Rep. Henry A. Waxman
Extension of Remarks
Response to 2006 USTR Special 301 Report
May 4, 2006

Mr. Speaker. Last week the USTR issued its annual Special 301 report evaluating intellectual property laws in foreign countries. During this year's review process, I wrote to Ambassador Portman along with a bipartisan group of my colleagues raising concern about the agency's consideration of complaints by the pharmaceutical industry against Israel. PhRMA had called on USTR to elevate Israel to the worst designation of "Priority Foreign Country" and work to block Israel's membership in the OECD because of pharmaceutical IP issues.

I am glad to see that the USTR chose not to take these drastic steps. Such action would have been unwarranted and damaging to an important ally. However, I am deeply disappointed that Israel did remain on the "Priority Watch List." Israel has worked in steadfast consultation with the U.S. to adopt broader protections for pharmaceutical products. Israeli lawmakers, under the leadership of then-Minister of Trade Ehud Olmert, passed legislation that strikes a balance between the need to provide strong protections for innovators and timely access to affordable treatment for the Israeli public.

Similar to a U.S. law, commonly referred to as Hatch-Waxman, the Israeli system provides patent extensions for delays in the drug approval process as well as 5 years of exclusive marketing rights for new drugs that enter the market. This is far beyond the level of protection required by the World Trade Organization agreement on Trade Related Aspects of Intellectual Property (TRIPS). Yet, by keeping Israel on the "Priority Watch List," the Special 301 report criticizes Israel just as harshly as major IP offenders like China and Russia, and more harshly than many other countries with weaker IP regimes.

These inconsistencies raise serious questions about how the agency makes its designations. I am particularly concerned about the report's inordinate emphasis on the protection of pharmaceutical test data submitted for the approval of new drugs. Of the 48 countries named in the report, 28 were criticized for inadequate test data protection - nearly double those cited on this issue in 2001.

USTR has insisted that the TRIPS "data protection" requirement be strictly interpreted like a Hatch-Waxman provision that mandates a 5-year period during which a generic copy cannot be approved. As one of the principal authors of that legislation, I find this position at best misguided and at worst immoral.

First, nothing in TRIPS requires any period of "data protection," much less 5 years. Article 39.3 of TRIPS only requires protection from "unfair commercial use" and there is certainly no global consensus about what that actually means. Second, the U.S. system is not a "one-size-fits-all" solution that is appropriate for all countries. For many poor countries, adoption of five years of "data protection" will deprive their citizens of any and all access to life-saving drugs.

When Special 301 Report designations become arbitrary and excessive, they lose their credibility and effectiveness. It is time for Congress to examine the process by which the USTR reviews intellectual property protection laws, weighs submissions from industry and related advisory committees, and ultimately, how it determines the status of the foreign countries in its annual report.