

FOREIGN PRICE CONTROLS JEOPARDIZE GLOBAL HEALTH AND RAISE DRUG COSTS FOR AMERICANS

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JULY 2018

COMMITTEE
TO UNLEASH PROSPERITY



Perhaps the most common complaint about the U.S. health care system is that Americans spend more on medical care than the citizens of any other nation without commensurate health benefits. While our health care delivery and insurance systems have many inefficiencies, one element that can drive up costs is global in scope: compared with citizens of other developed countries, Americans bear a disproportionate share of the hundreds of billions of dollars spent each year developing new drugs, vaccines, medical devices, and other life-saving health technologies.

For decades, the world has been free-riding on America's tremendous investment in R&D and medical innovation—including many of its richest nations. In this study, we demonstrate that this free-rider problem has two negative effects for global health:

- First, it unfairly imposes costs on American consumers, who are unwittingly subsidizing the rest of the world. President Trump talks about Putting America First, but foreign price controls put America last.
- Second and even more importantly, the free-rider problem hampers advancements in global health. Detailed studies have shown that when other nations artificially lower prices for drugs, vaccines, and other American-made health innovations, it has a negative effect on overall investment for the very R&D that leads to miracle treatments and cures in the first place. A new wonder drug can take more than a decade and as much as \$2.6 billion to produce. Foreign price controls lengthen the time horizon for the pharmaceutical industry to recapture these costs, which leads to underinvestment in global health.¹

In the medium and long-term, price controls are detrimental even to the nations that impose them. Drugs are a much more cost-effective way to treat illnesses compared with more expensive options—such as surgery or hospitalization. By preventing the development of new drugs and creating shortages, price controls can actually raise health care costs in these very countries, in addition to delaying the introduction of life-saving treatments.²

This is a classic “prisoner’s dilemma”, in which every nation has an incentive to lower its own costs by imposing price controls, but everyone is made less healthy and poorer as a result.

Since the U.S. is far and away the world leader in new drug development, with \$75 billion invested each year, Congress and President Trump must act decisively to end unfair foreign practices that endanger human health and progress. As the Trump administration moves forward with renegotiating trade deals, it should demand that other nations honor American pharmaceutical patents, appropriately value American-made innovations, and pay their fair share of the costs associated with producing new wonder drugs.

THE GLOBAL PAYOFF FROM NEW DRUGS AND VACCINES

The benefits of biomedical research and new drug development are self-evident. Longer, healthier lives, less pain and suffering, increased economic growth, lower medical costs, more opportunities for trade and travel—these are just some of the benefits humanity has reaped from the remarkable advances in medical knowledge over the last few decades.

Average life expectancy around the world jumped from 58.6 years in 1970 to 72 years in 2016, while many of the worst infectious diseases have been eradicated or are nearing eradication, including smallpox and polio.^{3,4}

Consider one of the great recent triumphs in medical science: HIV/AIDS research and treatment. This epidemic might well have rivaled the plagues of earlier periods, which wiped out as much as a quarter of the population. Instead, today 19.5 million people with HIV are on life-saving treatment with antiretroviral drugs.⁵

Even more exciting, a new generation of “biologic” medicines, tailored to the individual’s unique physiology, promises to revolutionize treatment of once-intractable illnesses like cancer, heart disease, and diabetes, among others. Already medical technology has contributed to a near 50 percent reduction in age-adjusted death rates from cancer, stroke, and heart disease over the last 50 years. Now scientists are hopeful that within the next 20 years we will see the emergence of cures and treatments for terrible and painful diseases including Alzheimer’s, ALS, Parkinson’s, epilepsy and multiple sclerosis.

These biological breakthroughs are definitely on the horizon. But the pace of this progress is being slowed by inequities in the global pharmaceutical marketplace, which allow a number of rich countries to enjoy the benefits of scientific progress without covering a fair share of the costs.

There’s another unintended and undesirable consequence: because American consumers are forced to cover the cost of free-riders in other nations, political pressure is mounting in Washington to impose domestic price controls as other nations have done. Many Americans complain—with justification—that they have to pay more for a drug than do the Canadians, Europeans, British or Chinese, prompting the Trump administration to investigate ways to lower drug prices at home. But the worldwide movement to impose stricter price controls is nothing more than a beggar-thy-neighbor strategy that risks a massive slowdown in drug development, to everyone’s detriment.

