March 3, 2010 ORAL TESTIMONY OF MAINE REP. SHARON TREAT
REGARDING THE USTR SPECIAL 302 REPORT ON BEHALF OF THE WORKING GROUP ON TRADE OF THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES

Good afternoon, I am Sharon Treat, a Maine State Representative and Executive Director of the National Legislative Association on Prescription Drug Prices (NLARX). I am here to testify on behalf of the NLARx Working Group on Trade, and its co-chairs Arizona Senator Meg Burton Cahill and Connecticut Representative Kevin Ryan.

The Working Group on Trade holds informational meetings for policy makers on emerging trade issues related to pharmaceuticals, and assists states in directly engaging with the U.S. Trade Representative through meetings and correspondence. The Working Group has helped states establish their own institutional mechanisms both to provide ongoing oversight over trade policy, and to educate their citizenry and policy makers about the connection between international trade policy and affordable prescription drugs.

We oppose the expansion of the Special 301 report into the realm of disciplining countries for implementation of effective and non-discriminatory pharmaceutical pricing policies. Additionally, we oppose the recent trend of the U.S. Trade Representative using trade agreements and negotiations to develop new international standards restricting the use of the most effective programs to restrain drug prices. These initiatives will directly and negatively affect the capacity of states to provide health care and pharmaceuticals to their residents through existing Medicaid and state-funded programs, and will cripple the ability of states to expand access to health care in the future.

The Working Group on Trade has been actively involved in providing comments on trade policy related to pharmaceutical purchasing and intellectual property over the past several years. State legislative members of the Working Group met several times with U.S. trade negotiators and expressed concerns that language used in the US-Australia Free Trade Agreement could provide a pretext for challenging state administration of Medicaid programs. The Working Group sought specific guarantees that any chapter on pharmaceuticals in a new trade agreement would not threaten their ability to manage drug costs through formularies and preferred drug lists. USTR staff took up this issue and honored the request from states to clarify in the text of the US-Korea Free Trade Agreement a specific exception for Medicaid.

In light of this background, we find it disheartening and disturbing that the USTR is moving forward with efforts to promote new international standards restraining domestic medicine pricing regulations (in the U.S. and abroad). Indeed, Ambassador Kirk recently expressed his "support" for broadening the discussion of a proposal by Pfizer to promote a new international trade agreement that would "discipline" U.S. and other wealthy country regulation of pharmaceutical monopoly markets. *This agreement would not exempt U.S. federal or state regulatory mechanisms: the international limitation of U.S. pricing programs would be core intent.*

We call on USTR to alter course and publicly announce that it is not in support of such an agreement and halt its use of Special 301 or other measures to pressure countries to change pharmaceutical pricing policies that do not violate any WTO norm.

Patents on medicines can create a particularly strong form of monopoly that, if left impervious to regulations affecting pricing power, can lead to extraordinarily high prices that harm social welfare. This is because medicines can be basic life necessities that few will do without and because many purchasers are insulated from price exposure by forms of insurance. State governments use a wide variety of regulatory tools and policies to restrain excessive pricing by medicine suppliers. These are often the same tools used by foreign governments that USTR describes as "unreasonable" in the Special 301 Report, and has sought to restrict or eliminate in recent trade agreements.

Nowhere is the use of these tools more widespread than in the states' implementation of Medicaid, a joint state/federal program that provides a comprehensive health insurance safety net to 60 million poor and disabled Americans. Medicaid costs topped $350 Billion in 2008, and it is the single largest state government expenditure after education.

A key component of Medicaid is the use of preferred drug lists (PDLs). The idea is simple – the best drugs should be preferred, and costs should be in line with effectiveness, not market power. More than forty states use PDLs for Medicaid and other programs, including state-funded prescription drug benefits for the elderly that "wrap around" Medicare Part D, and discount drug programs that are available to the non-elderly who do not qualify for Medicaid but who lack insurance that provides pharmaceutical coverage.

In U.S. states, as in other countries, these policies are being used effectively to reduce costs and promote public health by influencing prescribing decisions with evidence. Some examples:

• Iowa has saved $100 million dollars between 2005 and 2009. The state's Department of Human services reports that last year the state's PDL delivered savings equal to 34.7% of its total drug budget.

• Oregon reports saving 40% per prescription due to greater generic uptake resulting from its use of a Preferred Drug List in 2009.

• From 2006 to 2007, discounts negotiated by private companies for Medicare Part D were "substantially smaller" than those negotiated by state Medicaid programs, resulting in costs 30% higher for Medicare.

• Total Medicaid spending on pharmaceuticals decreased by 1.8% in 2007 (the most recent year for which data is available), while at the same time drug spending as a whole increased at a rate of 4.9%.

• According to the January 2003 annual report of the Office of Vermont Health Access, spending on acid reducers, anti-inflammatory drugs, and opiate analgesics dropped from $15.8 million to $12

million within 8 months of introducing the Medicaid PDL. Vermont saved over ten percent of its prescription drug budget for state employees ($2.8 million on total expenditures of $21.1 million) by restructuring the benefit to include a PDL.

Without access to these tools, states would simply be unable to provide comprehensive access to medicines in their Medicaid and other health insurance programs. Pharmaceutical costs can account for from 10-25% of the cost of these programs, even with the rebates and pricing tools currently available. At a time when states from Arizona and New Mexico and Washington State to Maine have announced plans to cut these same programs to address the severe budget shortfalls caused by the recession, USTR's initiatives are both ill-timed and incomprehensible.

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. Further, this Administration has embraced reform in partnership with the states and with a nod to best evidence-based practices pioneered at the state level. Preferred drug lists are a best practice that is illustrative of the approach the Administration is seeking to replicate in its national health reform initiative. 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."

It is difficult in the extreme for states to understand how the USTR's efforts to promote new international standards restraining domestic medicine pricing regulations, which will severely increase the cost of public health programs and limit the use of evidence-based tools, square with the effort to extend health insurance to all Americans.

This disconnect is all the more inexplicable given that pharmaceutical policy in the U.S. is in such need of reform. We spend more on pharmaceuticals than any other country in the world, in part because we oversubscribe costly new medicines when they are not better, and are often much worse, than cheaper alternatives. As the federal government continues working on health reform, it needs to learn from the states' pricing practices, not allow its USTR to attack them under the guise of Promoting innovation.

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." A traditional market access issue might be a discriminatory regulation that unduly burdens foreign suppliers, e.g. a preference for local IP-protected goods by national suppliers. However, the 2009 Special 301 report takes an incredibly broad interpretation of "market access barriers," extending it to "price controls and regulatory and other barriers [that] can discourage the development of new drugs."

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 nondiscriminatory operation of pharmaceutical price regulation, competition policy or other regulatory program 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.

We appeal to the Obama administration to change course and halt the use of Special 301 or other trade initiatives to internationally regulate domestic drug pricing programs that do not violate any World Trade Organization rule.