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How US Trade Policy Conflicts with Efforts by State Governments to Control Drug Costs

Mike Palmedo
American Public Health Association
November 5, 2007

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Pfizer on Industry Influence

Pfizer and IBM co-founded the Intellectual Property Committee… Our combined strength enabled us to establish a global private sector-government network which lay the groundwork for what became TRIPS. Standards and enforcement procedures incorporated in the GATT agreement on TRIPS have been extended and strengthened in other international agreements, such as NAFTA. Yet, there is more to be done...

- former Pfizer CEO Edmund Pratt Jr.,
paid advertisement in the Economist, 1995

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USTR on Reference Pricing

…even where a country's IPR regime is adequate, price controls and regulatory and other market access barriers can discourage the development of new drugs. These barriers may include unreasonable regulatory approval delays, linkages between dispensing and prescribing, and reference pricing and other potentially unfair reimbursement policies…

- USTR, 2007 Special 301 Report

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Preferred Drug Lists

- Used by over 40 states for Medicaid
- Steers patients toward preferred drugs
- Other medicines available with prior authorization
- Medicaid required to provide access to all drugs for which the manufacturer has an agreement with the federal government
- Very effective – inflation-adjusted spending on medicine actually declined in 2005

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Australia-US FTA

- Parties committed to “the need to promote timely and affordable access to innovative pharmaceuticals."
- Disclose procedural rules and guidelines used to assess a proposed listing
- Make available an “independent review process”

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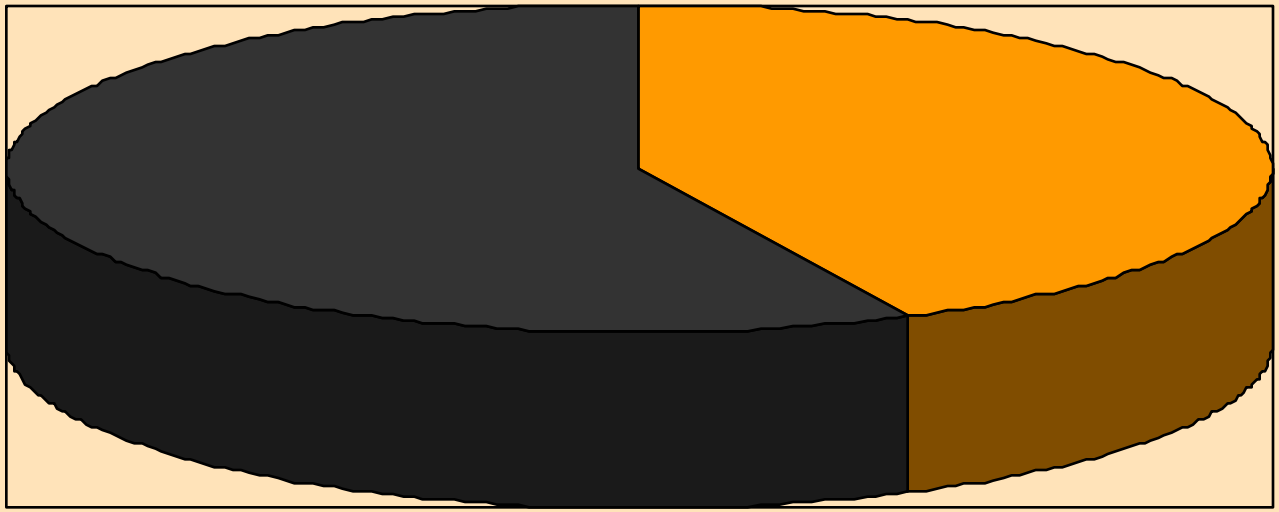
Who Funds Medicaid?

Federal 57% State 43%



Source: DHHS, Office of Assistant Secretary for Planning and Evaluation

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States Seek Medicaid Carve-Out

We seek an interpretation that federal guidelines and approval for state programs, including but not limited to Medicaid programs, are not "federal decisions" that require state programs to comply with the Annex. The purpose of this interpretation is to provide an explicit carve-out of state programs from Annex 2C.

- *Nat. Legislative Assoc. on Prescription Drug Prices Letter to US Trade Representative. May 26, 2005*

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The Korea-US FTA

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Reforms to Korean NHI

Old Reimbursement System

Negative List

National Health Insurance reimburses all drugs purchased by Koreans, unless the drug has been placed on a list of drugs that will not be reimbursed.

New Reimbursement System

Positive List

In order for a new drug to be reimbursed by the National Health Insurance, it must be placed on a list of cost-effective drugs that are covered.

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USTR Opposes Reforms

"…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."

-Assistant US Trade Representative Wendy Cutler
Chief US Negotiator for the US-Korea FTA

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Scope of Medicines Section

US-Australia FTA

- "Annex 2(c): Pharmaceuticals"

Korus FTA

- "Chapter 5: Pharmaceuticals and Medical Devices"

“Innovative” or “Patented”

US-Australia FTA

- Parties committed to “the need to promote timely and affordable access to innovative pharmaceuticals."

Korus FTA

- Parties committed to “access to high-quality patented and generic pharmaceutical products and medical devices.”
- When determining reimbursement for a specific product, parties shall "appropriately recognize the value of patented pharmaceutical products and medical devices in the amount of reimbursement it provides."

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Transparency

US-Australia FTA

- Ensure decisions within a specified period of time
- Disclose "procedural" rules and guidelines used to assess a proposed listing
- Make available an "independent review process"

Korus FTA

- Includes all of the mandates found in the US-Australia FTA
- Obstacles to any future reform of reimbursement system.
- Make available an "independent review body"

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State Leaders Speak Out Again

On behalf of states across the nation that use similar formularies to contain drug costs for Medicaid and other programs that may be affected by the FTA language, we request you to seek assurances from USTR in the upcoming hearing on the US-Korea FTA negotiations that USTR will not include limitations on cost-cutting drug formularies in any final agreement.

- AZ State Senator Meghan Cahill and
CT State Representative Kevin Ryan,
Letter to Trade Subcommittee of House
Ways & Means Committee, March 18, 2007

“Carve Out” for Medicaid

ARTICLE 5.8: Definitions –

…health care program operated by a Party’s central level of government means a health care program in which the health care authorities of a Party's central level of government make the decisions regarding matters to which this Chapter applies;[3]

FOOTNOTE 3:
For greater certainty, Medicaid is a regional level of government health care program in the United States, not a central level of government program.

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Bilateral Consultations with EU Nations on non-IP Pricing Issues

- Austria
- Belgium
- Bulgaria
- Cyprus
- Czech Republic
- Denmark
- Fainland
- France
- Hungary
- Itlay
- Lithuania
- Netherlands
- Poland
- Spain
- Slovakia
- Slovenia
- United Kingdom

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PhRMA Goals in Japan

- Win US pharmaceutical industry representation on the government body that negotiates drug prices *(Chuikyo)*
- Create an appeals mechanism for manufacturers unhappy with *Chuikyo's* decisions
- Establish an alternative price-setting scheme based on industry-submitted data for innovative new drugs
- Receive higher premiums for drugs found to be more innovative or useful than existing therapies
- Abolish re-pricing based on market expansion and stop Japan's annual price revisions

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PhRMA Goals in Germany

- Remove “jumbo groups” containing both brand-name and generic drugs from reference pricing scheme
- Establish clear guidelines for the removal of innovative drugs from the reference pricing scheme
- Change prescribing guidelines that encourage generic substitution when available

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Changes to reference pricing often sought by PhRMA

- No reference pricing based on comparisons of generic and patented medicines
- Greater access to decision makers who evaluate medicines for reference pricing
- Appeals process for decisions unfavorable to industry
- Removal of innovative drugs from systems of reference pricing

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Reference Pricing in States

- Often favor generic over patented drugs
- No required pharmaceutical industry representation in groups making decisions
- Processes are transparent, but states are not required to follow stringent guidelines found in FTAs

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Failed Industry Lawsuits

- Michigan: PhRMA v. Thompson, 362 F. 3d 817 (2004)
- Maine: PhRMA v. Walsh, 538 U.S. 644 (2003)
- Florida: PhRMA v. Medows, 304 F.3d 1197 (2002)

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Three Things to Remember

- The pharmaceutical industry opposes government use of reference pricing in other countries
- US trade officials try to influence reference pricing schemes abroad; try to make them more friendly to US industry interests
- State governments use reference pricing to control drug costs, and some of their methods are very similar to those used by foreign national governments.

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Thank You.

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