HEALTH GAP
GLOBAL ACCESS PROJECT

Written Submission from Health GAP

"Trading Views: Real Debates on Key Issues in TPP" hearing on access to medicines – U.S. House of Representatives Ways and Means Committee Hearing, Dec. 8, 2015

In its issue analysis paper, the Committee on Ways and Means posed three basic questions about the Trans Pacific Partnership and its impacts on access to medicines:

1. Does the current TPP text provide an appropriate balance between the need to incentivize innovation and to provide access to affordable medicines for patients in developing countries, like the balance struck under the May 10 Agreement of 2007?
2. Does the current TPP text either require changes to existing U.S. health or intellectual property laws, or prevent the United States from making reasonable changes to those laws?
3. What period of exclusivity is provided for biologic medicines, and is the period sufficient to incentivize the production of new biologic medicines in the future while also ensuring access to affordable medicines?

This submission from Health Global Access Project (GAP) discusses each of these issues and includes a chart analyzing relevant textual provisions and their impact on access to medicines.

I. The TPP does not provide an appropriate balance between innovations and access to affordable medicines for patients in developing countries.

Four parties to the TPP are classified as developing countries: Vietnam, Malaysia, Mexico, and Peru. These four countries are at different stages of development, but for each of them their gross national product per person is a fraction of the U.S.'s .[1] Low- and middle-income countries face multiple health challenges, not only from key infectious diseases like HIV, TB, malaria, dengue fever, and hepatitis C, but also from non-infectious chronic diseases. Although the common claim from the USTR and the U.S. pharmaceutical industry is that heightened intellectual property protections are good for low- and middle-income countries, the bulk of evidence and policy analysis refutes this claim, especially for low-income and lower-middle income countries like Vietnam but for other LMICs as well.[2] In these countries, public and private expenditures on health are orders of magnitude less than the U.S.[3] and the percentage of health expenditures devoted to medicines is varied but significant widely[4]. Out-of-pocket expenditures in these countries is quite high,[5] making the costs of medicines even more concerning.

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[1] 2014 World Bank figures: United States $54,630; Malaysia $10,628; Mexico $10,320; Peru $6551; Vietnam $2052.

[2] Brook K. Baker, *Debunking IP-for-Development: Africa Needs IP Space Not IP Shackles* in INTERNATIONAL ECONOMIC LAW AND AFRICAN DEVELOPMENT (Laurence Boulle, Emmanuel Laryea & Franziska Sucker eds. 2014).

[3] 2013 World Bank figures: United States $9146; Malaysia $423; Mexico $664; Peru $354; Vietnam $111.

[4] United States 9.3% (2013); Malaysia 8.8% (2009); Mexico 6.8% (2012); Peru 21.3% (2009); Vietnam 50.9% (2009).

[5] Malaysia 36.2%; Mexico 45.2%; Peru 66.1%; Vietnam 49.4%.

Although the Committee issue analysis paper suggests that the May 10, 2007 Agreement struck the proper balance with respect to access to medicines, even that Agreement does not go far enough to preserve policy space on intellectual property rights enshrined in the governing WTO Agreement on Trade-Relate Aspects of Intellectual Property Rights (TRIPS) and clarified by the Doha Declaration on the TRIPS Agreement and Public Health in November of 2001. The proper analysis for the Committee is the balance set in the TRIPS Agreement, not the half-way measures adopted in the May 10, 2007 Agreement that merely took the sharp edge off of some of the most draconian TRIPS-plus provisions that the U.S.T.R. was imposing in trade agreements with developing countries, e.g., with Peru, Panama, South Korea, and Columbia.

Against a more property TRIPS and Doha Declaration standard, the TPP's intellectual property provisions are excessive in the following respects:

