Congress of the United States

House of Representatives

Washington, DC 20515

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THINK PRESCRIPTION DRUG PRICES ARE TOO LOW?

CAFTA CAN HELP.

Under CAFTA, pharmaceutical companies would be granted new and extended patent protection in Central American countries, as well as new regulatory "incentives" that provide these companies additional shelter from price competition.

By preventing developing countries from accessing lower priced generic drugs, these expansive protections would thwart efforts by our CAFTA trading partners to combat AIDS, malaria and other major health threats. Costa Rica alone faces AIDS drug costs so steep that if it is forced to forgo generic drugs, available funds will cover only 18% of the AIDS patients who are being treated today.

And when United States law is harmonized with CAFTA standards, the drug industry could subject US consumers to additional months and years of monopoly drug prices. As it stands, generic competition is the only meaningful tool available to bring drug prices down. The last thing we need is to give the drug industry even more immunity from that competition.

At the level of government protection drug companies enjoy today, they have managed to consistently earn profits three times greater than any other Fortune 500 industry. Now the drug industry is exploiting CAFTA to win more competition-free time on the market.

Enough is enough.

On the reverse side of this document is a summary of the new drug industry protections contained in CAFTA. Whether you support or oppose CAFTA's other provisions, don't vote for higher drug prices. Send the authors of CAFTA back to the drawing board.

Sincerely,

SHERROD BROWN
Member of Congress

HENRY WAXMAN
Member of Congress

THOMAS ALLEN
Member of Congress

(over)

New Drug Industry Protections in CAFTA

1. Much like U.S. law, CAFTA provides for two forms of patent extension. The first one permits extensions based on delays in the patent examination process. The second one permits extensions based on delays in the drug approval process.

   While US law places limits on these extensions, CAFTA does not.

   In the US, the extension only applies to the active ingredient of a new drug and only permits the extension of the term of a single patent, not multiple patents. In contrast, CAFTA allows extensions for any and all patents covering a drug.

   In the US, the extension can only be 5 years long and the effective patent term (i.e. the duration of the patent from the time the product is approved) can not be longer than 14 years. In contrast, CAFTA has no limit on the length of the extension or the effective patent term.

2. Because both brand-name drugs and their generic alternatives can be assessed using the same safety and efficacy data, US law permits generic manufacturers to reference the brand company's data already on file with the FDA when seeking approval for a generic alternative. To reward brand companies for compiling the data, U.S. law grants these companies a five-year window in which generic drug manufacturers cannot rely on their data to gain marketing approval.

   CAFTA provides brand companies with "at least five years" of data exclusivity, opening the door to longer delays in access to affordable medicines.

3. Under NAFTA, when a drugmaker first gains approval for a new drug in either the United States, Canada or Mexico, the clock starts on a five-year period in which the drugmaker has exclusive rights to market that product. The same five years applies regardless of when the other countries approve the drug. If, for example, Mexico approves a drug two years after it was first approved in the U.S., the drugmaker would receive only three years of exclusivity in Mexico.

   Under CAFTA, drugmakers will five years of exclusivity upon introduction in each country. In addition, CAFTA permits drug companies to wait up to five years after introducing a drug in one country before introducing the drug in another CAFTA country and still retain the right to five years of data exclusivity upon approval in that market.

   For example, a drug introduced in the United States would get five years of exclusivity in the U.S. market. Five years later, it could be introduced in Costa Rica and get five years of exclusivity in the Costa Rican market. Although in Costa Rica the brand name company is only resubmitting clinical trial data generated for approval in the United States, a generic version could not approved in Costa Rica until ten years after the drug was first approved in the U.S.

4. Under US law, a brand-name drug company can delay FDA approval of a generic alternative by asserting that one of patents would be infringed if the generic is marketed.

   Under CAFTA, a generic drug ***cannot*** be approved ***unless*** that country's FDA can prove that no patent is being infringed.

5. US law also limits the kind of patents, such as those listed in the FDA Orange Book, that can be asserted by a brand name company in a challenge to a generic application and sets a two and half year time limit for patent disputes to be resolved.

   In contrast, CAFTA has no limits, opening the door to abuse and the potential for endless delays in the approval of generic drugs.