


## President Trump's prescription to reduce drug prices: from the campaign trail to American Patients First

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### ABSTRACT

**Background:** Drug prices in the United States are the highest in the world, restricting access to the domestic lower income population. President Trump campaigned heavily on promises to reduce drug prices.

**Methods:** A literature review was conducted through PUBMED, EMBASE, Media and grey literature to consolidate and analyze publications addressing President Trump's promises from the campaign trail as well as the shortcomings and achievements of the Trump administration.

**Results:** Major promises ranged from repealing and replacing Obamacare, expanding coverage, allowing cross-state insurance purchasing, and reducing drug prices. Main accomplishments of the Trump administration have been two executive orders (13765 and 13813), the proposition of the American Health Care Act, and the passing of the Tax Cuts and Jobs Act of 2017. The American Patients First blueprint further revealed the administration's strategies for lowering drug prices. The administration has also engaged in unconventional strategies, such as via bilateral leverage directly with trade partners.

**Conclusion:** The Trump administration has not yet been able to fulfill the major campaign promises, primarily the ones requiring legislative and/or administrative action. If enough legislative action is accomplished to implement the Trump administration's promises, the effects on the pharmaceutical industry could be direct, yet minimal, unless Medicare can directly negotiate with manufacturers.

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### Introduction

On January 20<sup>th</sup>, 2017, Donald Trump took hold of the White House Executive Office of the President. It was not until May of 2018 when President Trump, along with the current United States Department of Health and Human Services (HHS) Secretary, Alex Azar, revealed the administration's blueprint for the future of American Healthcare, titled 'American Patients First' (APF) [1]. In the APF blueprint, President Trump promised to slash drug prices for patients in need – a promise he had also declared on the campaign trail. While lobbying for the executive office of the President, President Trump made a number of promises to the American people related to the reform of healthcare. Since he has been in office, the Trump administration has delivered, as well as failed to deliver, on these promises. For example, while failing to abolish Obamacare in its entirety, President Trump has been able to take measures, via executive orders and other actions, to weaken it. Especially since the release of the APF blueprint, some Americans have begun to question if, and how, President Trump will follow through on his

campaign promises to improve American healthcare, specifically to reduce high drug prices and costs.

Currently, drug prices in the United States (US) are the highest in the world. US prescription drug spending is predicted to reach as high as \$610 billion dollars by 2021 [2]. This projection made by Quintiles IMS was actually reduced, due to a lower number of drugs being approved in 2016 than in previous years (due to pricing pressure and competition in the market) [2]. In 2016, with the elections fast approaching, President Trump heavily expressed his commitment to reducing drug prices, if elected President of the US. However, has he been able to achieve all the strategies proposed during his campaign? What has he accomplished during the time he has served as president? How will he be able to deliver on these promises as well as new ones proposed in the APF blueprint? President Trump's promises and achievements on the healthcare front have evolved since his time on the campaign trail, yet the ultimate appeal to his claims has remained that it will reduce prices for patients at the pharmacy level. Comparing what President Trump has promised to deliver for American patients to what he has actually achieved may be helpful in predicting to what extent he may actually

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deliver on the vision for the future of American health and drug prices laid out in the administration's APF blueprint.

### President Trump's campaign and high drug prices

During his campaign, President Trump's rhetoric relied heavily on the promise to repeal and replace the Affordable Care Act (ACA), provide insurance for everyone, make no cuts to social security, Medicare, and Medicaid, ensure no one will lose coverage once ACA is repealed, allow for health insurance to be purchased across state lines in a bid to promote competition, to maintain protection for people with pre-existing conditions, and to facilitate direct negotiation between Medicare and the pharmaceutical industry [3]. A summary of the promises President Trump made during his campaign and their potential impact is provided in [Table 1](#).

While President Trump's campaign called to revoke the ACA, it also focused on attacking high drug prices in the US. President Trump dedicated tremendous effort during the campaign to focus on the promise of allowing Medicare to negotiate drug prices directly with the pharmaceutical industry [4,5]. By allowing Medicare to negotiate directly with these manufacturers, President Trump claimed that Medicare would be able to save \$300 billion a year via discounts as the biggest buyer of prescription drugs [6,7].