AMERICA’S UNFAIR BURDEN

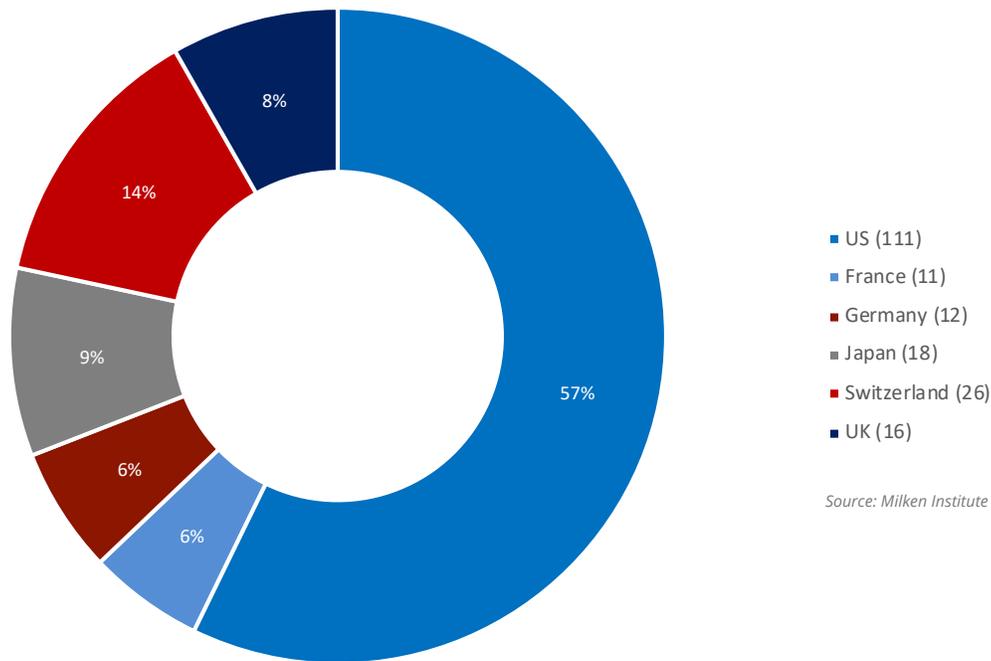
The U.S. accounts for half of global medical spending on R&D, and creates most new treatments— benefits freely shared with the rest of the world.

At the same time foreign governments use a variety of measures to keep drug prices artificially low and export the costs of drug development back to American consumers. They are able to do so because of the unique characteristics of the drug industry. The cost of developing a new drug can run as high as \$2.6 billion, and all the value produced is in the form of intellectual property (IP). Once the drug is developed, the marginal cost of producing one pill or treatment can be less than a few dollars or in some cases, pennies. This is why the patent system is indispensable, enabling companies to profit by developing new drugs and recapturing their R&D costs; without the lure of profits, investors will direct their capital to other endeavors.

Foreigners want to skip the burden of investing in R&D and pay closer to the marginal cost of each additional treatment. Drug companies routinely give away drugs for free through philanthropic and humanitarian initiatives, especially during times of genuine medical emergencies or in developing countries where citizens are far too poor to pay for R&D costs. But of course if every nation did that, the drugs wouldn’t exist in the first place.