- The TPP mandates patents on new uses, new methods of use, and new process for using known products, resulting in the proliferation of secondary patents and the evergreening of patent exclusivity on medicines resulting in higher prices and delay of generic competition.
- The TPP, unlike the May 10, 2007 Agreement, mandates patent term extensions to compensate for delays in granting patents or in issuing marketing approvals. Patent terms extensions for delays in granting patents are unnecessary in most countries either because of provisional patent rights granted to patent applicants or because of the de facto deterrent effect of pending patents on generic entry. Similarly, compensation for regulatory delays in granting marketing approvals punish patients with extended monopoly terms and higher prices where encouragement and support of faster regulatory procedures is a more appropriate policy response.
- The TPP imposes TRIPS-plus market/data exclusivity monopolies[6] on developing countries again delaying generic entry of competitive pricing. The TPP goes beyond the May 10, 2007 Agreement by mandating not only five years of data exclusivity on new small molecule medicines, but by requiring an additional three-year period of market exclusivity whenever marketing approval is granted on a new use of an existing medicine. Moreover, for the first time, the TPP requires data/market exclusivity with respect to biologics with two options – one requiring a flat eight years of exclusivity and the second requiring five firm years plus effective market protection for an equivalent three year period. Unlike the May 10, 2007 Agreement, the TPP puts no pressure on pharmaceutical companies to expedite registration of their medicines in TPP countries or risk losing the effective term of data/market exclusivity. Finally, unlike the May 10, 2007 Agreement, the TPP text does not directly clarify the right to adopt exceptions to data/marketing exclusivity to meet public health needs.[7]
- The TPP imposes TRIPS-plus patent/registration linkage, meaning that patent holders can seek to enforce their patents to prevent registration of follow-on generic products either by requiring drug regulatory authority to withhold marketing approval or by providing notice to the patent holder and effective judicial or administrative procedures to enforce the patent, including via injunctive relief.

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[6] See, Brook K. Baker, *Ending drug registration apartheid – taming data exclusivity and patent/registration linkage*, 34 AM. J. LAW & MED. 303-344 (2008).

[7] There is an indirect reference to this possibility in Art. 18.50.3.

- The TPP imposes TRIPS-plus and May 10, 2007 Agreement-plus protections for trade secrets, potentially negatively impacting public access to clinical trial and pharmaceutical content data that is essential to public health.
- Several features of TPP IP enforcement measures are TRIPS-plus including new levels of deterrent damages, including damages based on full market price; mandatory injunctions interfering with judicial compulsory licensing rights under TRIPS Article 44.1; enhanced border measures including with respect to goods in transit potentially leading to seizures of confusingly similar medicines in-transit; and enhanced criminal enforcement of IP rights.
- Even more significantly, the Investment Chapter creates new private enforcement actions by foreign rightholders directly against governments – so-called investor state dispute settlement. The TPP Investment Chapter defines intellectual property as protected investments and gives rightholders broad rights to seek private arbitration before three trade lawyers whenever their well-founded expectations of profits are thwarted by a foreign TPP's party's policy changes or administrative decisions. Relying on a comparable provision in NAFTA, Eli Lilly has brought a private arbitration claim against Canada seeking $500 million in damages because of Canada's highest courts' invalidation of two patents for failing to meet Canada's well-established patentability criteria.[8]
- The Procedural Fairness for Pharmaceutical Products and Medical Devices Annex (Annex 26-a) threatens increased pharmaceutical influence in medical reimbursement listings and pricing decisions in TPP countries.
- The TPP's varying transition periods for developing country parties temporarily ameliorates some of the TRIPS-plus and May 10, 2007 Agreement-plus provisions of the TPP, but does not necessarily do so as long as a long remains an developing country.

Table 1
TRIPS-plus TPP provisions and their negative impacts on access to affordable medicine

INTELLECTUAL PROPERTY CHAPTER PROVISIONS THREATENING ACCESS TO MEDICINES	
WEAKENED PERMISSIBLE STANDARDS OF PATENTABILITY	Leads to excessive granting of patents, including the proliferation of secondary patents that extend the length of exclusive (monopoly) rights
Weak standard of obviousness Art. 18.37.1, fn 30: obviousness to a person skilled or having ordinary skill in the art in light of the prior art	Precludes countries from adopting a more stringent standard for inventive step, e.g., significant technological advantage and assessment by persons highly skilled in the relevant arts.
Weak Standard on Inventiveness: Patents on new uses of known products Art. 18.37.2: Mandatory patents on new uses or new methods of using a know product	Perpetuates evergreening with new 20-year monopolies on patents covering a new medical use.

[8] Brook K. Baker & Katrina Geddes, *Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines - Eli Lilly V. Canada and the Trans-Pacific Partnership Agreement*, J. INTEL. PROP. L. (in publication 2016).

