



STATE OF VERMONT
GENERAL ASSEMBLY

COMMISSION ON INTERNATIONAL TRADE AND STATE SOVEREIGNTY

February 16, 2009

TO: Jennifer Choe Groves,
Senior Director for Intellectual Property and Innovation,
Chair of the Special 301 Committee

RE: 2010 Special 301 Review Comments, Docket Number USTR-2010-0003
Submitted electronically

On behalf of the Vermont Commission on International Trade and State Sovereignty, we write to oppose the recent use of the Special 301 report to suggest discipline of countries that implement effective and non-discriminatory pharmaceutical pricing policies. This change is concerning to states, like Vermont, who have been leaders in pharmaceutical cost-control, because it appears to be a broader effort by the U.S. Trade Representative (USTR) to promote a new international trade framework with domestic policy implications for states who seek to contain prescription drug costs.

International trade is an important component of economic well-being at the state level, and states have a strong interest in promoting their trade relationships with other countries. At the same time, states also have a strong interest in ensuring that their health, safety, environmental, and other policies—as reflected in law and regulation—are not undercut by our nation's international trade agreements. As long as those policies do not discriminate against foreign countries, or, in the case of countries with which we have investment agreements, against foreign investors, they should be compatible with the goal of facilitating and expanding international trade.

The Commission was created to assess the legal and economic impacts of international trade agreements on state and local laws, state sovereignty, and the business environment; to provide a mechanism for citizens and legislators to voice their concerns on these issues; and to make policy recommendations to the General Assembly, to the Governor, to Vermont's Congressional delegation, and to trade representatives of the United States government, as may be necessary to protect Vermont's job and business environment and state sovereignty from any negative impacts of trade agreements and enable Vermont to take advantage of the opportunities these agreements make possible. It is in this context that we submit these comments.

Vermont is a leader in health care reform, especially in the area of cost-containment. Through the state's pharmacy best practice and cost control program, Vermont Medicaid achieved a negative growth in its prescription drug spending in the last state fiscal year. This was achieved through the uses of a wide variety of policies designed to leverage better prices from pharmaceutical companies, encourage usage of lower-cost generics by prescribers and consumers, and use the best evidence in health care decision-making. For example, Vermont Medicaid uses an evidence-based preferred drug list (PDL), which is not dissimilar to formularies used in other countries. The purpose of the Medicaid PDL is to consider a combination of factors, including clinical efficacy and cost, when choosing preferred drugs, and to then use bulk purchasing and reimbursement power to negotiate larger rebates from drug companies as a

condition for gaining preferred access to the Medicaid market. These negotiated rebates, called “supplemental rebates”, are in addition to the mandatory rebate required under federal Medicaid law. This same strategy is used by foreign governments and is listed by USTR as “unreasonable” under the Special 301 report.

In addition, Vermont has sought to increase information for consumers who wish to purchase lower-cost drugs in other countries, including our neighbor to the north, Canada. In 2005, Vermont joined I-SaveRx, an initiative regulated by the state of Illinois, which provides a website to consumers who wish to directly purchase lower-cost drugs from pharmacies in Canada, Ireland, and other countries. The city of Burlington, Vermont, in an effort to reduce drug costs for city employees, began an importation program several years ago. USTRs efforts to discipline foreign countries for their effective pricing programs impacts Vermont consumers as well, because of the availability of importation programs in the state.

The pursuit of reduced regulation of pharmaceutical pricing in other countries’ government health care programs will necessarily limit the effectiveness of similar federal programs in the U.S., and potentially in state programs, because trade agreements are reciprocal. This is of concern due to the recent and disturbing trend of the United States Trade Representative to use trade agreements and pressure, including through Special 301, to push for the international regulation of pharmaceutical reimbursement programs.

States, including Vermont, raised concerns about USTR’s use of Free Trade Agreements with Australia and Korea to begin establishing international disciplines on pharmaceutical pricing programs. Submissions to and conversations with USTR and Congress warned that Vermont already uses the same tools that USTR was working to restrict in other countries. Attached is JRS 50 from 2006 passed by the Vermont Legislature articulating these concerns.

The 2009 Special 301 Report indicates that USTR has shifted its negotiating priorities to include restricting evidence-based pricing programs. The report states that “The United States also is seeking to establish or continue dialogues with Organization for Economic Cooperation and Development (OECD) members and other developed economies to address concerns and encourage a common understanding on questions related to innovation in the pharmaceutical sector.” The report lists Japan, Canada, France, Germany, New Zealand, Taiwan and Poland for administering “unreasonable . . . reference pricing or other potentially unfair reimbursement policies.” However, it is unclear from report what elements of these countries system rises to the level of “unreasonable” or “unfair.” In addition, these standards are not typically used in international trade agreements and the report does not allege that any of these countries’ policies violate most favored nation requirements or any other standard contained in a WTO or bilateral agreement.

