



Testimony of Public Citizen's Global Access to Medicines Program

House Committee on Ways and Means Democrats' Hearing on the Trans-Pacific Partnership and Access to Medicines

December 8, 2015

Ranking Member Levin and Members of the Committee, thank you for the opportunity to testify today on the consequences of the Trans-Pacific Partnership (TPP) for access to medicines. I am Peter Maybarduk, director of Public Citizen's Global Access to Medicines Program. Public Citizen is a national non-profit organization with more than 400,000 members and supporters. For more than 40 years, Public Citizen has worked to advance public health by ensuring the medicines prescribed to patients in the U.S. are safe and effective and promoting access to affordable medicines by fighting the monopolistic abuses of the pharmaceutical industry.

Competition has consistently proven the most effective means of reducing pharmaceutical prices and ensuring prices continue to fall over time, which in turn is essential to reducing healthcare costs, more efficiently allocating limited resources to improve health outcomes and saving lives all over the world. Prices of patented drugs are rising every year. Absent generic competition, there is little reason for drug companies to bring prices down. The brand-name pharmaceutical industry business model relies on maximizing profits by selling at very high prices to the few, rather than at affordable prices to the many.

Most countries, under pressure from high prices, ration treatment. Treatment rationing is getting worse, including in the United States. 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' use of bulk-purchaser negotiating power.

But if enacted, the TPP would establish and lock in rules that limit competition and contribute to preventable suffering and death.

- TPP rules would require countries to enact and maintain laws that expand drug companies' monopoly powers. This includes patent term extensions and patents on new uses of old medicines as well as marketing exclusivity rules that create pharmaceutical monopolies even when a product is off-patent.
- TPP rules would also provide pharmaceutical companies greater opportunity to influence government drug coverage and reimbursement decisions.

In sum, the TPP's medicine-related rules would lead consumers and government healthcare programs to pay higher prices on more drugs for longer— or for people to go without needed treatment.

And, the TPP's strongly enforced medicine-related terms would not be alterable absent consensus by all signatories. Thus, if enacted, the TPP would set the parameters to which this 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. The TPP's limits on future policy space could implicate high-profile reform efforts, first and foremost, for the Secretary of Health and Human Services to negotiate the price of prescription drugs on behalf of Medicare beneficiaries.

Many are aware that the TPP would reduce access to affordable medicines in the developing countries involved in the TPP. I will describe how 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. But it is important to understand that there are also implications for U.S. consumers, for Medicare and for the ability of Congress to introduce cost-cutting measures benefiting Americans in the future.

I will provide a quick guided tour through the TPP rules that limit competition and promote high medicine costs.

EVERGREENING PATENTS: If enacted, the TPP would require signatory countries to include in their domestic laws the grant of new 20-year patent monopolies for new uses or modifications of old medicines. This contributes to pharmaceutical firms attempting 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 deemed "unreasonable" or patent prosecution periods beyond a period of years – five years from application or three years from examination request. Patent term extensions 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 companies. 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 review proceeds more quickly than usual.

SPECIAL EXCLUSIVITY RULES, INCLUDING 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 special exclusivity periods for biologics. A separate, similar rule is included for conventional pharmaceuticals. These mean that the TPP would prohibit national regulatory authorities from granting marketing approval to competing biosimilar or generic products based on the originator product's safety and efficacy data for a period of years. These rules create product monopolies even in the absence of patents, or may outlast patents in some cases. Many TPP countries do not now provide such special exclusivity

rules for biologics. This is the provision that a group of cancer patient activists called the TPP “Death Sentence Clause.”

Dangers for U.S. Health Programs

The TPP’s cynically-named “Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices”¹ sets rules that TPP country health authorities would be required to follow regarding pharmaceutical and medical device procurement and reimbursement. The Annex 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.”² 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 physician’s office, and durable medical equipment.³

Under the TPP, then, these 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 constrains future policy reforms, including potentially the ability of the U.S. government to curb rising and unsustainable drug prices.

USTR claims that Medicare today is fully compliant with the proposed provisions of the TPP.⁴ Yet the ambiguous language of the TPP leaves our domestic healthcare policies vulnerable to attack by drug and device manufacturers. For example:

- Could companies use the Annex to compel Medicare to cover expensive products without a corresponding benefit to public health? Medicare reimbursement is limited to products that are “reasonable and necessary” for treatment. But the TPP “recognize[s] 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.⁵
- The TPP also requires countries to make available a review process for healthcare reimbursement decisions.⁶ Medicare national coverage determinations allow for appeals, but

¹ Annex 26-A. *Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices* is available at <https://ustr.gov/sites/default/files/TPP-Final-Text-Transparency-and-Anti-corruption.pdf>.

² Paragraph 26-A.6: Disputes.

³ Medicare Drug Coverage under Medicare Part A, Part B, Part C , & Part D. (2015, May 1). Retrieved June 9, 2015, from <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11315-P.pdf>

⁴ Jonathan Weisman, *U.S. Shifts Stance on Drug Pricing in Pacific Trade Pact Talks, Document Reveals*, The New York Times (June 2015), available at <http://www.nytimes.com/2015/06/11/business/international/us-shifts-stance-on-drug-pricing-in-pacific-trade-pact-talks-document-reveals.html>.

