

CPATH ♦ Center for Policy Analysis on Trade and Health

Bringing a Public Health Voice to Trade and Sustainable Development

DR-CAFTA Undermines Affordable Medicines; Pharmaceutical Industry's Role on USTR Advisory Committees

**Testimony by the Center for Policy Analysis on Trade and Health
to the
Ways and Means Committee
U.S. House of Representatives**

**Hearing on Implementation of the Dominican Republic-Central America Free Trade
Agreement (DR-CAFTA)**

Thursday, April 21, 2005

EXECUTIVE SUMMARY

The Intellectual Property (IP) provisions of the Dominican Republic - Central America Free Trade Agreement (CAFTA) would delay competition from generic medicines, helping to prop up high prices for brand name pharmaceuticals in the U.S., and effectively denying access to life-saving drugs in some of the poorest nations in the Americas. CAFTA IP provisions that would discourage generic competition include extended terms for patents and for data exclusivity, and linkage, which are further discussed below. They also present barriers to compulsory licensing.

These provisions contradict Congress' objectives in the Trade Act of 2002 to balance its interest in strengthening intellectual property rules with its interest in assuring access to affordable drugs. They reflect the published views of the U.S. Trade Representative's Advisory Committee on Intellectual Property Rights. Seven of 15 members of this Committee are affiliated with the pharmaceutical industry. There are no representatives of organizations concerned with the effects of trade on health. Addenda to this testimony document the IP Committee's comments and membership.

CAFTA would establish rules for trade among seven nations: the U.S., Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic. The rules apply to both the U.S. and to Central American countries. A side letter to the agreement on public health does not protect access to medicines.

How CAFTA Delays Affordable Prescription Drugs In The U.S. And Central America

CAFTA's IP rules extend two types of intellectual property rights that brand name companies now use to maintain monopoly control on the sale of prescription drugs: 1) Patents; and 2) Clinical trial test data. Generic competitors need to refer to these data to get regulatory approval for marketing. CAFTA's data exclusivity rules present an insurmountable barrier to a third key policy, compulsory licensing.

The rules increase pricing protections for brand-name drugs and delay competition by affordable generics. They would cause years of delay in providing access to affordable versions of new life-saving drugs by:

- Extending patent terms.
- Establishing periods of "marketing exclusivity" for brand name drugs, beyond current U.S. law. During this time, generic copies could not be approved for sale even if the brand name drug's patent has already expired.
- Requiring drug regulatory agencies to enforce the many independent patents claimed for each brand name drug.

The result would be to:

- Compromise access to affordable drugs in the U.S. if U.S. law is "harmonized" to match the drug regulatory rules in CAFTA and other agreements.
- Severely handicap the thriving generic industry in Guatemala and Costa Rica, and deter investment in new generics.
- Impede issuance of "**compulsory licenses**" that enable governments to authorize generic drug production, or compel lower prices by brand name drug companies. Countries can issue a compulsory license to compel generic production of a patented drug, in order to make the drug more widely available at an affordable price. In most cases, a government's credible threat to issue a compulsory license has induced brand-name companies to drastically lower their prices. Bayer lowered its price for Cipro after the U.S. threatened to issue a compulsory license for Cipro during the anthrax scare, for example. Under CAFTA, it is possible that countries could still overcome the originator company's patent right. But CAFTA's "data exclusivity" provisions present an insurmountable barrier to generic company access to the originator company's clinical trial data, and thus are a barrier to compulsory licensing.

Generic competition drastically reduces drug prices. According to Doctors Without Borders, generic competition led to a dramatic drop in cost for antiretroviral drugs for HIV/AIDS in Guatemala. In the first half of 2000, the lowest cost of treatment was \$10,439 per year per person for brand-name drugs and \$2,767 for generics. In less than a year, the price dropped to \$727 for brand-name drugs and \$201 for generics.