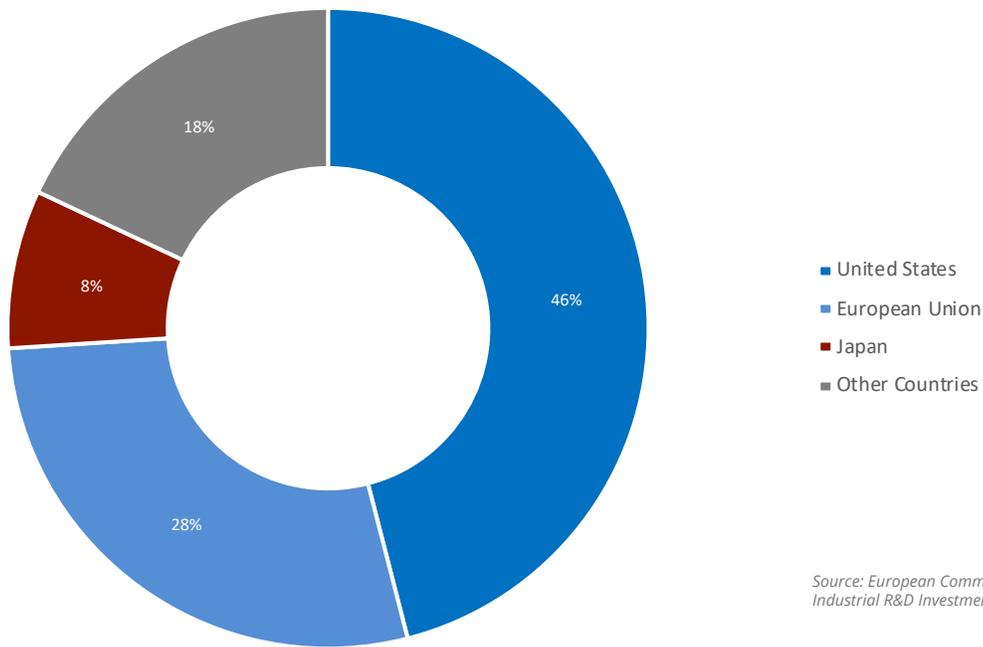
U.S. pharmaceutical companies were responsible for 57 percent of all new drugs discovered from 2001-2010, while according to UNESCO America accounts for 46 percent of all spending on life sciences R&D.^{6,7} This global dominance reflects a number of advantages, including the excellence of America's universities and laboratories, the cooperation of the National Institutes of Health, where much of the basic drug research occurs, a favorable regulatory regime—including strong IP protections—and above all the volume of our domestic market, which operates with few of the price controls prevalent in other rich countries.

NEW CHEMICAL ENTITIES BY HEADQUARTER COUNTRY



Overall, Americans spent \$324 billion on drugs in 2017, equal to 1.7 percent of GDP, for an average expenditure of around \$876 per person.⁸ By contrast the members of the European Union – with a population 58 percent larger than the U.S. – spent just \$250 billion on pharmaceuticals in 2014, for an average per capita expenditure of \$503 at contemporary exchange rates; the highest national expenditure in the EU, in Germany, was \$689 per capita.⁹ It's not just the EU, as other rich countries also spend less than the U.S. on pharmaceuticals: in 2016 Japan spent \$67 billion on drugs, or \$528 per capita, equivalent to 1.35 percent of GDP.¹⁰

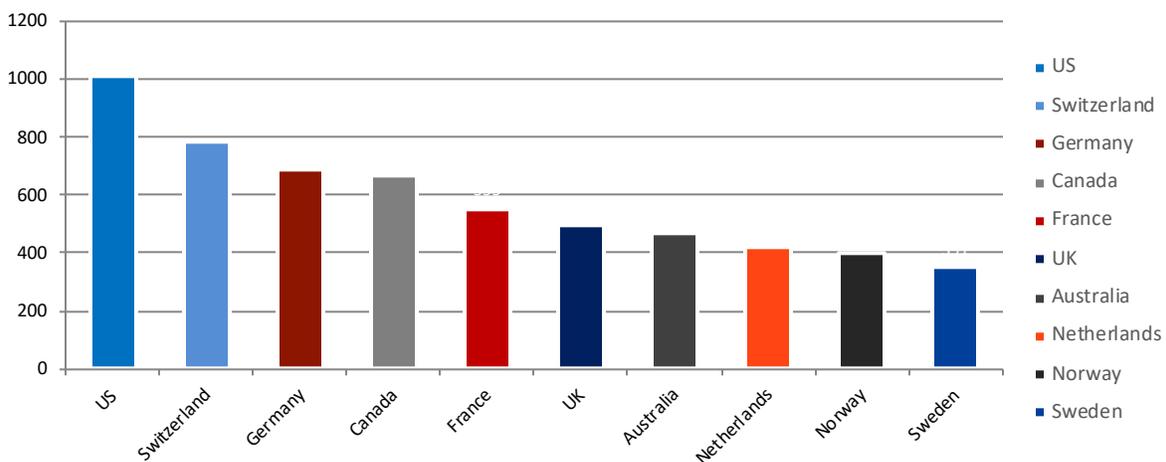
BIOPHARMACEUTICAL R&D SPENDING



Source: European Commission 2016 EU Industrial R&D Investment Scoreboard

How do foreign nations get away with this? These wealthy countries keep pharmaceutical prices depressed with a number of legal and regulatory ploys, such as reference pricing, which pegs prices of new medicines to an international average or lowest price, often calculated based on developing countries that have already instituted price controls (and don't have the ability to pay as wealthier nations do) or based on prices of older medicines; revenue and profit "clawbacks," forcing drug makers to give rebates after a certain amount of spending has been reached; and, when no other plausible pretext can be found, arbitrary price cuts and volume caps.