LONGER PATENT MONOPOLIES	Delays generic entry thereby increasing costs of medicines and potentially decreasing coverage.
Patent term adjustment Art. 18.46.3: Upon request, the term of a patent shall be adjusted to compensate for unreasonable delays in granting a patent if that delay is more than five years from the filing of the application or more than three years after a request for examination (Art. 18.46.4) Art. 18.48.2: To compensate for unreasonable curtailment of patent term as a result of pharmaceutical marketing approval, an adjustment to the patent term shall be made available.	
NEW DATA AND MARKETING APPROVAL RELATED MONOPOLIES	Creates new market exclusivities relating to regulatory data and registration decisions.
Create new 5- and 3-year monopolies on registration-related data for medicines Art. 18.50.1: submission of undisclosed data to secure marketing approval for a new pharmaceutical product shall prohibit marketing approval of a generic equivalent on the basis of the submitted information or the fact of marketing approval either domestically or in another country for a period of at least five years. Art. 1850.2: when new clinical information for a new indication, new formulation or new method of administration is required, an additional prohibition of at least three years shall be granted. (Note: There is an exception from this additional three-year requirement if the initial period of exclusivity is at least eight years Art. 18.54: these periods of data/registration-related monopoly protection shall not be affected by the expiration of any relevant patent.	Even when a medicine is not patented, this so-called data exclusivity grants a new form of monopoly protection that prevents marketing of more affordable generic equivalents. It is uncertain how this exclusivity might be overcome in the interests of public health.
Create new 8-year or 5-plus-3-year monopolies on registration-related data for biologics Art. 18.52.1(a): proposes up to 8 years of prohibiting market approval for bio-similar	Although there is no evidence justifying longer periods of data/registration exclusivity for biologics, the U.S. currently provides longer protection, meaning that bio-similars might come to the market much more slowly.

products that must rely on registration related data provided in support of a prior approved biologic. Alternatively, Art. 18.52.1(b): requires five years of data exclusivity and through other measures provide a comparable [additional three years] of effective market protection.	
Patent-Registration Linkage - prohibit marketing approval where a patent is claimed Art. 18.51.2: where a generic equivalent can seek marketing approval based on evidence of safety and efficacy of a prior approved product, such generic marketing approval shall be prevented where the generic equivalent or the approved use is claimed in a patent. As an alternative, under Article 18.5.1.1, a country shall provide notice of the marketing approval application and the identity of the applicant and provide procedures such as preliminary injunctions to adjudicate the validity or infringement of the claimed patent.	"Patent linkage" prevents registration and marketing of more affordable generic equivalents even when the claimed patent is subject to invalidation or when the applicant asserts the patent would not be infringed.
Undisclosed regulatory data is also considered a trade secret Art. 18.78.2	This might protect such data from disclosure as advocated by the proponents for public access to clinical trial data.
TRANSITIONAL PERIODS AND SPECIAL DEALS	
Transition period for certain countries with obligations relating to patent term restoration/extensions for regulatory delays, for patent-registration linkage, and for data/regulatory exclusivity Section K. **Additional country-by-country Annexes allowing continuation of certain practices.** Annexes 18-A-E	Although transition periods will provide temporary respite from the most onerous forms of patent term extensions, data-registration linkage, and data/regulatory exclusivity, countries will still have to maintain weakened provisions and then upgrade them when their transition period expires adversely affecting access to affordable generics. These Annexes are still TRIPS-plus and would still tend to delay entry of more affordable generic medicines.
ENHANCED REMEDIES FOR INFRINGEMENT	Enhanced remedies can deter and delay entry of generic equivalents into the market.
Enhanced civil remedies and presumptions Art. 18.71.1: requires expeditious remedies to prevent and deter infringement.	Fear of excess liability and injunctions that stop business activity can deter generics from developing and marketing competing generic equivalents when there is even the slightest

