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The impact of pricing provisions on U.S. Medicaid and other health access programs

One of the central challenges of our time is assuring access to affordable health care. As a state legislator in a rural US state, a board member of an NGO 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, it is one of my highest priorities.

The impact of trade policies on medicines affordability and availability is a key concern of state officials. The board of the National Legislative Association on Prescription Drug Prices voted in January to oppose including pharmaceutical pricing and transparency provisions in the TPPA; the Governor of Vermont has written to President Obama opposing these provisions; and state trade advisory commissions have raised similar concerns as well as testified before USTR on related issues in the 301 hearings. Why?

- Because we know that Medicaid and other state-federal drug access programs in the US *currently do not meet the transparency standards in the Australia and Korea FTAs – standards we know are the starting point for TPPA negotiations*.

- At least 40 states negotiate prices in the state-federal Medicaid program 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 and existing drugs in the same therapeutic class, not unlike private insurance companies or governments such as Canada, New Zealand and Australia. In my own state of Maine the PDL-based rebates have reduced the average cost to the state for pharmaceuticals purchased through public programs by 50% off list price.

  Like Maine, most US states do not now comply with the procedural provisions and appeal rights in KORUS, and applying these standards could interfere with the effective management of our programs. States revise drug lists on a regular basis and at times, on short notice, to take advantage of market changes and the availability of new generics, or to promptly reassess efficacy and safety based on new evidence. Most do not allow the drug manufacturers to sit on the committees deciding which drugs are on the lists, rejecting this as a major conflict of interest, yet KORUS Article 5.3.5(f) requires it.

- With the passage of the Affordable Care Act, the drug pricing provisions in Medicaid are changing from state-level rebate negotiations to a national pricing list that will look remarkably similar to the New Zealand's Pharmac and Australian Pharmaceutical Benefits Scheme or PBS - programs criticized by some US trade officials and pharmaceutical companies and targeted by trade provisions.

- Indeed, many state legislators have worked for years to transform US access to medicines programs to be *more like* the effective cost-containing programs in Australia and New Zealand, not less. *Millions of people in the US do not have regular affordable access to medicines.* A study released just this week by the Commonwealth Fund found the number of "*underinsured*" adults rose by 80 percent between 2003 and 2010, from 16 to 29 million. Nearly half (44%) of adults in the US -- 81 million people -- were either underinsured (generally paying high premiums for private insurance with high deductibles and inadequate coverage) or without any insurance in 2010. *Among adults with at least one chronic health condition, nearly four in ten uninsured adults and one-quarter of underinsured adults reported skipping doses or not filling a prescription for their condition because of cost.*

- Any language restricting drug pricing mechanisms in TPP countries would appear to directly challenge the new US Medicaid drug pricing system. State legislators are particularly worried about the KORUS text requiring governments to "appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides" – text that could get even worse in TPPA. We know from public statements of the pharmaceutical industry that they want to define "appropriately value" in a way that limits prices to in-country competitive markets.

  Such language applied to the United States, with some of the highest market prices for patented drugs anywhere, would simply lock in those high prices in perpetuity at a time when we are working hard to implement President Obama's vision of expanding affordable health care for everyone.

It would be a tragedy if the pharmaceutical provisions in the TPPA were to render our existing public health programs and the *Affordable* Care Act ***unaffordable*** by keeping US drug prices high, delaying the addition of generic versions of drugs to PDLs or the timely removal of drugs with emerging efficacy and safety concerns, or providing grounds for overturning legitimate evidence-based reimbursement decisions.

I know that, especially recently, there has been a good-faith effort by US trade negotiators to respond to these concerns. In response to the states' lobbying, the text of the KORUS agreement carves out Medicaid in a footnote. While this is helpful, it does not address the scope

of our problems with the KORUS pharmaceutical provisions nor assuage our worries about the future in TPPA. Why not?

- The carve-out doesn't exempt non-Medicaid programs heavily relied on to provide access to pharmaceuticals including the clinic-based 340B program of the Federal Public Health Act and the hospital-based Medicare Part B for seniors.

- The carve-out doesn't cover any ***new*** programs and thus locks the US in perpetuity to the ineffective, expensive pricing systems we have today. For example, could Medicare Part D be changed from a private insurance-based program to a centrally negotiated drug pricing program like Medicaid without triggering the pricing restraints in trade agreements? I wonder.

- What about the heavily subsidized insurance soon to be provided through the new Affordable Care Act, which is intended to fill the huge gaps in health coverage in the US? Pharmaceutical companies lobbied successfully to avoid price restraints in this program. Will Congress be allowed to change this law in the future as pharmaceutical market prices go ever higher? Will the US government have the money to pay for these subsidies in perpetuity if the sky is the limit?

  I doubt it; look at the deficit reduction and debt-ceiling mess that Congress is currently tangled up in. Or look at the cutbacks to health care and pharmaceuticals programs we are already experiencing even without these new trade provisions.

  Most U.S. states have faced budget cuts since at least 2008 caused by the ongoing worldwide recession. This year, many states ended or cut back prescription drug assistance programs and Medicaid eligibility. Maine's Governor proposed eliminating the MaineRx discount drug program and the state-funded Drugs for the Elderly Program, dropping Medicaid eligibility for childless adults, and reducing or eliminating the Medicare Savings Program assisting 40,000 seniors and some disabled Mainers with prescription drug payments, and cutting health insurance entirely for 30,000 low-income people. Through cost-shifting copayment increases and more fees, most of these cuts were prevented, but he has announced similar plans for 2012.

  Or look at the number of patients sitting on AIDS Drug Assistance Program (ADAP) wait lists, denied the life-saving treatment they need. Wait lists rose dramatically in the past two years, from 361 people in January 2010, to 9,217 individuals on wait lists in 12 states in August

2011. In addition, six states have limited eligibility - some by more than 50% - as a cost-containment measure, and seventeen states and the territory of Puerto Rico have cut program costs by reducing access through 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, or restricting eligibility criteria.

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 going forward to provide access to pharmaceuticals and medical devices to low income and middle class Americans, and populations with special health needs.

While one approach might be to expand the scope of the Medicaid carve-out in future TPAs, a better response would be to reconsider including the problematic provisions in the first place. 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. 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. Indeed, trade agreements may simply be an alternative method for the pharmaceutical industry to suppress pricing policies it has unsuccessfully and repeatedly challenged in the US courts.

If new US health care programs must conform to pricing and procedural disciplines in TPPA and other TPAs, the US will NEVER solve its health access problems, just as developing countries and other trading partners will be pressured to move closer to our own broken system. Assuring

access to health care to all should be among the highest priorities of those of us in government service.

Our goal must be to insure access to all people to essential medicines at prices that are affordable. ***The pharmaceutical pricing and transparency text in past FTAs does not advance this goal, and I urge all negotiators to move beyond these FTAs and reject these provisions as you negotiate what could be a new and better TPPA.*** Thank you.