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Access to Affordable Medicine & Peru/Colombia FTA Intellectual Property Rules

- **The Peru and Colombia FTAs contain the same "data exclusivity" rules in CAFTA which forbid access by generic producers to test data needed to obtain approval to market less expensive generic drugs.**
  Many in Congress found the CAFTA patent rules extending new five- to 10- year monopoly control of drug test data to be unacceptable because these rules undermine access to essential medicines by making generic drug production much more difficult. The Peru and Colombia "free trade" agreements (PUFTA and CUFTA) contain these same CAFTA data exclusivity terms which forbid generic producers from obtaining the safety- and efficacy- testing data necessary to obtain generic marketing approvals. PUFTA/CUFTA even ban access to this data for drugs whose patents have expired altogether and for drugs that are not patented in Peru or Colombia. PUFTA/CUFTA ban generic manufacturers from access to data for a five- year period even if a drug has not been registered in that nation, but if a drug is registered in the United States. An *additional* five years of exclusivity is granted once a brand-name company registers in Peru or Colombia, effectively forbidding marketing of generic versions for up to ten years. We respect the need for pharmaceutical companies to obtain returns on their investments. The FTAs require Peru and Colombia to provide the same 20-year monopoly right to market a drug that is provided in U.S. law. As we have seen in the United States, this has provided rich profits for pharmaceutical companies who have monopoly power to set high prices for their drugs.

- **PUFTA/CUFTA includes a de facto prohibition of compulsory licensing.**
  PUFTA/CUFTA's data exclusivity rules would also make compulsory licensing of patented drugs effectively impossible. PUFTA/CUFTA data exclusivity rules prohibit the use of data submitted by a patent holder at any point during the term of the patent unless the patent holder grants permission! (FTA Article 16.10.3(a)) Thus, even if a generics firm were issued a compulsory license by the government – as U.S. HHS Secretary Thompson threatened during the anthrax scare – the generic drug could not enter the market without the patent holder's permission because the generic producer could not obtain marketing approval without the test data. Even if Peru or Colombia issued a compulsory license for production of a patented drug during a medical emergency, as allowed under WTO rules, PUFTA/CUFTA's data exclusivity rules require permission by the patent holder before generic companies could use the test data to get approval to market such a drug. Yet, without access to the test data, a generic company could not obtain authorization to make even a compulsorily licensed drug available to the public: conducting new testing would be prohibitively costly and even if affordable would take too long in an emergency.

- **PUFTA/CUFTA's actual data exclusivity rules would undo the rights Peru and Colombia have under the 2001 WTO Doha Declaration on TRIPS and Public Health.**
  The 2002 Fast Track law explicitly instructed USTR not to include IPR terms that undermined the WTO TRIPS and Public Health Declaration. Appended to the FTA's IPR chapter is an "Understanding Regarding Certain Public Health Measures" that states: "Chapter Sixteen ([PRs] does not prevent the effective utilization of the TRIPS/health solution." Yet, the actual provisions of the text do just that. How could Peru or Colombia actually provide access for their people to compulsorily-licensed generic drugs produced in other countries as allowed under the WTO Declaration, if such drugs can be imported but cannot obtain marketing approval for distribution because the test data must be kept exclusive for ten years? In order to allow Peru and Colombia to effectively utilize the TRIPS/health solution, amendments must be made to the FTAs that state that the Parties waive the data exclusivity requirements in such cases.