2j4aTm4.

[13] Medicare Modernization Act of 2003, §1860D-11(i). http://1.usa.gov/1Y2QRmj.

[14] David Blumenthal and David Squires, 2016, Drug Price Control: How Some Government Programs Do It, The Commonwealth Fund, http://bit.ly/2hO9FKV.

[15] The Henry J. Kaiser Family Foundation, 2015, Health Insurance Coverage of the Total Population, http://kaiserf.am/2hNH7Bp.

Private rebates

Private rebates are one tactic used by pharmaceutical companies to keep prices high. Companies set their initial prices higher, but offer various rebates to different private-sector payers (e.g., insurers), based on the maximum amount that a payer is willing or able to pay. In some instances, the savings from rebates are passed on to consumers, but overall, private rebates increase drug prices. Additionally, since rebates are considered proprietary information, manufacturers and purchasers are permitted to keep rebate amounts confidential. This lack of transparency prevents market forces from restraining drug prices.

Pay-for-delay

Reverse payment patent settlement, or pay-for-delay, is another strategy used to inflate brand name drug prices and reduce competition by keeping less expensive generic alternatives off the market for a longer period. The Hatch-Waxman Act of 1984, which was intended to increase competition in the drug market, ironically led to this strategy by allowing brand name manufacturers to pay generic companies to keep their lower-cost generic alternatives off the market.

Drug coupons

Coupons from drug manufacturers help some consumers with the cost of their prescriptions, but increase overall spending by incentivizing consumers and providers to choose expensive, brand name drugs over more cost-effective options such as generics. Drug coupons reduce price transparency and, as a result, brand name drugs may temporarily appear more affordable to consumers. However, over time, these coupons increase health care system costs, including consumer costs, since the higher drug costs are passed on to the insurer who, in turn, raises premiums for everyone.

Policy Options

This section lists policy options aimed at reining in the growth of prescription drug prices by increasing transparency, affordability, and market efficiency.

I. Transparency

Permit the Department of Health and Human Services (HHS) to review the accountability of prescription drug price increases

One policy option would be for Congress to permit the Secretary of Health and Human Services to review the justification of extremely high-cost or rapidly increasing drug prices. The law could set standards that would trigger a review process to establish justification for the high cost or price increase, such as a price increase of 10 percent or more over a 12-month period.

Require pharmaceutical companies to report rebate rates

Under current law, rebates are considered proprietary information and therefore are not subject to reporting requirements or scrutiny by the public, the federal government, or even other payers. The use of a rebate system, however, allows pharmaceutical companies to set a higher initial price for drugs, which they then are able to negotiate down with payers based on their power and ability to pay. One policy option to increase transparency, and thereby increase market efficiency, would be to require pharmaceutical companies to publicly report their rebate rates for different payers.

Require pharmaceutical companies receiving public research funds to report all spending publicly

One policy option to increase transparency would be to require any pharmaceutical company that receives public funds for research and development to publicly report their entire budget. Such reporting would increase transparency, painting a clearer picture of how much these companies are spending on research and development, advertising, administrative costs, and other non-research expenses.

II. Affordability

Authorize the Secretary of Health and Human Services to negotiate drug prices for Medicare

Along with growing public attention to escalating drug costs has come a parallel interest in allowing the federal government to negotiate prices with pharmaceutical companies. The concept of allowing the federal government to negotiate Medicare drug prices has broad (82 percent) public support.[16]

[16] Ashley Kirzinger, Bryan Wu, and Mollyann Brodie, September 29, 2016, Kaiser Health Tracking Poll: September 2016, Kaiser Family Foundation, http://kaiserf.am/2dkS0YB.

Several different policy options and factors must be considered when extending powers of negotiation to the Secretary of HHS.