In the US, the government enjoys a capitalistic market environment, which means that price controls and regulations that other foreign countries may implement, such as Health Technology Assessment (HTA) agencies dedicated to the evaluation of therapies, are not legally nor formally required for pricing and reimbursement processes. Yet, strict regulation in preventing federal institutions, such as the Centers for Medicare and Medicaid Services (CMS), from direct negotiations with manufacturers is in place and highly controlled. Internationally, evaluation and pricing frameworks are applied to appraise therapies for the approval of pricing and national reimbursement through entities, such as HTAs. Summaries of HTA bodies' evaluation coverage and pricing mechanisms employed by select foreign countries are provided in [Tables 2](#) and [3](#).

Moreover, domestically, the pharmaceutical lobby in Washington D.C. has a powerful voice and also plays a major role in influencing legislation required to allow for direct negotiation between Medicare and manufacturers, which, if allowed, could be a powerful price controlling and regulation mechanism. In order to facilitate direct negotiation between the 2 parties, legislative action is required to amend the 2003 law established for Medicare Part D, which outlines prescription drug benefits. Medicare

Part D specifically bans direct negotiation between the government and pharmaceutical companies [17].

Another proposal President Trump made during his campaign to reduce drug prices was to allow cheaper, foreign pharmaceutical drugs to be sold in the US [18]. President Trump in 2016, claimed he was determined to remove 'barriers to entry into free markets for drug providers that offer safe, reliable, and cheaper products.' [19] This would allow patients in the US to obtain treatments at a much lower cost from countries, such as Canada or European countries, where drug prices are significantly lower. To facilitate the importation of foreign drugs, legislative action would also be required. At the time President Trump proposed this solution, several experts and governmental officials, including the former FDA Commissioner Mark McClellan, argued that the importation of drugs manufactured abroad may have negative implications, including the exposure of the American population to drugs manufactured abroad under different regulations and, therefore, exposure to potential unknown risks regarding safety and reliability. [18] Allowing the importation of cheaper, foreign drugs may be a route to introduce affordable options for American patients in need. During the elections, questions were raised as to the feasibility of changing legislation to accommodate this promise made by President Trump as well as to the potential consequences it could have.

The Trump Campaign's position on the reduction of high drug prices leaned heavily on 2 pillars, including others, but mostly on direct negotiation between Medicare and the pharmaceutical industry and the importation of cheaper, foreign drugs. While met with support as well as criticism, President Trump was able to win the elections and entered the Oval office carrying these promises to reduce drug costs.

In reaction to these promises and President Trump's assumption of office, analysts have argued along with the Congressional Budget Office (CBO), that the allowance of direct negotiation between the pharmaceutical industry and Medicare may not necessarily translate into a major effect on federal spending, but could rather result in a negligible effect. It must also be considered that there may not be much room for negotiation when therapies are increasingly innovative with advancing technology, translating into no competition or alternatives to be found in the market. This could potentially allow for manufacturers in the US to maintain their argument for the need of free-pricing, resulting in high prices as they seek returns on investment for cutting-edge, innovative therapies. While the ability for Medicare to negotiate with the industry directly would allow for lower drug prices and the importation of drugs from outside of the US would stimulate a competitive price setting, it can also be argued that

**Table 1.** comprehensive overview of President Trump’s promises and actions to lower US drug prices from the Campaign Trail to American Patients First.