Art. 18.72.3: requires presumption of meeting patentability requirements. Art. 18.74.2: mandating judicial authority to order injunctive relieve to prevent infringing goods from entering into channels of commerce. Art. 18.74.4: requiring that judicial authorities consider the market price or suggested retail price as a proper measure of damages. Art. 18.75: mandating judicial authority to apply provisional measures to redress or prevent imminent infringements.	risk that a patent will be infringed or that it might not be invalidated.
Enhanced border measures for confusingly similar products Art. 18.76: requiring border measures of detention or suspended release to prevent importation, exportation, and transshipment of confusingly similar trademark goods.	Provisions such as this have been used to seize generic medicines in transit that are lawful both in the country of production and eventual use. Such provisions can disrupt the normal international transportation and trade in generic medicines.
TRANSPARENCY CHAPTER ON PROCEDURAL FAIRNESS FOR PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES (ANNEX 26-A) THREATENS INCREASED PHARMA INFLUENCE IN MEDICAL REIMBURSEMENT LISTINGS AND PRICING DECISIONS	
Multiple opportunities for input and review of listing and reimbursement decisions Para26-A.2: Where a Party's national health care authorities operate or maintain procedures for listing new pharmaceutical products or medical devices for reimbursement purposes or for setting the amount of such reimbursement, the Party shall: (a) complete listing and reimbursement decisions with a specified period of time; (b) afford applicants timely opportunities to provide comments; (c) provide written information of the basis for its recommendations or determinations; and (d) provide a review or reconsideration process for an aggrieved applicant.	Pharmaceutical and medical device companies can increase the likelihood of favorable listing and reimbursement decisions through repeated access to countries' sovereign decision-making processes. Companies will have multiple chances to influence listing and pricing decisions, to scrutinize resulting decisions, and to thereafter challenge decisions previously rendered. These multiple inputs can result in more listings and higher prices and higher administrative costs for affected countries.
Dissemination of information to health professionals and consumers Para. 26-A.3: guaranteeing right to provide truthful and non-misleading internet site information to health professionals and	

consumers about approved products provided that the information includes a balance of risk and benefits and encompasses all approved indications for use.	
Party rights to consult on matters relating to listing and reimbursement issues Para. 26-A.4	This gives other countries direct opportunities to complain about individual decisions, patterns and practices of decisions, and decision-making criteria and processes.
INVESTMENT CHAPTER'S COVERAGE OF IP-RELATED INVESTMENTS AND INVESTOR-STATE-DISPUTE SETTLEMENT (ISDS)	
Definition of investment covers all intellectual property rights and other expected gains or profits and also IP-related licenses Art. 9.1: Definitions – investments (f) and (g)	
Foreign investors are entitled to multiple protections: Art. 9.4: national treatment (non-discrimination against foreign entities). Article 95: most-favored nation (the best investment protections given to anyone else). Article 9.6: fair and equitable treatment and full protection and security (in accordance with applicable customary international law minimums and so as not to deny justice in criminal, civil, or administrative adjudicatory proceedings according to due process principle embodied in the principal legal systems of the world). See also Annex 9-A. Art. 9.7: freedom from direct or indirect expropriation except for a non-discriminatory public purpose and upon payment of adequate compensation in accordance with due process. Although this Article does not ordinarily apply with respect to compulsory licenses or to the revocation, limitation or creation of IPRs, it does so only to the extent such decisions are consistent with the TPP IP Chapter and the TRIPS Agreement. Annex 9-B.3.(a)(ii): freedom from direct and indirect expropriation covers government action that interferes with distinct, reasonable investment-backed expectations.	Foreign investors can brings ISDS claims that domestic investors cannot. Companies can claim lack of fair and equitable treatment in health related regulatory and judicial decisions, including denial or revocation of patents, denials or restrictions on marketing rights, refusals to list IP-related products for reimbursement or to establish price controls, or required disclosure of registration-related data. Companies can claim indirect expropriation by restrictive changes in regulatory environments, including changes designed to promote public health. Indirect expropriation claims can be made to challenge patent-related decisions, including compulsory licenses. Countries will be severely restricted with respect to efforts to establish local pharmaceutical and medical device industries.

Annex 9-B.3.(b): non-discriminatory regulatory actions designed to protect public health can constitute indirect expropriation in rare circumstances. Art. 9.9: protection against performance requirements, e.g., export requirements, local content requirements, to transfer technology, and to adopt a royalty rate or license contract term.	
ISDS allow foreign entities to institute arbitration claims for losses of expected profits directly against country governments. Section B: Investor-State Dispute Settlement.	Foreign investors can elect to pursue largely secret arbitration before three-person panels even when they have failed to exhaust local judicial review or even if they've lost such review. Damage are unlimited and may either indirectly force or deter regulatory changes concerning public health and access-to-medicines safeguards.

