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TPP: The “Trade” Deal that Could Inflate Your Healthcare Bill

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[The Trans-Pacific Partnership \(TPP\)](#) is a massive “free trade” agreement currently being negotiated behind closed doors by officials from the United States and 11 other countries – Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. TPP negotiations started in 2008. The public cannot see the draft TPP text, and even members of Congress, after being denied the text for years, are now only provided limited access. More than 500 official U.S. “trade advisors,” most representing large corporations, have access. The Obama administration hopes to sign the TPP in late 2014. It is being designed as a “docking” agreement that would be open for other countries, such as China, Russia and Indonesia, to later join.

Although it is called a “free trade” agreement, the TPP is not really mainly about trade. Of the TPP’s 29 draft chapters, only five deal with traditional trade issues. Most would set rules on non-trade matters that affect our daily lives – medicine costs, food safety, Internet freedom, financial regulation and more. Existing and future U.S. domestic policies would be required to comply with the TPP’s rules. These constraints on policy space would be binding: failure to comply with TPP rules could result in trade sanctions being imposed against the United States unless and until we would change our policies to meet TPP requirements. The pact would also newly empower foreign corporations, including pharmaceutical firms, to directly challenge public interest policies and demand taxpayer compensation in extrajudicial tribunals. Unlike domestic laws, the TPP would have no expiration date, and any changes to its terms would require the consensus of all signatory nations.

The TPP: Big Pharma’s Backdoor Effort to Halt Reductions in U.S. Medicine Prices

Americans [pay far more for healthcare](#) than people in any other developed country, even though U.S. life expectancy falls below the average for developed countries. A major contributor to our bloated healthcare costs is the [high prices for medicines](#) in the United States. According to the Government Accountability Office, [U.S. drug prices increased more than 70 percent faster](#) than prices for other healthcare goods and services over 2006-2010. As a result, millions of Americans cannot afford the medicines they need to live healthy lives. Soaring drug prices also drive up the amount that taxpayers must pay to fund public health programs such as Medicare, Medicaid and programs covering the U.S. military and veterans. Indeed, rising healthcare costs are [the number one contributor to the U.S. government’s projected long-term budget deficits](#). To try to combat the twin problems of unaffordable healthcare and unsustainable deficits, U.S. federal and state governments already use several tools to tamp down the cost of drugs – for Medicare, Medicaid and for military healthcare under TRICARE and the Department of Veterans Affairs (VA). Many more such cost containment policies have been proposed.

Yet, the TPP threatens to chill such proposals and even roll back existing policies to rein in exorbitant medicine prices. Leaked draft TPP texts – an intellectual property chapter, investment chapter and healthcare annex – contain expansive rules that would constrain the ability of the U.S. government to reduce medicine prices. Getting these terms into the TPP was a key objective of large U.S. pharmaceutical corporations that stand to reap monopoly profits from expansive patent terms and

Big Pharma Is the TPP’s Biggest Lobby

Pharmaceutical firms have [filed more TPP lobbying disclosures than any other industry](#), according to a 2014 study by the Sunlight Foundation. In fact, pharmaceutical firms’ lobbying reports from 2009 to mid-2013 mentioned the TPP two and a half times more than the second-most-vocal industry. The TPP terms that cater to Big Pharma’s interests appear to be no accident.

restrictions on government cost containment efforts. This incentive may explain why [pharmaceutical corporations have lobbied Congress for the TPP more than any other industry](#). The TPP's threats to the affordability of U.S. healthcare have spurred major groups that have not traditionally taken part in trade policy debates to warn against the TPP's provisions. For example, AARP – representing more than 37 million Americans over the age of 50 – joined unions and consumer groups in [a November 2013 letter to President Obama to express “deep concern”](#) that texts proposed for the TPP would “limit[] the ability of states and the federal government to moderate escalating prescription drug, biologic drug and medical device costs in public programs.” The groups concluded that the TPP could “undermine[] access to affordable health care for millions in the United States and around the world.”

Monopoly Protections: Expansive Rights for Big Pharma, Expensive Medicines for Consumers

[Leaked draft intellectual property texts](#) for the TPP reveal broad patent and related monopoly protections for pharmaceutical corporations, which elevate the costs of medicines and medical procedures. Inserting these sweeping corporate privileges into the pact would undermine U.S. efforts to make healthcare more affordable:

- **Scrapping the Obama administration proposal to save more than \$4 billion on biologic medicines:** Biologics – the latest generation of drugs to combat cancer, rheumatoid arthritis and other diseases – are exceptionally expensive, [costing approximately 22 times more than conventional medicines](#). Under U.S. law, pharmaceutical corporations enjoy monopoly protections for biologic drugs, even in the absence of a patent, for a 12-year period of “exclusivity.” During these 12 years, the Food and Drug Administration is prohibited from approving more affordable versions of the drugs, [inflating the cost of these life-saving medicines](#) as pharmaceutical firms accrue monopoly profits. To lower the exorbitant prices and the resulting burden on programs like Medicare and Medicaid, the Obama administration’s 2015 budget would reduce the exclusivity period for biologics from 12 to seven years. The administration estimates this would [save taxpayers more than \\$4.2 billion](#) over the next decade just for federal programs. However, at the request of Big Pharma, U.S. trade negotiators are demanding [the 12-year exclusivity requirement for biologics in the TPP](#). This would lock into place pharmaceutical firms’ lengthy monopolies here at home. That is, Obama administration negotiators would effectively scrap the administration’s own proposal to save billions in unnecessary healthcare costs and lock in rules that would forbid future presidents or Congresses from doing so.