Major Promises	Current Status	Requires Legislative/ Administrative Action	Potential Impact
<b>Campaign Trail</b> Repeal and Replace ACA	In Progress	Yes	Millions of Americans lose insurance Increased premiums
Direct Negotiation between Medicare and Pharmaceutical Manufacturers	No progress	Yes	Negotiated lower drug prices President Trump claimed Medicare would save \$300 billion a year According to CBO: not necessarily reduces drug prices, could result in negligible effect Potentially no impact on pricing for new, innovative health technologies with no competition or alternatives on the market Increased price competition
Importation of cheaper, foreign pharmaceuticals	No progress – potentially abandoned on the federal level, yet is being pursued on the state level	Yes	Exposure to unknown risks regarding safety and reliability
Major Actions	Date	Required Legislative/ Administrative Action	Potential Impact
<b>In Office</b> Executive Order for Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal	January, 2017	No	According to IRS: would reduce administrative burdens on taxpayers by no longer requiring taxpayers to declare their health insurance status, this weakened a tool used to solicit participation in creating a robust, wide health insurance market
AHCA	May, 2017	Yes	Repeals parts of the ACA within scope of federal budget with modifications to Medicaid (cuts to Medicaid coverage) CBO projected that AHCA would: <ul style="list-style-type: none"> <li>• Increase number of uninsured by 24 million over 10 years</li> <li>• Decrease the federal budget deficit by \$119 billion by cutting Medicaid coverage for lower income Americans</li> </ul>
Executive Order to Promote Healthcare and Competition	October, 2017	No	Unclear if it could serve as a direct replacement for ACA Allows for insurance to be sold across state lines, potential to stimulate competition and provide affordable care options Promotes association health plans and HRAs to expand affordable coverage for American employers and employees Promotes and directs expansion of STLDI and ability to renew it Without paying for CSR subsidies: <ul style="list-style-type: none"> <li>• premiums for low-income persons can increase on ACA exchanges by as much as 20%</li> <li>• contribute \$200 billion to the budget deficit over a 10 year period</li> </ul> The deficit increase is due to the premium tax credit subsidy (the largest ACA subsidy) increases to offset increases in health insurance premium amounts, far outweighing savings from not paying the smaller CSR subsidy
Tax Cuts and Jobs Act of 2017	December, 2017	Yes	Increase premiums for sicker, American patients and increase the budget deficit at an estimated amount of \$200 billion; increase cost and access burdens for American patients Sole legislative law passed to directly affect the ACA Revocation of the individual mandate of the ACA penalty Increase premiums, particularly sicker American patient population Millions of Americans to be uninsured Reduce regulatory burden Increase rate of generic application approvals to stimulate competition and drive prescription prices down
CMS FDA	2017–2018 2017–2018	No No	
Major Promises	Status	Requires Legislative/Administrative Action	Potential Impact
<b>American Patients First – May, 2018</b> Improving Competition	In progress	Yes	Direct and indirect impacts on drug pricing and affordability <ul style="list-style-type: none"> <li>• Ex. of direct impact: increase drug competition</li> <li>• Ex. of indirect impact: value-based insurance</li> </ul>

(Continued)

**Table 1. (Continued).**

Major Promises	Status	Requires Legislative/Administrative Action	Potential Impact
Better negotiation for Medicare and Medicaid	No	Yes	See above under Campaign Trail Potential Impact
Incentives for Lower List Prices	In progress	Yes	Direct impact on list prices
Lower out-of-pocket costs caused by PBMs	No	Yes	Direct and indirect impacts on drug pricing and purchasing <ul style="list-style-type: none"> <li>• Ex. of direct impact: change in Medicare prescription drug coverage</li> <li>• Ex. of indirect impact: removal of gag clauses</li> </ul> Unclear if this will translate to a drug price reduction in the US
Pressure and Incentivize Foreign Countries to raise the prices of American Drugs Abroad	In progress	No	Unclear if this will translate to a drug price reduction in the US Result in pharmaceutical industry gaining in profits
Action	Date	Requires Legislative/Administrative Action	Potential Impact
<b>Additional Actions by the Trump Administration</b> Price Increase Freezes with major Pharmaceutical Companies (Pfizer, Novartis, Bayer, Roche, Merck KGaA, AstraZeneca)	July 2018 – Present	No	Unclear how this will address already highly priced drugs or the pricing system Not binding agreements; these companies have only agreed to freeze their price increases until the end of 2018
Pressure and Incentivize Foreign Countries to raise the prices of American Drugs Abroad	2018	No	Foreign countries will be pressured to raise US Drug Prices <ul style="list-style-type: none"> <li>• Japan and Germany have succumbed to delaying HTA implementation and to increasing US Drug Prices, respectively, in bilateral settings with President Trump</li> <li>• Foreign countries will resist pressure to raise US drug prices</li> <li>• UK has maintained commitment to provide low prices; yet, Prime Minister Theresa May has been vocal that she is interested in establishing a bilateral agreement with President Trump</li> </ul> Unclear if this will translate to a drug price reduction in the US Result in pharmaceutical industry gaining in profits