- **Price controls:** The most restrictive option would be for HHS to set a specific amount – such as a percentage of average costs or a maximum cap – on what the program will pay for prescription drug coverage. This option is similar to what most state Medicaid programs do to control costs.[17] Opponents of HHS involvement in controlling Medicare's drug costs frequently express concern over this particular policy option, and argue that price controls would compromise research and development and raise private sector drug costs.[18] However, as discussed above, there is a lack of transparency regarding pharmaceutical research and development expenditures making it difficult to confirm the validity of such concerns with greater price controls.
- **Negotiation backed by arbitration**: In a true negotiation process, HHS and drug manufacturers could have a set period of time during which they need to come to an agreement on prices. Comparative effectiveness research, which compares the clinical benefits of multiple treatment alternatives, could inform HHS decisions regarding the value of new prescription drugs.[19] If an agreement cannot be reached, an independent arbitrator could be appointed to decide between the two offers, or an independent expert could impose a third option based on research.[20]
- **Public Medicare-sponsored Part D plan:** Another policy option would be to develop a public Medicare-sponsored Part D plan that would compete on the market with the private plans. In this context, public and private plans would negotiate separately with pharmaceutical companies to obtain the best prices for enrollees. Cost savings would be dependent on whether or not the government is, in fact, able to negotiate drug prices better than private plans currently are able to do.[21]

Another policy option would be to develop a public Medicare-sponsored Part D plan that would compete on the market with the private plans.

[17] Ibid.
[18] David Hogberg, 2007, Letting Medicare "Negotiate" Drug Prices: Myths vs. Reality, The National Center for Public Policy Research, https://www.nationalcenter.org/NPA550MedicareDrugPrices.html.
[19] Topher Spiro, Maura Calsyn, and Thomas Huelskoetter, 2016, Negotiation Plus: A Framework for Value-Based Drug Pricing Negotiation, Center for American Progress, http://ampr.gs/2jcfL8a.
[20] Chuck Shih, Jordan Schwartz, and Allan Coukell, 2016, How Would Government Negotiation Of Medicare Part D Drug Prices Work?, Health Affairs Blog, http://bit.ly/2ipqtYf.
[21] Ibid.

Subject companies receiving public research funds to legal price constraints

Federal funding, largely through the National Institutes of Health, plays a key role in new drug development.[22] For example, one recent study found that public sector research institutions contributed to the discovery of more than 20 percent of all new drugs approved from 1990 through 2007, and this does not include public funding to private companies engaged in drug development. The Bayh-Dole Act, passed in 1980, does contain provisions to rein in high prices specifically for those drugs developed with federal funding. It states that almost any new drug invented wholly or in part with federal funds must be made available to the public on "reasonable terms."[23] As a number of scholars[24,25] and members of Congress have argued,[26] reasonable terms means reasonable prices. If the prices are unreasonable, the government can use its "march-in" rights to insist that the drug be licensed to other manufacturers.[27] If the company refuses, the government can then license it to third parties that will sell the drug at a more reasonable price. This law has been on the books for more than 35 years and yet these provisions have never been invoked. The current era of escalating drug prices would seem to provide justification for invoking this power.

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Negotiate drugs prices uniformly across all federal payers

To leverage and consolidate the negotiating power of the federal government to an even greater degree, one policy option is to combine all federal payers into a single negotiating body. Such a policy would involve Medicare, Medicaid, the Veterans Health Administration, the Department of Defense, the Indian Health Service, the Federal Employee Health Benefit Program, and all other public payers in collaboratively negotiating drug prices with pharmaceutical companies, leveraging the bargaining power of all agencies collectively.

Remove mandatory coverage status

The policy of requiring insurers to cover particular drugs is an essential patient and consumer protection. Nevertheless, it can give pharmaceutical

[22] Ashley J. Stevens, Jonathan J. Jensen, Katrine Wyller, Patrick C. Kilgore, Sabarni Chatterjee, and Mark L. Rohrbaugh, 2011, The Role of Public-Sector Research in the Discovery of Drugs and Vaccines. New England Journal of Medicine, 364(6), 535-41, http://bit.ly/2hO1z52.
[23] 35 U.S.C. §201 (f), https://www.law.cornell.edu/uscode/text/35/201.
[24] Peter S. Arno and Michael H. Davis, 2000, Why Don't We Enforce Existing Drug Price Controls: The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research. Tulane Law Review, 75, 631. http://bit.ly/2cQpBao.
[25] Walter D. Valdivia, 2011, The Stakes in Bayh-Dole: Public Values beyond the Pace of Innovation. Minerva, 49(1), 25-46, http://bit.ly/2h3Ngs5.
[26] Letter to Secretary of Health and Human Services, Sylvia Burwell and Director, National Institutes of Health, Francis Collins by members of Congress, March 28, 2016, http://bit.ly/2gVku9D.
[27] 35 U.S.C.§203 - March-in rights, https://www.law.cornell.edu/uscode/text/35/203.

companies excessive leverage in negotiations with certain payers. Carefully limiting mandatory coverage status has the potential to strengthen the bargaining power of insurers over pharmaceutical companies, but must be accompanied by policies that promote access to essential medications, such as through patient-friendly appeal rights and other consumer protections.

