Wide-Ranging Trump Drug Price Reduction Blueprint

Controversial Issues Included, Some Excluded

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President Trump’s May blueprint on how to lower drug prices has some aggressive, innovative aspects, and it seems clear that this administration is sincere in pushing to lower the costs of drugs for consumers and federal health programs. But the administration has its work cut out for it in actually achieving significant results, since each of the proposals in Trump’s American Patients First proposal disadvantages one or more players in the drug distribution chain, raising the possibility of political roadblocks.

The first of Trump’s proposals to get translated into action is his decision to publicize brand-name companies that refuse to provide samples to generic companies so they can do bioequivalence studies needed to win Food and Drug Administration (FDA) approval. Scott Gottlieb, the FDA Commissioner, announced that step a week after the president set out his multi-proposal plan. That “transparency” measure, however, is unlikely to scare brand-name companies.

What would be a much stronger step is passage of the CREATES Act (Creating and Restoring Equal Access To Equivalence Studies Act of 2017), which would allow generic companies to sue brand-name companies if the generic company took certain steps prior to going to court. The Trump plan does not mention the CREATES Act. PhRMA, the brand-name lobby, has been fighting the CREATES Act since it was first introduced in the current Congress a year ago (H.R. 2212). So the political difficulties of strengthening aspects of the Trump plan are evident.

The CREATES Act says that if a generic company convinces the FDA that its manufacturing procedures guarantee the same level of safety as the brand-name company’s, its handling of the product poses no risk to patients, and that it has tried but failed to get samples, the FDA can certify that the generic company is eligible for legal action for damages against the brand-name company. That proposal was considered, then rejected, for inclusion in the fiscal 2019 omnibus budget bill that Congress passed in February 2018. But Michael Brzica, Vice President of Federal Government Affairs for the Association for Accessible Medications, says, “The pharmaceutical manufacturers did effective work during the omnibus to gin up conservative fears about litigation, saying the bill would be a gift to the trial bar.” Trial lawyers are generally dedicated, deep-pocketed supporters of the Democratic party.

While the Trump drug price plan has its weaknesses, it is fair to say that the president has been more aggressive than previous presidents, even if he has not endorsed the CREATES Act. Eric Gascho, Vice President, Policy and Government Affairs, National Health Council, a group of patient advocacy organizations and other health care stakeholders, says, “We have to give this administration a lot of credit. There is a lot in this package to work with.” He notes that the impact some provisions will make is unclear. Moreover, he says, the details of some provisions are unclear in and of themselves, such as moving reimbursement for some Part B drugs, generally expensive drugs infused in a physician’s office, to Part D.

“From the patient’s perspective, we prefer to see a step-wise approach,” he adds. “We won’t see a massive game-changer policy going forward, but the administration is pushing the needle in the right direction.”

The administration is certainly turning up the rhetoric. No Secretary of Health and Human Services has ever been as blunt as Alex Azar, the former Eli Lilly executive, who said in explaining the Trump plan: “Drug companies have insisted we can have new cures or affordable prices, but not both. I’ve been a drug company executive—I know the tired talking points: the idea that if one penny disappears from pharma profit margins, American innovation will grind to a halt. I’m not interested in hearing those talking points anymore, and neither is the president.”

However, PhRMA President and CEO Stephen Ubl restated his group’s talking points regarding some of the president’s proposals. Although he conceded that some of Trump’s proposals could help make medicines more affordable for patients, “others would disrupt coverage and limit patients’ access to innovative treatments.” He reprised PhRMA’s opposition to eliminating the Part D’s six protected categories, where plans have to make “all or substantially all” drugs in six categories available to patients. The Obama administration tried a few years ago to undo three of those categories. But PhRMA, with substantial political help from patient advocacy groups, killed that effort. Ubl also frowned on the idea of moving Part B drugs to Part D, where their cost could be controlled by P&T committees.

A Senate committee held hearings on Trump’s American Patients First proposal in June. But given the trouble the House and Senate have had in getting to a vote on the CREATES Act, it is hard to believe that Congress will encapsulate the president’s proposals into one bill, much less strengthen those proposals and pass any legislation prior to the 2018 Congressional elections. ■