II. The TPP reduces policy space in the U.S. to make medicines more affordable at home.

There is a crisis in the U.S. concerning the costs of medicines, exemplified not only in the excessive price of Gilead's new hepatitis C direct acting antivirals[9] but in the price of other medicines as well, especially cancer medicines, specialty medicines, and biologics.[10] At the same time that U.S. taxpayers, via the National Institutes of Health and university-based research, subsidize basic and applied research that leads to two thirds of priority-review medicines,[11] the U.S. pays the highest prices of any country in the world to the major transnational pharmaceutical companies that inherit the fruit of those public investments.[12] Pharmaceutical companies spend far more on marketing than they do on research, especially after all the tax deductions and rebates they receive,[13] but they still make record profits. To compound the problem, these same high-profit companies pay minimum taxes, hoard their earnings overseas, and change domiciles via "inversion" mergers and acquisitions to avoid even more U.S. taxes.[14]

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[9] Senate Committee on Finance Report, THE PRICE OF SOVALDI AND IMPACT ON THE U.S. HEALTHCARE SYSTEM (Dec. 2015).

[10] Susan Jaffe, *USA grapples with high drug costs*, 386 LANCET 2127-28 (Dec. 2015), http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2815%2901098-3/fulltext.

[11] Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation*, 30 HEALTH AFFAIRS 332-39 (2011), http://content.healthaffairs.org/content/30/2/332.full.

[12] Alfred Engelberg, *How Government Policy Promotes High Drug Prices*, HEALTH AFFAIRS BLOG (Oct. 29, 2015), http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/.

[13] Mariana Mazzucato, "Big Pharma owes a debt to society," THE PROVIDENCE JOURNAL (Nov. 3, 2015), http://www.providencejournal.com/article/20151103/OPINION/151109838.

[14] "Billion Dollar Babies: The high cost of R&D is used to explain why drugs giants merge, and why they must charge high prices. The reality is somewhat different," THE ECONOMIST (Nov. 28, 2015) http://www.economist.com/news/business/21679203-high-cost-rd-used-explain-why-drugs-giants-merge-and-why-they-must-charge.

The American public is increasingly concerned about unchecked and escalating prices for medicines as is the American Medical Association. Seventy-seven percent of the general public want the President and the Congress to prioritize addressing high drug prices according to a recent Kaiser Family foundation report.[15] Similarly, a recently convened AMA task force will develop principles aimed at addressing high pharmaceutical prices and increasing patient access to needed medicines.[16]

Accordingly, any provision in the TPP that increased monopoly protections for medicines or that restricts the U.S.'s future policy space to enact sensible measures to reign in pharmaceutical profiteering should be avoided. Unfortunately, all of the TRIPS-plus measures described in the preceding section tie the U.S.'s hands every bit as much as they do our TPP partners. It is no longer plausible to believe that longer, broader, and stronger patents on medicines is good for the U.S. The rate of inflation in pharmaceutical costs greatly exceeds our national inflation rate, especially for biologics.[17] Biopharmaceuticals are becoming an increasing portion of our already bloated domestic spending on health. The U.S., for one of the first times in its history, is rationing medicines, including for hepatitis C where only the sickest are being prioritized for treatment while others are being told to come back when they have irreversible liver damage.[18] Our economic competitiveness is threatened by our health costs and millions of Americans are impoverished by the costs of medicines or do without.

The most serious Trojan-Horse provision for the U.S. in terms of access to affordable medicines in the TPP is investor-state-dispute-settlement. Every regulatory decision by the FDA, every effort by Congress or the courts to tighten up patenting criteria, every adverse patent decision, or pharmaceutical listing decision by Centers for Medicare & Medicaid Services could be subject to ISDS private arbitration. For example, when the U.S. Supreme Court recently reversed lower-court decisions and Patent and Trademark Office practice with respect to the patenting of genes and other biological isolates[19] it hugely frustrated the monopoly profit expectations of numerous foreign biotech companies. Under the TPP's Investment Chapter, those kinds of decisions could be subject to claims for billions of dollars.