PER CAPITA PHARMACEUTICAL SPENDING (2015)



U.S. per capita figure reflects list prices before standard rebates and discounts.

Source: FDA / OECD

Unsurprisingly, R&D spending in these countries is also markedly lower than in the U.S. In 2015, American pharmaceutical companies invested \$75 billion in developing new treatments and cures, up 10.3 percent from the year before.¹¹ That works out to a per capita investment of \$233. For comparison, that same year the European pharmaceutical industry spent around \$37.3 billion, for average per capita spending of \$73 on R&D.¹²

COMPETITION IS THE KEY TO LOWER PRICES

Developing new drugs is a costly business, requiring an average \$2.6 billion of R&D spending for each new treatment that receives approval. At the same time, the drugs developed by U.S. pharmaceutical companies are truly beneficial to all global citizens, as all people are susceptible to the ailments medicines are designed to treat.

To equalize the costs of drug development, the Trump administration has proposed a series of reforms to lower drug prices for Americans. Here's where innovation deserves another look, because pharmaceutical R&D isn't just the key to unlocking new cures: it's also one of the main ways of reducing prices for existing drugs, by encouraging competition in the marketplace. Conversely, while some of the White House's proposed reforms make sense, there is a danger that lowering prices and thus profits with artificial price controls here at home will chase investment outside the U.S. and slow the development of new drugs.

In fact, this could paradoxically raise health care costs for several reasons. First, research has shown that the entry of a new drug into the marketplace, often with additional benefits in the form of increased efficacy or tolerability, forces down the prices of other drugs in the same therapeutic class—even before their patents have expired. This is because, as physicians begin to sign prescriptions for the new entrant, insurers, pharmacy benefit managers and other intermediaries take advantage of this new competitor product to negotiate better deals for existing drugs. Similarly the introduction of several “me-too” or “follow-on” drugs with comparable efficacy diminishes differentiation for each, reducing the price premium drug makers can demand for them.^{13,14,15}

One of the most spectacular examples of the impact of new entrants on drug prices in recent years came in the fast-growing field of Hepatitis C treatments. Following Gilead's introduction of the breakthrough Hepatitis C cure Sovaldi in 2013, competitors rushed a number of drugs exploiting the same underlying biological mechanism to market, resulting in dramatic price drops across the entire therapeutic class. This competition has resulted in rebates and discounts ranging from about 22 percent in 2014 to about 40-65 percent today.^{16,17} This analysis doesn't include the overall cost savings projected from curing 2.9 million Americans with chronic Hepatitis C, including hospital stays and transplant costs, estimated at \$100.3 billion in the U.S.¹⁸

Hepatitis C drugs are just one of the more dramatic cases of new entrants bringing down prices by offering cheaper alternatives in the same therapeutic class. One study found that seven new “follow-on” drugs developed to treat conditions including non-Hodgkin's lymphoma, ovarian cancer, psoriasis, and Huntington's disease offered discounts over the incumbent drug ranging from 21 percent to 61 percent.¹⁹

It should be emphasized that these price reductions were achieved without resorting to artificial price controls and while all the competing drugs still enjoy patent protections, preserving marketplace incentives for continued innovation. These beneficial effects can be achieved relatively rapidly: the average time required to develop a “follow-on” drug has fallen from nine years in the 1970s to 1.7 years today. In fact, it’s not uncommon for competitors to develop follow-on drugs and file to begin clinical testing before the original drug has even received final FDA approval.²⁰

GLOBAL GOODS, GLOBAL RESPONSIBILITY

A growing body of research makes it possible to calculate the effects that foreign price controls have on R&D and drug accessibility, as well as the impact that more equitable drug pricing would have on innovation, and with it, the life expectancy of health consumers both in the U.S. and abroad. These gains, in turn, would yield long-term economic benefits resulting from decreased disease and mortality.

