USTR-2010-003

UNITED STATES TRADE REPRESENTATIVE

IN THE MATTER OF
2010 SPECIAL 301 REVIEW:
IDENTIFICATION OF COUNTRIES UNDER SECTION 182 OF THE TRADE ACT OF 1974

SUBMISSION OF CENTER FOR POLICY ANALYSIS ON TRADE AND HEALTH (CPATH)

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We call on the Administration to change course in using Special 301 regarding public health and access to medicines:

1. Ensure that Special 301 is not used to promote TRIPS-plus restrictions on access to medicines;

2. Adopt a policy guideline banning USTR from using Special 301 to punish nations which take regulatory action to promote public health and access to medicines;

3. Prioritize public health in U.S. trade policy. Include health experts and advocates in all levels of trade policy development, effective immediately.

4. Indicate support for Guatemala's Decree 16-2003, and the Guatemalan government's legal authority and obligation to purchase medicines at the most affordable price in order to treat the largest number of people.

In the past, Special 301 Reports reflected USTR policy, to target countries to watch when they used public health flexibilities permitted in TRIPS and the Doha Declaration to protect public health and promote access to medicines. Guatemala is a case in point.

CAFTA Raises Prices, Limits Availability of Life Saving Drugs for U.S. Trade Partners

Our recent report published in the peer-reviewed journal *Health Affairs* demonstrates how intellectual property rules in the U.S. - Central America Free Trade Agreement (CAFTA) keeps lower-priced generic versions of life-saving drugs off the shelves and out of the hands of some of the poorest people in our hemisphere.[1] Guatemala is increasingly unable to produce or import affordable medicines because of intellectual property provisions in CAFTA that were demanded by the U.S. pharmaceutical industry and have been aggressively enforced by the U.S. Trade Representative (USTR). As a result, the cash-strapped Guatemalan public sector faces higher prices – up to 846 percent higher – for important drugs to fight diseases such as diabetes and HIV/AIDS. People with HIV/AIDS have reported cutbacks in access to needed drugs.[2] (See Appendix 1)

The report focuses on **data exclusivity rules** and **patents** that are among the intellectual property provisions of CAFTA and other free trade agreements. Particularly alarming is that the rules not only

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keep affordable new generics from entering the market; they also function retroactively to remove existing medicines from the shelves. While patents already allow brand name drug manufacturers like Novartis and Merck to suppress competition from generic drug makers in the U.S. and abroad, data exclusivity is an additional bonus for this multi-billion dollar industry. Securing data exclusivity is a simple process for these companies, but it places insurmountable bureaucratic burdens on generics manufacturers. Generic drug makers typically rely on the clinical trial data already generated by brand-name manufacturers to demonstrate the safety and efficacy of their products. But CAFTA prohibits generic drug manufacturers from using the brand-name clinical trial data for a fixed period of years, sometimes even after the brand-name drug is no longer under patent. Without these data, generic versions cannot be approved for market.

The report examined a total of 77 data-protected drugs. Detailed tables in the article illustrate the ways in which both patent and data exclusivity protections influence Guatemalan health officials to purchase brand name pharmaceuticals, often at hundreds of times the cost of their generic counterparts. They also provide examples of generic drugs that were blocked from being marketed in Guatemala in the first place.

Example: The insulin made by Sanofi Aventis U.S., brand named Lantus, cost $50.31 per 100 ml in 2007 while a therapeutically equivalent generic insulin made by Drogueria Pisa de Guatemala cost $5.95 per 100 ml. Because Lantus is protected by data exclusivity until 2016, Guatemalans will continue to pay 846 percent more for this product than they would pay for its locally manufactured equivalent.

Example: Omnicef is an antibiotic which treats infections including pneumonia, and is made by the Illinois-based company Abbot. Because the process for formulating this drug is patented in Guatemala, a generic version was prevented from being produced or sold.

Example: The leukemia treatment named Gleevec, made by Novartis, also enjoys patent protection, although its expiration date could not be determined. Until it expires, affordable generic alternatives cannot be developed or sold in Guatemala.