ACA = Affordable Care Act, CBO = Congressional Budget Office, IRS = Internal Revenue Service, AHCA = American Health Care Act, HRAs = health reimbursement arrangements, CSR = cost sharing reductions, STD/LI = short-term limited duration insurance, CMS = Centers for Medicare and Medicaid Services, FDA = Food and Drug Administration, PBMs = pharmacy benefit managers, HTA = Health Technology Assessment, UK = United Kingdom, US = United States

these strategies did not address nor take into consideration research and development costs of drugs, which are factors in manufacturers' price setting. While President Trump entered office with expectations to deliver on these promises, whether or not they were achieved immediately upon entering, are still debated.

### President Trump's administration actions on high drug prices

The Trump administration has been able to make some advancements in reforming American healthcare. However, it seems that many of President Trump's promises made during the elections have not yet reached fruition. His main accomplishments, thus far, have been

stopping cost sharing reduction payments to insurers (these payments were introduced by the ACA as subsidies to reduce out-of-pocket spending required by the insured to pay), the passing of the Executive Order for Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, the passing of the Executive Order to Promote Healthcare Choice and Competition, the proposition of the American Health Care Act (AHCA), and the passing of the Tax Cuts and Jobs Act of 2017. The Trump administration has also been successful at reducing regulatory burdens by having CMS streamline reporting requirements and reducing paperwork. It has also seen an improvement on the rate at which the FDA is approving drugs as they have pushed the FDA to conduct quicker consideration and processing of generic applications; an increase in generics reaching the market is expected to stimulate competition and drive prescription drug prices down [20]. A summary of President Trump's achievements during his presidency and their potential impact is provided in Table 1.

When assessing these achievements, it could be argued that the focus of the Trump administration has been on abolishing the ACA, rather than on attacking the high drug prices. While the ACA has been taking some hits, until present day President Trump has still not been able to repeal it. The Trump administration has been able to weaken it through some actions, such as by dissolving the individual mandate penalty of the ACA and, therefore, alleviating the additional taxes imposed and designed to ensure that all, including the healthy, purchase health insurance.

**Table 2.** Summary of foreign HTA bodies coverage.

Country	All new original prescription drugs	All generics
France (HAS)[8]	✓	× (some exceptions)
Germany (IQWiG)[9]	✓	×
Hungary (TEI)[10]	✓	×
Italy (AIFA)[11]	✓	✓
Poland (AOTMiT)[12]	×	×
Spain (AETS)[13]	✓	✓
Sweden (TLV)[14]	✓	✓ (no health economic data required)
UK (NICE)[15]	×	×
UK (SMC)[16]	✓	×

HAS = Haute Autorité de Santé, IQWiG = Institute for Quality and Efficiency in Healthcare, TEI = OGYEI Health Technology Assessment Office, AIFA = Italian Medicines Agency, AOTMiT = Agency for Health Technology Assessment and Tariff System, AETS = National Health Technology Assessment Agency, TLV = Dental and Pharmaceutical Benefit Agency, NICE = National Institute for Health and Care Excellence, SMC = Scottish Medicines Consortium