USTR Advisory Committees Are Dominated by the Pharmaceutical Industry, and Lack Public Health Views

The Trade Promotion Authority Act of 2002 (PL 107-210; 19 USC 3802, Sec. 2102.(b)(4)(C), Trade Negotiating Objectives) calls on the U.S. Trade Representative (USTR) to balance Congress' interests in strengthening intellectual property rules, and in assuring access to affordable drugs. It calls for the U.S. to respect the World Trade Organization's Doha Declaration, which recognizes that trade agreements must support a nation's "right to protect public health and, in particular, to promote access to medicines for all." The USTR's Advisory

Committees are an important conduit for views from the concerned public, and could help balance these interests. However, there are no representatives for the public's health or for access to medicines on any of the USTR's Advisory Committees, including those that address intellectual property negotiations. Seven of 15 members of the Industry Trade Advisory Committee on Intellectual Property Rights (ITAC 15) are affiliated with the pharmaceutical industry. There are no representatives of organizations concerned with the impact of trade agreements on the health of individuals, communities, and vulnerable populations.

These advisory committees routinely advocate intellectual property provisions that delay and deny access to affordable drugs in the U.S. and abroad, while extending pharmaceutical company rights beyond U.S. patent law and the WTO TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property). They are referred to as “**TRIPS-Plus**” rules. There has been opposition to these policies in the U.S. and in our trading partners. Because there is no public health representation on the advisory committees, and trade negotiations are secret until the agreements are completed, this opposition has been expressed only after it has been too late to influence the agreement. Better representation during the process would contribute to more effective outcomes.

CAFTA Side Letter Does Not Assure Access to Medicines

A side letter to CAFTA, “Understanding Regarding Certain Public Health Measures,” does not protect access to affordable prescription drugs, including generics. As documented elsewhere by CPATH (www.cpath.org), the side letter's language leaves important loopholes about which government measures to provide medicines would be considered sufficiently “necessary” or urgent. Language that protects access to medicines should be unambiguous, should conform entirely with the spirit and letter of the World Trade Organization's Doha Declaration on the TRIPS Agreement and Public Health, and should be included in the main text of the agreement. IP provisions that could restrict access to affordable medicines should not be included in regional and bilateral trade agreements.

SPECIFIC CAFTA PROVISIONS THAT DELAY ACCESS TO AFFORDABLE MEDICINES

Extending Patents

1. CAFTA would cover plants as patentable. Patents of plants may directly impact the economic livelihood and health of local farmers who have traditionally depended on their knowledge of and access to medicinal and nutritional plants. Under CAFTA they may be required to pay transnational corporations that patent plants. Patenting of plants is not required by TRIPS.

CAFTA Provision: Article 15.9: 2. Nothing in this Chapter shall be construed to prevent a Party from excluding inventions from patentability as set out in Articles 27.2 and 27.3 of the TRIPS Agreement. Notwithstanding the foregoing, **any Party that does not provide patent protection for plants by the date of entry into force of this Agreement shall undertake all reasonable efforts to make such patent protection available. Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection.**

2. CAFTA gives very limited rights to provide exceptions to patents. The Bolar Amendment in the US authorizes generic companies to prepare for marketing approval in advance of the expiration of a patent, so that generic products may be available when the patent expires. Under CAFTA's weak language, a country "may provide" exceptions, suggesting it also may not, particularly if there is continuing pressure from US not to do so.

CAFTA Provision: Article 15.9: Patents.

15.9.3. A Party may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

3. Export of a generic appears to be prohibited, even if a patent has expired. US law explicitly permits the export of a generic pharmaceutical product once the patent has expired regardless of the existence of marketing exclusivity.

CAFTA Provision: Article 15.9: Patents.

15.9.5. Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, **the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements** of that Party.

4. CAFTA extends patents by up to 5 years from the date of filing a patent application in a country (beyond the 20 year patent term) for unjustified delays that may occur during the process of granting a patent. This could extend patents after the patent has expired in U.S.

This provision is independent from and cumulative to a related provision that **requires extension of length of patent term for an indeterminate period, to compensate a patent holder for unreasonable reduction of patent term due to market approval process.** "Unreasonable" is not defined. No clear criteria exist for determining the extension. No maximum period for the patent extension is specified. The clock can start after the patent expires in US.

In current U.S. law, patent extensions attributable to delays in marketing approval of a drug cannot be greater than 5 years.

CAFTA Provisions. Article 15.9 6. (a) Each Party, at the request of the patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent. For purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays.

