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STATE OF MAINE

Citizen Trade Policy Commission

February 17, 2010

Jennifer Choe Groves
Senior Director for Intellectual
Property and Innovation and Chair of the Special 301 Committee
Office of the United States Trade Representative

Re: Submission of Written Testimony and Notice of Intent to Testify at a Public Hearing Concerning the 2010 Special 301, Docket #USTR-2010-0003

Dear Ms. Groves:

On behalf of the Maine Citizen Trade Policy Commission (CTPC or Commission), we write to oppose the recent and disturbing expansion of the Special 301 report into the realm of disciplining countries for implementing effective and non-discriminatory pharmaceutical pricing policies. This letter, and our request to testify orally at the hearing that will be held in on Wednesday, March 3, 2010, is pursuant to the unanimous vote of the Commission at our January 8, 2010 meeting.

The Maine Citizen Trade Policy Commission was established by the Legislature in 2003 to assess and monitor the legal and economic impacts of trade agreements on state and local laws, working conditions and the business environment; to provide a mechanism for citizens and Legislators to voice their concerns and recommendations; and to make policy recommendations designed to protect Maine's jobs, business environment and laws from any negative impact of trade agreements. We have members representing the Maine House of Representatives, and Senate, the Maine International Trade Center, various state agencies, and members affiliated with citizen constituencies including small businesses, manufacturers, labor, environmental organizations, and small farmers.

Pursuant to our statutory mission, we have included a focus on health policy and trade issues, including pharmaceutical policy and in particular, the impact of that policy on Medicaid implementation and costs in the state. Our membership is determined by statute and includes a health professional. We have previously written to the U.S. Trade Representative concerning carving out Medicaid from free trade agreement provisions relating to pharmaceuticals. Legislative members of the commission have also met with USTR staff on these issues, and we were gratified that the Korea FTA included a footnote recognizing the role of the states implementing and paying for Medicaid and explicitly carving out these state programs.

Despite this past advocacy and the at least tacit recognition by the USTR that when trade agreements address pharmaceutical policy, there can be unintended and deleterious consequences for state health policy and access, it appears that the USTR has nevertheless embarked on an even broader effort to promote a new international trade framework to restrict domestic regulatory responses to excessive pricing by monopoly pharmaceutical suppliers.

This new direction concerns us greatly, because it will increase state health care costs and significantly reduce access to health care. The timing of this initiative is particularly questionable given the multi-million dollar deficits in state Medicaid budgets caused by the ongoing worldwide recession. The consequence of its implementation will be to reduce access to affordable health care at the very time the Administration is pushing for universal health coverage in partnership with the States.

Maine relies on evidence-based reimbursement decisions to restrain pharmaceutical prices. Like other states, Maine uses a wide variety of regulatory tools and policies to control excessive pricing by medicine suppliers. These are often the same tools used by foreign governments that USTR lists as "unreasonable" under Special 301 and has sought to restrict or eliminate in recent trade agreements. One of the most important of these state mechanisms is the Preferred Drug Lists (PDLs) in the Medicaid program.

More than forty states use PDLs for Medicaid and other programs. These are programs that, like those in other countries, use the bulk purchasing and reimbursement power of governments to pressure drug companies to accept steep reductions in their reimbursement prices as a condition for gaining preferred access to a large market. The industry calls these "price controls," governments call them "negotiation." Regardless, these are the same tools that USTR for several years has been highlighting as in need for a new international standard setting exercise to restrict domestic policy options.

Use of PDLs by Maine and other U.S. states has resulted in tremendous savings; eliminating or restricting this tool will have serious negative repercussions. The prices paid by the state of Maine for prescription drugs in its Medicaid program average around 50% of the "Average Wholesale Price" (AWP) as a result of both the federal Medicaid rebate, rebates through the state's supplemental rebate program, and a tiered PDL. The state also has improved its bargaining power while maintaining this basic approach by expanding the size of its

purchasing pool. At a time when brand-name drug prices and spending has increased in the double digits over a decade, Maine has been able to keep its drug spend relatively flat.

