

TPP: Threats to Affordable Medicines

Prices of patented drugs are rising every year. Absent generic competition, there is little reason for drug firms to bring drug prices down. The brand-name pharmaceutical industry business model relies on maximizing profits by selling at very high prices to the few, rather than affordable prices to the many. Most nations, under pressure from high prices, ration treatment – including here. The problem is especially grave in developing nations. The Trans-Pacific Partnership (TPP) would make matters worse. The more monopoly powers policymakers provide to the pharmaceutical industry, the more treatment we will have to ration.

In contrast, policies that provide access to affordable generic drugs are an important way to reduce spending on health care and improve access to treatment. So are policies that harness government health programs’ effective use of bulk-purchaser negotiating power combined with the related use of formulary lists of medicines that government programs will cover.

The administration says that the TPP is setting the new global standard. It is in that context that the terms of the final text must be judged: Is this the policy framework for access to medicine that we want to lock in for ourselves and export to others?

Consider what the TPP would do: require every signatory country to ensure its domestic laws expand drug companies’ monopoly powers, leading consumers and healthcare providers to pay higher prices on more drugs for longer— or go without needed treatment. TPP rules would require countries to enact and maintain laws that expand drug companies’ monopoly powers, including by providing:

- ◆ patent term extensions
- ◆ new 20-year monopoly patents on new uses of old medicines and other opportunities for “patent evergreening”
- ◆ marketing exclusivity protections that create monopoly rights even when a drug is off-patent
- ◆ greater opportunities for drug firms to influence government drug coverage & reimbursement decisions

In sum, if enacted the TPP would establish and lock in rules that limit competition and contribute to preventable suffering and death. These TPP rules are not about providing basic patent protections or anti-counterfeiting measures, as proponents suggest. All TPP countries already have those rules. There is no evidence that these rules would spur innovation or create jobs as the industry often says. There is evidence to the contrary on both fronts. Instead, TPP rules are lobbyist-driven bonuses for the industry.

The TPP’s strongly enforced terms would not be alterable absent consensus by all signatories. Thus, if enacted, the TPP would set the parameters to which the current and future Congresses, U.S. state legislatures and the governments of other TPP countries’ governments would be constrained with respect to policies for reducing medicine prices and protecting public health and the nations’ fiscal health. Just one

Critical example: The TPP's limits on future policy space could shut down high-profile reform efforts, first and foremost, for Medicare Part D price negotiations.

TPP RULES THAT LIMIT COMPETITION AND PROMOTE HIGH MEDICINE COSTS:

EVERGREENING OF PATENTS:

- ◆ The TPP would require every signatory country to include in its domestic laws the grant of new 20-year patent monopolies for new uses of old medicines (20 years for Viagra as a blood pressure treatment and another 20 years as an ED treatment) and facilitate the patenting of other minor modifications of existing medicines (for instance a new patent for the 24-hour version of a medicine that previously was dosed every six hours). This would allow pharmaceutical firms to “evergreen” their patents, maintaining a monopoly and high prices.

PATENT TERM EXTENSIONS:

- ◆ The TPP would also require countries to provide for patent extensions for regulatory review periods or patent prosecution periods deemed “unreasonable” (regulatory review) or beyond a period of years (prosecution periods) of five years from application or three years from examination request. Patent term adjustments significantly delay market entry of generic medicines and restrict access to affordable medicines. They force governments to extend existing patent monopolies beyond current 20-year terms at the request of pharmaceutical firms. While they are allocated ostensibly for “delays” in regulatory review or patent prosecution, variance in review periods is a normal part of each system, and patent terms are not shortened when reviews are speedier than usual.

EXCLUSIVITY FOR BIOLOGIC MEDICINES:

- ◆ The most controversial TPP medicine-related provision concerns biotech drugs, or biologics – medical products derived from living organisms. Biologics include many new cancer treatments, now averaging around \$190,000 per person per year. Most health systems cannot pay such prices without compromising other healthcare priorities. In the TPP, the pharmaceutical industry achieved its goal that every TPP country must provide new exclusivity periods for biologics. That means that the TPP would not allow national regulatory authorities to authorize the sale of products that rely on a competitor's safety and efficacy data, *even in the absence of patents*. This is the provision that a group of cancer patient activists called the TPP “Death Sentence Clause” as it would cut off access to drugs that are necessary to extend the lives of people suffering from cancer.
- ◆ Many TPP countries' current laws have no special exclusivity rights for such drugs. While TPP countries refused to agree to an automatic monopoly term longer than five years, the U.S. Trade Representative (USTR) insisted on text that will allow the U.S. government to pressure and pull countries towards a longer period – eight or even more years of protection. Since the final TPP text was released, administration officials have stated explicitly that the TPP requires eight years of biologics exclusivity monopoly.

NEW RIGHTS FOR PHARMACEUTICAL FIRMS TO MEDDLE IN GOVERNMENT POLICY DELIBERATIONS ON DRUG PRICING AND REIMBURSEMENTS:

- ◆ The TPP contains provisions in a cynically dubbed “transparency” annex which guarantees:
 - ◇ that drug companies have a role in government policy deliberations on what medicines will be included in government programs and prices;
 - ◇ that those decisions “recognize the value” of pharmaceutical products or medical devices through the “operation of competitive markets” or their “objectively demonstrated therapeutic significance,” regardless of whether there are effective, affordable alternatives; and
 - ◇ that drug firms have special rights to challenge government decisions that the firms oppose.

- ◆ Thus, if enacted, the TPP would reduce the flexibility and policy space that Congress and the other TPP countries’ governments would have to protect public health. Specifically, the provisions could limit the tools the U.S. government has to increase generic drug competition and get the best price for our nations’ seniors and for safety net providers.

- ◆ The “Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices,” expressly names the Centers for Medicare & Medicaid Services (CMS) as covered by its text. “...with respect to CMS’s role in making Medicare national coverage determinations.” Medicare’s national coverage determinations include whether Medicare Part A and Part B will pay for an item or service. Among other things, Part A and B cover drugs administered in a hospital or a doctor’s office, and durable medical equipment. Under the TPP, CMS determinations would be subject to a series of procedural rules and principles, the precise meaning of which are not clear and perhaps not knowable. Pharmaceutical companies could attempt to exploit the general language of the Annex to mount challenges to Medicare and health programs in many TPP negotiating countries. The Annex may constrain future policy reforms, including the ability of the U.S. government to curb rising and unsustainable drug prices.

- ◆ The Annex would apply to any future efforts related to expanding Medicare while reducing drugs costs, such as enacting national formularies and the right to negotiate drug prices as part of potential Medicare Part D reforms. In response to soaring drug costs, advocates have increasingly called on the government to enable the Secretary of Health and Human Services (HHS) to negotiate the price of prescription drugs on behalf of Medicare beneficiaries. Vital to this reform would be the establishment of a national formulary of medicines the program would cover, which would provide the government with substantial leverage to obtain discounts. The development of such a national formulary would be subject to the TPP’s requirements about what factors may or may not be considered in included medicines, and would pose significant administrative costs and enshrine greater pharmaceutical company influence in government reimbursement decision-making – all reducing the capability of the government to negotiate lower prices.

- ◆ The Annex would establish opportunities for drug firms to meddle in government medicine purchasing and pricing decisions by requiring TPP-country health authorities to follow procedures requiring industry involvement in decision-making regarding drug and medical device pricing and inclusion of medicines on formulary lists for reimbursement. It mandates that parties provide

opportunities for applicants to comment on reimbursement considerations “at relevant points in the decision-making process.”

- ◆ Could companies use the Annex to compel Medicare to cover expensive products without a corresponding benefit to public health? Now Medicare reimbursement is limited to products that are “reasonable and necessary” for treatment. But the TPP text requires decisions that “recognize the value” of pharmaceutical products or medical devices through the “operation of competitive markets” or their “objectively demonstrated therapeutic significance,” regardless of whether there are effective, affordable alternatives.
- ◆ The Annex also requires countries to make available a review process for healthcare reimbursement decisions. Medicare national coverage determinations allow for appeals, but only in a limited set of circumstances. Might this conditional appeal process be construed as insufficient, if companies argue the TPP grants them an unconditioned right to review?
- ◆ USTR claims that Medicare today is fully compliant with the proposed provisions of the TPP. Yet the ambiguous language of the TPP leaves our domestic healthcare policies vulnerable to attack by drug and device manufacturers.

ROLLING BACK CONGRESSIONAL DEMOCRATS “MAY 10, 2007” REFORMS FOR DEVELOPING COUNTRY ACCESS TO AFFORDABLE MEDICINES:

- ◆ The TPP would roll back the reforms made in the May 10, 2007 agreement that congressional Democrats extracted from President George W. Bush, with respect to U.S. trade agreement rules on medicines. The May 10 Agreement began to reduce the negative consequences of U.S. free trade agreements for access to medicines in developing countries. It did not eliminate these harms or create health benefits *per se*; it simply established some modest limits for how much harm U.S. trade policy would facilitate. The May 10 standard was seen by many Democrats and by public health advocates as the best that could be achieved during a Republican administration with the full expectation that a future Democratic president would build on the 2007 improvements for access. Unfortunately, the Obama administration abandoned the May 10 template early in the TPP negotiations, and worked aggressively to push the agenda of the pharmaceutical industry.
- ◆ The May 10 standard made patent term extensions optional for pharmaceuticals and provided important limitations on data exclusivity rules for developing countries. There were no transition periods by which developing countries were expected to adopt the more pro-monopolistic rules that applied to developed countries.
- ◆ Undermining the core premise of the May 10 Agreement standard, the TPP would require developing countries to transition to all of the same pro-monopolistic patent rules that apply to developed countries. The transition periods are short *and only apply to a few rules while the rest would apply immediately to all signatories*. Some countries have negotiated exemptions from one or two TPP rules. But the underlying rules are beyond the limits of May 10, and will apply to the

rest of the TPP parties, including developing countries that may join this aspired “living agreement” in the future. For instance:

- ◇ **Exclusivity:** Marketing exclusivity rules delay generic drug registration for a specified period of time by limiting the ability of generics manufacturers and regulatory authorities to make use of an originator company’s data.
 - ✓ The May 10 standard required that exclusivity terms runs for a five-year *concurrent* period, meaning that the clock runs on exclusivity from the date of first marketing in either the United States or the other country. This expedites generic entry.
 - ✗ **TPP rule:** Only Peru may run the exclusivity clock using the concurrent period rule. For all other countries, exclusivity runs for a minimum five years *from date of marketing approval in their country*, which may be considerably later than the first marketing approval, including cases that are purely a result of the pharmaceutical company moving slowly to register a product in a developing country. Countries also must choose between offering an extra three years exclusivity for new uses, forms and methods of administering products, or five years exclusivity for new combination products. And, for biologic drugs, the TPP includes USTR’s demand that countries adopt “other measures” toward providing a market outcome comparable to eight years of exclusivity. Malaysia and Brunei would have an “access window,” allowing them to foreclose marketing exclusivity if a company waits more than eighteen months to begin product registration.
- ◇ **Patent Term Extensions:** Patent term extensions significantly delay market entry of generic medicines and restrict access to affordable medicines.
 - ✓ Under the May 10th standard, patent extensions are optional. Countries may choose whether or not to provide for patent term extensions in their domestic laws.
 - ✗ **TPP rule:** The TPP requires countries to provide for patent extensions for regulatory review periods or patent prosecution periods deemed “unreasonable” (regulatory review) or beyond a period of years (prosecution periods) – five years from application or three years from examination request.
- ◇ **Additional ways the TPP extends monopoly rights relative to the May 10 standard:** While the May 10 Agreement did not make express reference to patent evergreening or other intellectual property rules that can compromise access to medicines, many health advocates take the content of the U.S.-Peru Trade Promotion Agreement as the standard. That agreement did not, for example, require the grant of patents for new uses of old medicines. In contrast, the TPP does. This would allow pharmaceutical firms to “evergreen” their patents, maintaining a monopoly and high prices.

THE TPP WOULD ALLOW DRUG FIRMS TO CLAIMS GOVERNMENT POLICIES VIOLATED THEIR INVESTOR RIGHTS RELATED TO INTELLECTUAL PROPERTY AND DEMAND TAXPAYER COMPENSATION IN INVESTOR-STATE TRIBUNALS

- ◆ As if these TPP intellectual property rules did not sufficiently privilege pharmaceutical firms, the TPP also would allow drug companies to *privately enforce* this public treaty by skirting U.S. laws and courts to challenge U.S. federal, state and local decisions and policies on grounds not available in U.S. law and do so before extrajudicial investor-state tribunals authorized to order payment of unlimited sums of taxpayer dollars. Neither consumers nor health advocates have any rights to privately enforce the TPP or to collect damages from the signatory governments if TPP rules cut off their access to affordable medicines.
- ◆ Contrary to administration claims that the TPP's Investment Chapter would limit the uses and abuses of the controversial investor-state dispute settlement (ISDS) regime, much of the text replicates, often word-for-word, the most provocative terms found in past U.S. ISDS-enforced pacts. Worse, the TPP would *expand* ISDS. For the first time in any U.S. free trade agreement pharmaceutical firms could use TPP to demand cash compensation for claimed violations of World Trade Organization rules on creation, limitation or revocation of intellectual property rights. Currently, WTO rules are not privately enforceable by investors.
- ◆ Many fixes and reforms included in a 2012 leaked draft version of the Investment Chapter have been eliminated. The final TPP text does include some new verbiage seemingly designed to counter the growing political blow back against ISDS. While the tone is different in some provisions, in practice the TPP's binding legal language does not constrain ISDS tribunals from making ever-expanding interpretations of the rights countries owe foreign investors and thus the compensation they can be ordered to pay foreign firms. And this is not a hypothetical threat. Eli Lilly is now suing Canada using NAFTA's ISDS regime demanding \$500 million in compensation over revocation of medicine patents on two drugs that did not meet Canada's patentability standards.
- ◆ With Japanese, Australian and other firms newly empowered to launch ISDS attacks against the United States, the TPP would *double* U.S. ISDS exposure. More than 1,000 additional corporations in TPP nations, which own more than 9,200 subsidiaries here, could newly launch ISDS cases against the United States. Currently, under ALL existing U.S. investor-state-enforced pacts, about 9,500 U.S. subsidiaries for foreign firms have such powers. Almost all of the 50 past U.S. ISDS-enforced pacts are with developing nations with few investors here. That is why the United States has managed largely to dodge ISDS attacks to date. But, the TPP would subject U.S. policies and taxpayers to an unprecedented increase in ISDS liability at a time when the types of policies being attacked and the number of ISDS case are surging.