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Example: In some cases, data protection bestowed on a brand name is retroactive, resulting in removal from the shelves of a generic that had already been in use. This was the case with the brand name drug Plavix, made by New Jersey based Sanofi-Aventis. Plavix is prescribed to prevent heart attacks and is currently protected under patent and data exclusivity in Guatemala until 2019. Two Guatemalan companies that had been producing its generic version have had their registrations revoked.

Trade Policy Advice is Unbalanced – Dominated by Corporate Advisers without Public Health Representation

The U.S. Trade Advisory Committee system, which provides advice on trade policy and trade negotiations to USTR and the President, is imbalanced. Trade Advisory Committees are dominated by advisers representing for-profit corporate interests, with virtually no representation from the public health community to protect the public interest by safeguarding and promoting health and access to medicines. As of the Summer of 2009, there were 27 representatives from the pharmaceutical industry alone on the various U.S. trade advisory committees, compared to 20 in 2005; four representatives from the pharmaceutical industry sit on the top Advisory Committee for Trade Policy and Negotiations (ACTPN). Without the benefit of balanced representation in the public interest from the public health community, U.S. policy reflected in Special 301 has prioritized commercial interests over access to medicines.

Recommendation: The Administration should prioritize public health in U.S. trade policy, and include health experts and advocates in all levels of trade policy development, effective immediately. In addition, the Administration should move to create a Tier 2 Public Health Advisory Committee on Trade (PHACT) as called for by two bills currently before Congress: HR 2293 and S.1644. The President should give this legislation his full support.

Guatemalan IP Laws – A Tug-of-War Over Restrictions on Access to Medicine

Intellectual property (IP) rules, in particular data exclusivity, have been a contentious legislative issue in Guatemala since the late 1990s, as the attached table demonstrates.

The main laws affecting intellectual property rules for medicines in Guatemala are the Law on Industrial Property and its secondary or accompanying rules. Guatemala was an initial signatory to the

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Marrakesh Accords of 1994 that created the WTO, and was thus a party to the TRIPS Agreement when it went into effect in 1995. As a less-developed country, it could have waited to implement patent laws until 2005. However, it did so in 1999, with Accord 712.991.

Key provisions of Accord 712.991 have been amended in almost every year since it was adopted. The rules on data exclusivity were changed on every occasion.

History of Guatemala Data Exclusivity Laws

LAW	Year effective	Data Exclusivity (DE)	Exceptions	New Chemical entity/ New Product	Repeal	Other
TRIPS (WTO)	**1995**	No barriers to competition. Protects undisclosed information against: breach of honest commercial practices; unfair commercial use	Necessary to protect the public, or steps to assure no unfair commercial use			
Accord 712.991	**1999**	Data must be accurate Content confidential	Allows special measures to manufacture or import drugs to assure adequate supply			
Decree 57-2000	**2000**	**15 years DE in effect**		New in Guatemala		
Decree 76-2002	**2002**	**Eliminates 15 year DE**				**U.S. Response: Guatemala added to 301 "Watch List"**
Decree 9-2003	**2003**	**5 years DE in effect** Data must require considerable effort to produce		New in Guatemala	Repeals 76-2002	
Decree 34-04	**2004**	**Eliminates 5 year DE**	Per Doha Declaration: To protect life or health; National emergency; To impede anti-competitive practices	NCE: New in the world New Product: new in the world	Repeals 9-2003	

LAW	**Year effective**	**Data Exclusivity**	**Exceptions**	**New Chemical entity/ New Product**	**Repeal**	**Other**
Decree 30-2005	**2005**	**5 years DE in effect**	Necessary to protect safe use of the drug To protect life or health Declared national emergency	New in Guatemala	Repeals 34-04	Trade agreements prevail over this law in case of conflicts
Decree 11-2006	**2006**	**5 years DE remains in effect**	New or different uses of the product are not protected.	New in Guatemala		
LAWS FOR HIV/AIDS DRUGS		**Provision**				**U.S. Response**
Decree 16-2003 Adds paragraph 15 to article 7, Decree 27-92, of the Law of Value-Added Tax	**2003**	Tax exemption to antiretroviral drugs for HIV/AIDS, and preference to generic and natural products.				Used to authorize purchases from PAHO and other donors. Guatemala cited in Special 301 Watch List
Decree 66-2007	**2007**	Government can only pay for 20% at a time for bulk purchases from PAHO, others				

