THIRD WAY

BLOG *Published October 31, 2018 • 5 minute read*

To Fight High Drug Prices, You Have to Be Focused

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In the United States today, eight-in-ten people worry about the cost of health care. [1] There is universal agreement that we need fixes that improve the health system's stability and security. A new bill called the Medicare Negotiation and Competitive Licensing Act of 2018 takes a stab at solving part of the cost problem using a tool known as compulsory licensing. [2] It is a valiant effort on a critical issue, but it may end up hurting more people than it helps and causing some unintended damage. As an alternative, policymakers should develop more focused strategies that could effectively address high drug costs without the negative side effects.

Under current law, the National Institutes of Health (NIH) has the authority to "march in" and require a drug manufacturer to grant additional licenses of a patent for specific public health purposes and to ensure availability of drugs developed under public funding. [3] A drug manufacturer expressly consents to this authority as a condition of receiving the public funding. The NIH, however, has never used this authority. This new bill would go further and grant the Secretary of Health and Human Services (HHS) unilateral

authority to override the original manufacturer's rights and grant other manufacturers the right to use a patent and other intellectual property protections under a compulsory license. The purpose would be to lower price for drugs used by Medicare beneficiaries. It would be the equivalent of threatening to take away a doctor's license in order to make a doctor work for lower Medicare payments, and this is where it gets complicated.

To implement this compulsory license of a manufacturer's patent and exclusive use of clinical data that it developed, HHS would let another manufacturer use that intellectual property to manufacture the drug for Medicare beneficiaries. The original manufacturer's only recourse would be to seek compensation in federal claims court. But courts would find it nearly impossible to rule fairly because new drugs don't have a sales history to establish revenue projections. Why would any manufacturer invest in developing new drugs for Medicare beneficiaries if they risk losing it all? That is one reason why NIH has never pulled the trigger on its march-in authority.

If there were to be any constructive federal process for re-examining existing patents, it would have to be very narrowly defined to solve a specific problem that cannot be solved in any other way. For example, policymakers could re-examine the circumstances that led former-HHS Secretary Tommy Thompson to threaten a patent for the antibiotic Cipro in order to bring down the cost of stockpiling the drug in response to the Anthrax attacks in 2001. [4] That very specific threat came under another law known as Section 1498 of the U.S. Federal Claims Court statute, which requires the federal government to compensate patent holders whenever it uses their patent without a license. [5]

To be sure, pharmaceutical pricing sorely needs reform. Some prominent economists have coined the term "confusopoly" to describe the opaque pricing practices that protect high profits for everyone involved in getting drugs to patients: manufacturers, pharmacy benefit managers, hospitals,

insurers, pharmacists, etc. [6] To fight efforts that obscure the actual value of drugs, Congress should do more to advance value-based contracts between health plans and manufacturers, similar to what they have already authorized for doctors and hospitals.

Congress should take several steps to protect patients from excessive drug prices by ensuring they only pay for value:

1. *Build on existing value-based payment models which incorporate drugs, like the Oncology Care Model and Accountable Care Organizations.* Drugs like chemotherapy, which patients generally receive from physicians and clinics, are currently included in many value-based payment models. [7] HHS should do more along those lines and support providers who want to pioneer additional value-based payment models in conjunction with health plans and other organizations who can help manage medicines. It should also encourage the development of safeguards for the unique needs of patients whose care comes under lump-sum, value-based payments.

2. *Require performance reporting for all drugs*. Performance reporting has become a critical method to hold health care delivery accountable for achieving good results for patients. Indeed, many drugs on the market today are already included in performance measures reported by providers and health plans. For example, report cards on the use of beta blockers to treat people with heart disease have helped correct their underuse. But newer drugs, like biologics and gene therapy, have not yet fallen under such reporting requirements. That should change, and performance reporting on all drugs should become routine.

3. *Make patient out-of-pocket prescription drug costs transparent and affordable at the point of prescribing*. The complex pharmaceutical supply chain and health benefit design mean that patients often don't know their copay or out-of-pocket cost of their medicine until after their physician has prescribed it. Instead, a doctor should be able to see the cost of the drug to the patient before prescribing it so together they can decide if it is the right drug based on a patient's preferences and budget. Even though most price negotiations are not public, patients still need to know the cost of a drug to them.

4. *Reduce coverage for less effective drugs*. Medicare and private health plans should base copayments on drugs that provide the biggest bang-for-the-buck for each patient.

5. *Eliminate barriers to value-based contracts*. Many laws that were intended to prevent abuses under fee-for-service payments have become obstacles to pay-only-for-value initiatives. As Third Way has previously recommended, such laws need to be modernized. [8]

6. *Ensure that patients have prompt access to generic drugs and biosimilars once patent protections for new drugs have expired*. As part of this, the U.S. Food and Drug Administration needs to finish its work to prevent regulations from hindering manufacturers of low-cost generics from getting samples needed to develop generics. If not, Congress should enact legislation to do the same.

Pay-for-value would hold drug manufacturers accountable for the price of a drug in relation to its benefit for patients while also ensuring patients can make informed decisions with their provider about choice of medicines. After all, patients want the benefits of new drugs, just at prices they can afford.

ENDNOTES

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