

## CAFTA SIDE LETTER DOES NOT PROTECT ACCESS TO MEDICINES

September 30, 2004

On November 14, 2001, the World Trade Organization adopted the Declaration on the TRIPS Agreement and Public Health (the Doha Declaration).<sup>1</sup> It states that the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Right) “does not and should not prevent [WTO] Members from taking measures to protect public health.”<sup>2</sup> Supporting public health involves “promoting both access to existing medicines and the creation of new medicines.”<sup>3</sup> Principal trade negotiating objectives established by Congress include respect for the Doha Declaration.<sup>4</sup>

However, the U.S.-Central American Free Trade Agreement (CAFTA) does not safeguard the Doha right to protect public health and promote access to medicines for all. Numerous provisions in CAFTA would limit competition among pharmaceutical companies, maintain high drug prices, and make it increasingly difficult for poor people in CAFTA nations to obtain essential medicines, including generics. CAFTA covers the U.S., Costa Rica, Guatemala, El Salvador, Honduras, Nicaragua and the Dominican Republic.

A Side Letter, “Understanding Regarding Certain Public Health Measures,”<sup>6</sup> does not adequately offset the intellectual property provisions of CAFTA, and fails to safeguard access to medicines. It is questionable whether side letters in general have any ability to provide enforceable exceptions to trade agreement text, or provide interpretive suggestions only. Even if the CAFTA Side Letter on Public Health Measures were enforceable, the following discussion highlights concerns about its limitations.

### Restricts the Right of CAFTA Countries to Safeguard Public Health – Falls Short of Doha

The Side Letter states that CAFTA’s intellectual property rights provisions (Chapter 15) “do not affect a Party’s ability to take **necessary measures** to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.”<sup>7</sup>

This language restricts a nation’s ability to protect public health in two ways: 1. measures to protect health must be “necessary;” 2. “access to medicines” focuses on specific diseases, i.e. HIV/AIDS, tuberculosis, malaria, and other epidemics, and on circumstances of “extreme urgency or national emergency.”

1. In international trade agreements, “**necessity**” is a high standard. Nations have successfully brought challenges before trade tribunals claiming that public health measures violate trade rights. The burden is on the nation attempting to implement the public health measure to prove that it is necessary. In past trade challenges to “necessary measures” provisions, a nation has had to meet a two-tiered test: 1. show that the

<sup>1</sup> World Trade Organization, WT/MIN(01)/DEC2, 20 November 2001; [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>2</sup> Id.

<sup>3</sup> WTO, “The Doha Declaration explained, Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health”; [http://www.wto.org/english/tratop\\_e/dda\\_e/dohaexplained\\_e.htm#trips](http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#trips).

<sup>4</sup> Division B Bipartisan Trade Promotion Authority, Title XXI-Trade Promotion Authority SEC. 2102 (b) Principal Trade Negotiating Objectives,(4) (C).

<sup>5</sup> U.S.-Central American Free Trade Agreement, Understanding Regarding Certain Public Health Measures, August 5, 2004, [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/DR-CAFTA/DR-CAFTA\\_Final\\_Texts/asset\\_upload\\_file697\\_3975.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/DR-CAFTA/DR-CAFTA_Final_Texts/asset_upload_file697_3975.pdf).

<sup>6</sup> U.S.-Central American Free Trade Agreement, Understanding Regarding Certain Public Health Measures, August 5, 2004, [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/DR-CAFTA/DR-CAFTA\\_Final\\_Texts/asset\\_upload\\_file697\\_3975.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/DR-CAFTA/DR-CAFTA_Final_Texts/asset_upload_file697_3975.pdf).

<sup>7</sup> Id.

health measure is necessary, i.e., that it is effective, and that no less trade restrictive measures were available to achieve the same public health purpose; and 2. if proven to be necessary, show that the proposed public health measure does not constitute a “disguised restriction on international trade” or “arbitrary or unjustifiable discrimination.” If an international trade tribunal determines that a measure in effect is discriminatory to trade, the measure may be found to be a violation of trade rules, even if the discrimination is unintended.<sup>8</sup> For example, a nation that imposes tariffs on tobacco imports may be challenged to “prove” that tariffs on tobacco products are “necessary” for tobacco control, and that tariffs are less restrictive on trade than, e.g., consumer health warnings.<sup>9</sup>

The Doha Declaration grants countries the “right to protect public health, and in particular, to promote access to medicines for all,” with no restriction that measures to protect health must be “necessary.”<sup>10</sup>

2. The focus on epidemics and circumstances of “extreme urgency” or “national emergency,” in the Side Letter, narrows the scope of a nation’s ability to protect public health set forth in The Doha Declaration.

### **Limits the Right of CAFTA Countries to Provide Access of Medicines to All**

The Side Letter states that CAFTA “Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.”<sup>12</sup> The “TRIPS/health solution” refers to the implementation of paragraph 6 of the Doha Declaration. Paragraph 6 specifically addresses the issue of countries which have insufficient or no capability to manufacture drugs, and are not able to afford high-priced patented pharmaceuticals. An agreement reached at the WTO in August 2003 provides a mechanism for “least-developed countries” (LDCs) which cannot produce drugs, themselves, to implement paragraph 6 by importing affordable drugs.<sup>13</sup> The TRIPS/health solution also **prohibits importation** by the United States and other developed countries of medicines that are exported under this agreement. The CAFTA Side Letter language therefore refers only to this August 2003 agreement for LDCs, but not to other important provisions of the Doha Declaration.

For example, the side letter does not address the issue of a nation granting compulsory licenses to produce affordable generic drugs to meet public health needs within its own borders. Compulsory licensing allows countries to authorize production of affordable generic versions of costly patented medicines while they are still under patent. The Doha Declaration mandates that each nation “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”<sup>14</sup> Compulsory licensing can be an important tool to provide affordable generic drugs to meet public health needs. In contrast, CAFTA Article 15.10.2, on intellectual property, directs CAFTA nations to prevent the marketing of generic versions and other forms of a patented drug without the permission of the drug patent owner.<sup>15</sup>

<sup>8</sup> Bloom J. Public health, international trade and the framework convention on tobacco control. Campaign for Tobacco-Free Kids. March, 2001. <http://tobaccofreekids.org>; Callard Cynthia, Collishaw Neil, Swenarchuk Michelle. An introduction to international trade agreements and their impact on public measures to reduce tobacco use. Physicians for a Smoke-Free Canada/Commonwealth Medical Association. April 2001.

<sup>9</sup> Cynthia, et.al.; Campaign for Tobacco-Free Kids. Public health and international trade. Volume II: Tariffs and Privatization. Washington, D.C. October 2002. <http://tobaccofreekids.org>.

<sup>10</sup> World Trade Organization, WT/MIN(01)/DEC2, 20 November 2001.

<sup>11</sup> World Trade Organization, WT/MIN(01)/DEC2, 20 November 2001.

<sup>12</sup> U.S.-Central American Free Trade Agreement, Understanding Regarding Certain Public Health Measures, August 5, 2004.

<sup>13</sup> WTO, “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health,” WT/L/540, 1 September 2003.

<sup>14</sup> World Trade Organization, WT/MIN(01)/DEC2, 20 November 2001.

<sup>15</sup> CAFTA Chapter 15, Article 15.10 Measures Related to Certain Regulated Products, 15.10.2.

The CAFTA Side Letter falls short of promoting access to medicines for all, as set forth in the Doha Declaration.

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<sup>16</sup> CAFTA Chapter 15, Article 15.10 Measures Related to Certain Regulated Products, 15.10.2.  
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