



## Policy Brief

Contacts:

Asia Russell 267-475-2645

Brook K. Baker 617-373-3217

## Response to USTR Fact Sheet on CAFTA and Access to Medicines

### Myths and Realities: U.S. Pressure on Guatemala Regarding Data Exclusivity, CAFTA and Access to Medicines

March 16, 2005

The Guatemalan Congress passed a law, Decree 34-2004, that came into force December 24, 2004, which was designed to increase access to affordable generic medicines by expediting registration or marketing approval of generic equivalents of new medicines. Under Decree 34-2004, generic manufacturers would be able to obtain market registration without repeating the clinical tests conducted by brand-name manufacturers. Instead, if they could show that their product was chemically equivalent and worked the same in the body ("bioequivalent") as a brand-name product, they would be able to obtain marketing authorization. In enacting Decree 34-2004, Guatemala was exercising its rights under the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration") to "take measures to protect public health... and to promote access to medicines for all." This law, passed with the overwhelming support of Guatemalan legislators, is fully compliant with the WTO TRIPS Agreement and minimizes the risk that the national drug regulatory authority will be blocked from using originator companies' previously submitted safety and efficacy data to approve marketing of more affordable generic equivalents.

The Office of the U.S. Trade Representative (USTR) and the U.S. Ambassador to Guatemala, John R. Hamilton, have attacked this new legislation. In a recent op-ed ("The FTA and Generics Do Coexist," *Diario Siglo Veintiuno*, 9 Jan. 2005), Ambassador Hamilton insists that Guatemala revoke the challenged legislation—although even Ambassador Hamilton states that "there can be no doubt" that Guatemala is acting in the interest of public health in supporting 34-2004—and that instead it grant "data exclusivity" rights to drug makers that will bar any use of safety and efficacy data for at least five years. This absolute bar, for which there is no legal recourse, will inevitably delay the sale of affordable generic medicines, meaning that fewer Guatemalan consumers will have access to life-saving medicines.

In support of its strong-arm tactics, the U.S. has launched a damaging disinformation campaign culminating in its USTR CAFTA and Access to Medicines Policy Brief, February 2005. As a result of U.S. free trade "myths" and unrelenting pressure, 34-2004 has been repealed: on March 10, 2005, the Guatemalan Congress passed 31-88, which repealed 34-2004. In addition, the Guatemalan Congress passed the text of CAFTA, despite massive civil society objection. CAFTA, if passed by all signatory countries, would require five years of protection over pharmaceutical test data. With these developments, "We no longer have any problem," assured Ryan Rowlands, U.S. Embassy spokesperson in Guatemala. However, people living with HIV and other sick people in Central America do have a problem. The U.S.'s myths must be refuted with the truth: Guatemala and other Latin American countries have a right, indeed an obligation, to guarantee access to more affordable generic medicines in order to address their multiple public health needs.

*Myth 1: Data exclusivity does not bar entry of generic equivalents; generic producers are free to submit their own test data.*

Reality: The U.S. administration argues that it is incredibly expensive for originator drug companies to discover and prove the safety and efficacy of new drugs, but then it argues that those costs would not bar entry of a generic competitor. To the contrary, not only would it be too expensive and time-consuming for generic companies to repeat clinical trials to gain access to small markets like Guatemala, it would also be ethically improper since the safety and efficacy of the underlying product (and its equivalents) have already been established.

*Myth 2: Big pharmaceutical companies must get higher profits from even small, poor countries like Guatemala in order to have incentives to invest in research and development.*

Reality: Profits from sales in poor countries are insignificant in creating incentives for future research and development. The U.S. drug industry is already the most profitable industry in the world. Sales to CAFTA countries comprise less than .5% of global drug sales (and all of Africa only 1.3%). U.S. drug companies make most of their sales (80%) and an even higher portion of their profits from the rich markets of North America, Europe, and Japan. They don't need to squeeze blood from poor consumers in Guatemala in order to bring a new medicine to the market.

*Myth 3: Big drug companies won't bother to register their new products in countries like Guatemala unless they are given data exclusivity (U.S.T.R. cites Jordan in this regard).*

Reality: Even with small quantity sales, drug companies still have incentives to sell drugs at a profit to middle-class and rich elites in smaller markets. Moreover, Big Pharma has been registering and selling its brand-name drugs in dozens of countries without data-exclusivity for the past 25 years. In addition to seeking data exclusivity monopolies, drug companies typically have underlying patent-based monopoly rights to their newest medicines, which already erect strong barriers against generic competition. The jury is still out whether Jordan and other countries will gain earlier access to new medicines because of data exclusivity.

*Myth 4: Only a few drugs are affected (25 out of 13,000) so Guatemalans should not be worried.*

Reality: Although it is true that data exclusivity will not apply to all drugs, it does apply to the newest medicines, many of which represent therapeutic breakthroughs, and, if implemented in the manner wanted by the U.S., will apply to most new medicines brought to market in Guatemala in the future. There's no reason that Guatemalans should not have access to affordable versions of the newest and most effective medicines even if those drugs are relatively few in number.

*Myth 5: The World Trade Organization's TRIPS Agreement requires Guatemala to adopt data exclusivity provisions.*

Reality: The U.S. administration is misrepresenting the standards required by the TRIPS Agreement. The relevant portion of the TRIPS Agreement, Art. 39.3, only requires protection of undisclosed data against "unfair commercial use" – basically theft or commercial espionage. Nowhere does it state that *exclusive* rights must be provided for a

given period. In fact, TRIPS makes clear that countries may decide for themselves what constitutes “unfair commercial use” and that there are many possible approaches to satisfy this requirement. Permitting a drug regulatory authority to do its job – assuring the quality, safety, and efficacy of medicines – is not unfair commercial use; it is a mandated public service. Prior to 1994, the U.S. tried to get its strict interpretation of data exclusivity into the TRIPS Agreement and failed – negotiators simply rejected its proposal. The TRIPS Agreement, as clarified by the Doha Declaration, ensures the primacy of public health and further ensures that intellectual property rules do not interfere with promoting “access to medicines for all.” Furthermore, the Trade Promotion Authority Act of 2002, §2102(b)(4)(C) requires the U.S. to uphold the Doha Declaration. The USTR is defying this requirement.

