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**PHARMACEUTICAL REIMBURSEMENT RESTRICTIONS AND PUBLIC HEALTH, ANALYSIS OF
U.S. AND OTHER TPP COUNTRY PRACTICES: *The impact of pricing provisions on U.S.
Medicaid and other health access programs***

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Assuring access to affordable health care is one of the highest priorities of policymakers and nongovernmental organizations at both the federal level in the United States and at the state and local levels. Indeed, it is one of the central challenges of our time. Certainly it is one of my highest concerns-- as a state legislator who walks door to door on a regular basis talking with the people of my district in rural central Maine, as a board member of an NGO that is dedicated to finding solutions to poverty and improving the lives of low income people, and as the director of an organization of state legislators working together to reduce prescription drug costs.

Thus the potential impact of trade policies on affordability and availability is a key concern, one that health advocates and policymakers in states across the U.S. are starting to voice publicly in forums such as this and with trade negotiators and our members of Congress. In particular, how trade agreements affect pricing of pharmaceuticals and the availability of generics has been of great interest.

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Policymakers at the state level have concerns about the inclusion of pharmaceutical provisions in the TPPA if those provisions are similar to or go beyond the Korea-US FTA (KORUS) and Australia pharmaceutical annexes. Our overall concern is that if similar provisions are adopted in the TPPA, they could be used to restrict current and future drug reimbursement and pricing options and result in increased costs of health care and reduced access to medicines at a time when those costs are already excessive and many people in the U.S. lack access to care.

The Maine Citizen Trade Policy Commission has adopted a policy statement in support of access to medicines, has written to our Congressional delegation objecting to pricing provisions of past FTAs, and has testified concerning the Special 301 Report. The Maine Legislature in 2011 enacted a Joint Resolution calling for greater transparency and consultation with states in the trade negotiation process.²

We have concerns about both procedural and substantive provisions in KORUS and US-Australia FTAs that we understand may be a starting point for TPPA discussions.

Procedural and transparency provisions. It is important that these provisions balance procedural fairness and transparency, a goal embraced by state leaders, with practical considerations. In other words, trade agreements should not impose unnecessary red tape or procedural hurdles on U.S. states or the federal government that interfere with the effective administration of Medicaid and other health programs, delay the addition of generic versions of drugs to PDLs or the timely removal of drugs with emerging efficacy and safety concerns, or provide grounds for overturning legitimate evidence-based reimbursement decisions.

At least 40 states negotiate prices based on an open formulary known as a preferred drug list (PDL). They compare evidence on the safety, efficacy, and cost-effectiveness of new drugs to existing drugs in the same therapeutic class, not unlike private insurance companies or foreign governments. States revise evidence based PDLs on a regular basis and at times, on short notice, to take advantage of market changes and the availability of new generic drugs, or to respond to new evidence of contraindications or clinical studies that require prompt reassessment of efficacy. Washington State has the most comprehensive such program which extends beyond pharmaceuticals; it has developed its own Health Technology Assessment Program, which contracts for scientific, evidence-based reports about the safety and efficacy of certain medical products including medical devices. This process informs reimbursement and coverage decisions for programs including Medicaid.³

It is also important that procedural so-called “transparency” trade provisions not become a mechanism to inject pharmaceutical industry influence and conflicts of interest into what is now

² Maine Legislature’s 2011 Joint Resolution on Trade:

http://www.mainelegislature.org/legis/bills/bills_125th/billpdfs/HP115201.pdf

Letters and testimony of the Maine Citizen Trade Policy Commission (MCTPC):

<http://www.maine.gov/legis/opla/citpoltradedocs.htm>

MCTPC 2009 assessment of trade impacts on Maine: <http://www.maine.gov/legis/opla/citpolassessments.htm>

2010 CTPC policy statement on trade: <http://www.maine.gov/legis/opla/citpol.htm>

³ For more about the Washington State program: <http://www.hta.hca.wa.gov/>

an evidence based process. For example, KORUS Article 5.3.5(f) would “*make all reimbursement decision-making bodies open to all stakeholders, including innovative and generic companies,*” inserting major conflicts of interest into the reimbursement and PDL decision by **requiring** that the very manufacturers that directly benefit from reimbursement and pricing decisions make those decisions. This violates the law in many U.S. states, as well as best practices for evidence based decision-making.

Substantive pricing provisions. Language in KORUS about “appropriately valuing” drugs, or requiring a premium for “innovative” products, or - as suggested by the pharmaceutical industry in public statements - possible new TPPA text requiring linkage of reimbursement and pricing decisions to in-country market prices, all raise red flags. Such language is designed to keep drug prices high, and the United States already has some of the highest pharmaceutical prices in the world.

State and federal Medicaid pricing and reimbursement models are changing as a result of the Affordable Care Act. Federal officials are moving for the first time to establish a national reference price list for Medicaid instead of the state-by-state negotiated rebate system currently in place. Such a national reference price system would be very similar to the systems in place in other countries including TPPA parties. Thus any FTA language restricting such pricing mechanisms would appear to directly challenge the new U.S. Medicaid drug pricing system.