15.9.6 (b) With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the **marketing approval process related to the first commercial marketing of the product in that Party.**

Data Exclusivity/Marketing Exclusivity

Generics manufacturers must be able to refer to the originator company's clinical trial data, presented to regulatory authorities to establish that the drug is safe and effective. Once the originator's drug is approved, a generic company only needs to show that its product is biologically equivalent, meaning that it works the same way in the human body as the originator's drug. If it cannot refer to the approval of the originator drug, it cannot obtain approval for marketing. A combination of CAFTA rules delay generic companies' ability to rely on originators' approvals.

1. No approval will be given to a generics manufacturer to use test data for marketing a generic product for at least 5 years for pharmaceutical products and 10 years for agricultural chemical products from the first approval of the patented drug in that country.

Problems:

Delay in marketing. If generic companies cannot rely on approvals based on pharmaceutical data from the brand drugs, they will effectively be barred from the market for years. Repeating the safety and efficacy tests required to obtain marketing approval would be costly, and expose human subjects to unnecessary and therefore unethical risk.

Multiple delays for indeterminate times. CAFTA prohibits generic companies from preparing generic drugs for marketing until **at least 5 years – possibly an undefined longer term** - for pharmaceutical products after approval is given to the originator drug company **in the new country**. The clock can therefore start after the patent expires in the U.S. These provisions also apply even when there is no patent in effect in a country.

These provisions go beyond U.S. law. Market/data exclusivity provisions of Hatch-Waxman cannot exceed 5 years.

Under TRIPS 39.3, test data can be protected only when national authorities require their presentation as a condition of marketing approval. Countries must protect undisclosed pharmaceutical test data from “unfair” commercial use. If a country accepts reference to approval given in a foreign country, there is no obligation to protect test data.

De facto barrier to compulsory licensing. This is a *de facto* prohibition of compulsory licensing for at least 5 years for pharmaceutical products. This is because there is no provision for issuing a compulsory license (CL) to override data protection. Such a CL can only be issued to override a patent, which is a separate right.

Countries can issue a “compulsory license” to compel generic production of a patented drug, in order to make the drug more widely available at an affordable price. In most cases, a

government's credible threat to issue a compulsory license has induced brand-name companies to drastically lower their prices. Bayer lowered its price for Cipro after the U.S. threatened to issue a compulsory license for Cipro during the anthrax scare, for example. Under CAFTA, it is possible that countries could still overcome the originator company's patent right. **But CAFTA's "data exclusivity" provisions present an insurmountable barrier to a generic company's ability to refer to the originator company's clinical trial data for marketing approval, and thus are a barrier to compulsory licensing.**

CAFTA Provision: Article 15.10: Measures Related to Certain Regulated Products.

1. (a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.

Question for USTR: CAFTA would delay competition by generic drug companies by many years, and prevent governments from issuing or threatening to issue compulsory licenses. How does this benefit consumers of drugs in the U.S. and other CAFTA countries? Why does it contradict the Doha Declaration, which authorizes governments to protect public health and access to medicines?

2. CAFTA extends the protection of test data beyond the signatories to the CAFTA agreement. It prevents reliance on test data which was previously presented to any foreign country in the world ("another territory"). It prevents reliance on prior approval of a drug in any foreign country, for at least 5 years for pharmaceutical products and 10 years for agricultural chemical products. The protection starts from the date that the patent holder seeks approval of the drug in a CAFTA country.

For example, a brand name company may have a product on the market in the U.S., but not in Guatemala. Guatemala could not authorize generic versions of the product for at least 5 years from a future date when the brand name company seeks approval in Guatemala. A country can require that the innovator company request approval within 5 years after obtaining marketing approval in another country, but does not have to do so. If a brand name company seeks marketing approval in Guatemala, for example, in the fifth year, this would delay authorization of a generic product for 10 years total (5 years due to marketing approval in the U.S., plus an additional 5 years after marketing approval is sought in Guatemala).

These provisions may also apply even if the patent holder has no patent or marketing approval in a CAFTA country.