**Table 3.** Overview of pricing mechanisms employed abroad for reimbursed prescription drugs.

	Free pricing	International reference pricing	National reference pricing	Price negotiations	Managed entry agreements
France[8]	×	✓ (critical for pricing innovative drugs)	✓ (by active substance and therapeutic class)	✓	✓ ( <b>price-volume +discount</b> )
Germany[9]	✓ • Free pricing for the first 12 months on market with negotiations to follow	✓ (supportive criteria)	✓ (By active substance, pharmacological class, therapeutic class)	✓ (drugs eligible to EBA with added benefit or no reference price groups)	✓ ( <b>discount</b> )
Hungary[10]	×	✓ (main criteria)	✓ (By active substance, pharmacological class, therapeutic class)	✓ (informal)	✓
Italy[11]	×	✓ (supportive criteria)	✓ (by active substance)	✓	✓ ( <b>complex</b> )
Poland[12]	×	✓ (supportive criteria)	✓ (By active substance, pharmacological class, therapeutic class)	✓	✓
Spain[13]	×	✓ (supportive criteria)	✓ (by active substance)	✓	✓ ( <b>regional</b> )
Sweden[14]	×	×	×	× (acceptance of rejection)	✓ ( <b>CED</b> )
UK[15, 16]	✓ (indirect profit control through PPRS)	×	×	× (indirect profit control through PPRS)	✓ ( <b>PAS</b> )

UK = United Kingdom, CED = Coverage with Evidence Development, PAS = Patient Access Scheme, PPRS = Pharmaceutical Price Regulation Scheme

In terms of his direct effect on health reform and drug prices, President Trump has passed 2 executive orders, proposed the AHCA, and passed the Tax Cuts and Jobs Act in order to contain high drug prices. However, these efforts have mainly targeted dismantling the ACA. Executive Order 13765, also known as the Executive Order for Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, signed hours shortly after President Trump's inauguration in January 2017, set out interim procedures in the anticipation of the repeal of the ACA [21]. This order has allowed for the President to take all legal measures to 'minimize the unwarranted economic and regulatory burdens of the [ACA].' It has also been associated with the Internal Revenue Service no longer requiring tax filers to declare the status of their health insurance and, therefore, allowing them to avoid any penalties incurred by previously not declaring this status. However, Executive Order 13765, has been criticized for its potential to increase insurance premiums rather than to help with the affordability of drugs [22].

Following the Executive Order 13765, on May 4<sup>th</sup>, 2017, the AHCA was passed by the House of Representatives in a close vote of 217–213, so close it could be a potential indicator of uncertainty surrounding the proposed act [23,24]. The AHCA was proposed as the manifestation of the 'Replace and Repeal Obamacare' slogan for Trump's campaign against the ACA. The AHCA was proposed and passed by President Trump and supporting representatives in his administration as a replacement for the ACA and further sought to, at the very least, repeal parts of the ACA within the scope of federal budgeting, such as reducing Medicaid support and capping federal funding per each Medicaid enrollee. Essentially, the CBO at the time, projected that the AHCA would cause 24 million people to lose coverage over the following decade and to decrease the federal budget deficit by \$119 billion – mainly at the cost of cutting Medicaid coverage to lower income Americans [25]. Ultimately the AHCA did not succeed in passing in the Senate, yet it can be argued that it remains a testament to the ability of the Trump administration to propose a replacement so quickly after election and it provides a window into the administration's strategies for healthcare provision and access to drugs for patients. The question remains as to what will be proposed next and potentially implemented by the Trump administration to replace the ACA.

The second executive order, Executive Order 13813, titled the Executive Order to Promote Healthcare Choice and Competition across the United States, was signed in October of 2017 [26–28]. The order called for the allowance of insurance to be sold across state lines in the hopes of stimulating competition and expanding affordable care

options to patients. It also facilitated for the promotion and expansion of association health plans and health reimbursement arrangements to increase affordable coverage options for American employers and their employees. Furthermore, the order promoted and directed for the expansion of short term, limited- duration insurance, making it able to renew these policies indefinitely. Ultimately, many affordable plans and options were provided at the cost of services, which may potentially make it more appealing for healthier Americans to purchase these cheaper plans, despite the fewer services included in these packages. The executive order has been criticized as it may increase the premiums of sicker, American patients as well as increase the budget deficit – estimated to increase at an amount of \$200 billion [29,30]. If implemented, this could also mean that American patients may have to pay more and encounter obstacles in obtaining drugs and healthcare.

