



Free Trade Agreements May Threaten States' Right to Control Drug Costs Through Preferred Drug Lists

Mike Palmedo

American University, Washington College of Law
Project on Information Justice and Intellectual Property
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The United States is only industrial country in the world without a national system to restrain monopoly drug prices. Faced with rising pharmaceutical costs and responsibility for drug procurement through programs such as Medicaid, state governments seek innovative ways to fund purchases necessary for the provision of quality care to their citizens. One powerful cost-saving tool has been the Preferred Drug List, but the U.S. Trade Representative has taken actions that threaten the ability of states to reign in drug costs through this mechanism.

Preferred Drug Lists in the United States

Pioneered by California in the early 1990s, Preferred Drug Lists, or PDLs, are now in use in at least 40 states and have resulted in tremendous savings.¹ Michigan officials estimate that their state PDL saved \$60.5 million in its first year of operation.² Texas saved 140 million over two years.³ Florida saved almost half a billion dollars between 2000 and 2002 in drug purchases for its 2.2 million Medicaid recipients.⁴

Though each state's program is unique, Preferred Drug Lists generally work by guiding prescribers towards the most cost effective medicine for a specific illness or condition. An appointed committee evaluates existing therapies based on safety, efficacy and price to determine the most cost effective medicines. When a particular listed drug is not right for a patient, he or she may be reimbursed for a different drug after prior authorization is obtained by the prescriber from a state office set up for such authorizations. Three examples below show how implementation of PDLs can vary from state to state.⁵

- In Florida, a governor-appointed committee consisting of five physicians, five pharmacists and one consumer representative meets quarterly, and recommends which drugs should be placed on the list. Their recommendation is based on research and reviews of drugs and classes conducted by a private company, and on input from the public. When a Florida prescriber needs to obtain prior authorization for a drug not on the list, he or she calls the Therapeutics Consultation

¹ Data compiled by the National conference of State Legislatures.

² December, 2004. The Commonwealth Fund. *Michigan: Preferred Drug List & National Medicaid Pooling Initiative*. www.cmwf.org

³ January 2005. Texas Health and Human Services Commission. "Preferred Drug List Annual Report."

⁴ "The Rx Factor." By Misha Sigal. Pew Center on the States. <http://www.governing.com/medicaid/drug.htm>

⁵ March 2005. Colorado Health Institute Policy Brief. *Medicaid Preferred Drug Lists – A Review of Three States*. Available at www.coloradohealthinstitute.org

Program, where the call is answered by pharmacy technicians who approve 80% of requests immediately based on available criteria; and refer the remaining requests to a doctor or pharmacist.

- Missouri's Director of Social Services appoints three physicians, three pharmacists and one nurse to the committee, which considers a variety of data when determining its PDL – medical information from the Oregon Health Sciences University; Missouri-specific data collected by the University of Missouri Drug Information Center; further clinical and economic data from two private-sector companies. The Committee makes recommendations to the Medicaid Pharmacy Administration Program, and then drug manufacturers and consumers have three months to submit testimony before the final decision is made. Prior Authorization is given to prescribers through an online system 75% of the time. When it is not granted online, the prescriber must call the Pharmacy Administration Programs PA line, where pharmacy technicians are able to authorize 97% of the requests.
- In Washington, the PDL is part of a Prescription Drug Program which is carried out as a joint effort by the Washington Healthcare Authority, the Department of Social and Health Services, and the Department of Labor and Industries. The directors of all three agencies appoint members to the Pharmaceutical and Therapeutics Committee, which consists of four physicians, four pharmacists and two ancillary healthcare providers. This committee uses evidence based investigations from the Oregon Health Sciences University to decide which drugs to recommend for placement on the PDL, but the Committee only examines safety and efficacy, not cost. After the committee makes its recommendation to the three agencies, the agencies then add cost consideration to the decision. Washington's Prior Authorization process is similar to those in Florida and Washington, although it has a system in place allowing doctors that formally support the PDL more flexibility in prescribing non-listed drugs.

Industry Efforts to Stop Preferred Drug Lists

The pharmaceutical industry launched three separate lawsuits against state programs in Maine, Michigan and Florida, claiming federal Medicaid laws prevented their use of PDLs in their Medicaid and expanded Medicaid programs. The industry lost all three cases, with federal courts, including the US Supreme Court upholding states' rights to negotiate prices through PDLs.⁶

While the industry has been unsuccessful in attacking PDLs in the courts, it has quietly lobbied for trade policies which attack them abroad, with implications for programs in the U.S.⁷ Free Trade Agreements are "international executive agreements with Congressional approval" and as such they have the legal status of binding federal law, which have preemptive effect over state law.⁸ International trade law includes precedents that municipal laws can be interpreted as evidence of compliance or non-compliance with international obligations.⁹

⁶ PhRMA v. Meadows, 304 F.3d 1197 (2002); PhRMA v. Walsh, 538 U.S. 644 (2003); PhRMA v. Thompson, 362 F. 3d 817 (2004)

⁷ The pharmaceutical industry hires more lobbyists than any other industry and spent over \$800 million on political donations between 1998 and 2005. A good source for more information on the industry's lobbying clout is "Drug Lobby Second to None - How the pharmaceutical industry gets its way in Washington," published by the Center for Public Integrity. Available online at: <http://www.public-i.org/rx/report.aspx?aid=723>

⁸ 2006. Public Citizen. *States Rights and International Trade*.

⁹ December 19, 1997. *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/DS50/AB/R.

In addition, the Trade Promotion Authority Act instructs the US Trade Representative to “achieve the elimination of government measures such as price controls and reference pricing”¹⁰ (This is listed as a formal negotiating objective for USTR.) Two particular trade agreements include clear attempts to “eliminate” foreign cost-containment measures, endangering similar programs in the US. The US-Australia FTA includes provisions meant to hamper the functioning of Australia’s Pharmaceutical Benefits Scheme, and Korea’s efforts to institute a national PDL may scuttle the free trade negotiations between our two countries. To protect savings on drug purchases, states have an interest in seeking clarification of the language of the US-Australia Free Trade Agreement, and ensuring that federal trade negotiators do not ban reference pricing in the Korean Free Trade Agreement.

US-Australia FTA

Provisions sought by the pharmaceutical industry and included in the US-Australia Free Trade Agreement may threaten state PDLs. Annex 2C of the agreement concentrates on federal healthcare agencies; but state Medicaid programs are proposed under federal guidelines and are approved by federal officials, so they may fall under the jurisdiction of the agreement.

The problematic section of the annex is article 1(c). While the wording is vague, it can be interpreted to forbid cost considerations for state Medicaid programs. The text reads:

Parties are committed to the following principles... (c) the need to promote timely and affordable access to innovative pharmaceuticals... without impeding a Party’s ability to apply appropriate standards of quality, safety, and efficacy

“Cost” is explicitly missing from the list of what can be considered when a Party to the agreement is “promot[ing] timely and affordable access” to new drugs.

The purpose of the Annex is to hamper pharmaceutical cost control. For years, the American drug industry has urged American trade officials to attack Australia’s Pharmaceutical Benefits Scheme. Every year the Pharmaceutical Research and Manufacturers Association (PhRMA) gives two formal “Special 301” submissions to the U.S. Trade Representative (USTR) outlining their top concerns with policies held by American trading partners.¹¹ Complaints about the Australian system of reference pricing appear in nearly all of these submissions. Furthermore, the US-Australia Free Trade Agreement was the first bilateral FTA to include an annex specifically on pharmaceuticals. While the annex was meant to crack down on perceived excesses of the Australian Pharmaceutical Benefits Scheme, the terms of the agreement apply to both parties.

Members of Congress have expressed concern that the trade agreement could harm domestic drug programs. On January 15, 2004, a group of democratic Representatives including Nancy Pelosi, Steny Hoyer, and Charles Rangel wrote President Bush, warning

First, we are deeply concerned about the proposal’s implications for the United States... Individuals potentially affected by the proposal include the elderly who

¹⁰ Trade Promotion Act of 2002. Section 2102(8)(D).

¹¹ Each year the Pharmaceutical Research and Manufacturers Association submits comments to USTR for the Special 301 report, and for the NTE report on Barriers to Trade. Both of these submissions include country-by-country complaints about perceived trade barriers.

receive Medicare, working people on Medicaid... and a myriad of state and local governments throughout the United States.¹²

To date, there has been no formal clarification of whether Annex 2(c) applies to state Medicaid programs. In October 2005, members of the National Legislative Association on Prescription Drug Prices working group on trade met with Assistant USTR Barbara Weisel requesting formal clarification. Last January, the state senate of Vermont unanimously passed a resolution urging USTR to “pursue an exchange of interpretive notes” with Australia to formally ensure state programs are not covered under the Annex. Similar resolutions have been introduced in other state legislatures. Pressure is building on USTR to formally clarify the meaning of Annex 2(c), but so far it has remained silent.

US-Korea FTA

Another threat to state use of PDLs arises from the USTR’s position in negotiations for a Free Trade Agreement with Korea. While the U.S. and Korea negotiate an FTA, the Korean Ministry of Health and Welfare has been attempting to reform its National Health Insurance’s reimbursement policy – by initiating what is essentially a national-level preferred drug list. Stopping Korea from this action has become a top priority of the American trade officials.

At the heart of the proposed reform is the change from a so-called Negative List for reimbursement to a Positive List. Currently, Korea’s National Health Insurance covers all drugs by default, other than certain drugs which are on a Negative List that disqualifies them from coverage. The Ministry of Health and Welfare wants to change to a Positive List, approach where the National Health Insurance only covers drugs that are on the list. In order for a new drug to be placed on the Positive List, it will first be tested for cost effectiveness.

In December 2006, the Korean team for the Pharmaceutical Working Group left the fifth round of negotiations. Last July, the second round collapsed when the American delegation learned of the reforms. Assistant USTR Wendy Cutler, who is in charge of the American negotiating team, lashed out at the Koreans, claiming

...the decision to proceed with this plan is inconsistent with both the mandate of the pharmaceuticals working group and the market opening spirit of the KORUS FTA

...The positive list system as explained to our delegation by the Ministry of Health would discriminate against innovative drugs which are the types of drugs that are mainly supplied by U.S. and other foreign companies.¹³

The United States has a history of threatening Korea over medicines policy. In 2001, Commerce Secretary Don Evans wrote the Korean Health Minister and threatened a “serious trade dispute” if Korean plans to reform medicine reimbursement policies went into effect. In the past, U.S. State Department officials have worried that pressures against Korean drug pricing policy could apply to American programs. In an October 2003 memo, Robert Armstrong warned that “FDA and HSS have ... found a number of their [PhRMA’s] suggestions to be problematic from the standpoint of U.S.

¹² Jan 9, 2004. Letter from nine congressional Democrats to President Bush.
<http://www.cptech.org/ip/health/c/australia/housedems01152004.pdf>

¹³ July 14, 2006. Statement of Assistant USTR Wendy Cutler on the Conclusion of the Second Round of Negotiations of the KORUS FTA. Available online at www.ustr.gov

Domestic practice.” Later that year, Thomas Jung wrote that US States “are taking the same approach the ROKG is taking: containing costs by scrutinizing prescription drugs, particularly brand name drugs.”

Conclusion

States have saved millions of dollars by purchasing or reimbursing drugs through Preferred Drug Lists. Recent and ongoing trade negotiations have threatened their right to continue this practice. Rules in the Australian trade agreement are unclear and potentially harmful, and trade negotiators risk setting a negative precedent in ongoing talks with Korea. Yet positive outcomes in both of these situations are still possible if state level health officials engage federal trade officials and express concern over these threats to their PDLs.