The US State Department intervened directly to influence the adoption of increasingly stronger intellectual property laws and regulations. At one point, the US threatened that Congress would not approve CAFTA, unless Guatemala adopted laws that were harmonious with CAFTA's IP rules on data exclusivity and other matters, prompting letters of protest from members of the U.S. Congress including Representatives Charles Rangel and Henry Waxman on January 26, 2005.[3]

Protecting Public Health, Promoting Access to Medicines, and Getting Listed on the Special 301 Watch List

In 2000, Decree 57-2000 authorized brand-name companies to register their products for data protection for 15 years. A list of 22 data protected drugs was created.

Two years later, in 2002, **Decree 76-2002 eliminated the rule on 15 years of data exclusivity**, resulting in no data exclusivity of any time period for drugs. **The US responded by adding Guatemala to the Special 301 Watch List**[4], a prelude to possible trade sanctions. Under past USTR

policy involving Special 301, countries identified as having problems "with respect to IPR protection, enforcement, or market access for persons [companies] relying on intellectual property" are put on a "Priority Watch List" and "Watch List," and are subject to increased U.S. attention.[5] The US was then Guatemala's most important trading partner, as it remains today, acting as the market for 36% of Guatemalan exports and the source of 40% of its imports.[6]

In 2003, **Decree 9-2003** repealed Decree 76-2002, and **implemented five years of data exclusivity**.

Recommendation: The Administration should ensure that Special 301 is not used to promote TRIPS-plus restrictions on access to medicines.

Increasing Access to HIV/AIDS Drugs and Placement on the Special 301 "Watch List"

Drugs for HIV/AIDS have become more affordable through competition from generics, and through purchases from donor organizations such as the Pan American Health Organization (PAHO) and the Clinton Foundation. These options are being increasingly limited in Guatemala.

In 2003, **Decree 16-2003** provided some tax exemptions and other benefits for generic drugs, including medicines for HIV/AIDS. This law remains an object of pharmaceutical industry protest, and was the subject of the 2007 and 2008 301 Watch Listings for Guatemala.[7] PhRMA and its member companies operating in Guatemala recommended that Guatemala remain on the Special 301 **Watch List** in 2009 and that the issue related to Decrees 16-2003 be "quickly and effectively resolved." Guatemala remained on the 2009 Watch List.[8] (See Appendix 2)

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Comparison of Prices of 5 and 15-Year Data Protected with Non-Data Protected Drugs on Open Contract [9]

Data-protected drug (brand name/active ingredient)	Non-data-protected drug (active ingredient)	2007 Open Contract Price	Price difference, data-protected versus non-data-protected
Protease Inhibitor:			
Kaletra, lopinavir/ritonavir oral solution, 80/20 mg/ml, bottle 160 ml; data protection: 15 yrs		$472.09	
	Lopinavir/ritonavir (brand name Kaletra)	PAHO price: $284.89	Kaletra commercial price costs 166% more than PAHO price

As a result of this pressure from the pharmaceutical industry in the U.S., Guatemala decided to discontinue purchasing medicines for HIV/AIDS from the Pan American Health Organization at a discounted rate. Instead, the government instructed the Ministry of Health to purchase these drugs directly from brand-name originator drug companies at full price. The price of these drugs increased in some cases by a factor of 13, forcing the Ministry of Health to sharply curtail the medicines and services it was able to provide.

It would be important for the Administration to signal its support for Guatemala's return to an affordable policy on the purchase of medications.

Recommendations:

The Administration should adopt a policy guideline banning USTR from using Special 301 to punish nations which take regulatory action to promote public health and access to medicines;

Specifically, the Administration should indicate support for Guatemala's Decree 16-2003, and the Guatemalan government's legal authority and obligation to purchase medicines at the most affordable price in order to treat the largest number of people.