President Trump's administration experienced major success on the healthcare front when the Tax Cuts and Jobs Act was passed in December of 2017. This Act included a direct hit to the ACA and is currently the only binding legislation that affects the ACA as a healthcare law directly. The Act has revoked the individual mandate penalty of Obamacare, which requires every American citizen to secure health insurance or to pay a penalty if they fail to do so. This Act, however, was criticized as it could potentially drive premiums up as well. With the repeal of the individual mandate penalty, it is expected that increases in health insurance premiums will accelerate, even fewer insurers will offer plans under the ACA, and that the downward trend in the proportion uninsured will reverse [31,32]. While the intention of this was to dismantle a core part of the ACA, it is predicted that if younger, healthier Americans choose to opt out of having insurance, insurance and coverage providers will be forced to raise their premiums on the remaining sicker American population; additional factors could also be considered in a predicted increase of premiums, such as socioeconomic backgrounds determining affordability and awareness.

While the Trump administration has been able to make some strides, President Trump's time in office has shown that he has not yet been able to fulfill his major campaign promises, primarily the ones requiring legislative and/or administrative action. Collectively, he has spent most of his energy in an effort to repeal and replace Obamacare. As no consensus was reached on the ACA's replacement, President Trump's executive orders have been essential tools in the administration's attempts to dismantle the ACA. Furthermore, his support of importing cheaper, foreign-manufactured drugs fell silent at this time and could have been interpreted

as the abandonment of this as a strategy to provide more affordable options to American patients.

### American Patients First: President Trump and his administration on high drug prices today

In May of 2018, President Trump and HHS Secretary Alex Azar released the APF blueprint, outlining the administration's major strategy to tackle high drug prices and out-of-pocket costs. The APF blueprint also reiterated promises made on the campaign trail. A summary of President Trump's promises made in the APF blueprint and their potential impact is provided in Table 1. The APF blueprint identified 4 areas of issue in the American drug market, including high list drug prices, senior and government programs (Medicare and Medicaid) overpaying for drugs due to lack of the latest negotiation tools, high and rising out-of-pocket costs for consumers, and foreign governments free-riding off of American investment in innovation. The Trump administration has proposed to solve these issues by improving competition, implementing better negotiation (specifically directly between Medicare and the pharmaceutical manufacturers), offering incentives for lower list prices, lowering out-of-pocket costs caused by pharmacy benefit managers (PBMs), and pressuring and incentivizing foreign countries to raise the price of American drugs abroad.

The majority of the solutions proposed by President Trump have been included in the White House fiscal year budget for 2019 [33]. Many of these strategies proposed require amendments to Medicare Part D and Part B as well as working closely with the FDA and the CMS. In order to promote competition, President Trump has proposed to prevent gaming of regulatory processes, where pharmaceutical companies have sought to block competition from generic products entering the market, and to promote innovation and competition for biologics by having the FDA issue new policies and increase education on interchangeability. For better negotiation, proposed APF strategies included, value-based care (to hold manufacturers accountable for outcomes) and the allowance of Part D plans to adjust formulary or benefit design during the benefit year, evaluating options to allow high-cost drugs to be priced or covered differently based on indication, and working with Department of Commerce, U.S. Trade Representative, and the U.S. Intellectual Property Enforcement Coordinator to determine the source of drug price disparities between the US and other developed countries. The APF blueprint also called for the FDA to consider the inclusion of prices in direct-to-consumer advertising as well as to

direct CMS to make Medicare and Medicaid prices more transparent and to develop proposals related to the ACA's Maximum Rebate Amount provision. The fourth solution brought forth by the APF blueprint is an effort to reduce patient out-of-pocket spending by prohibiting Part D plan contracts from enacting gag clauses (these prevent pharmacists from telling patients when they can pay less by not using their insurance). It further requires that Part D Plan sponsors provide additional information about drug price increases and lower-cost alternatives when explaining current benefits to their members. The Trump administration's APF blueprint also suggests that manufacturers be required to reveal the prices of their therapies in direct-to-consumer advertisements. However, if the price were to be included in advertisement along with the removal of the gag clause, it is critical to further educate patients, to ensure that not only the most affordable treatment is purchased, but that the most beneficial treatment is provided to the patient. While the most beneficial treatment option may not necessarily be the cheaper option, it may avoid overspending on ineffective treatments.

