Trans-Pacific Partnership & U.S. State Efforts to Control Drug Prices

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U.S. trade policy seeks to limit the systems of evidence-based pricing used by foreign countries to control pharmaceutical costs. However, U.S. state governments use the same types of strategies to control costs for Medicaid and other programs that purchase drugs. Negotiated discounts lead to large cost savings, which states rely upon to continue to serve low-income Americans.

All systems of evidence-based pricing are unique, but they typically involve the comparison the safety, efficacy and cost-effectiveness of new medicines to existing therapeutic equivalents. Pharmacy and Therapeutic (P&T) Committees construct open formularies known as Preferred Drug Lists (PDLs) which steer patients towards favored drugs. Though federal law ensures Medicaid patients can access unlisted drugs, manufacturers are willing to offer substantial discounts to be included in the PDLs.

The Free Trade Agreements (FTAs) negotiated with Australia and Korea contained provisions that place conditions on the construction of formularies. Both FTAs require governments to offer higher reimbursements for 'innovative' or 'patented' products than generics. This conflicts with many U.S. state laws and/or regulations that require PDLs or pharmacists to favor *less* expensive medicines whenever possible. For instance:

- 10-144 MaineCare Benefits Manual, Chapter II, § 80 instructs the P&T Committee to consider costs when two drugs are equally safe and effective. The regulation also mandates generic substitution when FDA-approved generics are available.
- N.Y. PUB. HEALTH LAW § 272(10) (McKinney 2010) instructs committee members to consider cost when two drugs have comparable safety and efficacy.
- 18 V.S.A. § 4605 (Vermont) requires pharmacists to substitute generic drugs for brand name drugs, even if the branded drug is prescribed, unless otherwise instructed by the subscriber or if the purchaser agrees to pay the difference in price.

The Australia and Korea FTAs also require governments to grant drug companies more access to the P&T committees that construct formularies. The FTAs set up various procedural roadblocks – including appeals processes – that favor the industry over the governments in the negotiations. Few states would meet these requirements.

State governments have warned repeatedly that these provisions could interfere with their health programs. In response to state lobbying, the Korea FTA contained a 'carve-out' to protect Medicaid from the provisions of the FTA. Though trade officials may view their efforts to push back against evidence-based drug pricing as only affecting foreign nations, we view them as an effort to establish new international norms favoring the branded industry over government entities. We expect that that the industry will eventually seek to apply these norms in the United States. (See forumdemocracy.net for examples of letters, submissions, and testimony by elected state officials.)

Other trade policy vehicles are used to limit the effective negotiation of pharmaceutical prices abroad. US Trade Representative Ron Kirk has expressed support for a Pfizer-sponsored proposal for a trade agreement to "set disciplines" on reference pricing. His office's annual Special 301 Report continues to criticize trading partners for price negotiations, even though the issue falls outside of the Report's legislated mandate to focus on intellectual property.

Currently, the USTR is drafting negotiating text for the Trans Pacific Partnership (TPP). This will be the first new FTA for the Obama Administration. State leaders have urge Ron Kirk and his staff to exclude any provisions on pharmaceutical pricing from the text of the TPP, as well as any future agreements.