USTR-2010-0037

UNITED STATES TRADE REPRESENTATIVE

IN THE MATTER OF
2010 SPECIAL 301 REVIEW:
IDENTIFICATION OF COUNTRIES UNDER SECTION 182 OF THE TRADE ACT OF 1974

SUBMISSION OF U.S. STATE HEALTH ORGANIZATIONS:

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SUMMARY

We write to oppose the use of the Special 301 Report to discipline effective and non-discriminatory pharmaceutical pricing policies. This shift, disturbing on its face, is all the more concerning because it is evidently part of a broader effort by USTR to promote a new international trade framework to restrict domestic regulatory responses to excessive pricing by monopoly pharmaceutical suppliers. This agenda is not authorized by any statute or administrative directive, and the agenda is incredibly unwise at a time when the U.S. is struggling to find ways to restrain its own health costs. To the extent there are best practices in the U.S., they are at the state governmental level and they follow the same basic policies and principles of foreign countries that USTR seeks to discipline. Reciprocal enforcement of USTR standards to state programs would obliterate the effectiveness of Medicaid pricing programs and threaten the administration's policy goal of reducing the cost of healthcare in this country.

States have repeatedly contacted federal officials opposing this radical agenda, as will be further described below. In this Special 301 submission, State representatives appeal to the Obama administration to change course and halt the use of trade pressure or negotiations to

internationally regulate domestic drug pricing programs that do not violate any World Trade Organization rule.

STATEMENT OF INTEREST

ARGUMENT

A. States Rely on Evidence-Based Reimbursement Decisions to Restrain Pharmaceutical Prices

Patents on medicines can create a particularly strong form of monopoly that, if left impervious to regulations affecting pricing power, can lead to extraordinarily high prices that harm social welfare. This is because medicines can be basic life necessities that few will do without and because many purchasers are insulated from price exposure by forms of insurance.

State governments use a wide variety of regulatory tools and policies to restrain excessive pricing by medicine suppliers. These are often the same tools used by foreign governments that USTR describes as "unfair" in the 2010 Special 301 Report, and has sought to restrict or eliminate in recent trade agreements.

Although it is commonly posited by industry that foreign countries "free ride" on U.S. pharmaceutical prices, U.S. federal government agencies and state governments use policy tools that are similar to foreign governments – and pay similar prices. One of the most important tools states use are Preferred Drug Lists (PDLs) in the Medicaid program. More than forty states use PDLs for Medicaid and other local health programs.[1] Similar tools are used by almost every bulk purchaser of drugs – including private insurance companies, branches of the U.S. federal government and most other industrialized countries. These programs use bulk purchasing and reimbursement to pressure drug companies to reduce prices as a condition for access to a large

[1] *Recent Medicaid Prescription Drug Laws and Strategies: 2001-2010*, NATIONAL CONFERENCE OF STATE LEGISLATURES (Nov. 2010), *available at* http://www.ncsl.org/default.aspx?tabid=14456.

market. PDLs are substantially similar to the programs in other countries that USTR and industry criticize as unreasonable price controls.

Use of PDLs by U.S. states has resulted in tremendous savings:

- The New York State Medicaid Preferred Drug Program reports that its Preferred Drug List saved the state $380.5 million in the fiscal year ending March 2010.[2]
- The Texas Health and Human Services Commission estimates that use of its Medicaid preferred drug list saved the state approximately $246 million from 2008 to 2009.[3]
- Oregon reports saving 40% per prescription due to greater generic uptake resulting from its use of a Preferred Drug List in 2009.[4]
- From 2006 to 2007, discounts negotiated by private companies for Medicare Part D were "substantially smaller" than those negotiated by state Medicaid programs, resulting in costs 30% higher for Medicare.[5]
- Total Medicaid spending on pharmaceuticals decreased by 1.8% in 2007 (the most recent year for which data is available), while at the same time drug spending as a whole increased at a rate of 4.9%.[6]
- The President's budget for 2008 specifically noted that Medicaid allows states "to use [such] private sector management techniques to leverage greater discounts through negotiations with drug manufacturers."[7]

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[2] N.Y. STATE MEDICAID PREFERRED DRUG PROGRAM, ANNUAL REPORT TO THE GOVERNOR AND LEGISLATURE FOR STATE FISCAL YEAR APRIL 1, 2009 - MARCH 31, 2010 (Sept. 2010), *available at:* http://www.health.state.ny.us/health_care/medicaid/program/docs/annual_report_preferred_drugs_2009-10.pdf

[3] TEX. HEALTH & HUMAN SERV. COMM'N, ANNUAL REPORT TO THE TEXAS LEGISLATURE (June 2010), *available at* http://www.hhsc.state.tx.us/reports/2010/Preferred-Drug-List-2009.pdf.

[4] OREGON PRESCRIPTION DRUG PROGRAM, NEWSLETTER (Jan. 2010), *available at* http://www.oregon.gov/OHA/OPDP/docs/OPDPNewsletterJan2010.pdf?ga=t.

[5] U.S. HOUSE COMM. ON OVERSIGHT & REFORM, MAJORITY STAFF, MEDICARE PART D: DRUG PRICING AND MANUFACTURER WINDFALLS (July 2008), *available at* http://www.cmhda.org/breaking_news/documents/0807_Breaking%20News_Medicare%20Part%20D%20report%20house%20of%20reps%207-08.pdf.

[6] Micah Hartman et al., *National Health Spending In 2007: Slower Drug Spending Contributes To Lowest Rate Of Overall Growth Since 1998*, 28(1) J. HEALTH AFFAIRS 246-61 (2009).

[7] Leighton Ku, Andy Schneider & Judy Solomon, *The Administration Again Proposes to Shift Federal Medicaid Costs to States*, CTR. ON BUDGET & POLICY PRIOIRTIES (Feb. 14, 2007), *available at* http://www.allhealth.org/BriefingMaterials/The_Admin_Shifts_Medicaid_Costs-CBPP-647.pdf.

- According to the January 2003 annual report of the Office of Vermont Health Access, spending on acid reducers, anti-inflammatory drugs, and opiate analgesics dropped from $15.8 million to $12 million within 8 months of introducing the Medicaid PDL. Vermont saved over ten percent of its prescription drug budget for state employees ($2.8 million on total expenditures of $21.1 million) by restructuring the benefit to include a PDL.[8]

The big difference between prices in the U.S. and prices in other countries is that we have a large number of people who are not covered by any pooled purchasing plan and therefore are subject to un-negotiated retail prices at the pharmacy. These individuals pay the highest prices for medicines, prices that have been estimated at between 58 and 118 percent more for patented brand-name drugs than buyers in Canada and western European countries.[9]

The rational policy response to the pricing problem in the U.S. would be to study what successful governments in the U.S. and abroad are doing to restrain excessive pricing and apply those models here. Instead, USTR has been joining an industry campaign to obliterate successful programs.

B. USTR Has Been Using Trade agreements and Special 301 to Promote International Restrictions on Domestic Pharmaceutical Pricing Programs

Two past Free Trade Agreements – with Australia and Korea – include chapters that impose restrictions on pharmaceutical reimbursement programs. These were negotiated under a lapsed Congressional mandate to "achieve the elimination of government measures such as price controls and reference pricing."[10] Implementation of this negotiating principle to restrain

[8] Letter from Ginny Lyons and Kathleen Keenan, Vt. State Representatives, to U.S. Cong. Representatives (Apr. 18, 2007).
[9] Victoria Colliver, *U.S. Drug Prices 81% Higher Than in 7 Western Nations/Study of Name Brands Shows Steep Rise in Differential Since 2000*, S.F. CHRONICLE, Oct. 29, 2004, http://articles.sfgate.com/2004-10-29/business/17447944_1_drug-prices-brand-name-health-care (last visited on Feb. 17, 2010).
[10] 19 U.S.C. § 3802(b)(8)(D) (Expired, 2007).

pharmaceutical price regulations was always highly controversial. The same guidance legislation required that trade agreements respect the Doha Declaration on TRIPS and Public Health.[11] The Doha Declaration on TRIPS and Public Health requires USTR to protect the rights of all countries to use TRIPS flexibilities to promote access to medicines to all, including the flexibility to adopt regulations of excessive pricing and other abuses of the patent monopoly power.[12]

The bilateral FTA negotiated between the US and Australia included procedures for industry to participate in and legally challenge pharmaceutical reimbursement programs. In the 2006 negotiation of the US - Korea FTA, negotiations broke down at one point with Korea's refusal to negotiate away a national "positive list" drug reimbursement formulary very similar to state Medicaid preferred drug lists. Chapter 5 of the FTA ultimately included severe restrictions on drug reimbursement programs, including an obligation for governments to "appropriately recognize the value of patented pharmaceutical products,"[13] and an opportunity for industry to appeal unfavorable drug reimbursement decisions.

State leaders are concerned that the Trans Pacific Partnership (TPP), currently under negotiating by the U.S. and nine other countries, will include a similar pharmaceuticals chapter. To date, USTR has not released any negotiating text, but USTR staff has stated that they are

[11] 19 U.S.C. § 3802(b)(4)(C) (Expired, 2007).
[12] *Cf.* Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 8, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round, 1869 U.N.T.S. 299 [hereinafter TRIPS] (stating that members may "adopt measures necessary to protect public health" and specifically counsels that appropriate measures "may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."); 2009 Rep. of the Special Rapporteur on the Right to Health for the General Assembly, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (noting that freedom to adopt regulatory price controls are an important TRIPS flexibility), *available at* http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf (last visited on Feb. 17, 2010).
[13] United States-Korea Free Trade Agreement, U.S.-S.Korea, art. 5.2(b)(i), June 30, 2007, *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text [hereinafter U.S-Korea FTA].

currently considering proposals for a pharmaceutical chapter in the TPP.[14] The pharmaceutical industry is lobbying for the inclusion of such a chapter, and has specifically requested that USTR use Chapter 5 of the Korea FTA as a model.[15]

State officials repeatedly warned USTR and Congress that the norms being pressed by the U.S. in these pharmaceutical chapters would cripple state Medicaid programs.[16] As the administration recognized, U.S. Medicaid programs "are taking the same approach" as the

[14] Sean Flynn, *USTR Considering Pharmaceutical Pricing Restrictions in TPP; Refuses to Follow May 10th Agreement on IP-Medicines Issues*, INFOJUSTICE.ORG (Feb. 8, 2011), http://infojustice.org/archives/1110; *see also* Michael Palmedo, POLITICO: *States: Trade Deal Will Mean Higher Drug Prices*, INFOJUSTICE.ORG (Feb. 11, 2011), http://infojustice.org/archives/1124 (referring to Brett Coughlin's 2/11/11 article on Politico).

[15] *See* IP Task Force for the Business Coalition for TPP, *Key Goals and Objectives." Leaked confidential memo to USTR*, INFOJUSTICE.ORG (December 2010), http://infojustice.org/wp-content/uploads/2011/01/businesscoalitionletter-dec2010.pdf; *PhRMA Written Comments Concerning the Proposed Trans-Pacific Partnership Free Trade Agreement with Singapore, Chile, New Zealand, Brunei Darussalem, Australia, Peru, and Vietnam*, Docket ID: USTR-2009-0002. (March 11, 2009).

[16] *See* S.J. Res. 50, (Vt. 2006) (urging USTR to "pursue an exchange of Interpretive notes" with Australia to formally ensure state Medicaid programs would not be covered by Annex 2(c)); Letter from Liz Figueroa & Sheila Kuehl, State Senators, Ca., to Office of the U.S. Trade Representative (2005); Letter from Nat'l Legislative Ass'n on Prescription Drugs, to ??? (May 2005) (warning about the dangers of the free trade agreement and asked for a binding interpretation that it did not cover U.S. state programs); Letter from Christine Gregoire, Governor, Wa., to ??? (Mar. 2006) (expressing concerns over the FTA); Letter State Legislators, Wa., to the Wa. State Cong. Delegation (March 2006); Letter from Meg Burton Cahill, State Senator, Ariz. & Kevin Ryan, State Representative, Conn., to Members of the House Ways & Means Comm. Subcomm. on Trade (Mar. 18, 2007) (stating that legislators are "extremely troubled by, and strongly oppose, USTR's efforts to alter public reimbursement formularies in the Korea FTA"); *Hearing Before the Subcomm. on Trade of the H. Comm. on Ways & Means* 110th Cong. (Mar. 20, 2007) (statement of National Legislative Association on Prescription Drug Prices) (warning that the language applied to Medicaid programs would "give pharmaceutical companies rights to block and delay implementation of the most important and proven medicine cost-control tools available."); Letter from Ginny Lyons, State Senator, Vt., & Kathleen Keenan, State Representative, Vt, to Senator Patrick Leahy, Senator Bernard Sanders & Representative Peter Welsh, (Apr. 18, 2007) (asserting that "Vermont uses a similar 'positive list' approach [as Korea]"); *Submission to USTR by the National Legislative Association for Prescription Drug Prices* in response to the Request for Comments on the US-Korea FTA (Sept. 15, 2009), *available at* http://www.reducedrugprices.org/read.asp?news=4264; Letter from the Vt. Comm. on Int'l Trade and State Sovereignty, to President Obama (Aug. 27, 2010), *available at* http://www.forumdemocracy.net/article.php?id=552; Letter from Sharon Anglin Treat, Me. Rep., Ginny Lyons, Vt. Rep., Kathleen C. Keenan, Vt. Rep., Charles F. Weed, N.H. Rep., & Peggy Rotundo, Me. Rep., to Ambassador Ron Kirk, U.S. Trade Representative (Sept. 16, 2010), *available at* http://www.forumdemocracy.net/article.php?id=554; Resolution Opposing the Inclusion of a Pharmaceuticals Chapter in the Trans-Pacific Partnership, NAT'L LEGISLATIVE ASS'N ON PRESCRIPTION DRUG PRICES (Jan. 21, 2011), a*vailable at* http://www.reducedrugprices.org/read.asp?news=6132.

governments of Australia and Korea – "containing costs by scrutinizing prescription drugs, particularly brand name drugs."[17]

C. The 2010 Special 301 Report Continues USTR's Promotion of International Restraints on Pharmaceutical Reimbursement Programs

In 2010, elected state officials submitted comments to USTR[18] and testified at the March hearing,[19] expressing our concerns that USTR was acting inappropriately by using the Special 301 Report to target pricing and reimbursement strategies similar to those used at home. Vermont Governor Douglas and Maine Governor Baldacci wrote the Department of Health and Human Services warning that trade policy conflicted with state pharmaceutical programs.[20]

The 2010 Special 301 Report contains additional evidence of USTR's radical shift of its negotiating priorities into the arena of restricting evidence based pricing programs. The 2010 Special 301 Report singles out Finland, France, Italy, Japan, Korea, New Zealand, Poland, and Taiwan for administering "unreasonable . . . potentially unfair reimbursement policies."

It is unclear what USTR is complaining about in these examples because, as in other areas of the report, there is insufficient explanation, citation or description of any objective standard accompanying the complaint. There are no allegations in the Report that any of these policies violate most favored nation or any other WTO norm or bilateral agreement. Nor is there

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[17] Thomas Jung, *State Department Cable*, (Sept. 9, 2003), *quoted in* James Love, *Korea FTA Negotiations on Medicines Will Harm Us Too*, HUFFINGTON POST, (July 12, 2006, 05:58 PM) http://www.huffingtonpost.com/james-love/korea-fta-negotiations-on_b_24929.html.

[18] *See Special 301 Watch*, PROGRAM ON INFO. JUSTICE & INTELLECTUAL PROPERTY, http://wcl.american.edu/pijip/go/301 (documenting various submissions including the Joint 2009 Special 301 Submission by U.S. State Health Organizations, the individual 2009 Special 301 Submissions by the Maine Citizen Trade Policy Commission, the National Legislative Association on Prescription Drug Prices (NLARx), the Vermont Commission on International Trade and State Sovereignty).

[19] *See id.* (documenting testimonies of Sean Flynn, Counsel for the Forum on Democracy and Trade; ME State Rep. Sharon Treat for the Maine Citizens Trade Policy Commission; ME State Rep. Sharon Treat for the NLARx Working Group on Trade; Robin Lunge for the Vermont Commission on International Trade and State Sovereignty).

[20] Letter John Baldacci, Governor, Me., to Kathleen Sebelius, U.S. Sec'y of Health and Human Serv. (Apr. 27, 2010), *available at* http://bit.ly/hbIFKT; Letter from Jim Douglas, Governor, Vt., to Kathleen Sebelius, U.S. Sec'y of Health and Human Serv. (May 3, 2010), *available at* http://bit.ly/fyshjz.

an adequate explanation for how the programs fall under the statutory criteria for Special 301 review, a point explained more fully below.

Viewed against the background of past experience, states assume that USTR is targeting the same policies that it has in the past – i.e. innovative reimbursement policies that effectively restrain medicine pricing in similar ways as state preferred drug lists and other public policies in the U.S. We oppose this use of Special 301. The U.S. should not be negotiating for the limitation of programs abroad that are the best practices in the field here at home.

D. USTR's Advocacy of International Restrictions on Domestic Pharmaceutical Pricing Policies Will Limit U.S. Programs

1. USTRs Agenda Will Limit Effective Programs in the U.S.

In the past, USTR has explained that the requirements imposed through its agreements do not apply to U.S. programs because of a host of technical interpretations and definitions.[21] These definitional carve outs have done little to assuage state concerns.[22] Trade agreements are reciprocal by definition. It is foolhardy to think that USTR can negotiate deep restrictions in the regulatory authority of other countries and not have the same programs in the U.S. affected.[23]

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[21] *E.g.*, U.S-Korea FTA, *supra* note 13, art. 5.8 (restricting pharmaceutical programs at the "central level of government," and a footnote to Article 5.8 states that "Medicaid is a regional level of government health care program in the United States, not a central level of government program." To avoid the successful VA program, the agreement was made applicable only to "reimbursement" programs, not procurement).

[22] Comment from National Legislative Association on Prescription Drug Prices Working Group on Trade, to USTR on the Korea-US Free Trade Agreement (Sept. 15, 2009) (expressing concern about the inappropriate "use of trade policy to create a new set of international norms" on pharmaceutical pricing), *available at* http://www.reducedrugprices.org/read.asp?news=4264 (last visited on Feb. 17, 2010).

[23] *See id*. (stating "While USTR may view its efforts to push back against evidence based pharmaceutical pricing as only affecting foreign countries, we view it as the use of trade policy to create a new set of international norms. The branded pharmaceutical industry will eventually seek to apply these norms in the United States to the detriment of access to affordable medicines in the US – whether through specific FTAs, or as part of a broader pharmaceutical policy."); *see also Would the Price be Right?: Hearing before U.S. S. Comm. On Health, Education, Labor & Pensions*, 109th Cong. (Feb. 17, 2005) (statement of Kevin Outterson, Associate Professor, Boston University Law School) (stating that "[c]onsider the negotiations between USTR and the EU: we demand that they modify an important social policy, universal access to care, and raise their drug prices to match our own. If they respond at all, it will be to call us hypocrites, and to demand that we sacrifice our veterans, public health clinic patients, and Medicaid recipients in the bargain.").

Indeed, Ambassador Kirk has publicly expressed support[24] for a broad debate on how trade policy could be used to set international standards to "discipline" pharmaceutical reimbursement programs.[25]

2. USTR's Agenda Will Damage State "Re-importation" Policies

USTR efforts to discipline effective pricing programs in Canada and other advanced pharmaceutical markets threaten state re-importation programs that facilitate parallel trade of patented medicines. Vermont, Illinois, Rhode Island, Minnesota, Kansas, Missouri, Minnesota, California, Wisconsin, and the District of Columbia allow their citizens to purchase pharmaceuticals from Canada or other countries where direct to consumer prices are much lower than in the U.S. These programs, which have saved millions of scarce health dollars, will be ineffective if the U.S. forces other successful countries to abandon effective policies and raise prices for needed drugs.

E. USTR Lacks Statutory Authority to Promote Restrictions on Non-Discriminatory Pharmaceutical Pricing Policies

The USTR lacks any statutory authority to pursue the limitation of foreign or US pharmaceutical market regulation that restrains patented medicine pricing.

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[24] Ambassador Ron Kirk, Remarks at the Global Intellectual Property Center Annual Summit (Sept. 30, 2009), *available at* http://www.ustr.gov/about-us/press-office/speeches/transcripts/2009/september/remarks-ambassador-ron-kirk-global-intelle

[25] *See* Letter from Jeff Kindler, CEO, Pfizer, and John Barton, Professor, Stanford Univ., to the U.S. Senate Comm. on Fin. (Aug. 13, 2008), *available at* http://www.wcl.american.edu/pijip/go/pfizer08132008; *see also, A Discussion with Prof. John Barton*, PROGRAM ON INFO. JUSTICE & INTELLECTUAL PROPERTY (Feb. 19, 2009), *available at* wcl.american.edu/pijip/go/barton (last visited on Feb. 17, 2010) (stating that the Pfizer proposal includes as "a trade goal the achievement of a sector-specific trade agreement" that would ensure that high prices in wealthy countries subsidize lower prices for some populations in poor countries. In the rich countries like the U.S., the agreement would impose internationally binding restrictions on regulatory authority that would "ensure that pricing and reimbursement policies recognize and reward innovation, and to set disciplines on government practices that undermine incentives for innovation." The proposal would also demand that wealthy country aid programs limit use of generic drugs and pay high prices even for distribution in developing countries with no patent protections on the drugs).

The Special 301 authorizing statute requires the identification of countries that lack adequate intellectual property protection or that "deny fair and equitable market access to United States persons that rely upon intellectual property protection."[26] A traditional market access issue might be a discriminatory regulation that unduly burdens foreign suppliers, e.g. a preference for local IP-protected goods by national suppliers. However, the 2010 Special 301 report takes an incredibly broad interpretation of "market access barriers," extending it to "potentially unfair reimbursement policies [that] can discourage the development of new drugs."[27]

Policies that affect the "development of new drugs" are not market access issues. Neither TRIPS nor any other international trade agreement places any restrictions on the non-discriminatory operation of pharmaceutical price regulation, competition policy or other regulatory program that may affect the price of drugs. This interpretation is too broad as a matter of law and of policy. USTR should not be, and lacks the statutory authority to, negotiate or impose new international standards for medicine pricing policies.

There is no statutory requirement to use trade negotiating authority to restrict foreign pricing programs. But the U.S. is still bound by its commitment to the Doha Declaration. When interpreting any ambiguity in the statutory term "market access" in the Special 301 authorizing statute, USTR should use the Doha Declaration and its human rights obligations as a guide,[28] and avoid the use of trade pressure that will predictably threaten access to medicines for all. We appeal to the Obama administration to change course and halt the use of Special 301 or other

[26] 19 U.S.C. § 2242(a)(1)(B).
[27] OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2009 SPECIAL 301 REPORT, *available at* http://www.ustr.gov/about-us/press-office/reports-and-publications/2009/2009-special-301-report.
[28] *See* 2009 Report of the Special Rapporteur on the Right to Health, *supra* note 12, at 17 (defining the "need to have strong pro-competitive measures to limit abuse of the patent system" as a human rights duty imposed by the internationally recognized right to health).

trade initiatives to internationally regulate domestic drug pricing programs that do not violate any World Trade Organization rule.