Unmitigated Prices: Limiting the Government’s Ability to Control Rising Drug Costs

[A leaked draft TPP annex](#) with the Orwellian title “Transparency and Procedural Fairness for Healthcare Technologies” would set broad limits on governments’ prerogatives to negotiate or mandate lower drug prices, including for taxpayer-funded programs such as Medicare, Medicaid and veterans’ and military health programs. Pushed by U.S. negotiators, these proposed TPP rules would conflict with existing and proposed policies to reduce healthcare costs for seniors, military families and the poor:

- **Rolling back medicine cost savings for U.S. veterans:** The U.S. government uses automatic price reductions to secure lower drug costs for U.S. veterans who benefit from health programs administered by VA. [U.S. law allows VA to access drug prices at 24 percent below average market prices](#), and requires drug companies to offer these reduced prices for VA-administered programs as a condition for their medicines being included in other government health programs. However, this cost-saving mechanism could run afoul of the proposed TPP annex, which requires government drug reimbursements to be based on “competitive, market-derived prices,” or on a system that “appropriately recognizes[] the value” of the drugs. The government-mandated price-setting system for VA programs would be subject to challenge as not being “competitive” and “market-derived.” VA-secured prices that fall significantly below the prices of patented drugs also could be challenged under the TPP as not “appropriately recognizing” drugs’ value. These TPP provisions, if enacted, could expose the U.S. government to challenges before international tribunals for not rolling back policies that cut healthcare costs for veterans and taxpayers.

- Threatening policies that make medicines more affordable for the poor:** U.S. federal and state governments currently use several methods to tamp down the prices of drugs provided to low-income families through Medicaid. For example, the U.S. federal government requires drug corporations, as a condition for having their drugs covered by Medicaid, to sign discount agreements that [oblige the firms to provide the state and federal governments with rebates to lower the cost of the drugs](#). These rebates have resulted in [a 45 percent reduction in Medicaid spending](#) for brand-name drugs. State governments can further cut costs by, for example, negotiating lower prices with drug companies in return for placing their medicines on a Preferred Drug List (PDL) – a list of medicines that the state’s Medicaid program will cover without requiring prior authorization from a doctor. States have calculated substantial cost savings from usage of PDLs: New York saved an estimated [\\$381 million](#) in one recent year, while Texas saved an estimated [\\$115 million](#) and Utah saved an estimated [\\$434 million](#). Such Medicaid cost containment measures could be challenged under the TPP. Leveraging the government’s buying power to set prices could be attacked as not being “market-derived” or as “appropriately recognizing” the value of patented drugs. Some argue that the TPP provisions would primarily target federal policies, while Medicaid is administered by state governments. But even if limited to federal policies, the pact’s proposed terms directly contradict Medicaid’s federal cost control efforts, such as requiring drug firms to sign discount agreements. And state-level tools like PDLs could still be challenged under the TPP as part of a program created and controlled by the federal government.
- Challenging Obamacare cost reductions for seniors:** Before implementation of the landmark Patient Protection and Affordable Care Act of 2010, seniors faced a gap in Medicare drug coverage. After passing a given threshold of drug costs, Medicare beneficiaries went from having to pay 25 percent of a drug’s cost to having to pay 100 percent out of pocket, until reaching a second threshold at which Medicare again covered most costs. Closing this “doughnut hole” was a key objective of the Affordable Care Act, which [required drug manufacturers to offer a 50 percent drug price discount to Medicare beneficiaries within the coverage gap](#) if they wanted their drugs to continue being covered under Medicare. As a result of this discount and a gradual increase in Medicare coverage, Medicare beneficiaries within the coverage gap were only responsible for 47.5 percent of brand-name drug costs in 2013 and will be responsible for only 25 percent by 2020. But under the TPP, the requirement for drug companies to halve the price of their drugs within the coverage gap could be challenged for neither reflecting “competitive market-derived” prices nor “appropriately recognizing[] the value” of patented drugs. The Obama administration’s TPP healthcare annex thus threatens the cost savings that the administration’s own signature health law has provided to seniors.
- Chilling future reforms that could further reduce healthcare costs for retirees:** Governments in countries ranging from New Zealand to Japan have kept healthcare costs in check by leveraging the government’s large purchasing power for taxpayer-funded public health programs to negotiate lower drug prices with pharmaceutical corporations. In contrast, for Medicare, which [covers more than 50 million Americans](#), the U.S. government is barred by law from directly negotiating drug prices with pharmaceutical corporations. Many policymakers, healthcare professionals and even [President Obama](#) have called for changes to this law so that the government could ask drug companies to provide lower prices in exchange for getting subsidized access to millions of Medicare recipients. Other reform proposals, including [legislation now pending](#), would have the federal government set maximum prices for drugs covered by Medicare (as it does for health programs provided to veterans) or require that drug companies provide drug rebates (similar to the rebates required under Medicaid). Indeed, [the White House itself has proposed requiring drug companies to pay Medicaid-like rebates](#) to providers for treating low-income Medicare beneficiaries. The administration estimates this would deliver \$117 billion in savings over 10 years. However, the TPP presents an obstacle to these proposals to control soaring Medicare costs. All of the above-mentioned policies involve direct government intervention in price setting, conflicting with the TPP requirement for market-derived prices, and inviting challenges for failing to “appropriately recognize” the value of patented drugs.
- Undermining drug discounts for underserved communities:** Under a program known as 340B, the U.S. federal government enables nongovernmental health centers – including migrant health centers, homeless health centers, children’s hospitals and family planning centers – to offer their diverse constituencies more

