MEMO: Three Burning Questions about the Leaked TPP Transparency Annex and Its Implications for U.S. Health Care

June 10, 2015

Today, WikiLeaks published the draft Trans-Pacific Partnership (TPP) "Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices." This Annex sets rules that TPP country health authorities would be required to follow regarding pharmaceutical and medical device procurement and reimbursement. The draft is dated December 17, 2014. An earlier version leaked in 2011. Unlike that document, the new leak expressly names the Centers for Medicare & Medicaid Services (CMS) as covered by the text, "with respect to CMS's role in making Medicare national coverage determinations." Under the TPP, then, these determinations would be subject to a series of procedural rules and principles, the precise meaning of which are not clear and perhaps not knowable.

Pharmaceutical companies could attempt to exploit the general language of the annex to mount challenges to Medicare and health programs in many TPP negotiating countries. The Annex would constrain future policy reforms, including the ability of the U.S. government to curb rising and unsustainable drug prices.

Medicare's national coverage determinations include whether Medicare Part A and Part B will pay for an item or service. Among other things, Part A and B cover drugs administered in a hospital or a physician's office, and durable medical equipment.[1] Below are questions to which the American public and members of Congress should have full and complete answers before voting on whether to cede trade promotion authority (fast track) to the Obama administration.

1. **What guarantees are there that the TPP's requirements would not override existing procedures for Medicare?**

The Office of the United States Trade Representative (USTR) claims that Medicare today is fully compliant with the proposed provisions of the TPP. Yet the ambiguous language of the TPP leaves our domestic healthcare policies vulnerable to attack by drug and device manufacturers. For example:

- Could companies use the Annex to compel Medicare to cover expensive products without a corresponding benefit to public health? Medicare reimbursement is limited to products that are "reasonable and necessary" for treatment. But the TPP "recognize[s] the value" of pharmaceutical products or medical devices through the "operation of competitive markets" or their "objectively demonstrated therapeutic significance," regardless of whether there are effective, affordable alternatives.

[1] Medicare Drug Coverage under Medicare Part A, Part B, Part C , & Part D. (2015, May 1). Retrieved June 9, 2015, from http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/11315-P.pdf

- The TPP also requires countries to "make available a review process" for healthcare reimbursement decisions. Medicare national coverage determinations allow for appeals, but only in a limited set of circumstances.[2] Might this conditional appeal process be construed as insufficient, if companies argue the TPP grants them an unconditioned right to review?

- Similarly, the TPP mandates that parties provide opportunities for applicants to comment on reimbursement considerations "at relevant points in the decision-making process." Though Medicare national coverage determinations allow for comments in certain stages of the process, these determinations may be vulnerable to legal challenge depending on the construction of "relevant points."

2. Would the TPP constrain pharmaceutical reform efforts in the U.S.?

In addition to its application to Medicare Part A and B, the Annex would apply to any future efforts related to national coverage determinations by the CMS, including potential Medicare Part D reforms.

In response to soaring drug costs, advocates have increasingly called on the government to enable the Secretary of Health and Human Services to negotiate the price of prescription drugs on behalf of Medicare beneficiaries. Vital to this reform would be the establishment of a national formulary, which would provide the government with substantial leverage to obtain discounts. [3]

The development of such a national formulary would be subject to the requirements of the TPP. These procedural requirements would pose significant administrative costs, enshrine greater pharmaceutical company influence in government reimbursement decision-making and reduce the capability of the government to negotiate lower prices.

3. Could the inclusion of this Annex in the TPP bolster the case of a pharmaceutical company that is suing the United States?

Investor-State Dispute Settlement is a mechanism that has been a prominent feature of U.S. trade and investment pacts over the last two decades. It allows foreign companies to challenge directly government policies which they claim impinge on their expected future profits, demanding unlimited sums in taxpayer compensation.

Would a foreign pharmaceutical company that has launched an investor-state suit against a government for a reimbursement decision use this annex to bolster their case? The company could attempt to claim that their legitimate expectations have been frustrated, making reference to the expectations created by the annex.

Contact: Peter Maybarduk, +1 202 588 7755; pmaybarduk@citizen.org

[2] "Department of Health and Human Services; Centers for Medicare & Medicaid Services [CMS-3285-N] Medicare Program; Revised Process for Making National Coverage Determinations," 78 Federal Register 152 (7 August 2013), pp. 48164 - 48169.

[3] Outterson, K., & Kesselheim, A. (2009). How Medicare Could Get Better Prices On Prescription Drugs. Health Affairs. Retrieved June 9, 2015, from http://content.healthaffairs.org/content/28/5/w832.full