While the current state-by-state reimbursement system has its flaws, it has nonetheless resulted in substantially reducing the cost of prescription drugs for 58 million Americans. For example, the prices paid by the State of Maine for prescription drugs in its Medicaid program average around 50% of the “Average Wholesale Price” as a result of the federal Medicaid rebate, additional discounts through the state’s supplemental rebate program, group purchasing with other states, and a tiered PDL. During a decade when brand-name drug prices and spending has increased annually in the double digits, 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 in the U.S.

Is the KORUS Medicaid carve-out effective? Since Medicaid is a joint federal-state program (funded by both the federal and state governments; administered by states according to federal guidelines) it was unclear whether the terms of the Australia FTA would apply to Medicaid. State leaders sought a binding clarification from USTR that Medicaid could not be affected by these provisions, but no such clarification was received.

Subsequently, during the negotiation of the KORUS FTA, state leaders lobbied – successfully – for a specific carve out of Medicaid in the text of the agreement. The pharmaceutical provisions apply to negotiations conducted by the “central” government, and a footnote to Article 5.8 reads: “*For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.*”

As state leaders have become better educated about the overlap between trade policy and state government programs, they now understand the potential reach of TPPA and other FTAs into the complex web of state-federal partnerships, a web which is particularly complicated and

extensive in health care. State leaders now recognize that FTA pharmaceutical pricing and transparency provisions could be applied to core state health policies outside of Medicaid, such that a Medicaid carve out will not adequately protect these programs.

For example, **Medicare Part B** sets statutorily-defined prices for pharmaceuticals used in medically necessary services for Medicare beneficiaries (disabled and older persons). **Section 340B of the Federal Public Health Act** requires drug companies to provide statutorily-defined discounts on covered outpatient drugs purchased by federally-funded clinics and other safety net providers as a condition of having their drugs covered by Medicaid – at prices that are substantially *lower* than Medicaid. *Neither of these programs is part of “Medicaid”.*

As Vermont Governor Shumlin pointed out in his June 1, 2011 letter to US Trade Representative Ron Kirk,⁴ 340B programs include all of his state’s federally qualified health centers and Fletcher Allen Health Care, Vermont’s largest teaching hospital. In addition, Vermont has begun a new 340B pilot project with Rutland Regional Hospital to provide broader 340B access through local pharmacies.

Vermont is not alone in its extensive use of the 340B program, a program that is a central level of government health care program also operated by the states, and which is NOT part of Medicaid. An increasing number of states are turning to the program to expand access to affordable health care, and new partnership opportunities with private-sector pharmacies were authorized in the Affordable Care Act, which will likely expand the reach, and state reliance on 340B, even more. Some examples of expanded 340B programs in the states include:

- **Vermont** H. 792 (enacted 2010): Supporting state collaboration with community health centers, critical access hospitals and sole community hospitals to care for individuals with disabilities, mental health needs and substance abuse issues, and supporting 340B participation for newly eligible hospitals.
- **Connecticut** H.B. 5545 (enacted 2010): Requiring community health centers participating in state general assistance program to enroll in 340B and provide pharmacy services via in-house or contract pharmacies.
- **Kansas** S.B. 572 (enacted 2010): Subsidizing the cost of pharmaceuticals purchased by community health centers through 340B and dispensed to low income patients using sliding scales.
- **Utah’s** Medicaid program has a sole source contract with a 340B hospital for providing factor products and case management services to hemophilia population statewide; the parties are exploring expansion of program to other disease groups.
- **Pennsylvania’s** Medicaid managed care organization has contracted with a community health center to manage a high-cost chronically ill enrollee population and to provide pharmacy services at lower prices.

⁴ Vermont Governor Peter Shumlin wrote on June 1, 2011 to U.S. Trade Representative Kirk and President Obama to oppose the inclusion of a pharmaceutical or healthcare annex in the TPPA. The letter is posted here: <http://freepdfhosting.com/6ee2e21e4c.pdf>. Letters and resolutions concerning prior TPAs have been written by officials or commissions in states including California, Vermont, Maine, Washington State, Connecticut, Arizona, West Virginia, Massachusetts, Alaska, Hawaii, and New Hampshire. Some of these letters and resolutions are posted here: <http://www.wcl.american.edu/pijip/go/trade-statedocs>.

- **340B and correctional populations:** In 2001, the Texas Legislature passed Senate Bill 347 to implement a program to access 340B pricing for prisoner medications, translating into significant savings of 30 to 35 percent over previous prices. **Virginia** has also used 340B to obtain medicine for correctional institutions, as have county jails, such as Dade County's in **Florida** and San Bernardino County's in **California**.

The largest individual cost drivers for a state Medicaid program include such populations or disease states as mental health patients, transplant recipients, hemophiliacs, People Living With HIV/AIDS, or other categories of patients with expensive and chronic disease states. The 340B Program is relied on by many states to provide these expensive pharmaceuticals to these high-risk populations.