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APPENDIX 1

Latino USA

Report: CAFTA Pushes Up Cost of Vital Medicines

August 25th, 2009 | Published in Newsroom Alerts

CAFTA puts lifesaving medicine out of reach for sick Guatemalans
The story of a Guatemalan woman living with HIV

WASHINGTON DC – Why can't sick Guatemalans get lifesaving treatments they need?

"No hay dinero," states Jakelin Johana Cucyan Sosa, a Guatemalan woman living with HIV, "There is no money." There is no money for hospitals or for patients like her.

A crisis has been deepening for sick Guatemalans since the US- Central American Free Trade Agreement (CAFTA) pushed the cost of medicine in their country out of their reach. A new report by the Center for Policy Analysis on Trade and Health (CPATH) documents just how prices have changed, and why.

Since CAFTA went into effect in Guatemala in early 2006, life has only gotten harder for Sosa, who lives in San Miguel Petapa, Guatemala. Sosa is one of an estimated 59,000 people in Guatemala living with HIV. According to USAID, Guatemalans are one-sixth of Central America's HIV-infected population. When CAFTA increased drug prices in the Central American country, the cost of managing HIV/AIDS increased dramatically. Most recently, the government took another step backwards by cutting off drug purchases from PAHO and the Clinton Fund, which offer lower prices. Unable to get funding for the suddenly more expensive drugs, Sosa's healthcare facility, a small, donations-based clinic called Hogar Marco Antonio Clinic, lost the ability to provide adequate treatment.

Diagnosed with HIV in 2003 when she sought treatment for a cold that would not go away, Sosa was referred to a clinic that provided her with a regimen of antibiotics to fight opportunistic infections. She then began visiting Hogar Marco Antonio, where donations from the NGO Doctors Without Borders made it possible for the clinic to provide antiviral medication. In addition to managing her own illness, Sosa is a caregiver for her husband, who is also HIV positive. Her husband is receiving antiviral drugs through IGSS, a government agency, because he is retired with a disability. He is bedridden and often deals with bedsores which complicate his care. Sosa also cares for their two daughters, Frida, 11, and Sabrina, seven.

Sosa is now nearly blind due to a toxoplasmosis parasitic infection, a common infection that has severe consequences only in people with HIV, AIDS, or with a compromised immune system. She can no longer see her daughters growing older, but she wants to remain alive to care for them and see that they reach adulthood.

Treatment through Hogar Marco Antonio is free for patients, so Sosa's care is not dependent on ability to pay for medicine. However, when the cost of medicine rose dramatically due to CAFTA,

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her clinic had to make tough decisions about what they could do and couldn't afford to do for their patients.

The report by CPATH shows that some drug prices increased up to 846 percent in Guatemala after CAFTA went into effect. This was due to intellectual property provisions that kept less expensive generic drugs off the market, leaving hospitals and clinics to buy expensive imported pharmaceuticals. CPATH's report also discusses the ongoing tug of war within the Guatemalan government between advocates for more affordable medicines and supporters of the brand name drug industry.

Unable to stretch the meager funding it has to pay for medicine and its other operations, Hogar Marco Antonio has had to reduce the level of assistance it can provide. The clinic lowered the daily dosages for the drugs it provides in order to be able to provide more patients with some level of treatment. Sosa still got medication, but since there was less to go around, she got less of it.

Patients with more expensive regimens are now given medication in short increments of eight days, although the increments used to be longer. Sosa reports that many of her fellow patients were no longer able to afford to take time off of work and travel every eight days to the clinic. Many patients have disrupted their treatment, and some have given up altogether on the treatment of their disease. According to the World Bank, about 75 percent of Guatemalans live below the poverty line, defined as income that is insufficient to provide basic goods and services.

As a result of her poor eyesight and the need to care for her husband and two daughters, Sosa has had trouble finding work. She struggles to be able to afford to travel to the clinic every eight days. She has moved her family in with her mother and sister, who help with the children and caring for Sosa's husband.