A study published by the U.S. Department of Commerce in 2004 found that foreign price controls in just a small number of OECD countries had reduced R&D funding by between \$5 billion and \$8 billion per year, or 11 percent to 16 percent of privately funded R&D worldwide, preventing the development of three to four new drugs annually. The research also confirmed that increased revenues and free cash flow are directly correlated with increased R&D spending, predicting that increased R&D would result in lower costs for U.S. consumers by fostering competition between new and existing classes of drugs, driving down the prices of the latter.²¹

Another study by the Boston Consulting Group estimated that by depressing global pharmaceutical R&D, price controls in OECD countries had prevented the development of 35 to 40 new drug classes over the previous decade. The study also found that price controls are correlated with reduced or delayed patient access to new treatments in those markets, producing additional negative economic impacts including increased costs from emergency room visits and hospital stays. Finally, the BCG research agreed with the Commerce Department finding that price controls abroad result in higher prices for U.S. consumers, due to the absence of competition between existing drugs and new treatments foregone due to price controls. The researchers concluded that, “By imposing government cost controls on prices and restraining the market penetration of innovative therapies in their home markets, OECD governments are, in effect, sharply reducing the global returns to pharmaceutical innovation and the global pool of cash available for research on new medicines.”²²

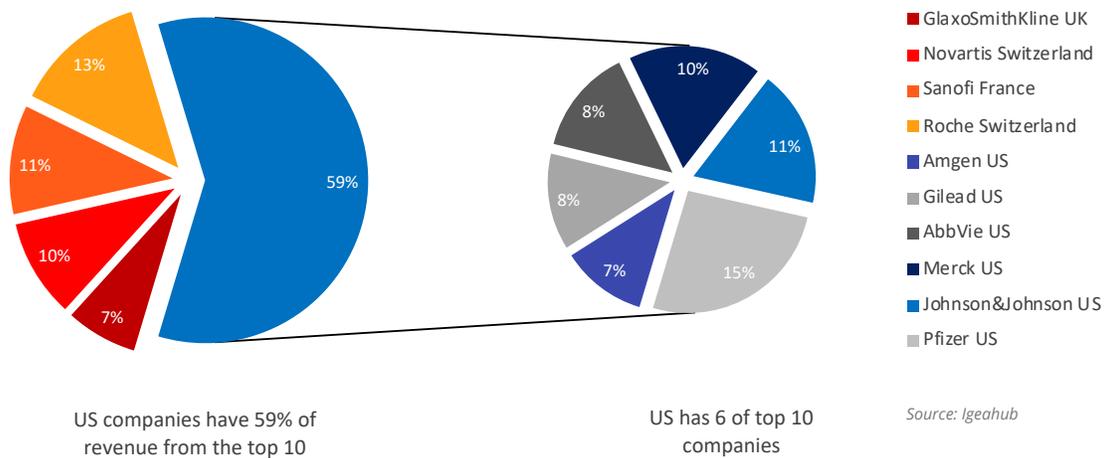
More recently, researchers have predicted the impact of reducing or eliminating foreign price controls using a model developed with support from the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the World Economic Forum, among others. If OECD countries lifted price controls altogether, the study estimated the resulting increase in pharmaceutical R&D investment would yield eight to 13 new drugs per year through 2030, increasing the average life expectancy of a 15-year-old individual living in the U.S. today by 1.1 to 1.6 years (while adding 0.6 to 0.9 years to the life expectancy of a 45-year-old). The benefits aren’t limited to the U.S., as eliminating price controls would also result in substantial gains in longevity in other countries as well. The potential economic gains from increasing longevity run into the trillions of dollars worldwide.²³ Other recent research has found similar trends.²⁴