In closing, it appears that USTR is targeting the innovative reimbursement policies that effectively contain prescription drug costs in similar ways as state preferred drug lists and other public policies have. The Commission opposes the use of the Special 301 Report to negotiate for the limitation of programs in other countries that are emulated by states as best practices. The Commission requests that USTR clarify that it is not in support of trade agreement provisions which may restrict state innovation and refrain from pressuring countries to change pharmaceutical pricing policies that do not violate a WTO standard.

Please let us know if we can provide more information or if you would like to discuss the issue further with us by contacting our staff, Robin Lunge at 828-0290.

Sincerely,
Submitted electronically

Ginny Lyons, Co-Chair
Senator, Chittenden County

Kathleen Keenan, Co-Chair
Representative, St. Albans

Cc: Members, Commission

NO. R-488. JOINT RESOLUTION RELATING TO INTERNATIONAL TRADE AGREEMENTS AND PHARMACEUTICAL DRUG PROGRAMS.

(J.R.S.50)

By Senators Lyons, Ayer, Bartlett, Campbell, Collins, Condos, Cummings, Dunne, Gander, Giard, Illuzzi, Kitchel, Kittell, Leddy, MacDonald, Miller, Mullin, Scott, Sears, Welch and White,

Whereas, Vermont is a recognized national leader among states in the provision of quality health care to all citizens, and

Whereas, managing health care costs is an essential component of state efforts to ensure continued citizen access to a broad range of health care services, and

Whereas, prescription drug purchases are the fastest-growing component of state health care spending, and

Whereas, of all states, Vermont has one of the highest percentages of populations who are served by Medicaid or state-funded drug-purchasing programs, and

Whereas, states have taken the lead in developing innovative solutions to combating the steep rise in prescription drug costs, and

Whereas, recent state and federal court decisions have reaffirmed the ability of states to adopt policies designed to manage prescription drug costs, and

Whereas, language of the recent trade agreements into which the United States has entered with Australia, including Annex 2-C on pharmaceuticals, uses a definition of a “federal health care program” that is ambiguous and that creates uncertainty in the management of state health care administration, and

Whereas, United States Trade Representative Robert Portman has assured states in writing that state programs are “not covered” by recent trade agreements signed by the United States, and

Whereas, this written assurance itself has no legal power in the case of a complaint filed by a trading partner of the United States regarding state administration of health care programs, and

Whereas, all trade agreements into which the United States has entered include the potential for an exchange of interpretive notes through which a party to the agreement can clarify the scope of a measure included in a trade treaty or an annex to that treaty, and

Whereas, such interpretive notes have the force of international law, *now therefore be it*

Resolved by the Senate and House of Representatives:

That the General Assembly urges the United States Trade Representative (USTR), following appropriate consultation with states to pursue the exchange of an interpretive note with the government of Australia clarifying

that state administration of Medicaid programs and pharmaceutical assistance programs under the Medicare Modernization Act is *not* included in the definition of a “federal health care program” under Annex 2-C of the United States-Australia Free Trade Agreement, *and be it further*

Resolved: That the General Assembly urges the USTR to discuss with the general assembly and Vermont state health care officials what health care programs *are* covered by the Annex 2-C definition of “federal health care program” as found in Annex 2-C of the Australia Free Trade Agreement, *and be it further*

Resolved: That the General Assembly urges the USTR to carve out and protect state administration of health care programs, including the purchase of prescription drugs, in all current and future negotiations of trade agreements, *and be it further*

Resolved: That a copy of this resolution be sent to Senator Charles Grassley, chair of the Senate Finance Committee; Senator Orrin Hatch, chair of the Senate Subcommittee on International Trade; Representative Bill Thomas, chair of the House Ways and Means Committee; Representative Clay Shaw, chair of the House Subcommittee on Trade; Senator Judd Gregg, chair of the Senate Committee on Health, Education, Labor, and Pensions; Senator Bill Frist, chair of the Senate Subcommittee on Public Health; the Congressional delegation of the State of Vermont; United States Trade Representative Robert Portman; Assistant United States Trade Representative and chief negotiator on pharmaceuticals Barbara Weisel; and Vermont Attorney General William Sorrell.