⁵ Paragraph 26-A.1: Principles (d).

⁶ Paragraph 16-A.2: Procedural Fairness (e).

only in a limited set of circumstances.⁷ Might this conditional appeal process be construed as insufficient, if companies argue the TPP grants them an unconditioned right to review?

- The TPP mandates that parties provide opportunities for applicants to comment on reimbursement considerations “at relevant points in the decision-making process.”⁸ Though Medicare national coverage determinations allow for comments in certain stages of the process, these determinations may be vulnerable to legal challenge depending on the construction of “relevant points.”

In addition to its application to Medicare Part A and B, the Annex would apply to any future efforts related to national coverage determinations by the CMS, including 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 to negotiate the price of prescription drugs on behalf of Medicare beneficiaries. Vital to this reform would be the establishment of a national formulary, which would provide the government with substantial leverage to obtain discounts.⁹ The development of such a national formulary would be subject to the requirements of the TPP. These procedural requirements could pose significant administrative costs, enshrine pharmaceutical company influence in government reimbursement decision-making and reduce the capability of the government to negotiate lower prices.

The May 10 Agreement

With respect to how the TPP’s medicine patent terms would affect developing nations – both those now in the TPP and the many developing nations that could join in the future were the pact enacted – for Democrats an important measure is how the final TPP text measures up to the May 2007 standards.

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. Provisions affecting pharmaceutical prices and access were among the most contentious in the

⁷ “Department of Health and Human Services; Centers for Medicare & Medicaid Services [CMS-3285-N] Medicare Program; Revised Process for Making National Coverage Determinations,” 78 Federal Register 152 (7 August 2013), pp. 48164 - 48169.

⁸ Paragraph 26-A.2: Procedural Fairness (c).

⁹ Outterson, K., & Kesselheim, A. (2009). How Medicare Could Get Better Prices On Prescription Drugs. Health Affairs. Retrieved June 9, 2015, from <http://content.healthaffairs.org/content/28/5/w832.full>

TPP negotiations. TPP provisions¹⁰ requiring patent term extensions and marketing exclusivity for new uses and forms of old drugs clearly exceed the bounds of May 10.

EXCLUSIVITY: Marketing and data 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.

- **May 10th standard:** Exclusivity normally runs for a five-year concurrent period, meaning that the clock runs on exclusivity from the date of first marketing in the United States or agreement territory (and could potentially be shorter than five years). This expedites generic entry.
- **TPP rule:** Exclusivity runs for a minimum five years.¹¹ Countries also must choose between offering an extra three years of exclusivity for new uses, forms and methods of administering products, or five years of exclusivity for new combination products.¹²
 - Only Peru may run the exclusivity clock by the concurrent period measurement.¹³ Each other country must provide at least five years of exclusivity from the date of marketing approval in its 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. Malaysia will have an “access window,” allowing it to foreclose marketing exclusivity if a company waits more than eighteen months to begin product registration.¹⁴
 - For biologic products, countries must adopt “other measures” toward providing a comparable market outcome, which may mean a longer exclusivity period.¹⁵ A TPP Commission shall review the biologics exclusivity period,¹⁶ under likely industry pressure to lengthen it. Many TPP countries' current laws have no special exclusivity rights for such drugs. While many TPP countries refused to agree to a biologics exclusivity term longer than five years, 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. The eight-year position is dangerous, will likely cost lives, and contravenes the May 10 Agreement. And, since the final TPP text was released, administration officials have stated explicitly that the deal requires more than five years of biologics exclusivity monopoly.

¹⁰ See TPP Intellectual Property Chapter, available at <https://ustr.gov/sites/default/files/TPP-Final-Text-Intellectual-Property.pdf>.

¹¹ TPP Article 18.50.1.

¹² *Id* at Art. 18.50.2.

¹³ *Id* at Annex 18-D Peru Part 2.

¹⁴ See *id* at Annex 18-C Malaysia.

¹⁵ See *id* at Art. 18.52.1.

¹⁶ See *id* at Art. 18.52.3.

PATENT TERM EXTENSIONS:

- **May 10th standard:** Patent term extensions are optional. Countries may choose whether or not to make available patent term extensions for pharmaceuticals.
- **TPP rule:** Patent extensions are required 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.¹⁷

ADDITIONAL RULES: While the May 10 reforms did not make express reference to patent evergreening or other intellectual property rules that can compromise access to medicines, many observers take the content of the U.S.-Peru Trade Promotion Agreement as the May 10 standard. That agreement did not, for example, require the grant of patents for new uses of old medicines. The TPP does, meaning companies can repurpose an old drug and receive a new twenty-year patent term.¹⁸

Investor-State

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 nor 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 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 the 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

¹⁷ See *id* at Art. 18.46.

¹⁸ See *id* at Art. 18.37.2.

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. Yet if adopted, 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.

Conclusion

The Obama administration frequently 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 we want to lock in for Americans and export to others?

TPP rules are not about providing basic patent protections or anti-counterfeiting measures, as White House messaging sometimes suggests. All TPP countries already have those rules. There is no compelling evidence that these rules would spur innovation or create jobs, as the industry often says. Instead, the terms relating to medicine in the final TPP text lock in lobbyist-driven bonuses for the brand name pharmaceutical industry.