Maine's approach to drug pricing is consistent with the approach taken in the majority of states. Indeed, the President's budget for 2008 specifically noted that Medicaid "allows states to use [such] private sector management techniques to leverage greater discounts through negotiations with drug manufacturers."[1] Maine's current Supplemental Budget as proposed by Governor John E. Baldacci would already cut back on pharmaceutical access programs such as Drugs for the Elderly,[2] a program initiated in the early 1970's – the first such program in the Nation – in an effort to balance the budget in light of reduced revenues due to the economy.

Although it is commonly posited by industry that foreign countries "free ride" on U.S. pharmaceutical prices, U.S. governments that use policy tools that are similar to foreign governments pay similar prices. The prices paid by state Medicaid programs or the Veterans Administration hospitals, for example, are frequently *lower* than Canadian and European prices.[3] Similar tools are used by almost every bulk purchaser of drugs – including private insurance companies, branches of the U.S. federal government and most other industrialized countries.

The Maine Citizen Trade Policy Commission opposes USTR's promotion of international restrictions on domestic pharmaceutical pricing programs. As noted above, we are concerned about a recent and disturbing trend of the United States Trade Representative using trade agreements and pressure, including through Special 301, to push for the international regulation of ***domestic*** pharmaceutical reimbursement programs.

Maine and other states have repeatedly raised concerns about USTR's recent use of Free Trade Agreements with Australia and Korea to begin establishing international disciplines on pharmaceutical pricing programs. In several submissions to USTR and Congress we have warned that U.S. states already use the same tools that USTR was attempting to restrict abroad. The Korea agreement included a radical provision appearing to allow industry appeals of government pharmaceutical reimbursement decisions on whether they adequately respected the "value" of patented pharmaceutical products. Such provisions, if applied to state pharmaceutical pricing programs, would significantly hamper the operation of important public health programs.

The 2009 Special 301 Report contains additional evidence of USTR's shift of its negotiating priorities into the arena of restricting evidence based pricing programs. The Report singles out Japan, Canada, France, Germany, New Zealand, Taiwan and Poland for administering "unreasonable . . . reference pricing or other potentially unfair reimbursement policies." The Report further states that:

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[1] Budget of the United States Government, FY 2008. Available at www.whitehouse.gov.
[2] See information posted at: http://www.maine.gov/dhhs/mainerx/del.htm
[3] See the 2004 Annual Report of the West Virginia Pharmaceutical Cost Management Council, available at http://www.wvc.state.wv.us/got/pharmacycouncil/.

> 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.

It appears to the Commission that USTR is targeting the same policies that it has in the past – i.e. innovative reimbursement policies that effectively restrain medicine pricing in a manner similar to 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 right now here at home***

Finally, we are concerned that the actions of USTR threaten best practices needed for health reform. Maine has been a leader in expanding access to health care for its residents and identifying and implementing best practices to rein in excessive medical cost and promote public health.[4] Pharmaceutical policy in the U.S. is a major component of health policy – and costs – and is no less in need of reform. We spend more on pharmaceuticals than any other country in the world. Maine and other U.S. states are effectively using policies to reduce costs and promote public health by influencing prescribing decisions with evidence. As the federal government continues working on health reform, we strongly urge that it learn from these examples, and not allow its USTR to negotiate them out of existence.

Thank you for your consideration.

Yours sincerely,

Senator Troy Jackson, Chair

Representative Margaret Rotundo, Chair

cc: Ron Kirk, USTR
John Baldacci, Governor
Member of Maine's Congressional Delegation

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[4] Initiatives include Dirigo Health, the Maine Quality Forum, increased transparency of medical pricing and quality (including a first-in-nation web-based disclosure) and the Advisory Council on Health Systems Development which just issued a draft report on payment reform. See http://www.maine.gov/governor/baldacci/policy/health_care.html