*Myth 6: CAFTA permits Guatemala to take measures it considers necessary to protect public health, particularly with regard to the epidemics of HIV/AIDS, TB, and malaria.*

Reality: The exact language of CAFTA creates ironclad protection for pharmaceutical test data with no textual exceptions for registering medicines produced pursuant to compulsory licenses. While patents that block access to medicines can be remedied through compulsory licenses and other TRIPS-compliant safeguards, there is no such recourse for data exclusivity. The U.S. is using vague assurances about rights to protect public health for “epidemics such as HIV/AIDS, tuberculosis and malaria to offset explicit language that takes away such rights. “Sign this contract, but rely on my good intentions” doesn’t work when you buy a used car and it shouldn’t work in trade agreements either.

*Myth 7: The “side letter” to CAFTA on public health<sup>1</sup> should give legally sufficient assurances about U.S. intentions and residual flexibilities to protect public health.*

Reality: As in other recent free trade agreements, the U.S. has drafted a “side letter” to CAFTA, which it says grants adequate flexibilities to Central American countries to address their public health needs. However, there are multiple inadequacies in the proposed side letter including:

- the side letter is subordinate and it does not supercede the exact, contradictory language in CAFTA on intellectual property. If the U.S. were serious about clarifying public health exceptions to data exclusivity, it would include such language in the body of CAFTA itself;
- the side letter references HIV/AIDS, TB, malaria, and other epidemics and/or matters of extreme urgency or national emergency, suggesting that other public health concerns might not be covered by the alleged public health exception. Guatemala has a larger AIDS epidemic than any country in the region. But a carve-out for specific diseases undermines efforts to increase access to medicines for all public health problems, and recalls relentless U.S. efforts to restrict the scope of the Doha Declaration over the past three and a half years;
- the side letter suggests that CAFTA countries will only be free to use the August 30, 2003 Decision<sup>2</sup> when in fact countries have additional and pre-existing flexibilities under

---

<sup>1</sup> The second paragraph of the “Understanding Regarding Certain Public Health Measures” states: “The implementation of provisions of Chapter 15 of the Agreement does not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all. This will concern, in particular, cases such as HIV/AIDS, tuberculosis, malaria and other epidemics as well as circumstances of extreme urgency or national emergency.”

<sup>2</sup> The Paragraph 6 Implementation Decision of 30 August 2003 addressed the sourcing problem faced by countries with insufficient domestic manufacturing capacity which therefore had to rely on export/import of generic medicines to meet their public health needs. Because certain provisions in TRIPS prevented large-scale export of medicines produced

- the TRIPS Agreement and the Doha Declaration (e.g., ordinary compulsory licenses permitting domestic production or importation, parallel importation, competition-based compulsory licenses, and even limited exceptions);
- the side letter's total reliance on the August 30 Decision system inappropriately suggests that using that system will be easy when in fact there are multiple substantive and procedural barriers in that system
  - the side letter limits countries to take only measures that are "necessary," a term that is interpreted extremely rigidly in international trade law, permitting exceptions only when there is no other alternative whatsoever or only when such an exception is the least obtrusive option;
  - despite the side letter, investment clause provisions in CAFTA might permit pharmaceutical companies to sue Guatemala if it were to grant an exception to data exclusivity in contradiction to the language of Art. 15.10;
  - the side letter provides insufficient legal certainty to generic companies to undertake efforts to formulate, test, and register a bio-equivalent generic drug – those efforts are too costly and time consuming to undertake lightly, and they will not be attempted if there is any residual uncertainty about the legality of such efforts.

*Myth 8: Letters from USTR to Congress give additional assurance about public health flexibilities in FTAs.*

Reality: The U.S.T.R. sent a "clarifying" letter to Congress on July 19, 2004, about a public health side letter to the U.S.-Morocco FTA. In that letter, the General Counsel to the U.S.T.R. argued that data exclusivity provisions would not "stand in the way" of compulsory licenses necessary to protect public health and to effectively utilize the August 30 decision. This letter contains some of the same deficiencies discussed above. Moreover, a letter clarifying a letter hardly creates the legal certainty necessary to embolden developing countries to issue compulsory licenses or to motivate generic companies to undertake costly and risky investments in product formulation and drug registration only to serve relatively small and poor markets. Congressional leaders should not be fooled by the "fool's gold" of non-binding, after-the-fact, and deceptively crafted written or oral assurances.

## **Conclusion**

The U.S. is attempting to impose its will, and the interests of its pharmaceutical industry, on weaker neighbors to the south, like Guatemala. Guatemala exercised its sovereign right to try to ensure access to newer and more effective medicines to meet its citizens' public health needs. Rather than let Guatemala exercise the legal freedom it and other WTO members had gained in the Doha Declaration to guarantee access to affordable medicines, and rather than let Guatemala interpret the public health side letter as having any legally binding effect, the U.S. is instead threatening dire consequences to Guatemala and its neighbors. There may be many reasons to oppose the proposed CAFTA text other than its enhanced monopoly protections for the world's richest drug companies, but the provisions on data exclusivity and U.S. actions against Guatemala are enough to justify opposition both in the U.S. and in Central America.

---

pursuant to an ordinarily compulsory license, poorer and smaller countries like Guatemala needed to have a system permitting such production-for-export/import.