

USTR-2010-003

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:
NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES
WORKING GROUP ON TRADE, THE VERMONT COMMISSION ON
INTERNATIONAL TRADE AND STATE SOVEREIGNTY, AND THE FORUM ON
DEMOCRACY AND TRADE**

Sean Fiil-Flynn (Counsel of Record)
Meredith Jacob
Mike Palmedo
Program on Information Justice and Intellectual Property
American University Washington College of Law
4801 Massachusetts Ave NW
Washington DC 20016
(202)274-4157

February 18, 2010

SUMMARY	1
STATEMENT OF INTEREST	2
ARGUMENT	3
<i>A. States Rely on Evidence-Based Reimbursement Decisions to Restrain Pharmaceutical Prices.....</i>	<i>3</i>
<i>B. USTR Has Been Using Trade agreements and Special 301 to Promote International Restrictions on Domestic Pharmaceutical Pricing Programs.....</i>	<i>5</i>
<i>C. The 2009 Special 301 Report Continues USTR’s Promotion of International Restraints on Pharmaceutical Reimbursement Programs</i>	<i>7</i>
<i>D. USTR’s Advocacy of International Restrictions on Domestic Pharmaceutical Pricing Policies will Limit U.S. Programs</i>	<i>8</i>
1. USTRs Agenda Will Limit Effective Programs in the U.S.....	8
2. USTR’s Agenda Will Damage State “Re-importation” Policies	9
3. USTR is Threatening Best Practices Needed for Health Reform	9
<i>E. USTR Lacks Statutory Authority to Promote Restrictions on Non-Discriminatory Pharmaceutical Pricing Policies</i>	<i>10</i>

SUMMARY

We write to oppose the recent and disturbing 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

The National Legislative Association on Prescription Drug Prices' Working Group on Trade helps states establish institutional mechanisms both to provide ongoing oversight over trade policy, and to educate their citizenry and policy makers about the connection between international trade policy and affordable prescription drugs. It is comprised of state legislators, trade and Medicaid experts, and representatives of state attorneys general. The Working Group is co-chaired by Arizona State Senator Meg Burton-Cahill and Connecticut State Representative Kevin Ryan.

The Vermont Commission on International Trade and State Sovereignty was established by the Vermont General Assembly in 2006 to assess the legal and economic impacts of international trade agreements on state and local laws, state sovereignty, and the business environment. As part of this charge, the Vermont Commission closely examined the transparency offered and public participation process utilized by the U.S. Trade Representative (USTR) in the negotiation of trade agreements.

The Forum on Democracy and Trade's mission is to support public officials engaged in global trade debates. Forum participants work to ensure that U.S. trade policies are consistent with, and deferential to, the principles of federalism as enshrined in the constitution.

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 “unreasonable” in the 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.¹ One of the most important tools of states are Preferred Drug Lists (PDLs) in the Medicaid program. More than forty states use PDLs for Medicaid and other local health programs. 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 reduce prices as a condition for access to a large 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:

¹ See *The 2004 Annual Report of the West Virginia Pharmaceutical Cost Management Council*, available at <http://www.wvc.state.wv.us/got/pharmacycouncil/>.

- Iowa has saved \$100 million dollars between 2005 and 2009. The state's Department of Human services reports that last year the state's Preferred Drug List delivered savings equal to 34.7% of its total drug budget.²
- Oregon reports saving 40% per prescription due to greater generic uptake resulting from its use of a Preferred Drug List in 2009.³
- 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.⁴
- 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%.⁵
- 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."⁶
- 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.⁷

The big difference between prices in the U.S. and prices in other countries is that we currently have a large number of people who are not covered by any pooled purchasing plan and

² Iowa Department of Human Services, <http://www.resultsiowa.org/humansvs.html> (last visited Feb. 12, 2010).

³ Oregon Prescription Drug Program Newsletter, Jan. 2010.

⁴ Report of the U.S. House Committee on Oversight and 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.

⁵ Micah Hartman, Anne Martin, Patricia McDonnell, Aaron Catlin, and the National Health Expenditure Accounts Team *National Health Spending In 2007: Slower Drug Spending Contributes To Lowest Rate Of Overall Growth Since 1998*, J. Health Affairs, 28(1), 246-61 (2009).

⁶ Budget of the United States Government, FY 2008. available at <http://www.hhs.gov/asrt/ob/docbudget/2008budgetinbrief.pdf>

⁷ Letter from Ginny Lyons and Kathleen Keenan, Vermont State Representatives, to US Congressional Representatives. Apr. 18, 2007.

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.⁸

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

Ambassador Kirk recently expressed his “support” for broadening the discussion of a proposal by Pfizer to promote a new international trade agreement that would “discipline” pharmaceutical reimbursement programs in the U.S. and abroad.⁹ This statement is extremely concerning to state officials, as have previous efforts of the past USTR to use trade agreements to regulate 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

⁸ Victoria Colliver, *U.S. Drug Prices 81% Higher than in 7 Western Nations/Study of Name Brands Shows Steep Rise in Differential Since 2000*, San Francisco Chron. (Oct. 29, 2004).

⁹ See Testimony of Jeff Kindler, Pfizer CEO, before the Senate Finance Committee (Jul. 15, 2008), available at http://media.pfizer.com/files/news/kindler_testimony_sfc_071508.pdf (last visited on Feb. 17, 2010). See also, A Discussion with Prof. John Barton, sponsored by PIJIP (Feb. 19, 2009) available at wcl.american.edu/pijip/go/barton (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).

controls and reference pricing.”¹⁰ Implementation of this negotiating principle to restrain 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 opportunity for industry to appeal drug reimbursement decisions that do not “appropriately recognize the value of patented pharmaceutical products.”¹³

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.¹⁴ As the

¹⁰ 19 U.S.C. § 3802(b)(8)(D). Expired, 2007

¹¹ 19 U.S.C. § 3802(b)(4)(C). Expired, 2007

¹² *Cf.* TRIPS Article 8 (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 Report of the Special Rapporteur on the Right to Health, delivered to 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 Korea-US FTA, Art. 5.2(b)(i).

¹⁴ *See* Vermont State Senate Resolution J.R.S. 50 (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)); from Liz Figueroa and Sheila Kuehl, California state Senators, to USTR in 2005; from National Legislative Association on Prescription

administration recognized, U.S. Medicaid programs “are taking the same approach” as the governments of Australia and Korea – “containing costs by scrutinizing prescription drugs, particularly brand name drugs.”¹⁵

C. The 2009 Special 301 Report Continues USTR’s Promotion of International Restraints on Pharmaceutical Reimbursement Programs

The 2009 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 2009 Special 301 Report singles out Japan, Canada, France, Germany, New Zealand, Taiwan and Poland for administering “unreasonable . . . reference pricing or other 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 listing decisions. 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 an adequate explanation for how the programs fall under the statutory criteria for Special 301 review, a point explained more fully below.

Drugs 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); from Washington Governor Gregoire March 2006 (expressing concerns over the FTA); from four Washington state legislators to the Washington State Congressional Delegation March 2006; Letter from Meg Burton Cahill, Arizona State Senator, and Kevin Ryan, Connecticut State Representative, to Members of the House Ways and Means Committee Subcommittee 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”); National Legislative Association on Prescription Drug Prices, Testimony before the Subcommittee on Trade of the House Committee on Ways and Means, Mar. 20, 2007 (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, Vermont State Senator, and Kathleen Keenan, Vermont State Representative, to Senators Patrick Leahy and Bernard Sanders, and Representative Peter Welsh, (Apr. 18, 2007) (asserting that “Vermont uses a similar ‘positive list’ approach [as Korea]”).

¹⁵ Thomas Jung, State Department Cable, Sept. 9, 2003, quoted in http://www.huffingtonpost.com/james-love/korea-fta-negotiations-on_b_24929.html

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. 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.¹⁶ These definitional carve outs have done little to assuage state concerns.¹⁷ 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.¹⁸ Indeed, Ambassador Kirk has publicly expressed support for a broad debate on how trade policy

¹⁶ *E.g.*, The Korea FTA only restricts 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.

¹⁷ National Legislative Association on Prescription Drug Prices Working Group on Trade, Comments 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).

¹⁸ *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.”); Testimony of Kevin Outterson, Boston University Professor, before the U.S. Senate, Health, Education, Labor & Pensions Committee: Hearing on *Drug Importation: Would the Price Be Right?* (Feb. 17, 2005) (“[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.”).

could be used to set international standards to “discipline” pharmaceutical reimbursement programs.¹⁹

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.

3. USTR is Threatening Best Practices Needed for Health Reform

This administration is committed to national health reform which relies on finding and utilizing the best practices for restraining health costs through evidence based policies that promote public health. Pharmaceutical policy in the U.S. is in sore need for such reform. We spend more on pharmaceuticals than any other country in the world, in part because we oversubscribe costly new medicines when they are not better, and are often much worse, than cheaper alternatives. In U.S. states and in other countries policies are being used effectively to

¹⁹ See Testimony of Jeff Kindler, Pfizer CEO, before the Senate Finance Committee (Jul. 15, 2008), *available at* http://media.pfizer.com/files/news/kindler_testimony_sfc_071508.pdf (last visited on Feb. 17, 2010). See also, A Discussion with Prof. John Barton, sponsored by PIJIP (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).

reduce costs and promote public health by influencing prescribing decisions with evidence.²⁰ The idea is simple – the best drugs should be preferred, costs should be in line with effectiveness, not market power. As the federal government continues working on health reform, it needs to learn from these examples, not allow its USTR to negotiate them out of existence.²¹

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.

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.”²² 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 2009 Special 301 report takes an incredibly broad interpretation of “market access barriers,” extending it to “price controls and regulatory and other barriers [that] can discourage the development of new drugs.”²³

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

²⁰ Testimony of Meredith Jacob to the Illinois House Committee on Human Services, (Mar. 4, 2009); National Physicians Alliance. The Sale of Physician Prescribing Data Raises Health Care Costs — The National Physicians Alliance Calls for a Ban. Issue Brief. www.npalliance.org; Michael Fischer & Jerry Avorn, *Economic Implications of Evidence-Based Prescribing for Hypertension: Could Better Care Cost Less*, 291 JAMA 1850, 1854 (2004).

²¹ Letter from Sean Flynn and Maine State Rep. Sharon Treat, on behalf of National Legislative Association on Prescription Drug Prices, to Sen. Baucus, Chairman of the U.S. Senate Finance Committee (Jan. 11, 2007), available at wcl.american.edu/pijip/documents/NLARxLtrtoSenFinanceCommittee.pdf (last visited on Feb. 17, 2010).

²² 19 U.S.C. § 2242(a)(1)(B).

²³ 2009 Special 301 Report.

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,²⁴ 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 trade initiatives to internationally regulate domestic drug pricing programs that do not violate any World Trade Organization rule.

²⁴ See 2009 Report of the Special Rapporteur on the Right to Health, *supra* note 11, 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).