

USTR-2010-003
2010 SPECIAL 301 REVIEW, SEC. 182 OF THE TRADE ACT OF 1974

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INTELLECTUAL PROPERTY
ON BEHALF OF FORUM ON DEMOCRACY AND TRADE

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The Forum on Democracy and Trade's mission is to support public officials engaged in global trade debates.

This oral submission builds on the written submission by the Forum and the National Legislative Association on Prescription Drug Prices. I serve as counsel to each group.

We are here to oppose the recent and disturbing use of the Special 301 Report to discipline effective and non-discriminatory pharmaceutical pricing policies.

The 2009 Special 301 Report singles out Japan, Canada, France, Germany, New Zealand, Taiwan and Poland for administering "unreasonable . . . reference pricing or other potentially unfair reimbursement policies."

It is unclear what USTR is complaining about in these examples because, as in other areas of the report, there is insufficient explanation, citation or description of any objective standard accompanying the listing decisions. There are no allegations in the Report that any of these policies violate most favored nation or any other WTO norm or bilateral agreement. Nor is there an adequate explanation for how the programs fall under the statutory criteria for Special 301 review.

Viewed against the background of past experience, states assume that USTR is targeting the same policies that it has in the past – i.e. innovative reimbursement policies that effectively restrain medicine pricing in similar ways as state preferred drug lists and other public policies.

We oppose this use of Special 301. The U.S. should not be negotiating for the limitation of programs abroad that are the best practices in the field here at home.

A. USTRs Agenda Will Limit Effective Programs in the U.S.

Although it is commonly posited by industry that foreign countries “free ride” on U.S. pharmaceutical prices, U.S. federal government agencies and state governments actually pay similar prices as Canada and other targeted countries in the 301 watch list.¹

One of the most important tools of states is Preferred Drug Lists (PDLs) in the Medicaid program. More than forty states use PDLs for Medicaid and other local health programs. These programs work in part by incentivizing pharmaceutical companies to lower their prices as a condition for gaining access to a preferred purchasing list. This is the same tool foreign governments use to lower drug prices in public programs abroad.

U.S. opposed the inclusion of pharmaceutical chapters in the Australia and Korea free trade agreements. State officials repeatedly warned USTR and Congress that the norms being pressed by the U.S. in these pharmaceutical chapters would cripple state Medicaid programs.

In the past, USTR has explained that the requirements imposed through its agreements do not apply to U.S. programs because of a host of technical interpretations and definitions. But these definitional carve outs have done little to assuage state concerns. Trade agreements are reciprocal by definition. It is foolhardy to think that USTR can negotiate deep restrictions in the regulatory authority of other countries and not have the same programs in the U.S. affected.

States are concerned with Ambassador Kirk’s support of the Pfizer/Barton proposal for a new international agreement to “discipline” pharmaceutical reimbursement programs in developed countries.

¹ See the 2004 Annual Report of the West Virginia Pharmaceutical Cost Management Council, *available at* <http://www.wvc.state.wv.us/got/pharmacycouncil/>.

We call on the administration to review this trend developed in the past administration and reject its continuation now.

B. USTR's Agenda Will Damage State "Re-importation" Policies

USTR efforts to discipline effective pricing programs in Canada and other advanced pharmaceutical markets threaten state re-importation programs that facilitate parallel trade of patented medicines.

Vermont, Illinois, Rhode Island, Minnesota, Kansas, Missouri, Minnesota, California, Wisconsin, and the District of Columbia allow their citizens to purchase pharmaceuticals from Canada or other countries where direct to consumer prices are much lower than in the U.S. These programs, which have saved millions of scarce health dollars, will be ineffective if the U.S. forces other successful countries to abandon effective policies and raise prices for needed drugs.

C. USTR is Threatening Best Practices Needed for Health Reform

This administration is committed to national health reform which relies on finding and utilizing the best practices for restraining health costs through evidence based policies that promote public health.

Pharmaceutical policy in the U.S. is in sore need for such reform. We spend more on pharmaceuticals than any other country in the world. In U.S. states and in other countries policies are being used effectively to reduce costs and promote public health by influencing prescribing decisions with evidence. As the federal government continues working on health reform, it needs to learn from these examples, not allow its USTR to negotiate them out of existence.

D. USTR Lacks Statutory Authority to Promote Restrictions on Non-Discriminatory Pharmaceutical Pricing Policies

The USTR lacks any statutory authority to pursue the limitation of foreign or US pharmaceutical market regulation that restrains patented medicine pricing.

The Special 301 authorizing statute requires the identification of countries that lack adequate intellectual property protection or that “deny fair and equitable market access to United States persons that rely upon intellectual property protection.” Nondiscriminatory pricing policies do not fall within this ambit.

Extending trade rules into core regulatory concerns that do not discriminate against foreign trade is a radical departure from traditional doctrines supporting state sovereignty.

Policies that affect the “development of new drugs” are not market access issues. Neither TRIPS nor any other international trade agreement places any restrictions on the non-discriminatory operation of pharmaceutical regulation that may affect the price of drugs. This interpretation is too broad as a matter of law and of policy. USTR should not be, and lacks the statutory authority to, negotiate or impose new international standards for medicine pricing policies.

There is no statutory requirement to use trade negotiating authority to restrict foreign pricing programs. But the U.S. is still bound by its commitment to the Doha Declaration. When interpreting any ambiguity in the statutory term “market access” in the Special 301 authorizing statute, USTR should use the Doha Declaration and its human rights obligations as a guide, and avoid the use of trade pressure that will predictably threaten access to medicines for all.