While the APF blueprint aims to deliver high quality care along with affordability for those in need, it could be argued that the solutions proposed by Trump's administration are weak on the pharmaceutical industry. Reactions to the APF blueprint have been quite critical with many regarding it as attacking the middlemen, the PBMs, rather than addressing the real issues of research and development costs and the pricing system in place. A testament to a rather laidback reaction on behalf of the pharmaceutical industry to President Trump's APF blueprint was the rise in pharmaceutical stocks just after his speech, where stocks of PBMs and biotech companies still outperformed the market [34,35]. Other analysts, such as Leernik Partners' Analyst David Larsen, have suggested that the APF blueprint shows that Trump's administration understands the pulse of the market and if his strategies are implemented, the industry will be impacted with time. However, others, such as the experts at The Economist, have argued that President Trump's APF blueprint will not reduce drug prices. According to The Economist, one effective strategy would be the prohibition of pharmaceutical companies delaying the arrivals of generic versions of their drugs after patents expire. Some critics also highlighted that many plans put forth during President Trump's would require legislative or administrative action, which would be difficult to implement. However, it is interesting to note that some critics have strayed away from directly stating

that drugs should be priced based on outcomes of objective value frameworks to gain approval and coverage. It also seems unlikely that President Trump will have influence on international pricing of US drugs via legal routes. President Trump may rely heavily on bilateral negotiations to pressure foreign countries to raise the price of American drugs by leveraging strategies outside of their domestic pricing control measurements. The Economist goes as far to suggest that adapting a European model of pricing for drugs in the US, such as HTA agencies, to scrutinize the value of therapies may prove to be more effective price control measurements for drugs [36].

### The Trump administration's alternative routes seeking lower drug prices

Most recently, the Trump administration has pursued unconventional strategies outside of legislative and administrative actions to prevent drug price increases. President Trump has, in fact, been successful in pushing back major pharmaceutical manufacturers' plans to raise drug prices. On July 9<sup>th</sup>, 2018, President Trump tweeted in direct response to Pfizer's July 1<sup>st</sup> price increases, declaring that 'Pfizer & others should be ashamed that they have raised drug prices for no reason. They are merely taking advantage of the poor & others unable to defend themselves, while at the same time giving bargain basement prices to countries in Europe & elsewhere. We will respond!' [37] The next day President Trump and Pfizer Chief Executive Ian Read, had a 10–15 minute call that resulted in Pfizer postponing the price increases until the end of 2018 or until President Trump's APF blueprint went into effect [38–40]. Shortly after on July 19<sup>th</sup>, 2018, President Trump tweeted out 'Thank you to Novartis for not increasing your prices on prescription drugs. Likewise to Pfizer. We are making a big push to actually reduce the prices, maybe substantially, on prescription drugs.' [41,42]

Novartis, like Pfizer, has promised to refrain from increasing price for the remainder of the 2018 year [43]. However, it is interesting to note that Read has revealed that President Trump has promised to abolish drug rebates, which may have a serious impact on PBMs [44]. If drug rebates are abolished, pharmaceutical companies would be able to maintain their profits as price decreases and their effects would be diverted to and felt by the intermediaries, the PBMs. Yet, this is unlikely to address the price of innovative drugs over expensive drugs as they enjoy a monopoly. It is unclear how effective President Trump's strategy of directly addressing big pharmaceutical companies on his social media platform will be. Both Pfizer and Novartis made

no permanent commitments to end all price increases now and in the future. Additional major pharmaceutical manufacturers, such as Roche, Bayer, Merck KGaA, and AstraZeneca, joined Pfizer and Novartis in freezing their plans for price increases for the second half of 2018 [45–48]. Some have argued that pressuring pharmaceutical manufacturers to refrain from increasing prices does not directly address the issue of the drug pricing system or reducing the cost of drugs, which may already be extremely high and unaffordable for American patients.