PHARMACEUTICAL R&D'S ECONOMIC CONTRIBUTION

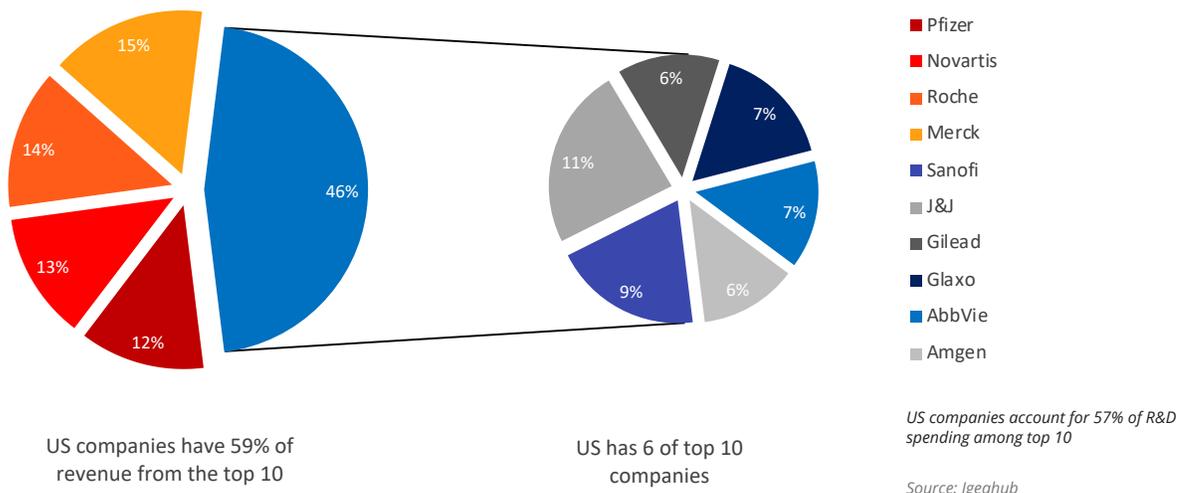
In addition to its central role in driving innovation, the scale of pharmaceutical R&D makes it a mainstay of the U.S. economy, generating high-paying jobs and adding to the nation's stock of IP, the lifeblood of the modern information economy.

U.S. drug makers rely more on R&D than their foreign counterparts, reflecting their greater focus on innovation, with an "R&D intensity" (a measure linking R&D to economic output) of 17.1 percent for the U.S. pharmaceutical sector overall, compared to 13.1 percent in Europe and 13.3 percent in Japan.²⁵ That also puts pharmaceuticals ahead of all other American economic sectors in terms of R&D intensity, beating out computers and electronics, software, and aerospace.²⁶

TOP 10 DRUG COMPANIES BY 2017 PHARMACEUTICAL REVENUE



R&D SPENDING AMONG TOP 10 COMPANIES



This focus on innovation translates into around 290,000 jobs for Americans employed by the pharmaceutical manufacturing industry, and more than 800,000 jobs in the broader biopharmaceutical industry. These employees enjoy average annual employee compensation of \$129,527, compared to a national average of \$58,603.²⁷ The pay premium extends to virtually all subsectors within the pharmaceutical industry, with an average annual wage for workers employed in production at U.S. drug makers that is 16% higher than the national average for all manufacturing production occupations.^{28,29} The U.S. drug industry also contributes to a larger network of secondary employment, with each pharmaceutical job supporting five additional jobs in other sectors, spanning categories like manufacturing, food service, retail and childcare.³⁰

Among American “IP-intensive” industries, pharmaceuticals lead the way in terms of export value, with global exports of \$51 billion in 2017.³¹ It’s also a growth industry, as the U.S. share of the expanding global pharmaceutical market is projected to increase from 40.3 percent in 2015 to 41 percent by 2020.³² Once again, this analysis doesn’t address the wider economic benefits for both the U.S. and the world resulting from longer, healthier lives, such as reduced medical costs, fewer lost work hours, increased educational attainment, and so on.

PAYING FOR INNOVATION REQUIRES SHARED COSTS

There is little question that America is seeing a voter backlash against what are perceived as high prices for drugs and other medical products. There are a number of ways to bring efficiencies and competitive forces into our medical delivery system that would sharply cut costs for hospitalization, treatments, physician services and drugs. But part of the solution has to be a more even global reimbursement of biomedical research costs. As the U.S. seeks more equitable treatment from trade partners—most importantly, a reduction of trade barriers against American products across a range of categories—trade negotiators must push for a fairer distribution of the costs for pharmaceutical R&D, starting with the suspension of price controls in foreign countries.