III. Biological exclusivity in the TPP is too long given existing barriers to entry of biosimilars.

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[15] KAISER HEALTH TRACKING POLL: OCTOBER 2015, http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/.

[16] *Physicians calls for fairness in drug prices, availability*, AMA WIRE (Nov. 17, 2015), http://www.ama-assn.org/ama/ama-wire/post/physicians-call-fairness-drug-prices-availability?utm_source=FBPAGE&utm_medium=Social_AMA&utm_term=281158990&utm_content=other&utm_campaign=article_alert.

[17] Express Scripts, 2014 DRUG TREND REPORT (2015) (6.5% inflation for traditional medicines and 25.2% for specialty medicines), http://lab.express-scripts.com/drug-trend-report.

[18] Keith Alcorn, *Almost half of US Medicaid recipients denied funding for hepatitis C Treatment*, *4-state study shows*, NAM AIDSMAP (Nov. 17, 2015), http://www.aidsmap.com/Almost-half-of-US-Medicaid-recipients-denied-funding-for-hepatitis-C-treatment-4-state-study-shows/page/3014924/; AASLD, Leading Liver Doctors: Hepatitis C Patients Must Be Treated (Nov. 16, 2015), http://www.aasld.org/events-professional-development/liver-meeting/press/leading-liver-doctors-hepatitis-c-patients-must-be-treated.

[19] *Ass'n for Molecular Pathology v. Myriad Genetics, Inc*., 133 S. Ct. 2107 (2013).

The TPP provides either for 8-years of data/marketing exclusivity or for 5-years of data/marketing exclusivity plus another comparable three-year period of market protection. In any event, it seems clear that the U.S. will seek to enforce an effective 8-year term of freedom from competition by biosimilars in TPP partners. The Federal Trade Commission has previously concluded that it was unnecessary for the U.S. to provide any period of exclusivity on biological products,[20] and President Obama has attempted to shorten the existing 12-year exclusivity to just 7 years in each of his past five budget requests. Strong lobbying resulted in the adoption 12 years of data/market exclusivity for biologics in the Affordable Care Act, but without compelling justification for the same. The TPP provision for biologic exclusivity is both TRIPS-plus and bad policy. Rather than encouraging the development and marketing of biosimilars, which might offer at least modest cost savings, the TPP erects permanent barriers that will do virtually nothing to incentivize more biologic innovation, but will perpetuate longer periods of monopoly pricing while delaying biosimilar entry. No term of data/market exclusivity is needed to incentivize biologic innovation.

IV. Conclusion – TPP Provisions Threatens Access to Medicines Domestically and with TPP Partners and Creates a Dangerous Precedent for the Future

The TPP dangerously strengthens patent and data-related monopolies and pharmaceutical company enforcement powers, and it sets a dangerous precedent for the U.S.T.R.'s continuing attack on TRIPS-compliant public health flexibilities in India and elsewhere, including countries where PEPFAR focuses its efforts. Instead of creating more policy space for ensuring access to affordable medicines domestically and abroad, the TPP does the exact opposite. The message for this Committee is that the TPP dangerously expands monopoly power over medicines just as the US public and public officials are waking up to the excesses of pharmaceutical pricing. Not only do the TPP's heightened IP standards and enforcement powers negatively impact people with HIV and other health needs in the TPP region, they also tie our hands domestically, giving transnational pharmaceutical companies even more power to charge high prices, to delay generic competition, and to even sue the U.S. if they are seriously disgruntled with future efforts to reign in corporate greed.

As an HIV-focused advocacy organization, Health GAP is primarily focused on ensuring affordable access to the most effective medicines for preventing, treating, and eventually curing the disease. A significant number of people with HIV live in TPP partner countries and will have their access to newer medicines adversely impacted by TPP IP, investment, and transparency provisions. Moreover, people with HIV in the TPP region, who suffer many other medical conditions and diseases including opportunistic infections, will have unnecessarily limited access to medicines. Of course, Health GAP is deeply concerned about other global health conditions as well and the right of access to the benefits of scientific advancement no matter where people live. Accordingly, Health GAP strongly recommends that Congress reject the TPP on the basis of its negative impacts on access to medicines both domestically and abroad.

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[20] Federal Trade Commission Report, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION (2009), available at: https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf.