Dedicated to eliminating the barriers to global access to affordable life-sustaining medicines for people living with HIV/AIDS

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HEALTH GAP (GLOBAL ACCESS PROJECT) ORAL SUBMISSION IN THE MATTER OF 2010 SPECIAL 301 REVIEW MARCH 3, 2010

Health GAP is an organization of U.S.-based AIDS and human rights activists, people living with HIV/AIDS, public health experts, fair trade advocates and concerned individuals who campaign against policies that deny AIDS treatment to millions and fuel the spread of HIV. Health GAP is dedicated to eliminating barriers to global access to affordable, life-sustaining HIV medicines as key to a comprehensive strategy to confront and ultimately stop the AIDS pandemic.

Health GAP campaigns for drug access and the resources necessary to sustain access for people with HIV/AIDS across the globe. We work with allies in the global South and in the G-8 countries to formulate policies that promote universal access, mobilize grassroots support for those policies, and confront governmental policy makers, the pharmaceutical industry and international agencies when their policies or practices block access.

Health GAP is challenging past practices of the United States Trade Representative (USTR) with respect to its annual Special 301 List on three principal grounds: (1) the U.S. commitment to universal access to antiretroviral and other drug therapy for people living with HIV is being undermined by USTR trade policies, including Special 301 Listings, that pressure countries to adopt TRIPS-plus intellectual property protections, that undermine countries' ability to use TRIPS-compliant measures to access more affordable medicines of assured quality, and that ultimately cause the U.S., the world's major underwriter of antiretroviral medicines for developing countries, to pay excessively high prices for improved first-line and new second- and third-line medicines; (2) contrary to its obligations under the Doha Declaration on the TRIPS Agreement and Public Health that require the U.S. to maintain policy space for WTO Member States to prioritize public health and access to medicines for all, the USTR consistently disregards developing countries' obligation to ensure access to essential medicines for their residents; and (3) continued use of the Special 301 Listing is a prohibited form of unilateral trade threat by the United States in violation of its commitments to a multilateral system of dispute resolution within the WTO.

1. Special 301 Listings Undermine U.S. Commitment to Universal Access

In 2003, in his State of the Union address, President Bush launched the President's Emergency Plan for AIDS Relief, seeking appropriations of $15 billion over a five year period and promising to prevent 7 million new infections and "to treat at least 2 million people with life-extending drugs." In his preface to this pledge, President Bush stated, "Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from $12,000 a year to under $300 a year, which places a tremendous possibility within our grasp."[1]

The price tag of $300 per year was based on the cost at the time of generic antiretroviral medicines, priced at 1/40 of the cost of brand-name originator products. Those same medicines now cost $80/per person per year.[2] To increase its ability to procure these lower-cost generic medicines, the U.S. government developed at fast-track, tentative approval mechanism at the Food and Drug Administration that allowed generic producers to establish U.S.-standard quality, safety and efficacy with considerable assistance and speed and at no cost. As of February 2006, 106 generic ARVs had been approved.[3]

The U.S. is now the largest funder of antiretroviral therapy in the world, and PEPFAR has been reauthorized at the level of $48 billion for its second five years.[4] Out of the 4 million people on treatment at the end of 2008, it was directly supporting treatment for 2.485 million and was indirectly supporting many more through the Global Fund to Fight AIDS, Tuberculosis and Malaria and otherwise.[5] In FY 2008, the U.S. PEPFAR program spent $202 million on ARVs. Before that, spending on ARVs increased from $106 million in 2005 to $131 million in 2007 while the proportion of funds spent on generic ARV increased from 11% to 27% and to 57% and the proportion of generics by volume increased to 73% (see side chart).

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[1] Text of President Bush's 2003 State of the Union Address, Washington Post (Jan. 28, 2003). Available at http://www.washingtonpost.com/wp-srv/onpolitics/transcripts/bushtext_012803.html.
[2] Clinton Foundation, Antiretroviral (ARV) Price List (Aug. 2009). Available at http://www.clintonfoundation.org/files/chaiarvpricelistaugust2009english.pdf.
[3] FDA, Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan. Available at http://www.fda.gov/internationalprograms/fdabeyondourbordersforeignoffices/asiaandafrica/ucm119231.htm.
[4] Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, P.L. 110-293.
[5] Technical Note on PEPFAR's Reporting Methodology – FY 2009 PEPFAR Results. Available at http://www.pepfar.vo/2009results/.

Table 4: Percentage of Antiretroviral Drugs Delivered by All PEPFAR Partners in 2007 That Were Generic				
Quarter Delivered	Branded (# of Packs)	Generic (# of Packs)	Grand Total (# of Packs)	Percentage Generic
1	800,283	1,321,381	2,121,664	62%
2	830,515	2,583,924	3,414,439	76%
3	700,654	2,892,753	3,593,407	81%
4	554,131	1,236,508	1,790,639	69%
Not Specified*	159,933	365,182	525,115	70%
Totals	**3,045,516**	**8,399,748**	**11,445,264**	**73%**
* Not all programs reported delivery dates, meaning that those deliveries could not be designated into a specific quarter				

Source: 2007 Annual ARV Procurement Survey

Estimated yearly savings generated through use of generic ARV was: $12,158,680 in 2005), $30,571,682 in 2006, and $72,931,420 in 2007, for a total savings of $115,661,782 over 3 years.[6] In addition to its own ARV procurement, the U.S. is the biggest donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria,[7] which by the end of 2008 had spent nearly $4.4 billion on AIDS programs, roughly a third of which was spent on ARV treatment and monitoring, which necessarily included a significant amount for ARVs. [8]

In addition to these funded commitments to ARV therapy, the U.S. has made repeated promises to expand treatment even further and to achieve Universal Access to AIDS prevention, treatment and care. It did so first, incrementally, in 2000 with Goal 6 of the Millennium Development Goals,[9] thereafter ratified in 2001 with a United Nations General Assembly Declaration of Commitment on HIV/AIDS.[10] Subsequently, at the United Nations General Assembly High-Level Meeting on AIDS in 2006, the U.S. and other countries promised to work towards what is now call Universal Access by 2010.[11] In successive G-8 meetings since 2005, the U.S. recommitted to Universal Access,[12] promising to provide needed resources through bilateral and multilateral channels including the Global Fund.

As a Senator and a presidential candidate, President Obama, as well as Vice President Biden and Secretary Clinton made repeated commitments to scale up the US response to global

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[6] Charles Holmes et al., Abstract - Measuring Progress in Reducing the Costs of ARV Drugs Purchased by the President's Emergency Plan for AIDS Relief, 2005 to 2007. 16th Conference on Retroviruses and Opportunistic Infections (2009). Available at http://retroconference.org/2009/Abstracts/35741.htm.

[7] U.S. has donated over $4.3 billion to the Global Fund between 2001 and 2009, representing approximately 29% of total contributions. Available at www.theglobalfund.org/documents/pledges_contributions.xls.

[8] Global Fund, Scaling up for Impact Report – 2009. Available at http://www.theglobalfund.org/documents/publications/progressreports/ProgressReport2008_high_en.pdf.

[9] *United Nations Millennium Declaration*, A/RES/55/2. 18 September 2000. Available at http://www.un.org/millennium/declaration/ares552e.pdf.

[10] United Nations General Assembly, Special Session on HIV/AIDS. *Declaration of Commitment on HIV/AIDS*. 25-27 June 2001. Available at http://data.unaids.org/publications/irc-pub03/aidsdeclaration_en.pdf.

[11] United Nations General Assembly. *Political Declaration on HIV/AIDS*. A/RES/60/262. 15 June 2006. Available at http://data.unaids.org/pub/Report/2006/20060615_HLM_PoliticalDeclaration_ARES60262_en.pdf.

[12] G8 Summit 2005, *The Gleneagles Communique*. 2005. Available at http://www.unglobalcompact.org/docs/about_the_gc/government_support/PostG8_Gleneagles_Communique.pdf. *G8 Summit 2006 St. Petersburg. Fight against infectious diseases*. 2006. Available at http://en.g8russia.ru/docs/10.html. G8 Summit 2007 Heiligendamm. *Growth and Responsibility in Africa*. Available at http://www.g-8.de/Content/DE/Artikel/G8Gipfel/Anlage/Abschlusserkl_C3_A4rungen/WV-afrika-en,templateId=raw,property=publicationFile.pdf/WV-afrika-en.pdf. G8 *Hokkaido Toyako Summit Leaders Declaration*, 2008. Available at http://www.mofa.go.jp/policy/economy/summit/2008/doc/doc080714_en.html; see also G8, *Toyako Framework for Action on Global Health - Report of the G8 Health Experts Group*. 2008. Available at http://www.mofa.go.jp/policy/economy/summit/2008/doc/pdf/0708_09_en.pdf. G8 Summit 2009, L'Aquila. *Responsible Leadership for a Sustainable Future*. Available at http://www.g8italia2009.it/static/G8_Allegato/G8_Declaration_08_07_09_final,0.pdf.

AIDS, including through adoption of trade policies that ensure access to affordable generic medicines.[13]

Although treatment reached over 4 million people at the end of 2008,[14] an additional 10 million patients who need treatment under new WHO treatment guidelines are still without medicines,[15] and many millions more will require treatment over the next decade. These patient need treatment in their own right, but there is also growing evidence that treating HIV/AIDS might be one of the best ways to prevent HIV transmission. A growing body of observational evidence from discordant couples and informed scientific modeling has reinforced the idea that treating HIV so-as to reduce the viral load to undetectable levels could have a dramatic impact in reducing the risk of transmission.[16] This evidence is so compelling that WHO has undertaken to explore the benefits of treatment-as-prevention more rigorously,[17] and there is already a consensus that treatment could be the next major prevention tool.

In addition, the new treatment guidelines recommend discontinuation of d4T (stavudine) and its replacement with a more expensive tenofovir- or zidovudine-based regimens (cost comparison $210 or $149 vs. $80 per person per year).[18] Not only are first-line medicines becoming more expensive, but newer second- and third-line regimens are even more 8 to 30 times more expensive (see chart below).[19] According to a Report of the U.K. All Party Parliamentary Working Group on AIDS, *The Treatment Timebomb*, "The number of people needing HIV treatment will rise over the next two decades and so will the cost of treatment. This is because better, more effective treatments have come on the market and should be offered to patients, and also because, over time, more people will move from first to second (and later) line regimens, which are more expensive."[20]

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[13] See for example, "The Obama-Biden Plan to Combat Global HIV/AIDS," available at: http://change.gov/pages/the_obama_biden_plan_to_combat_global_hiv_aids

[14] WHO, *Towards universal access: scaling up priority HIV/AIDS interventions in the health sector: progress report 2009*. Available at http://data.unaids.org/pub/Report/2009/20090930_tuapr_2009_en.pdf. UNAIDS, *AIDS epidemic update - November 2009*. Available at http://data.unaids.org:80/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf.

[15] WHO, Rapid Advice: Antiretroviral Therapy for HIV Infection in Adults and Adolescents (Nov. 2009). Available at http://www.who.int/hiv/pub/arv/rapid_advice_art.pdf.

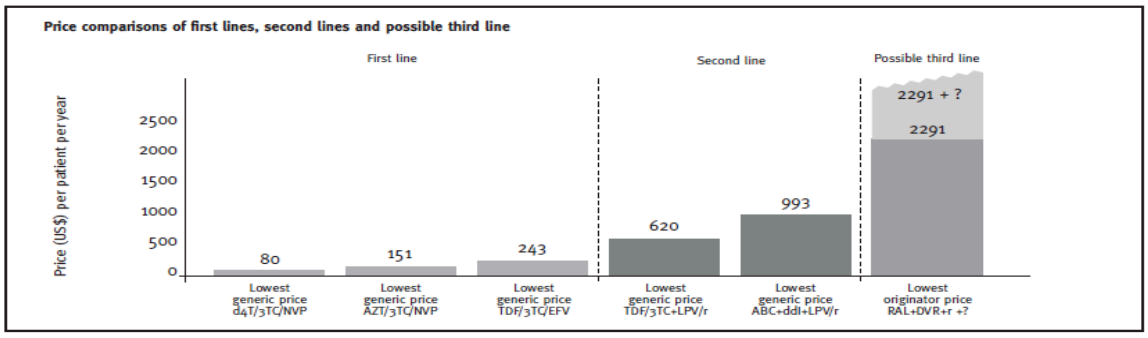
[16] Reuben M Granich et al., *Universal voluntary HIV testing with immediate antiretroviral therapy as a strategy for elimination of HIV transmission: a mathematical model*, 373 Lancet 48-57 (Jan. 3, 2009) http://download.thelancet.com/pdfs/journals/lancet/PIIS0140673608616979.pdf?id=9d3ded37aa4dcc76:-ced7b81:12338a96449:534e1250791687161. Derek Thaczuk & Michael Carter, *Antiretroviral treatment lowers rates of HIV transmission in heterosexual couples in Africa*, Aidsmap News (Feb. 10, 2009). http://www.aidsmap.com/en/news/EE59A107-93DF-4B9B-AE5E-5E86DF018B41.asp?type=preview. Granich R., Crowley S., Vitoria M. et al. 2010. Highly active antiretroviral treatment for the prevention of HIV transmission. *AIDS*. 13:1 online. Available at http://www.jiasociety.org/content/13/1/1. Donnell D et al. Abstract- ART and the risk of heterosexual HIV-1 transmission in HIV-1 serodiscordant African couples: a multinational prospective study. Seventeenth Conference on Retroviruses and Opportunistic Infections (2010). Available at http://www.retroconference.org/2010/Abstracts/39222.htm.

[17] *See*, WHO, *Antiretroviral Therapy for HIV Prevention* (2009). Available at http://www.who.int/hiv/topics/artforprevention/en/.

[18] MSF, Untangling the Web of Antiretroviral Price Reductions (12th Ed.).

[19] MSF, Untangling the Web of Antiretroviral Price Reductions (12th Ed.). Available at http://utw.msfaccess.org/background/challenges.

[20] Available at http://www.aidsportal.org/repos/APPGTimebomb091.pdf.



It is clear that this Administration's pledged commitment to universal access to AIDS treatment cannot be met unless ARV prices are affordable. Although generic companies in India and other producing countries were able to reverse engineer and manufacture pre-TRIPS medicines at a fraction of the cost of brand-name patented versions, those same opportunities have dwindled with respect to post-TRIPS medicines. Accordingly and as a result of India having become fully TRIPS-compliant in 2005, a number of newer ARVs remain much more costly because the patent holder faces no generic competition from India or elsewhere.

It is in this context that the USTR's pursuit of heightened intellectual property protections for pharmaceutical products and its "punishment" of countries that use TRIPS-compliant flexibilities by means of its Special 301 Annual Reports is so counterproductive. For the U.S. to be the world's major procurer of AIDS medicines at the same time that the USTR is pursuing policies that will reduce the U.S.'s ability to procure cheaper ARVs is an example of extreme policy incoherence at its worst.

The Submission of Global Health Organizations, including Health GAP, highlights the many ways that the USTR has pursued TRIPS-plus intellectual property protections and the many other ways that the USTR has improvidently listed countries because of their fully TRIPS-compliant utilization of lawful flexibilities. Special 301 Reports have listed countries for use of compulsory licenses (Thailand and Brazil), for refusing to expand scope of patentability to second uses (Brazil), for failure to extend patent terms (Israel), for failure to adopt patent/registration linkage (12 countries in the 2009 Special 301 Report), for failure to grant data exclusivity (multiple countries for multiple years), and for failure to adopt extraordinary enforcement measures, including border measures that might unreasonably interfere with the legal trade and transshipment of generic medicines. Each and every one of these listings has the potential to increase the cost of medicines in developing countries, some of which cost is likely to be borne by U.S. taxpayers. In this regard, far too much attention has been given to the interests of pharmaceutical companies and far to little to the more compelling foreign policies objectives that seek greater access to medicines for poor people in poor countries.

2. The USTR is Ignoring U.S. Commitments made in the Doha Declaration

In November of 2001, the U.S. joined every other WTO Member Country and signed the Doha Declaration on the TRIPS Agreement and Public Health.[21] The Doha Declaration emphasized the gravity and primacy of developing countries' public health needs,[22] clarified Member's right to promote access to medicines for all,[23] and specifically reconfirmed countries' broad discretion to issue compulsory licenses and to permit parallel importation.[24] In addition, the Doha Declaration also promised to resolve the production-for-export/import problem facing countries with inefficient manufacturing capacity.[25] Finally, the Doha Declaration proposed an extension of the transition period for least-developed country members concerning their obligations to grant and enforce product patents on pharmaceutical products, and their obligation to comply with data protection and mailbox-market-exclusivity rules.[26]

Instead of respecting the binding U.S. commitments to global public health and access to medicines, codified in the TRIPS Agreement, the USTR has used the Special 301 reporting systems and other measures such as bilateral trade agreements and direct pressure on countries in attempt to ensure countries abrogate their right to legislate and utilize TRIPS-compliant flexibilities to promote access to affordable generic medicines of assured quality. The General Accounting Office has confirmed this tendency in its recent assessment of USTR Trade Policy.[27]

3. The USTR May Be Violating its Obligation to Use the WTO Multilateral Trade Dispute Mechanisms to the Exclusion of its Unilateral Special 301 Listing Sanctions

The Marrakesh Agreement Establishing the World Trade Organization. Article 23.2 states "Members shall not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this understanding." Similarly the WTO Panel Report, United States – Sections 301-310 of the Trade Act of 1974, found that use of the U.S. 301 system, as used by a superpower, constituted undue leverage on other Members and could in certain circumstance be an illegal trade act.[28] Although the WTO dispute resolution mechanism is not a strong vehicle for vindication of developing countries trade interests, it should and does provide a degree of protection against unilateral trade bullying by the US or other WTO members. Accordingly, continued use of the Special 301 Listing by the USTR is a prohibited form of unilateral trade threat in violation of the U.S.'s commitments to a multilateral system of dispute resolution within the WTO.

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[21] Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, Doha, Nov. 9-14 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm.

[22] *Id.* ¶ 1.

[23] *Id.* ¶ 4.

[24] *Id.* ¶ 5 (b), (c), (d).

[25] *Id.* ¶ 6.

[26] *Id.* ¶ 7

[27] GAO, Rep to Congressional Requesters, U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification, GAO-07-1198 (2007). Available at http://www.gao.gov/new.items/d071198.pdf.

[28] ¶ 7.89, WT/DS152/R (Dec. 22, 1999).

4. Conclusion

For the above stated reasons, Health GAP requests that the USTR conduct a top to bottom review of its use of Special 301 Lists. Health GAP further requests that the USTR refrain from listing countries that lawfully refuse to adopt TRIPS-plus flexibilities or that utilize TRIPS- and Doha-compliant flexibilities to increase access to medicines. As a condition of respecting the U.S. endorsement of the Doha Declaration and for the purpose of achieving greater policy coherence with the Obama Administration's Global Health Initiative,[29] which seeks improved health outcomes in developing countries not only with respect to HIV/AIDS, tuberculosis and malaria, but also with respect to child and maternal health, sexual and reproductive health, neglected diseases, and health system strengthening more broadly, the USTR should act affirmatively to promote access to medicines by promoting implementation of the TRIPS flexibilities affirmed in the Doha Declaration, instead of erecting intellectual property protections that serve only to increase pharmaceutical industry profits. Those monopoly-based profits come at too high a cost in terms of health outcomes for people living with HIV and other people seeking to secure healthy and productive lives in developing countries. [30]

[29] *Statement by the President on the Global Health Initiative*. May 5, 2009. Available at http://www.whitehouse.gov/the_press_office/Statement-by-the-President-on-Global-Health-Initiative/.

[30] This testimony was prepared by Brook K. Baker with contributions from Asia Russell.