These provisions also create **barriers to compulsory licensing** during emergencies. As noted above, during the anthrax scare in the U.S., the threat by HHS to issue a compulsory license for the antibiotic Cipro induced Bayer, the manufacturer, to drastically reduce its price. Under CAFTA a generic licensee could not use the safety and efficacy data from Bayer or rely on its previous regulatory approval, but also would not have had time to repeat Bayer's clinical trials.

CAFTA Provision: 15.10.1. (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of

(1) evidence of prior marketing approval in the other territory, or

(2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory,

for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.

3. New Product. A new product does not have to contain a new chemical entity. Under TRIPS, data protection applies to new chemical entity, not to an undefined new product. Test data protection does not apply to second uses, new formulations or changes in doses. Under TRIPS, a country can require a drug company seeking test data protection to prove that this is the result of a substantial investment.

CAFTA Provision. 15.10.1. (c) For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.

Linkage

CAFTA links the registration of drugs with the existence of a patent for a pharmaceutical product. The terms “shall implement measures...to prevent” requires the country’s drug regulatory agency, which is responsible for ensuring safety and efficacy, to take on the additional responsibility of legal enforcement of existing patents. There are typically many patents associated with a single drug, administered by a patent office. Neither the U.S. nor Central American countries have the administrative capacity to coordinate patent office functions with drug regulatory authorities.

In the U.S., the FDA informs patent holders through the so-called “Orange Book” about requests made by third parties regarding the same drug. The patent holder bears the responsibility to ensure that its intellectual property right is not violated. The patent holder can take the case to court to stop an application for registering a generic drug.

CAFTA Provision: 15.10.2. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party:

15.10.2. (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.

CONCLUSION

CAFTA presents numerous new obstacles to competition by generic drug companies. These provisions in many cases exceed the requirements of TRIPS and U.S. law. CAFTA would delay access to life-saving generic drugs by many years, and contribute to additional deaths from HIV/AIDS and other conditions. The legal architecture established by CAFTA will maintain higher drug prices in the U.S.

CAFTA fails to respect Congress' negotiating objective to implement the Doha Declaration on public health and access to medicines. Instead, it advances monopoly rights for pharmaceutical companies that maintain high drug prices. It reflects the opinions of the USTR advisory committees, which include numerous pharmaceutical company representatives, and no representatives of public health.

ADDENDUM I: USTR ADVISORY COMMITTEE REPORTS ON CAFTA UNDERMINE ACCESS TO AFFORDABLE MEDICINES

The Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) was the predecessor to the present Industry Trade Advisory Committee on Intellectual Property (ITAC 15). Like ITAC-15, IFAC-3 had numerous pharmaceutical company representatives, and no representatives of public health. It consistently advised the USTR to advance negotiating positions that strengthen IP rights for pharmaceutical companies, beyond TRIPS rules.

The March 2004 Report of the Industry Functional Advisory Committee on Intellectual Property Rights for Trade Policy Matters (IFAC-3) regarding Intellectual Property Provisions in the US-Central America Free Trade Agreement stated:

“CAFTA takes into account the significant legal and technological developments that have taken place since the TRIPS and NAFTA agreements ... to establish clear precedents in most key areas of IP protection for future FTA negotiations.” (p.4)

“IFAC-3 views the TRIPS Agreement as reflecting minimum international norms of intellectual property protection that most countries should already have in place. The role of the FTAs is to clarify, where necessary, those obligations and to improve upon them by enhancing the level of intellectual property protection in the negotiating partner.” (p.5)

“The patent section of CAFTA provides a number of clarifications and improvements to the protection standards articulated in the TRIPS Agreement. Once implemented, these standards will improve the effectiveness of patent protection in the CAFTA countries.

“IFAC-3 notes that CAFTA is the first to be completed with countries that are not among the more advanced developing countries, indeed some with relative low per capita incomes. That these countries found it in their interest to significantly increase their levels of IPR protection beyond that required by TRIPS is testament to the principle that high levels of protection benefit indigenous creators and inventors in the same manner as they do in developed countries.” (p.4)

In fact, the TRIPS-Plus provisions of CAFTA do not represent U.S. policy, or the best interests of the people of the U.S., Central America and the Dominican Republic.