While foreign governments employ all kinds of regulatory ruses and bureaucratic smokescreens to artificially depress drug prices, rolling back a handful of the worst distortions would go a long way towards restoring transparency and reciprocity to the global pharmaceutical marketplace. These include:

1. Compulsory licensing as usually practiced refers to national governments stripping drug makers of patent protections for new drugs on trumped-up grounds of a “national emergency,” without the need to first seek a voluntary compromise with patent holders, allowing their domestic drug makers to produce generic versions when no real emergency exists. India for example has used compulsory licensing to build its lucrative generic drug industry, which sells the generic versions for a substantial profit as well as for export, giving the lie to the alleged emergency and cost concerns.^{33,34,35}
2. International reference pricing is another deceptive strategy in which rich countries peg prices to an average or even lowest price drawn from a “sample” of other countries, typically excluding “outliers” on the high end (that is, their peers in the developed world) while stacking the figures with low-income countries and countries that have already adopted onerous price controls.³⁶ In addition to deterring innovation this has been found to delay introduction of new drugs in countries that implement it by over a year.³⁷

3. Health technology assessment (HTA) describes various systems for evaluating the clinical and cost-effectiveness of new drugs, which informs the price set by the government as well as health rationing decisions. However HTA is rendered incoherent by the absence of a rigorous methodology, based on empirical findings and consistently applied, leading the U.S. to disband its Office of Technology Assessment in 1995.^{38,39,40,41} This incoherence allows assessors to formulate their own, arbitrary measures for cost-effectiveness.⁴² According to research commissioned by the European Union, HTA as currently practiced “contributes to impeded and distorted market access, leading to... negative effects on innovation.”⁴³
4. Therapeutic reference pricing compares the effectiveness of new and existing drugs for the same conditions, grouping them in broad “therapeutic reference classes” to justify price controls on new treatments on the grounds that they are interchangeable with older ones.⁴⁴ This unsophisticated approach typically fails to recognize incremental advances, as well as variations in efficacy and tolerability among patients and the fact that a single drug can be indicated for different conditions, and further distorts pricing decisions by mixing generic and patented drugs in the comparison set.^{45,46,47}
5. Counterfeiting drugs and vaccines blatantly violates American IP. This is a big problem in nations like China, where IP protections are virtually unenforced.^{48,49} IP is a central pillar of American (and global) prosperity in the 21st century. It is the lifeblood of the modern information economy, and a growing percentage of the value-added that America brings to the global marketplace. Like so many of America’s other IP-intensive products—such as computer software, copyrights, robotics, artificial intelligence, music and movies—our pharmaceutical products require stringent IP protections to be clearly and unapologetically laid out in our trade agreements and vigorously enforced by the Trump administration.

By fostering competition and increasing the number of new entrants to the international drug marketplace, a more equitable system for sharing the costs of pharmaceutical innovation will lead to lower drug prices both in the U.S. and abroad, not to mention increased longevity, higher standard of living, and economic gains measured in the trillions. American innovation is shared openly with the world. Its costs should be too.

