CAFTA Facts

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CAFTA and Access to Medicines

- **Under global trade rules and U.S. bilateral trade agreements, countries have access to medicines in their fight against HIV-AIDS and other epidemics.**

  - The U.S. played a key role in the Doha WTO Ministerial (Nov. 2001) reaffirmation that global trade rules allow countries to decide what constitutes a health emergency and to issue compulsory licenses to produce drugs needed to fight epidemics.

  - In August of 2003, the U.S. led the work towards a WTO consensus that allows poor countries without domestic drug production capacity to issue compulsory licenses to import drugs needed to combat diseases such as HIV/AIDS, malaria, tuberculosis and other infectious epidemics.

- **The FTA will not affect Guatemala's ability to take measures necessary to protect public health or to use the WTO solution to import drugs.**

  - The FTA expressly states that nothing in the IP chapter affects that country's ability to take measures necessary to protect public health.

    - Specifically, the United States and Guatemala confirmed their understanding that the IP chapter does 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."

  The CAFTA expressly states that nothing in the agreement will affect a country's ability to take measures necessary to protect public health.

  - The FTA also expressly states that it will not prevent effective utilization of last year's WTO consensus allowing developing countries that lack pharmaceutical manufacturing capacity to import drugs under compulsory licenses.

- **Stronger patent and data protection increases the willingness of companies to release innovative drugs in free trade partners' markets, potentially increasing, rather than decreasing, the availability of medicines.**

  - The U.S.-Jordan FTA, signed in 2000, contained an intellectual property chapter that covered data protection.

  - Since 2000, there have been 32 new innovative product launches in Jordan, a substantial increase in the rate of approval of innovative drugs, helping facilitate Jordanian consumers' access to medicines.

  - Since enactment of the FTA, the Jordanian drug industry has begun to develop its own innovative medicines. This is an example of how strong intellectual property protection can bring substantial benefits to developing countries.

- **"Data Protection" provisions in the FTA are part of the broad framework to protect innovation.**
    - Before a drug can be sold, the drug must first be approved by a regulatory agency as being safe and effective.
    - Regulatory approval is a long and costly process designed to ensure the safety and effectiveness of the product.
        - For example, the U.S. FDA requires extensive testing before it approves a drug.
        - Clinical trials take an average of 7-10 years.
        - The process is very risky. On average, only 20-30% of drugs that reach the last phase of testing actually receive approval.
    - The data that results from these tests is extremely valuable.

- **Protecting such data is consistent with longstanding U.S. and international practice.**
    - Global trade rules (the Trade-Related Aspects of Intellectual Property, or TRIPS) already require protection for data submitted for marketing approval. Article 39.3 of TRIPS requires countries to protect such data against "unfair commercial use."
    - There is no circumstance in which the FTA requires that data that an innovator submits for new chemical entities receive a data protection period longer than five years.
    - Competitors can apply for approval at <u>any</u> time using their own data. After the period of protection is over, other producers can apply for marketing approval by relying on the innovator's data.
    - CAFTA's data protection terms are similar to or less than protections in other countries. Virtually every OECD country provides data protection. While the US protects data for 5 years, the EU protects data for 6-10 years.
    - Data protection provides an incentive to launch innovative drugs in developing countries, and after five years, test data used to certify an innovative drug can be used to approve a generic version.