Proscribe the use of rebates

Private rebates to payers give pharmaceutical companies disproportionate negotiating leverage since companies are able to set prices high and then reduce them according to the bargaining power of individual payers. Setting high baseline prices for drugs inevitably drives up costs and gives pharmaceutical companies a financial and bargaining advantage. Proponents argue that limiting or eliminating private rebates would level the playing field between payer and manufacturer and lead to true negotiation between the two groups, which in turn would lower prices for consumers. It is important that rebates through Medicaid and other federal or state programs not be included in such a policy option, rather applying only to private rebates.

Proscribe the use of copay coupons

Copay coupons – seemingly helpful tools for lowering prescription drug prices for consumers – are in fact raising overall health care costs for both individuals and insurers.[28] One strategy for reducing costs would be to forbid drug manufacturers from issuing copay coupons to consumers and providers. Since coupons hide the actual cost of prescription drugs from consumers and even providers, this policy option would also increase transparency. Consumers and providers could make decisions based on the true costs of their choices, and potentially make more financially conservative decisions, such as choosing a generic option over a brand name drug.

[28] P.A. Ubel and P.B. Bach, 2016, "Copay assistance for expensive drugs: a helping hand that raises costs" [published online October 11, 2016], Annals of Internal Medicine, doi:10.7326/M16-1334.

End corporate tax deductions for direct-to-consumer drug marketing

How direct-to-consumer (DTC) marketing affects the health of the American people is subject to a great deal of controversy. On the one hand, proponents of the practice argue that it increases consumer awareness of medical conditions and the drugs available to treat them. Opponents, however, argue that these practices drive consumers towards requesting higher-cost brand name drugs over equally effective lower-cost brand or generic drugs, and express frustration that money spent on marketing could be used for research and development, instead.[29] The United States is one of the few countries that allows DTC advertising (New Zealand is the only other developed nation that does).[30] In 2015 alone, pharmaceutical manufacturers spent more than five billion dollars on drug advertising.[31] One policy option is to end corporate tax deductions for DTC drug marketing. These tax deductions incentivize spending on marketing, and their removal may shift spending from marketing to research and development.

Allow re-importation of drugs

Another option for containing growth in prescription drug costs would be to allow the re-importation of drugs from foreign countries. Allowing re-importation directly by consumers could potentially pose dangers to their health and safety if drugs and their supply chains were not adequately regulated. Allowing re-importation through well-regulated manufacturer, wholesale, and pharmacy pathways, however, could achieve cost savings without compromising safety. These large-scale institutions would be better equipped to monitor drug safety as outlined by the FDA under the Drug Supply Chain Security Act.[32] Changing the law to facilitate re-importation could require provisions mandating that savings be passed on to consumers when setting drug prices.[33]

[29] C. Lee Ventola, 2011, Direct-to-consumer pharmaceutical advertising: Therapeutic or toxic?, Pharmacy and Therapeutics, 36(10): 669-674, 681-684, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/.
[30] U.S. Food & Drug Administration, n.d., Keeping Watch Over Direct-to-Consumer Ads, Updated June 14, 2016, http://bit.ly/2idFdGb.
[31] Rebecca Robbins, 2016, Drug makers now spend $5 billion a year on advertising. Here's what that buys. Stat News, March 9, 2016. http://bit.ly/2irKBH3.
[32] U.S. Food & Drug Administration, n.d., Are you ready for the Drug Supply Chain Security Act? Updated December 15, 2016, http://bit.ly/2il5Qcz.
[33] For further analysis of this issue, see: Monali J. Bhosle and Rajesh Balkrishnan, 2007, Drug reimportation practices in the United States, Therapeutics and Clinical Risk Management, 3(1), 41-46, http://bit.ly/2ihNvSz.