1. Central Americans cannot afford drugs now and CAFTA will make the problem worse.

The vast majority of Salvadorans and Guatemalans cannot afford brand name drugs. Many people do not have health insurance and must pay for medicines out-of-pocket. Guatemala has one of the highest rates of HIV/AIDS in the region and the population suffers from many diseases, both those associated with poverty as well as those, such as cancer and diabetes, common in the developed world. Guatemala and Costa Rica have a relatively thriving generics industry for pharmaceuticals, the main source of medicines in those countries. The Guatemalan generic drug industry adamantly asserts that CAFTA will undermine their operations and deprive more Guatemalans of access to drugs.

2. Guatemalans did not willingly accept CAFTA provisions related to IP and health.

Guatemalan law on data exclusivity (DE) has changed several times since 2000. Most recently, last November, law 9-2003 imposing DE was repealed, by vote of an overwhelming majority of the Guatemalan Congress, even though CAFTA requires such data exclusivity rules. In December 2004, a new law went into effect that is compliant with TRIPS and has a very limited protection of test data against commercial theft or fraud.

On January 9, the U.S. Embassy issued a statement suggesting that Guatemala’s action on DE could mean that not one single member of the US Congress would vote in favor of CAFTA. (This misleading statement was subsequently contradicted by several members of Congress.) The statement insisted that Guatemala revert to the CAFTA standard, which, again, exceeds what TRIPS requires. Guatemala subsequently passed yet another new law which the U.S. has declared is compliant with CAFTA.

3. Costa Rica did not willingly accept CAFTA provisions related to IP and health. The official Costa Rican position is that IP and health services should not be included in CAFTA. Costa Rica agreed to include these issues as a trade off for other perceived economic benefits.

4. When health deteriorates in Central America, the U.S. is affected. A high proportion of immigrants to the U.S. come from Central America. The vast majority of immigrants are young and healthy when they arrive in the U.S. They pay taxes that contribute in part to the expense of U.S. health services. Nevertheless, when their health deteriorates due to lack of medicines, they are more likely to experience illness while in the U.S.

ADDENDUM II: Members of the USTR Advisory Committee on Intellectual Property Rights

Industry Trade Advisory Committee on Intellectual Property Rights - ITAC 15

Chairman

Mr. Eric H. Smith
President
International Intellectual Property Alliance

Vice-Chairman

Mr. Jacques J. Gorlin
President
The Gorlin Group

Ms. Catherine P. Bennett - **P**
Vice President, Federal Tax and Trade Policy
Pfizer, Inc.

Hope H. Camp, Jr., Esq. - **P**
Consultant
Law Offices of Hope H. Camp, Jr., P.C.
Representing Eli Lilly and Company

Susan K. Finston, Esq. - **P**
Associate Vice President for Intellectual Property
Pharmaceutical Research and Manufacturers of
America

Morton David Goldberg, Esq. - **P**
Partner
Cowan, Liebowitz & Latman, P.C.

Mr. Francis (Frank) Z. Hellwig, Esq. - **A**
Senior Associate, General Counsel
Anheuser-Busch Companies, Inc.

Dr. Joseph Anthony Imler - **P**
Director, Public Policy
Merck & Company, Inc.

Ms. Mary A. Irace
Vice President, Trade and Export Finance
National Foreign Trade Council, Inc.

Jeffrey P. Kushan, Esq. - **P**
Trade Counsel
Sidley, Austin, Brown & Wood LLP
Representing Biotechnology Industry Organization

Shira Perlmutter, Esq.
Vice President and Associate General Counsel,
Intellectual Property Policy
Time Warner Inc.

Mr. Timothy P. Trainer
President
International AntiCounterfeiting Coalition

Neil I. Turkewitz, Esq.
Executive Vice President, International
Recording Industry Association of America

Mr. Herbert C. Wamsley - **P**
Executive Director
Intellectual Property Owners Association

Ms. Deborah E. Wiley
Senior Vice President, Corporate Communications
John Wiley and Sons, Inc.
Association of American Publishers, Inc.

Total Members = 15

Key: **P** = Associated with the Pharmaceutical Industry
A = Associated with the Alcohol Industry

Total Industry Representation Related to Public Health and Health Care:
Pharmaceutical Industry: 7
Alcohol Industry: 1