Endnotes

- ¹ <https://www.help.senate.gov/imo/media/doc/Aldonas-SenHELP-Rx-2-17-05.pdf>
- ² <https://2016.trade.gov/td/health/phRMA/PhRMA%20-%20ANNEX%20D.pdf>
- ³ <https://data.worldbank.org/indicator/SP.DYN.LE00.IN>
- ⁴ <https://www.weforum.org/agenda/2017/05/7-deadly-diseases-the-world-has-almost-eradicated/>
- ⁵ <https://news.un.org/en/story/2017/07/561942-aids-related-deaths-decline-195-million-people-life-saving-treatment-un-report>
- ⁶ <https://www.xconomy.com/seattle/2014/09/02/which-countries-excel-in-creating-new-drugs-its-complicated/>
- ⁷ http://www.unesco.org/new/en/media-services/single-view/news/world_leader_in_life_sciences_targets_more_rational_drug_dev/
- ⁸ <https://www.iquia.com/-/media/iquia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf>
- ⁹ <https://www.oecd-ilibrary.org/docserver/9789264265592-en.pdf?expires=1527177623&id=id&accname=guest&checksum=F3B9D6737BB554ECBCD84FBF0DC2DF5D>
- ¹⁰ <http://www.reuters.com/article/us-japan-pharmaceuticals-prices-idUSKBN14907Z>
- ¹¹ <https://www.phrma.org/industryprofile/>
- ¹² https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf
- ¹³ http://www.who.int/intellectualproperty/submissions/en/Submission_DiMasi.pdf
- ¹⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5659838/>
- ¹⁵ <https://www.lifescienceleader.com/doc/me-too-drug-sales-return-via-competitive-pricing-or-marketing-0001>
- ¹⁶ <https://www.fiercepharma.com/financials/gilead-s-hep-c-guidance-comes-far-short-expectations-as-abbvie-s-mavyret-scoops-up-share>
- ¹⁷ <https://www.biopharmadive.com/news/gilead-hepatitis-c-revenues-slide-fourth-quarter-earnings/516494/>
- ¹⁸ <https://academic.oup.com/cid/article-pdf/61/2/157/16787679/civ220.pdf>
- ¹⁹ <https://www.huronconsultinggroup.com/-/media/Resource-Media-Content/Life-Sciences/Disruptive-Pricing-Huron-White-Paper.pdf>
- ²⁰ http://blogs.sciencemag.org/pipeline/archives/2011/01/26/those_meloo_drugs
- ²¹ <https://www.help.senate.gov/imo/media/doc/Aldonas-SenHELP-Rx-2-17-05.pdf>
- ²² <https://2016.trade.gov/td/health/phRMA/PhRMA%20-%20ANNEX%20D.pdf>
- ²³ https://www.ispor.org/research_pdfs/58/pdffiles/PHP216.pdf
- ²⁴ http://healthpolicy.usc.edu/Global_Burden_of_Medical_Innovation.aspx
- ²⁵ http://phrma-docs.phrma.org/files/dmfile/PhRMA_GoBoldly_Economic_Impact.pdf
- ²⁶ <https://www.nsf.gov/statistics/2017/nsf17320/>
- ²⁷ <http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.pdf>
- ²⁸ https://www.bls.gov/oes/current/naics4_325400.htm#51-0000
- ²⁹ <https://www.bls.gov/oes/current/oes510000.htm>
- ³⁰ <http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.pdf>
- ³¹ <https://www.phrma.org/graphic/2017-u-s-biopharmaceutical-exports>
- ³² <https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf>
- ³³ <https://www.reuters.com/article/us-india-patents-usa-idUSKCN0WP0T4>
- ³⁴ <https://www.forbes.com/sites/johnlamattina/2013/04/08/indias-solution-to-drug-costs-ignore-patents-and-control-prices-except-for-home-grown-drugs/#e8302472cba7>
- ³⁵ http://www.business-standard.com/article/current-affairs/compulsory-licensing-soon-for-export-of-generic-drugs-by-india-11503090013_1.html
- ³⁶ http://www.ecipe.org/app/uploads/2014/12/ECIPE_Policy_Brief_IRP_30_May_FINAL_pdf.pdf
- ³⁷ https://scholar.harvard.edu/files/lucamaini/files/reference_pricing_as_a_deterrent_to_entry.pdf
- ³⁸ <https://www.sciencedirect.com/science/article/pii/S1098301516313055>
- ³⁹ <https://www.euractiv.com/section/health-consumers/news/commission-reassures-worried-member-states-on-health-technology-assessment/>
- ⁴⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2980346/>
- ⁴¹ <https://www.slideshare.net/BahmanAmani/health-technology-assessment-in-the-united-states>
- ⁴² <http://www.astrid-online.it/static/upload/7787/7787e169a7f0afc63221153a6636c63f.pdf>
- ⁴³ https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/com2018_51_en.pdf
- ⁴⁴ <https://pdfs.semanticscholar.org/cbfd/5e783d98eb4f32df73dd0ba1e4aa577d58cc.pdf>
- ⁴⁵ <https://www.ncbi.nlm.nih.gov/pubmed/23389487>
- ⁴⁶ <https://bmcpulmed.biomedcentral.com/articles/10.1186/1471-2466-12-35>
- ⁴⁷ <http://www.crai.com/sites/default/files/publications/therapeutic-reference-pricing.pdf>
- ⁴⁸ <http://money.cnn.com/2018/03/23/technology/china-us-trump-tariffs-ip-theft/index.html>
- ⁴⁹ <https://ustr.gov/sites/default/files/2016-China-Report-to-Congress.pdf>