Cap out-of-pocket copays for prescription drugs

Another option for controlling drug costs is implementing a cap on out-of-pocket copay costs for prescription drugs across all insurers for any drug approved by the FDA. While such a policy has the potential to reduce costs in the short term, it could lead to negative long-term consequences such as increased premiums or the removal of certain drugs from coverage, either of which could increase out-of-pocket costs for consumers.[34] Therefore, it would be critical to pair such an option with a companion plan to control the baseline cost of drugs as well.

Restore the prescription drug rebate for dually eligible beneficiaries transitioning into Medicare Part D

One policy option to alleviate the costs of prescription drug spending in Medicare would be to restore the existing Medicaid rebates for people dually eligible for Medicare and Medicaid. When these individuals transitioned to Medicare Part D coverage after the benefit was established, these rebates were lost to the Medicare program but retained in state Medicaid programs. In 2013, the Congressional Budget Office (CBO) estimated that restoring this rebate for dual eligibles would generate about $15 billion of savings per year. For further details, please see the CBO analysis.[35]

Use the Center for Medicare and Medicaid Innovation (CMMI) authority to test new payment models for drug prices

The Center for Medicare and Medicaid Innovation (CMMI), developed as part of the Affordable Care Act, has been a launch pad for a variety of new ideas surrounding value-based pricing, reimbursement, and insurance. Up until this point, however, the program has not been well utilized to push the envelope on Medicare Part D innovation, particularly related to prescription drug pricing. Experimenting with innovative policy ideas for value-based prescription drug payment plans and increased transparency in prescription drug pricing would be a promising role for CMMI in the future. Such innovations could be developed in collaboration with a diverse range of stakeholders to better ensure buy-in and successful implementation.

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[34] Yevgeniy Feyman, 2016, Out-of-Pocket Caps: The Wrong Way to Tackle High Drug Prices, Manhattan Institute, Issue Brief: Health Policy, http://bit.ly/2ipgMsY.
[35] Congressional Budget Office, 2013, Require Manufacturers to Pay a Minimum Rebate on Drugs Covered Under Part D of Medicare for Low-Income Beneficiaries, http://bit.ly/2jgbC0T.

III. Market efficiency

Shortening exclusivity periods

There are numerous factors lengthening exclusivity periods for new drugs, during which one drug company has a monopoly on that market for the length of the protection period. Such exclusivity is particularly problematic with the expanding class of biologic drugs, where the exclusivity period is currently set at 12 years. Even for more traditional drugs, however, the average duration of exclusivity periods is increasing as a result of extensions granted for such activities as testing an existing drug's effects on children. Reducing exclusivity periods would enhance market competition and permit more cost-effective generic drugs to reach the market sooner.

Prohibiting the pay-for-delay arrangements for manufacturers

The pharmaceutical industry's attempts to push back competition from generics are a substantial hurdle for reining in drug prices. A major source of this lack of competition is due to pay-for-delay arrangements, whereby manufacturers use settlement payments to incentivize competitors to delay the release of generic drugs. Prohibiting this cost-increasing form of monopoly building would increase competition in the pharmaceutical market and would likely lower costs across the board.[36]

Scaling up cost-saving initiatives

When innovative ideas for cost-saving initiatives prove effective, it is critical that these options are not only recognized, but also scaled up to maximize savings. CMMI, state initiatives, accountable care organizations, and other innovators have likely discovered numerous successful methods of controlling prescription drug prices that simply have not been scaled up to their full potential. The federal government should consider investing in research, evaluation, and implementation plans to scale up successful local initiatives.

[36] Gregory H. Jones, Michael A. Carrier, Richard T. Silver, and Hagop Kantarjian, 2016, Strategies that delay or prevent the timely availability of affordable generic drugs in the United States, Blood, 127:1398-1402; doi: http://dx.doi.org/10.1182/blood-2015-11-680058.

Conclusion

The crisis of affordability surrounding prescription drugs is well established, and will escalate without action by the federal government. By increasing transparency in pharmaceutical pricing and spending, enhancing the affordability of drugs for payers of all types, and improving market efficiency within the industry, major improvements in the current landscape are possible. There is no silver bullet that will single-handedly provide relief for all the American people; however, a thoughtful package of policies can reduce the burden of drug costs on our government, economy, and citizens.

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