Bilateral negotiation and one-on-one dialogue, such as the call held between President Trump and Read, may prove to be influential not only domestically, but in international negotiations when pressuring trade partners to raise the price of American drugs abroad. In the Trump administration's latest engagements with foreign trade partners, several have seemed to succumb to the pressure applied by President Trump and trade representative, Bob Lighthizer. After a meeting with Japan, a country previously committed to cost control of pharmaceuticals, Japanese health officials delayed the implementation of their HTA agency and processes [49,50]. Furthermore, when faced with importation taxes on American automobiles, Germany has pre-emptively proposed to end all importation taxes as President Trump could leverage this to achieve progress in negotiating US drug prices increase halts [45,51]. However, some countries have seemed to push back, such as the United Kingdom (UK) where the National Health Service has maintained that they will stay committed in providing the most affordable healthcare to their patients [52]. However, Prime Minister Theresa May, has been open about her desire to enter into bilateral agreements with the US and President Trump's administration, upon a potential UK Brexit [53–55]. It, therefore, seems that bilateral negotiating is proving successful for President Trump's administration in applying pressure on and leveraging their advantages over foreign countries potentially to raise the prices of US drugs. It remains unclear if this will directly translate into a reduction of US drug prices domestically, unless pharmaceutical manufacturers lower drug prices at home in the US as these prices are raised abroad.

Apart from President Trump's federal and foreign efforts to reduce drug costs, states have moved ahead in the attempt to reduce prescription drug spending. In fact, as of July 2018, individual states had collectively introduced 160 bills with 37 being enacted into law to contain rising drug prices. These measurements have ranged from addressing PBMs, calling for more transparency and disclosure, with states such as Colorado



and Mississippi adopting measurements to prohibit or entirely abolish gag clauses. Several states also now allow for importation of cheaper, foreign drugs from Canada with Vermont allowing for wholesale purchase of drugs from Canada. Twenty-six bills have been introduced with 5 becoming law to promote transparency, for example requiring manufacturers to provide additional data and justification when increasing prices. Furthermore, other laws now restrict the use of step-therapy, requiring patients to fail on certain therapies prior to being eligible to try alternatives. Arizona and Tennessee have also passed measures to promote off-label use of certain drugs in alignment with FDA guidelines. Many states are making strides forward not so differently from President Trump's promises and strategies during his campaign and presidency so far [56,57]. A summary of additional achievements President Trump has made until present day and their potential impact is provided in Table 1.

## Conclusion

By examining President Trump's journey from the campaign trail throughout his presidency until now, it seems to be a conservative observation that although his main promises have been maintained and consistently repeated by him, the majority have yet to be fulfilled. His accomplishments during his time in the white house, such as FDA streamlining of generic applications and the repeal of ACA penalties for individuals to be insured, may create access issues for drugs patients need and may not directly influence drug prices, with the exception of generic competition potentially driving price wars. Major promises remaining to be fully realized include the repeal of ACA, allowing Medicare to negotiate with the pharmaceutical industry directly, exploring importation of cheaper drugs, and preventing lower pricing of American drugs abroad.

If Medicare was able to directly negotiate, prices of drugs could potentially be reduced substantially. The importation of foreign drugs and the interference of international pricing of American drugs would have seemed unlikely; if given time and the opportunity that legislative and administrative action would have allowed, it could be predicted that prices may be reduced through the importation of drugs.

President Trump may very well continue to repeat his support for the same promises made stemming from his campaign days throughout his presidency. However, overall, the strategies the administration is proposing to fulfill these promises, seem to indirectly affect the price of drugs while President Trump continues to avoid hurting the pharmaceutical manufacturers who, considering the

rise in their stocks post-release of the APF blueprint, feel unthreatened.

The Trump administration's success in achieving some of these promises could be attributed to his power with executive orders and the ability to quickly influence partial legislation and/or administrative action – such as repealing ACA individual mandate penalties contingent on the purchase of insurance. Yet, the lack of fulfillment of his major promises could be attributed to several factors, including the power of the pharmaceutical lobby in Washington, the extensive legislative action required for implementation, and/or due to the innate characteristic that these strategies do not tackle high drug prices or the pricing system directly. It could be argued that these strategies would simply redistribute the burden of cost throughout the industry, unless Medicare is eventually allowed to negotiate directly with the pharmaceutical industry.

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