AIDS drug assistance programs (ADAPs) are just one example of the reliance by states on 340B. ADAPs are critical in providing HIV/AIDS treatment to low-income, uninsured, or underinsured patients within the United States and its territories. ADAPs are eligible to participate in the 340B program as either a direct purchaser of discounted drugs or by receiving rebates from manufacturers (similar to Medicaid drug rebate program). Direct purchase ADAPs receive better pricing – about 15-20 percent better – than rebate model ADAPs. With new opportunities to contract with multiple contract pharmacies (authorized by the Affordable Care Act in 2010), direct purchase ADAPs can have the same large pharmacy networks as rebate model ADAPs and create new state savings.

Trade-driven pharmaceutical price increases would devastate state health care and Medicaid budgets and further delay or eliminate treatment for millions of Americans. Most U.S. states have been facing budget cuts in successive budgets since at least 2008, resulting from revenue shortfalls caused by the ongoing worldwide recession – cuts that have hit health care funding especially hard. This year, many states have ended or cut back prescription drug assistance programs and Medicaid eligibility.

As an example, even with the availability of PDL-based rebates and federal matching funds, the 2011 budget proposed by Maine Governor Paul LePage would have eliminated the state's MaineRx discount drug program, eliminated the state-funded Drugs for the Elderly Program, dropped Medicaid eligibility for childless adults, and reduced or eliminated the Medicare Savings Program assisting 40,000 seniors and some disabled Mainers with prescription drug payments. Through cost-shifting copayment increases and additional fees, most of these cuts were postponed, but are likely to be proposed again in 2012.

Nationwide, the number of patients sitting on AIDS Drug Assistance Programs (ADAP) waiting lists, denied the life-saving treatment they need, have risen dramatically over the past two years. In January 2010, 361 individuals were on ADAP waitlists; that number grew to 7,873 across eleven states as of May 5, 2011 (a 2100% increase over less than sixteen months). Recent data published by the National Alliance of State and Territorial AIDS Directors reports that as of August 11, 2011, there were 9,217 individuals on ADAP waiting lists in 12 states, representing a 20% increase over a four month period. These states include Alabama, Arkansas, Florida, Georgia, Idaho, Louisiana, Montana, North Carolina, Ohio, South Carolina, Utah, and Virginia.

In addition to these waiting lists, six states, including Arkansas, Illinois, North Dakota, Ohio, South Carolina, and Utah have limited eligibility - some by more than 50% - as a cost-containment measure. Seventeen states and the territory of Puerto Rico reported instituting other cost containment strategies including, among others: reduced formularies, capped enrollment, monthly or annual expenditure caps, disenrolling clients not accessing ADAP for 90-days, discontinuing reimbursement of laboratory assays, instituting client cost sharing, and restricting eligibility criteria. Other states are considering adopting waiting list of additional cost-shifting measures.

In sum, should negotiators include language similar to the KORUS pharmaceutical pricing and transparency provisions in the TPPA, even with the Medicaid carve-out, those provisions could cripple our ability to provide access to pharmaceuticals and medical devices to low income and middle class Americans and populations with special health needs. That the TPPA is a multi-country treaty is of particular concern because the policies and disciplines it adopts will be enforceable by such a wide range and large number of trading partners.

While one approach is to expand the scope of the KORUS Medicaid carve-out in future TPAs, a better response would be to reconsider inclusion of the problematic provisions in the first place. Even if the KORUS footnote language is redrafted to carve out more than Medicaid, we question the value of including such provisions in reciprocal trade agreements where key provisions supposedly do not apply to most of the existing and planned U.S. and state pharmaceutical and medical device reimbursement programs. It seems unlikely that such a one-sided agreement, which imposes tough restrictions on other countries but not our own, will remain unchallenged and not vulnerable to future interpretations that may be inconsistent with current U.S. intent.

Moreover, the very existence of these provisions inevitably will add to pressure from the pharmaceutical and medical device industry – which is already great - to replace current U.S. pricing and reimbursement provisions that are protected by specific carve outs, with programs that are not so protected.⁵ There is a likelihood that new programs will have to conform to pricing and procedural disciplines in TPPA and other TPAs, leading to ever-higher health care costs and reduced access to health care, especially for low-income residents of our states.

As discussed above, U.S. Federal government agencies and state governments essentially use the same policy tools as foreign governments for public medicine purchasing and reimbursement, and they pay similar prices. We believe it to be inadvisable to use trade agreements and pressures to push pharmaceutical and medical device pricing policies abroad that we do not follow here at home.

⁵ Trade agreements may simply be an alternative method for the pharmaceutical industry to suppress pricing policies it has unsuccessfully challenged in the US courts. In the early 2000s, the industry launched three separate lawsuits against state programs in Maine, Michigan and Florida, claiming federal Medicaid laws prevented the use of PDLs in their programs. However, the plaintiffs lost all three cases, with federal courts, including the U.S. Supreme Court, upholding states' rights to negotiate prices through evidence based PDLs. Soon after, the industry urged trade officials to seek restrictions on evidence based drug pricing abroad, and the Australia-US FTA was the first bilateral trade deal to include a section directly addressing the pricing of pharmaceuticals [Annex 2(c)].