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Does the "Trade Enhancing Access to Medicines (TEAM)" Approach to Pharmaceutical Market Access, Transparency & Pricing Conflict with the Goal of Affordable Medicines?

The U.S. Trade Representative recently released a white paper proposing an initiative in the TPPA called "Trade Enhancing Access to Medicines (TEAM)." The white paper outlined a series of goals for the Trans-Pacific Partnership to enhance access to medicines in TPP countries through a "new strategic initiative" involving "fresh thinking." The white paper states that the proposals are designed "to promote trade in, and reduce obstacles to, access to both innovative and generic medicines, while supporting the innovation and intellectual property protection that is vital to developing new medicines and achieving medical breakthroughs."

If TEAM truly represents a new approach, that would be a very welcome development, because there are very real concerns with the direction of medicines-related provisions in the TPPA. Unfortunately, the TEAM does not appear to represent a truly new direction in U.S.

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policy. While the paper is very general and does not include actual text to evaluate, it does not repudiate the most problematic aspects of the Korea and Australia FTAs, nor does it explain or reject the provisions of the leaked TPPA intellectual property text. The white paper also does not include any specifics on what the U.S. position is concerning data exclusivity or patent term extensions for pharmaceuticals. It appears that the USTR still supports extending monopoly rights through data protection that operates independent of patent rights, a policy that will delay the introduction of generics and increase medicine costs in the US as well as other TPP countries.

Although headlined as a "21st century Asia-Pacific trade agreement that reflects U.S. priorities and values," the white paper appears to be more likely to keep medicine prices high than earlier agreements negotiated by the USTR in the Bush Administration. This seems at odds not only with the lofty goals articulated in the white paper and by President Obama, but also with the President's most significant policy initiative, the Affordable Care Act.

Over the past several years, U.S. state legislators and governors have repeatedly voiced concerns about provisions on pharmaceutical pricing, transparency and patent protections in the Australia and Korea FTAs, because these provisions are inconsistent with existing pricing practices in U.S. state-federal health care access programs; because they delay the introduction of generics to the marketplace; and because they will prevent future innovation and reform of the U.S. health care system, which is the most expensive in the world.

For example, the board of the National Legislative Association on Prescription Drug Prices, an organization of state legislators working to increase access to affordable medicines in the U.S., 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. State trade advisory commissions have raised similar concerns and have testified before USTR on related issues in the 301 hearings. ***Why?***

- Because state officials, who implement Medicaid and other state-federal drug access programs in the U.S., know that these programs *currently do not meet the transparency standards in the Australia and Korea FTAs – standards that apparently continue to be endorsed by the USTR in the TPPA.*

- 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 U.S. 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 U.S. 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.*

- The USTR is promoting pharmaceutical pricing provisions in the TPPA that appear to directly challenge the new U.S. Medicaid drug pricing system adopted under President Obama's Affordable Care Act. 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." USTR's TEAM white paper does not repudiate this approach, nor does it publicly reject 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 U.S. 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.

U.S. trade negotiators have made some effort to respond to these concerns; 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 U.S. 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? It doesn't seem that it could.

- The carve-out doesn't remove conflicts between the TPPA and the Affordable Care Act, which is intended to fill the huge gaps in health coverage in the U.S. Pharmaceutical companies lobbied successfully to avoid price restraints in this program, which provides taxpayer-funded subsidies to purchasers of health insurance. Will Congress be allowed to change this law in the future if the TPPA locks in pharmaceutical market prices? If not, how will the U.S. government have the money to pay for these subsidies in perpetuity if the sky is the limit?

Drug costs continue to go up, especially for lifesaving drugs with only one manufacturer. Two thirds of the drugs on a list of key cancer drugs and vaccines published by the National Cancer Institute are only available from a single manufacturer, and the prices are extremely high. Today it is not uncommon for a new cancer drugs to be priced at more than $5 thousand per month, or as much as $50,000 to $75,000 or more for a course of treatment, for just a single drug. Such prices

are out of reach for developing countries, and they are also out of reach for anyone in the U.S. without health insurance and increasingly, are driving public drug purchase budgets into the red and depriving poor and middle class Americans of access to necessary medicines.

Example: earlier this week I had a conversation with the woman who cuts my hair. She is a survivor of breast cancer and she owes her life to medicines; but without adequate insurance she had to pay a very large proportion of her medical costs out of pocket. Her anti-nausea pills cost her $1,800 per pill, and she had to take a course of 3 for each chemotherapy treatment. On her income, these pills are out of reach.

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.

Consider 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, dis-enrolling clients not accessing ADAP for 90-days, discontinuing reimbursement of laboratory assays, instituting client cost sharing, or restricting eligibility criteria.

In short, if language similar to the KORUS pharmaceutical pricing and transparency provisions are included in the TPPA, even with the Medicaid carve-out, those provisions could greatly

limit access to pharmaceuticals and medical devices for 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 text supposedly does 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 U.S. health care programs must conform to pricing and procedural disciplines in TPPA and other TPAs, the U.S. 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 TEAM white paper asserts this as the U.S. goal, but does not contain any details that back up this assertion. ***The pharmaceutical pricing and transparency text in past FTAs, and the leaked TPPA intellectual property text do not advance this goal. The TEAM white paper does not reject this failed approach, nor does it outline a meaningful alternative.***

The best way to address these concerns is to have an inclusive and transparent negotiating process. The white paper states that USTR will convene a TEAM Task Force composed of experts throughout the government to consider innovative trade policy approaches to promoting access to

medicines. However, the USTR is not following its own commitment. The TEAM white paper was developed without consulting state officials who implement health programs in the U.S., and the state-level advisory committee to USTR was not briefed on the paper until this week. Providing access to health care is one of the central imperatives of our time. Trade policy must have as a top-level goal assuring access to affordable medicines to all. ***I urge all negotiators to move beyond past FTAs and develop new norms that will insure that this objective is carried out.***