affordable drugs. The federal government [requires pharmaceutical firms to offer discounted drug prices to 340B-covered health centers](#) via rebates, as a condition for having their drugs covered by Medicaid. As a federally-run program that mandates below-market prices, the program could be challenged as a violation of the proposed TPP rules requiring drug prices to be market-derived or to reflect the value of patented drugs. In addition, the leaked TPP annex would require the U.S. government to allow pharmaceutical corporations to appeal drug pricing decisions such as the rebate amounts set under the 340B program, though they have very limited appeal rights for such decisions under U.S. domestic law. The TPP would thus give pharmaceutical corporations a new means of challenging 340B policies that reduce drug prices for underserved populations.

Investor Privileges: Empowering Big Pharma to Directly Attack U.S. Health Policies

[A leaked draft investment chapter](#) reveals that the TPP would grant foreign firms the power to skirt domestic courts, drag the U.S. government before extrajudicial tribunals, and directly challenge patent laws and medicine cost containment policies as violations of their new TPP foreign investor “rights.” The tribunals, comprised of three private attorneys, would be authorized to order unlimited taxpayer compensation for domestic policies perceived as undermining pharmaceutical corporations’ “expected future profits.” Effectively, this system would elevate individual pharmaceutical firms to the same status as the countries that may sign the TPP, empowering such firms to privately enforce the public agreement. Such extreme “investor-state” rules have been included in past U.S. “free trade” agreements, [forcing taxpayers to pay firms more than \\$430 million](#) for toxics bans, land-use rules, water and timber policies and more. Just under U.S. pacts, more than \$38 billion is pending in corporate claims against patent policies, pollution cleanup requirements, climate and energy laws, and other public interest policies. This includes a \$500 million claim that U.S. pharmaceutical corporation Eli Lilly launched in 2013 against Canada’s legal standard for granting patents. The firm is demanding compensation because Canadian courts enforcing Canadian patent law ruled that two of Eli Lilly’s medicines failed to meet the Canadian standard to obtain a patent, which requires demonstrating a drug’s promised utility. This is [the first attempt by a patent-holding pharmaceutical firm to use the extraordinary investor privileges](#) provided by U.S. “trade” agreements as a tool to push for greater monopoly patent protections. The TPP would vastly expand the investor-state threat to U.S. public health policies, given the thousands of corporations based in TPP countries that would be newly empowered to launch cases against U.S. laws on behalf of any of their [more than 14,000 U.S. subsidiaries](#).

Fast Track: Railroading Democracy to Roll Back Healthcare Reforms and Medicine Price Savings?

How could a deal like the TPP get past Congress? With an antidemocratic procedure known as [Fast Track](#). This extreme and rarely-used maneuver, cooked up by President Nixon, empowered executive branch negotiators, advised by large corporations, to “diplomatically legislate” by unilaterally negotiating and signing deals that rewrote swaths of non-trade policy. Then Congress was required to vote yes or no within 90 days of such an agreement being submitted – with no amendments and limited debate. As a candidate, President Obama said he would replace this antidemocratic process that Congress has only permitted to be in effect for five of the last 20 years. But now he is asking Congress to grant him Fast Track authority – in part to sidestep growing public and congressional concern about pacts like the TPP. We must ensure that Fast Track never again takes effect and instead create [an open, inclusive process](#) for negotiating and enacting trade agreements in the public interest.

More Information on How the TPP Threatens Access to Affordable Medicines

- Factsheet: [TPP: Harmful Provisions for Access to Medicines](#)
- Memo: [Proposed TPP Rules Could Undermine Drug Cost Containment Provisions of Medicare, Medicaid and Veterans’ Health, Hurting Seniors, Military Families and the Poor](#)
- Memo: [U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada’s Patent Policy](#)
- Factsheet: [The TPP Threatens Access to Affordable Cancer Treatments and Other Biologics](#)
- Memo: [What’s New in the WikiLeaks TPP Text?](#)
- Memo: [Public Interest Analysis of Leaked TPP Investment Text](#)