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REVIEW ARTICLE

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Why "American Patients First" is likely to raise drug prices outside of the United States

Monique Dabbous[a], Cyprien Milea [b], Steven Simoens[c], Clement François[a], Claude Dussart[d], Lylia Chachoua[e], Borislav Borissov[f] and Mondher Toumi [a]

[a]Public Health Department, Aix-Marseille University, Marseille, France; [b]International Affairs, Sciences Po, Paris, France; [c]Department of Pharmaceutical and Pharmacological Sciences, KU Leuven Department of Pharmaceutical and Pharmacological Sciences, Leuven, Belgium; [d]EA 4129 P2S (Parcours, Santé, Systémique), Lyon University, Lyon, France; [e]Public Health Department, Market Access Society, Paris, France; [f]Prescriptia, Sofia, Bulgaria

ABSTRACT

Background: The Trump administration's 'American Patients First' blueprint proposes to reduce drug prices in the USA by increasing drug prices abroad, ex USA. The possibility of the Trump administration to raise drug prices ex USA through legal action via the WTO and bilateral negotiations with foreign trade partners was reviewed.
Methods: A literature review was conducted through PUBMED, EMBASE, Media and grey literature to consolidate publications of the Trump administrations' policies and strategies towards foreign countries and drug prices.
Results: The Trump administration has withdrawn from and halted major multilateral agreements including the TPP, Paris Agreement, TTIP, UNESCO, NAFTA (now USMCA), and NATO. The Trump administration has been successful in bilateral negotiations for pharmaceuticals' pricing, as seen with Japan, South Korea, Germany, and Mexico and Canada.
Conclusion: The objective of raising prices abroad is attainable. Action through the WTO is unlikely, due to its nondiscriminatory principle. Bilateral trade negotiation have proven more promising. In this bilateral framework, financial security and military protection are strong assets for the USA to levy higher drug prices abroad. Although raising drug prices ex USA is possible, further questions as to whether this will directly translate into lower drug prices for American patients are raised.

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Introduction

In a bid to act upon his electoral promise of lowering drug prices in the US, President Donald Trump unveiled the 'American Patients First' (APF) plan in May of 2018 [1]. The APF set concrete objectives and outlined potential strategies for the reduction of drug prices. Paying due consideration to the important funding of the Republican Party from the pharmaceutical industry, the Trump administration has proposed two corrective measures to reduce drug prices in the USA of America (USA). The first measure is the transferring of low discount offers to patients, which are currently being enjoyed by the intermediaries of the chain, such as distributors, pharmacy benefit managers, and insurers [2]. A second measure proposed by the Trump administration is to increase the prices of drugs abroad, ex USA [3], thereby, supposedly enabling a reduction in prices at home. This paper focuses on the latter option, the pursuit of increasing drug prices ex USA.

Increasing the prices of drugs abroad was initially requested by the union of pharmaceutical companies, known as Pharmaceutical Research and Manufacturers of America (PhRMA) [4]; rising drug prices in the US was also addressed prior to President Trump taking office in a report issued by the Department of Commerce, via the International Trade Administration, on 2016 Top Markets Report Pharmaceuticals [5]. The objective of raising prices ex USA has also gained traction due to President Trump's accusation of foreign governments free-riding off of American investment in innovation [3,6,7]. The rationale behind this, is that drugs cost more for patients in the USA (US), where they are developed and owned, than for patients in foreign countries, despite the products being identical (in terms of manufacturer, composition, and formulation) [6], all while foreign governments do not contribute to US expenditures. As President Trump expressed himself in his remarks on the APF, '[the USA] will also demand fairness overseas. When foreign governments extort unreasonably low prices from US drug makers,

CONTACT Monique Dabbous monique.dabbous@univ-amu.fr Public Health Department, Aix-Marseille University, Marseille, France

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Americans have to pay more to subsidise the enormous cost of research and development.'[7]

In practical terms, the US and the Trump Administration have two major potential routes in order to raise the price of drugs abroad. One is pursuing legal action via the World Trade Organization (WTO), in order to combat what the Trump Administration considers to be discriminatory mechanisms placed on US products [8–11]. Another route, as mentioned in President Trump's APF remarks, is the employment of bilateral negotiation settings with foreign trade partners to achieve drug price increases.

The following analysis explores the possibility of the US increasing drug prices abroad and its implications. It will examine the plausibility of legal action via the WTO, and via pressuring trade partners' in bilateral negotiations, with a focus on Canada, Mexico, Germany, Japan, Korea, and the UK (UK). It also raises the question as to whether or not raising drug prices abroad will directly translate into lower prices for Americans at home. The subject of this paper has been left largely untouched by the academic and journalistic spheres, despite it being at the heart of numerous ongoing bilateral negotiations and discussions.

The current state of health affairs in the US and internationally

At first glance, as claimed by the Trump administration, foreign countries seem to be free-riders of American research in the industry. According to the Organization for Economic Cooperation and Development (OECD), the US is the highest spending country in terms of health, spending close to 17% of their GDP [12], with a considerable 11.9% of health spending contributing to pharmaceuticals spending [13]. The US bears the highest drug bill per capita in the world, which is only expected to increase [14]. Other countries, generally, have much lower health and pharmaceuticals expenditures compared to the US, as can be seen in Table 1. Internationally, retail drug prices are also much lower; the same drug in America can cost three to five times more than its price abroad [6,15,16]. This illustrates a situation in which foreign countries price US products much lower than are priced in the US and do not contribute to American expenditures, which could potentially further fund American innovation and pharmaceutical products. President Trump has declared that 'it's unfair and it's ridiculous, and it's not going to happen any longer. It's time to end the global freeloading once and for all [7].'

However, this view must be considered as nuanced. President Trump's idea of freeloading is based on American expenditures, as well as the gap between US and foreign drug prices. First, these expenditures must be considered relative to GDP. Pharmaceutical expenditures, in the US, represent 2% of their GDP. Looking at Table 1, this is still a relatively high percentage, compared to countries of interest, but the gap between US expenditures and other countries' expenditures is substantially less and it is lower than Japan's percentage for instance.

When examining pricing in freeloading, President Trump's claims must be contextualized by two further points. The gap between high prices in the US and European prices serves to boost profits and dividends of the pharmaceutical industry, not research, with price differences due to market structures. A study [17] conducted by Patricia Danzon determined that high health and pharmaceuticals expenditures cannot be solely due to high drug prices in the US: while examining supply, demand, and consumption of pharmaceuticals internationally, Danzon's study concluded that launching and diffusion of pharmaceuticals, along with formulary preference, off-brand generic consumption, and distribution costs are among major factors contributing to US pharmaceuticals expenditures. In addition, a recent study has shown that not only are drug prices higher in the US, but the prices of brand-name drugs have risen considerably in the last six years and will continue to increase – at least at a rate of once or twice a year; This study conducted by Wineinger et al, attributes these drug price increases to the current rebate system, which incentivizes high list prices and a greater reliance on rebates, increasing overall cost of drugs for patients and particularly private insurers [18]. While foreign markets often have rules and price control

Table 1. International overview of health and pharmaceuticals expenditures.

		Health Expenditure			Pharmaceuticals Expenditure			
Countries	GDP (million US Dollars)	Expenditure (US dollars/capita)	% of GDP	Expenditure Adjusted per GDP	% of Health Spending	Expenditure (US dollars/capita)	% of GDP	Expenditure Adjusted per GDP
Canada	1,625,361	4826	10.4%	.0029	17.8%	860	1.86%	.0005
France	2, 765, 185	4902	11.5%	.0017	13.9%	663	1.60%	.0002
Germany	4, 050,525	5728	11.3%	.0014	14.3%	777	1.59%	.0002
Japan	5,369, 479	4717	10.7%	.0008	19.7%	874	2.15%	.0002
Korea	1, 877, 123	2897	7.6%	.0015	22.5%	653	1.71%	.0003
USA	**18, 624, 475**	**10,209**	**17.1%**	**.0005**	**11.9%**	**1174**	**2.04%**	**.0001**
UK	2, 806, 915	4264	9.7%	.0015	11.4%	476	1.11%	.0002

GDP = Gross Domestic Product, USA = USA of America, UK = UK.

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measures enforced by Health Technology Assessment (HTA) agencies and health technology pricing committees, the US enjoys a capitalistic, free-pricing system. This US approach to pricing points towards a market structure where drug prices are set at the highest possible price at which the market can absorb them with drug prices continuing to increase over time.

Freeloading, in this argument, is based on expenditures and drug prices. Following this analysis, while US expenditures are higher than other countries' expenditures, the gap between US and foreign expenditures in health and pharmaceuticals, relative to GDP, is much less striking; and high prices in the US are not driven by high research expenditures, but by health policies and the pharmaceuticals' ecosystems. Thus, the price difference between US and ex US may in fact be precipitated by US internal factors.

US and global pricing systems

This paper considers drug price as the visible drug list price. In the USA, drug prices vary depending on the healthcare stakeholder and their negotiating ability and power. Furthermore, both in the USA and worldwide, there are confidential discounts applied to products. Therefore, while there is more than one 'price' for a drug, the paper acknowledges the Trump administration's referral to drug prices as public, visible list prices. Currently in the US, manufacturers are free to set the prices of their drugs upon market authorization. It is left to the discretion of the private payers to negotiate rebates and discounts in order to regulate prices and facilitate access of drugs to patients, while States and Federal Government health insurance programs (Medicare, Medicaid, and Veterans Affairs) do not have options for price negotiation [19]. In comparison with other countries, especially those in the European Union (EU), the US has much higher drug prices and immediate access. The APF blueprint directly attributes the low prices of drug prices abroad to price control measurements employed by European and foreign countries, by leveraging their single payer systems [1].

Internationally, single payer systems often refer to HTA agencies to make value assessments of incoming drugs. National reimbursement and prices of these products are decided based on HTA value appreciation. They consider evidence, such as effectiveness and economic studies of the drug, including cost-effectiveness and budget impact analyses, when making an assessment. HTA agencies act as a market access barrier. If the drug is not cost-effective, shows little value, and/or has weak supporting evidence, it may not be recommended for reimbursement, or it will be reimbursed at a lower price than the manufacturer desired.

These formal, legal procedures followed by foreign countries are based on transparent frameworks used to ensure that health products entering the market are at a price that reflects their value and the respective payer affordability.

Two routes to raising drug prices internationally

The WTO and pharmaceuticals

Since its establishment in 1995, the WTO has been the main multilateral organization in aiming to maintain transparent and fair international trade, while lowering tariffs. This includes pharmaceutical products as the WTO's 1995 Pharmaceuticals Agreement called for the elimination of tariffs on pharmaceutical products [20,21]. The function and activities of the WTO rests on legal principles, stemming from the WTO's founding agreements (mainly[1] GATT,[2] GATS, and[3] TRIPS). Among these principles lies that of nondiscrimination. According to nondiscrimination, a state must treat all of its trade partners as it treats its 'most favored nation,' i.e. its most favored trading partner. In other words, tariffs applied to one country must be applied to all others, ensuring that no country discriminates against another, in terms of trade.

Applying this nondiscrimination principle to pharmaceuticals, this means that if there ever were tariffs imposed by one state on another, they would also have to be applied to all of its trade partners. Assuming that other countries respect the nondiscrimination principle, it is impossible for them to discriminate against the US in terms of drug tariffs, without giving the same treatment to other nations. However, there are few tariffs on pharmaceuticals [20], and tight HTA regulations in most countries ensure that new medical products are treated equally in their evaluation, no matter their provenance. President Trump's claims that other countries discriminate against the US by deliberately setting low prices for American drugs, is not consistent with current practice as drug market access regulation apply equally to all drugs including domestic ones in most US allied countries. As such, the Trump administration cannot ask countries to modify

[1]GATT = General Agreement on Tariffs and Trade.
[2]GATS = the General Agreement on Trade in Services.
[3]TRIPS = the Agreement on Trade-Related Aspects of Intellectual Property Rights.

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their HTA rules via the WTO, as they are already nondiscriminatory. President Trump claims that non-tariff measures – meaning direct price influencers such as export subsidies or exchange rate manipulations [22] – are being used to discriminate against US pharmaceutical products will not be receivable by the WTO.

Currently, drugs in allied countries are subject to very low or no value-added tax (VAT). The customs drug tariffs are usually nonexistent or if applied, are low. President Trump's argument of American discrimination based on tariffs will likely not be considered valid by WTO. Therefore, the US is unlikely to pursue legal action through the WTO: the nondiscrimination principle will swiftly rebuff American claims, since countries treat equally medical products from the US and ex US, from both tariff and non-tariff perspective.

President Trump's move from multilateralism to bilateralism

President Trump's vision of multilateralism

Since Donald Trump has taken office, he has been vocal and swift in his decisions to resign from significant multilateral agreements for one major underlying reason: these agreements are not beneficial to American citizens. All multilateral agreements and their effects are summarized in Table 2. Accordingly, only three days after taking office (23 January 2017) [23], President Trump withdrew the US from the Trans-Pacific Partnership (TPP), which aimed to regulate copyrights and patents while facilitating trade between the numerous signatories. Shortly thereafter, the President withdrew from the Paris Agreement (1 June 2017) [24], which ambitioned to manage climate change multilaterally. The President then halted negotiations with the EU on the Transatlantic Trade and Investment Partnership (TTIP) (21 January 2017) [25–27]. Finally, President Trump announced the US' withdrawal from the United Nations Educational, Scientific and Cultural Organization (UNESCO) (12 October 2017) [28–30], which will take effect in December 2018. These examples reflect a desire to retreat from multilateralism, which is to be replaced by the Trump administration with bilateral agreements and interpersonal negotiations.

The most striking example of the American shift from multilateralism to bilateralism, is the North American Free Trade Agreement (NAFTA) (27 August 2018) [31], which includes the US, Canada, and Mexico. President Trump has been vehemently critical of NAFTA, suggesting the US would withdraw from the Agreement. This had the effect of luring Mexico into bilateral negotiations with the US over a new trade deal (27 August 2018) [32–34]. President Trump then warned Canada that it risked being left out of a new deal between the three countries if it did not negotiate [35–37]. By strong-arming Canada into negotiations, the Trump Administration has succeeded in replacing NAFTA with the USA-Mexico-Canada Agreement (USMCA). While this is a three party agreement, the Trump administration was able to succeed in establishing the USMCA by leveraging bilateral negotiating.

President Trump is simultaneously disregarding the supposed unity of the European Union (EU) and instead has been approaching each EU member directly in bilateral settings. He has expressed his openness to a valuable trade deal between the UK and the US, should Theresa May lead a hard, no deal Brexit. However, with a new prime minister (PM) set to replace Theresa May and the majority of members of parliament voting against a no deal Brexit, a new PM could attempt to bypass this by suspending parliament [38–40]. Boris Johnson, the newly elected PM, may attempt to execute a no deal Brexit, however, in light of his recent criticisms of President Trump, it is unclear whether a bilateral agreement will be reached or a bilateral relationships truly established between the two [41,42]. The Trump Administration has also indirectly threatened Germany Chancellor Angela Merkel to impose tariffs on German cars. Since then, Chancellor Merkel has been lobbying her European partners to remove tariffs on cars altogether [43], reflecting the influence that the US President can have on European countries. The Trump administration has even flirted with Poland and Hungary to spawn bilateral negotiations outside of the EU framework. Poland has formally requested

Table 2. Multilateral agreements withdrawn from or halted by the Trump administration.

Agreement	Date of Withdrawal or Halt	Effect
TTP	23 January 2017	Deregulation of copyrights and patents
Paris Agreement	1 June 2017	America relinquished climate control responsibilities
TTIP	21 January 2017	Pres. Trump halted talks with the EU
UNESCO	12 October 2017	US will maintain a non-member observer status
NAFTA (now the USMCA)	31 August 2018–1 October 2018	Pres. Trump has replaced NAFTA with USMCA
NATO	July 11–12, 2018	Pres. Trump threatened to withdraw, if other countries do not increase their defense spending

TPP = Trans-Pacific Partnership, TTIP = Transatlantic Trade and Investment Partnership, UNESCO = United Nations Educational, Scientific, and Cultural Organization, NAFTA = North American Free Trade Agreement, NATO – North Atlantic Treaty Organization, USMCA = USA-Mexico-Canada Agreement.

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that the US establish a military base called 'Fort Trump' on their territory, while offering to pay 2 billion dollars for this facility [44]. In fact, this has been a trend in President Trump's foreign policy: suggesting that allies pay, in return for American military protection. This was most visible at the 2018 NATO Summit, in which he ordered other countries to increase their defense spending: the other states accepted. It is no coincidence that President Trump has also had success in negotiating with South Korea and Japan, who rely on the US for protection from North Korea. The President suggested that they pay for American protection, amidst rising tensions between the US and North Korea. In the renegotiations of the Free Trade Agreement (FTA) with South Korea, the US obtained numerous concessions. Japan also seems to have succumbed to bilateral pressure, as will later be discussed. American dominance over Japan, as well as Korea, was noticed when these two countries ceased oil imports from Iran altogether, under American pressure [45].

The issue with Iran humbled even larger powers. France, the UK, and Germany saw their companies leave Iran, the most emblematic example being that of Total, who relinquished one of the biggest natural oil reserves in the world [46]. In fact, European states will also likely find themselves subject to being pressured into concessions because of American military protection. During the Libyan war, within just days, France and the UK had exhausted their rockets and depended on US supplies daily to pursue their military operations [47,48]. The French and UK armies could not defeat disorganized Libyan opponents without American support, revealing European states' striking military dependence on the US. President Trump aroused fears over this dependence when he publicly raised doubts about German sovereignty and its affiliation to Russia. Germany is likely to be President Trump's first target in Europe. In response, while acknowledging the US pressure, the German Chancellor Merkel declared there are no alternative options to reliance on US military protection, thus, disagreeing with French President E. Macron who advocated for a need of an EU military independent force to protect EU member states.

American negotiations, under President Trump, have taken a turn towards bilateralism. While multilateral negotiations take time, coordination, and require alliances, a bilateral approach seems to bring quicker, more apparent results with less resistance, and best reflects President Trump's personality. President Trump's predecessors defended American interests with some restraint, while the Trump administration currently does not hesitate to apply the full weight of American power on its counterparts. Indeed, there is a recurring pattern of achieving commercial concessions from US allies, in exchange for American military protection, whether it is implicit or explicit. This may undermine American influence abroad in the long run, but from a short-term perspective, it is enabling the world's dominant power to impose its demands on foreign nations, notably on allies.

Bilateralism and pharmaceutical trade agreements

President Trump is caught between two conflicting interests. While lowering US drug prices is one of his electoral promises, which will be evaluated during the next elections, there remains the pharmaceutical industry lobby, PhRMA, one of the major lobbies in Washington D.C., which generally focuses on obtaining the support of Republicans [49]. President Trump cannot directly act on drug prices domestically without upsetting either his voters or the pharmaceutical industry; his focus is, thus, directed at American drug prices abroad, which the Trump administration claims will translate into lower prices back home. From this lens, raising drug prices abroad is understandably an important objective for President Trump.

The case of South Korea is the most informative, as negotiations have already concluded. President Trump suggested Korea pay for American protection when tensions with North Korea were escalating. Shortly, thereafter, South Korea accepted to renegotiate its FTA with the US, which notably resulted in a pledge from South Korea to ensure 'fair treatment for US pharmaceutical exports,'[50] amongst other concessions. The US international Trade Commission interprets this to mean that US exports of pharmaceuticals to South Korea are likely to increase, as are their prices [51].

Negotiations with Japan offer an interestingly different model. Whilst with Korea, ongoing progress was made public, agreements between President Trump's administration and Japanese Prime Minister Abe's administration, seem much more implicit. Indeed, bilateral negotiations are, by nature, surrounded by secrecy and may include non-written, spoken agreements that arise between leaders over diverse issues, including pharmaceuticals. In 2017, Japan announced its intention to lower drug prices [52]: this was highly contested by the US [53,54]. The US Embassy reportedly intervened regularly in discussions over drug prices, generally asking that the revision of prices be halted. Well-informed local sources suggested that pharmaceuticals have been at the heart of all negotiations between Japan and the US. After a meeting with President Trump, Japanese Prime-Minister Abe and Health Minister Kato postponed the implementation of a Japanese HTA agency by two years; the HTA agency would have acted as a price erosion measure of pharmaceuticals. Some experts have highlighted and questioned the temporality of President Trump's visit and the delay in HTA implementation. Poland has also experienced direct pressure from the Trump Administration on drug pricing

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and reimbursement. In October of 2018, Roche and Genentech's Tecentriq® received a negative reimbursement recommendation from the Polish HTA body, AOTM. In response to this negative recommendation, the US ambassador, Georgette Mosbacher, personally wrote a letter to the Polish Ministry of Health, expressing the unfair treatment of the US and its products. Two months following the receipt of this letter, Tecentriq® was found to be included on the Polish National Health Fund's (NFZ) reimbursement list, despite having a high cost and 'extremely unfavorable' pricing for the NFZ [55–57]. Furthermore, it is not uncommon for the US to threaten the Polish NFZ, as well as other foreign national health payers, by refusing to sell the drug on their market, if the price set for the drug in Poland or the respective foreign country is perceived as less than favorable. In response, the NFZ has agreed to the reimbursement of US products, even if the product was deemed to be not cost-effective by respective HTA agencies; ultimately, the NFZ succumbs to these threats and pressures in order to provide patient access to these drugs and therapies [58]. Therefore, the direct pressure by US representatives on its trade partners has resulted in clear action taken by trade partners, favorable to the US and US products to facilitate market access.

The other countries targeted by President Trump are publicly less clear – or perhaps they are also very implicit. After President Trump clearly announced his plan to increase drug prices abroad, the UK government and the NHS firmly maintained that drug prices will continue to abide by specific regulations and are, therefore, non-negotiable [49]. However, with a no deal Brexit looming over its head, the UK government may eventually have to bow down to the Trump administration's wishes, if the new PM is insistent and forceful enough to suspend Parliament to push the no deal Brexit through. The need for a US-UK trade deal would then become imperative for the UK. In such a trade deal, with a weakened UK, the US could obtain heavy concessions [59,60], including those on pharmaceuticals. A similar approach was taken with Canada and Mexico. Mexico was lured into negotiations over a new NAFTA deal, and Canada found itself isolated and forced into negotiations. The Trump administration was successful in replacing the NAFTA deal with the USA-Mexico-Canada Agreement (USMCA), which also addressed pharmaceuticals, the implications of which are most recently being analysed [61]. The EU will also become a target of the Trump Administration.

The Trump administration has, thus far, experienced relative bilateral success in influencing Japan, Korea, and Germany into action, but it has also experienced resistance from the UK with France likely to follow suit. While the Trump administration faced initial resistance from Canada, ultimately the US was able to establish the USMCA. Additionally, the EU may have only little room to maneuver in front US super-power. President Trump will continue relying on his bilateral approach to increase drug prices abroad. Military protection will be his main tool to leverage, one which few of the targeted nations can neglect.

Discussion

President Trump and the WTO for pharmaceutical pricing

It is unlikely for a legal route via the WTO to serve US interests. The nondiscrimination principle entails that one country cannot discriminate against a particular state's products; as such, it is impossible to set lower prices for American products specifically. Furthermore, in countries that have HTA bodies, and drug pricing committees, as previously mentioned, prices are well structured, transparent, and based on scientific grounds rather than the product's origin, further rendering discrimination against US products improbable. No discriminatory tariff could be argued. Legal action from the US would be rebuffed: President Trump's theory of countries freeloading off of American investments and innovation will, therefore, most likely not find a solution via the WTO.

President Trump's bilateralism and pharmaceutical manufacturers

Under President Trump, American foreign policy has undergone a shift from multilateralism to bilateral negotiations. In multilateralism, super-power countries must establish allies to support their position and goals. In a multilateral setting, the Trump administration needs to treat its allies in a more constructive manner. In a bilateral context, an ally's voice becomes void and the Trump administration levers security against commercial concessions, which may prove effective beyond the already successful cases. President Trump goes beyond foreign policies in a bilateral approach and commercial segments, such as the pharmaceutical industry, are in his scope.

Pharmaceutical manufacturers from Germany, as well as from Switzerland, including Roche, Bayer and Merck KGaA, have engaged in price freezes for their drugs [62]. While this does not mean that any official policy has been adopted to raise drug prices, it could be interpreted as influential non-tariff measures used to leverage a deal in favor of supporting President Trump's plan to reduce US drug prices at home by ending global freeloading. After President Trump dissuaded Pfizer from increasing drug

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prices, Novartis, Bayer, and AstraZeneca followed suit [62–65]. This voluntary pattern of decisions may also reveal a strategy from manufacturers to request counter measures in return for the increase of ex USA prices of drugs applied by the Trump administration, including an interdiction of discounts to intermediates along the chain from manufacturers to patients was also considered.

Innovation and research and development

President Trump's APF blueprint initially stated that foreign countries are free-riding off of American innovation and investment. In an attempt to fairly share the cost of innovation, the Trump administration wants to raise drug prices abroad. However, it remains unclear whether or not this will directly translate into lowered costs back home for Americans. Without drug prices being lowered in the US as drug prices are being raised abroad, it is unclear how this will translate into a fair sharing of pharmaceuticals expenditures – in fact, it even seems unlikely. It also begs the question whether high drug prices will mean more investment in research and development for these innovative therapies, or whether it simply means additional profits for major pharmaceutical companies.

As such, the techniques used to affect drug prices described in this paper, do not address the issue of initially highly priced drugs in the US, and the American health market structure. All in all, there are doubts concerning the link between the actions undertaken by President Trump, and his initial objective of lowering drug prices at home.

Potential ex USA reaction and actions

Ex USA countries may still try to resist drug price increases. In order to prevent price increases in a bilateral setting, foreign countries may have to give in to the USA in another field or industry. However, this may not be satisfactory for the Trump administration as it has committed to stop freeloading and to obtain drug price increases ex USA, explicitly. Moreover, the Trump administration adamantly believes in a direct link between raising drug prices abroad and lowered drug prices back home, even though there has been doubt expressed on this direct link [3].

To combat price increases, a reduction in the reimbursement rate for foreign national health insurance (NHI) may be pushed for. However, as the scope of medicine is already considered expensive in most countries abroad where they are reimbursed at a 100% rate by law, reimbursement reduction may not be an option. Therefore, it may be suggested that an increase in NHI premiums follow suit, yet this is already very unpopular, especially as these premiums are already perceived as too high in many countries. In this case, patients may refer to supplementary private insurance, which ultimately means a transfer of cost to patients, who already consider that they are paying too much. Other possibilities to combat drug price increases is to restrict access by not granting reimbursement to the full indication, but only to specific populations that have the highest needs for this product or to entirely delay reimbursement of the drug.

Ultimately ex USA, the price increase is likely and may be very difficult to mitigate. This will weigh heavily on NHI budgets and may significantly deepen existing deficits. Beyond budget impact, drug price increases will likely be associated to restricted access and, therefore, drive the universal health coverage toward a dual coverage set up, public and private insurances, for the wealthiest population who can afford to do so, ultimately increasing inequity. An additional effect of varying degrees of influence by the USA and the varying degrees of resistance from foreign trade partners, may be that overall prices will remain high, just reduced at various levels. Therefore, the various list prices across countries and varying degrees of resistance may influence the traditional launch sequence of products, by driving manufacturers to launch in countries with the highest reimbursement rates and highest prices, followed by lower reimbursement rates and prices, establishing a new, more simultaneous launch approach, yet based on the USA's bilateral approach and power over trade partners.

Conclusion

The objective of raising drug prices ex US is attainable and likely to happen. The Trump administration will not pursue any legal route via the WTO due to their non-discriminatory principles as well as strict public health regulations in foreign states that cannot be challenged. President Trump, without hesitancy, will continue to seek success in pressuring foreign countries and leaders to succumb to US demands by leveraging bilateral negotiation settings and applying economic and political pressure on its trade partners. In a bilateral negotiation setting, the US has the high ground and will continue to have the upper hand due to their dominant position on all fronts – economically, militarily, and diplomatically. Most recurrent, is the strategy of using security as a lever to obtain trade benefits. Briefly put, President Trump monetizes defense in exchange for commercial concessions, including pharmaceuticals. Accordingly, most of his counterparts, such as the EU, Canada, Japan, and Korea rely on the US for their homeland security, a power imbalance that the Trump administration

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exploits. This analysis supports a high likelihood that drug prices will increase ex USA before the end of President Trump's mandate. An important point to stress is that no matter the route taken by President Trump, its effects will outlast him. This is due to a general inertia within policy makers and the US administration, as they will defend a cause for which they have worked for under President Trump. However, in this particular approach, it is unclear whether President Trump's actions will yield any direct, long-term effects on pharmaceuticals cost reduction for American patients; most experts doubt that this will be the case. Yet, raising prices of pharmaceuticals ex USA may have a significant impact on the deficit of national health insurance systems, potentially leading to significant restrictions of access to innovation for patients. Sustainability of the national health insurance system is already questioned by policy makers in many countries. An increase of pharmaceutical expenditures may lead to dramatic changes of insurance policies favoring a development of two levels of insurance and enhancing inequity in access, especially across Europe, with Japan potentially forced to revise its universal generous coverage policy.

Disclosure statement

No potential conflict of interest was reported by the authors.

ORCID

Cyprien Milea http://orcid.org/0000-0002-3784-7200
Mondher Toumi http://orcid.org/0000-0001-7939-7204

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