Another service that Sosa's clinic has had to eliminate altogether due to the high cost of medicines is lab work. The clinic diverted funds from lab work to the provision of medicines. This lab work that used to be done every three months to monitor treatment. The work is essential to directing treatment and making it more effective, but because of the funding crisis that the clinic is now in, it is no longer available. This makes it harder for Sosa to know how many more days she has left, whether she will be there when 11-year old daughter Frida graduates from school, or whether Sosa will ever live to know her grandchildren.

Sosa can only hope that the Guatemalan government and its trading partners make basic decisions to make her treatments more affordable. She is a member of Mujeres Positiva, an organization for women working with hospitals to provide medicines, and working to encourage the government to increase funding for hospitals and clinics. But the provisions of CAFTA are pushing cost of generics to the top shelf. Until drugs become more affordable, there is only so much that they can do.

For more information on how CAFTA's intellectual property provisions have caused an increase in the cost of medicines for people like Jakelin Johana Cucyan Sosa, please see the peer-reviewed CPATH report in Health Affairs journal, at www.healthaffairs.org.

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The Center for Policy Analysis on Trade and Health (CPATH) is a project of the Center for Policy Analysis, a nonprofit organization dedicated to improving population health in the United States and internationally. CPATH is a widely recognized leader and a reliable resource in the debates on global trade and health. CPATH has encouraged public health leaders to articulate their stake in protecting public accountability.

CPATH conducts multi-disciplinary research, analysis and advocacy about the impact of international trade and increased privatization, deregulation, and decentralization of vital human services on health. Focusing on the relationship between trade and health, CPATH has assessed the impact of trade agreements and proposals, including NAFTA, GATS, FTAA, and World Trade Organization disciplines, on the health care system in the United States, including "safety net" services such as community clinics and public hospitals, and on domestic regulations in the United States that protect population health which might be subject to challenge as unnecessary barriers to trade.

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The print edition of Health Affairs containing the Shaffer and Brenner article will be published in January, 2010.

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APPENDIX 2

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) SPECIAL 301 SUBMISSION 2008[10]

GUATEMALA

In 2007, Guatemala suspended two regulations, issued by the Health Authority in December, 2006, that limited patent linkage and threatened test data protection. Despite entry into force of the DR-CAFTA, patent linkage has not yet been fully implemented. Regrettably, implementation has been delayed by the Ministry of Economy's failure to act upon proposals developed by the Ministry of Health. Regarding market access, Guatemala has not corrected the tax discrimination caused by Decree 16-2003 against R&D products that has been in force for more than four years.

For these reasons, PhRMA members recommend that Guatemala remain on the **Watch List** in 2008, and strongly recommend that Guatemala be subject to out-of-cycle review if an effective linkage system is not provided promptly or if the level of data protection decreases.

Intellectual Property Protection

Patent Linkage

Local producers of copied products are advocating against application of Government Accord 351-2006 before Ministry of Health and Ministry of Economy officials at both the political and technical levels. This Accord provides patent linkage and requires prospective registrants to provide sworn statements regarding their authorization to market the product. The Ministry of Health, during the second half of 2007, proposed language and procedures to provide clarity and simplify application of the Accord. However, local manufacturers opposed the proposal and sought the involvement of the Ministry of Economy, which in turn has delayed discussions and prevented full implementation of the patent linkage provisions by the Ministry of Health. The Ministry of Economy's intervention calls into question whether the patent linkage system will be effectively enforced.

Market Access Barriers and Tax Discrimination

PhRMA member companies believe that Decree 16-2003 discriminates against innovative pharmaceutical products by establishing value-added tax exemptions and other benefits for "generic" and "natural" medicines and to "salts" used in the manufacture of such products. This discriminates between products that depend on intellectual property and originate in the United States and copied products of domestic or foreign origin. The decree provides advantages to "generic" and "natural" products in government tenders, calling for the Government to favor those products over innovative products. The decree also discriminates against innovative pharmaceutical products by requiring government health entities to favor the prescription of generic products. R&D companies have presented the President of the Republic and the Ministry of Economy with proposals aimed at eliminating discrimination; however, these proposals have not been acted upon.

