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## **Exporting Monopoly Rules Does Not Lower U.S. Prescription Drug Prices**

### ***Forcing higher prescription drug prices in other countries will not lower drug prices in the U.S.***

Reports suggest that one of the policies under consideration by the Trump Administration task force ostensibly working to find policy solutions towards lowering drug prices is to lengthen prescription drug monopolies in foreign countries to ensure “that American consumers do not unfairly subsidize research and development for people throughout the globe.”<sup>1</sup>

It has been a longstanding goal of multinational prescription drug corporations to expand monopoly rules in place in the U.S. and other high-income countries to lower- and middle-income countries through multilateral fora as well as regional and bilateral trade agreements. Despite the success of the prescription drug corporate lobby in expanding monopolies globally through the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>2</sup>, the North American Free Trade Agreement (NAFTA)<sup>3</sup>, the Central America Free Trade Agreement (CAFTA)<sup>4</sup>, and numerous other international agreements, drug prices in the U.S. have not been reduced.

It is folly to believe that making other countries – many that would face even worse health consequences from high drug prices than those experienced in the U.S. – pay more for medicine by requiring longer and stronger monopoly periods would do anything to make medicine more affordable here. Higher international prices would not diminish domestic pharmaceutical greed or monopoly pricing power, but they would lead to unnecessary suffering and death in lower- and middle-income countries.

### ***Monopolies drive high drug prices***

The Department of Health and Human Services estimates that Americans will spend more than \$500 billion on prescription drugs in 2017.<sup>5</sup> The vast majority of that amount will be spent on brand name drugs protected by government-granted monopolies.

Expanding monopolies in other countries will not lower prices for Americans because it would not address the rules providing monopolies here or other rules shaping the prescription drug market in the U.S. that enable price gouging.<sup>6</sup> Generics make up 89 percent of the prescriptions dispensed in the United States, but only account for 26 percent of prescription drug spending.<sup>7</sup> The Food & Drug Administration’s (FDA) analysis of generic competition and prescription drug prices has shown that robust generic competition dramatically reduces prices relative to that of the brand name product.<sup>8</sup>

Legislation proposing an additional six months of marketing exclusivity for a limited set of products alone could cost Americans at least \$3.9 billion, and could easily reach \$11.6 billion.<sup>9</sup> The Federal Trade Commission (FTC) found that reverse payment (i.e. pay-for-delay) deals that delay competition cost Americans \$3.5 billion annually.<sup>10</sup> Another study showed that abuses of the FDA’s Risk Evaluation and Mitigation Strategies (REMS) program—that unduly delay and prevent generic competition—cost Americans \$5.4 billion annually.

### ***Claims that R&D justifies exorbitant U.S. prices are not borne out by evidence***

Current high prices in the U.S. are not justified by R&D costs, and making other countries pay more will not make R&D justifications for high prices any more valid. A recent report by the U.S. Department of Health & Human Services found that pharmaceutical corporations set prices not because of R&D spending, but to maximize profits.<sup>11</sup>

Similarly, the bipartisan investigation into Gilead's pricing of the hepatitis C treatment sofosbuvir (brand name Sovaldi) found that "[a] key consideration in Gilead's decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price."<sup>12</sup>

Prescription drug corporations receive 176 percent of their *global* research and development costs from the pricing premium that Americans pay for prescription drugs beyond prices in other wealthy countries alone.<sup>13</sup> Pharma firms regularly spend more on sales and marketing than they do on research and development.<sup>14</sup> And even by their own measures, pharma's corporate profits exceed what they spend on R&D – in 2015, the 20 largest pharmaceutical corporations recorded *profits* (not revenues) of 134 percent what they spent on R&D.<sup>15</sup>

### ***Exporting pharma monopolies punishes countries with public health crises***

In 1996 after substantial government funding, the first effective combination therapy for HIV/AIDS hit the market at \$12,000 a year. At the height of the HIV/AIDS epidemic in South Africa—with nearly 7,000 people dying a day worldwide—PhRMA and 39 other multinational corporations sued Nelson Mandela and the government of South Africa for providing affordable HIV/AIDS treatment.<sup>16</sup>

At the behest of these companies, the U.S. government threatened to withhold trade benefits and to impose sanctions if the South African government did not permit pharmaceutical companies to set whatever price they wanted. Between 1998 to 2001—when public pressure finally forced the companies to drop the litigation—690,000 people died from HIV/AIDS in South Africa alone.<sup>17</sup>

Today, 17 million people are receiving treatment, largely thanks to generic competition lowering drug prices to \$100 a year.<sup>18</sup>

### ***The current impact of international expansion of monopolies on global health***

Expanding pharma monopolies in developing countries would fuel the spread of new epidemics and inflict suffering on people living on less than \$2 a day. Today, one-in-three individuals living in developing countries still lacks access to the most basic of essential medicines—including antibiotics and vaccines.<sup>19</sup>

Despite supporting human rights standards that guarantee a right to health, current U.S. trade policy already limits individuals' access to essential medicines by expanding pharmaceutical monopolies.

By threatening additional trade retaliation and further expansion of monopoly rules internationally, the U.S. only further limits access to lifesaving medicines for vulnerable peoples and threatens the lives and safety of people abroad, while further entrenching prescription drug monopoly rules at home.

### ***The real solutions***

Instead of allowing prescription drug corporations to dictate foreign policy and continue to price gouge Americans, Public Citizen supports a comprehensive package of reform measures to increase generic competition and lower drug prices for all Americans. The *Improving Access to Affordable Prescription Drugs Act* (S.771, H.R.1776) increases transparency around drug prices and R&D; allows Medicare to negotiate lower prices for seniors; curbs monopoly abuses and contains a host of other reforms that will actually lower prices in the U.S.<sup>20</sup> The *Stop Price Gouging Act* (S.1369) limits egregious pharma price hikes.<sup>21</sup> These and other serious remedies that restrict the monopoly power of prescription drug corporations are the real solutions that Americans need.

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