Damage Estimate

At the time of reporting PhRMA is not able to provide a specific estimate of the damages incurred in 2007 attributable to trade barriers related to intellectual property protection and market access.

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From the USTR Website:

In June 2006, USTR created a new Office of Intellectual Property and Innovation. Intellectual property issues were previously covered at USTR in the Office of Services, Investment and Intellectual Property. USTR also appointed a Chief Negotiator for Intellectual Property Enforcement. The creation of this new office and additional staff dedicated to intellectual property at USTR enhances our focus on protecting and enforcing IPR.[11]

The United States is concerned that Guatemala's health authorities have issued procedures that may undermine some of the protections against unfair commercial use for pharmaceutical data generated to obtain marketing approval under the CAFTA–DR.[12]

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[1] Shaffer, Ellen R. and Brenner, Joseph E., A Trade Agreement's Impact On Access To Generic Drugs, *Health Affairs*, 28, no. 5 (2009): w957-w968 (Published online 25 August 2009), doi: 10.1377/hlthaff.28.5.w957, http://content.healthaffairs.org/cgi/content/abstract/28/5/w957?HITS=10&hits=10&author1=shaffer&maxtoshow=&andorexactfulltext=and&FIRSTINDEX=0&resourcetype=HWCIT&fulltext=guatemala&searchid=1&RESULTFORMAT=.

[2] Report: CAFTA Pushes Up Cost of Vital Medicines, CAFTA puts lifesaving medicine out of reach for sick Guatemalans, *The story of a Guatemalan woman living with HIV*, Latino USA, Washington, DC, August 25th, 2009.

[3] Posted online at http://www.cpath.org/id5.html.

[4] Office of the United States Trade Representative. 2003 Special 301 Watch List. http://ustraderep.gov/Document_Library/Reports_Publications/2003/2003_Special_301_Report/Special_301_Watch_List.html

[5] According to the USTR "Pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988 and the Uruguay Round Agreements Act (enacted in 1994) ('Special 301'), under Special 301 provisions, USTR must identify those countries that deny adequate and effective protection for IPR or deny fair and equitable market access for persons that rely on intellectual property protection. Countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies, or practices have the greatest adverse impact (actual or potential) on the relevant U.S. products must be designated as 'Priority Foreign Countries.'

"Priority Foreign Countries are potentially subject to an investigation under the Section 301 provisions of the Trade Act of 1974.

"USTR has created a 'Priority Watch List' and 'Watch List' under Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons [companies] relying on intellectual property. Countries placed on the Priority Watch List are the focus of increased bilateral attention concerning the problem areas."

http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file324_9334.pdf, accessed 3/16/2008.

[6] Trade Compliance Center, U.S. Department of Commerce. Guatemala: January 2002. Press Release, Press/TPRB/184, 18 January 2002. http://tcc.export.gov/Country_Market_Research/All_Research_Reports/exp_005742.asp.

[7] Shaffer and Brenner, op.cit.

[8] Pharmaceutical Research and Manufacturers of America (PhRMA) SPECIAL 301 SUBMISSION 2009, http://www.ipophil.gov.ph/ipenforcement/phrma_submission.pdf; Office of the United States Trade Representative, 2009 Special 301 Report, http://www.ustr.gov/sites/default/files/Full%20Version%20of%20the%202009%20SPECIAL%20301%20REPORT.pdf.

[9] Shaffer and Brenner, op.cit.

[10] Pharmaceutical Research And Manufacturers Of America (PhRMA) Special 301 Submission 2008. p. 247-8.

[11] Office of the United States Trade Representative, 2007 Special 301 Watch List, http://www.ustr.gov/sites/default/files/asset_upload_file60_11126.pdf; Office of the United States Trade Representative, 2008 Special 301 Watch List, http://www.ustr.gov/sites/default/files/asset_upload_file193_14872.pdf.

[12] Office of the United States Trade Representative, 2007 Special 301 Report, http://www.ustr.gov/sites/default/files/asset_upload_file230_11122.pdf. Office of the United States Trade Representative, 2008 Special 301 Report, http://www.ustr.gov/sites/default/files/asset_upload_file553_14869.pdf.

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