State of Vermont
OFFICE OF THE GOVERNOR

June 1, 2011

The Honorable Barack Obama
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

As the Office of the United States Trade Representative prepares its negotiating text for the Trans Pacific Partnership Agreement (TPP), the pharmaceutical industry and others are seeking the inclusion of a pharmaceuticals chapter that would set disciplines on pricing and reimbursement programs abroad. After reading the letter sent to you last week by 28 Senators calling on you to maintain strong IP rights in the Trans-Pacific Partnership Trade Agreement, I want to respond with examples that illustrate how some of the requests made in that letter may impact states. Since trade agreements are reciprocal in nature, it is important to consider that millions of Americans rely on programs such as Medicaid, the 340B pricing program, and Medicare Part B that engage in the same types of pricing and reimbursement policies that the pharmaceutical industry and signatories to the Senate letter of May 17th oppose.

State legislators and Governors have previously notified federal officials that these types of provisions will threaten U.S. programs that serve low income citizens.[1] For instance, my predecessor Vermont Governor Douglas wrote the Obama Administration to express his concern with "a trade policy that will conflict with the ability of the states and the Federal government to continue best practices to control pharmaceutical prices."[2] Last September, five state legislators warned against "the continuation of an ill-conceived agenda to use trade policy to restrict foreign and domestic medicine pricing programs."[3]

[1] For copies of letters and resolutions from state governors, legislators and representative organizations, see http://forumdemocracy.net/section.php?id=228
[2] Letter from VT Governor Douglas to DHHS Secretary Kathleen Sebelius. May 3, 2010. http://forumdemocracy.net/article.php?id=567
[3] Letter from five state legislators to USTR, September 16, 2010. http://forumdemocracy.net/article.php?id=554

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U.S. Federal government agencies and state governments use the same policy tools as foreign governments for public medicine purchasing and reimbursement, and they pay similar prices. For example, Section 340B of the Veterans Health Act of 1992 requires drug companies to provide statutorily-defined discounts to Federally-qualified state and local health programs as a condition of having their drugs covered by Medicaid. In Vermont, these programs include all of our federally qualified health centers, and Fletcher Allen Health Care – our largest teaching hospital. In addition, Vermont has begun a new 340B pilot project with Rutland Regional Hospital to provide broader 340B access through local pharmacies. Medicare Part B sets statutorily-defined prices for pharmaceuticals used in medically necessary services for Medicare beneficiaries. State Medicaid programs use open formularies to steer patients towards the most cost effective drugs in their therapeutic class. Pharmaceutical companies offer discounts in order to be listed on the preferred drug lists.

The pharmaceutical industry advocacy group, PhRMA has recently circulated lobbying documents asking for the inclusion in the TPP of pharmaceutical provisions "founded on the provisions contained in Chapter 5 of the U.S.-South Korea FTA."[4] These provisions apply to American and Korean agencies in the "central level of government" that "operate or maintain procedures for listing pharmaceutical products" or are responsible for "setting the amount of reimbursement for pharmaceutical products." Through a series of technical provisions and carve outs, the Korea FTA attempts to only apply its mandates to pharmaceutical programs in Korea. It applies only to reimbursement,[5] whereas most federal programs (VA, GSA) implement price restraints through direct purchasing. It also contains a specific carve out for Medicaid.[6] But because the FTA was negotiated with minimal public input, and because general principles are likely to prevail over finely crafted exceptions, state officials are concerned that U.S. programs will be threatened by the provisions in the Korea FTA and similar norms exported to other agreements (e.g. the TPP). Two specific U.S. reimbursement programs – 340B and Medicare Part B -- are directly threatened by the Korea FTA because they do not fall within any of the agreement's exceptions.[7]

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[4] PhRMA. "The Need for a Strong Pharmaceuticals Chapter in the Trans-Pacific Partnership Free Trade Agreement." April 2011.

[5] Korus FTA, Chapter 5, footnote 1: "Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for health care agencies that engage in government procurement. Chapter Seventeen (Government Procurement), rather than this Chapter, shall apply to government procurement of pharmaceutical products.

[6] Korus FTA, Art. 5.2: "To the extent that health care authorities at a Party's central level of government operate or maintain procedures for listing pharmaceutical products, medical devices, or indications for reimbursement, or setting the amount of reimbursement for pharmaceutical products or medical devices, under health care programs operated by its central level of government,1 the Party shall…" Footnote 3 to the chapter specifies that "Medicaid is a regional level of government health care program in the United States, not a central level of government program."

[7] Article 5.3(e) of the Korea FTA requires health authorities to "make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination." 340B and Medicare Part B reimbursement prices are set by statute and do not offer any possibility of independent review.[7]

The Korea FTA contains a footnote classifying Medicaid as a regional government program, thus exempting it from the provisions of the otherwise reciprocal trade agreement. But there is no guarantee that a TPP Pharmaceuticals chapter would contain the same carve-out. Even if a chapter was proposed that did include a Medicaid carve-out, state leaders believe it is inappropriate for U.S. trade policy to advance restrictions on pharmaceutical pricing programs that U.S. programs do not meet but for technical carve outs.

Inclusion of disciplines on pharmaceutical pricing and reimbursement programs in the TPP could allow our trading partners to challenge cost controls used by 340B, Medicare Part B and Medicaid. These programs serve vulnerable populations in the U.S., and trade policy should not put them at risk. Neither the TPP nor any future trade agreement should restrict these programs' ability to set discounts or negotiate reimbursements.

Sincerely,

Peter Shumlin
Governor of Vermont

CC: Ambassador Ron Kirk, USTR
Secretary Kathleen Sebelius, DHHS
Cindy Mann, Director of the Center for Medicaid and State Operations
Hon. Bernie Sanders, Senator for Vermont

Article 5.2(c) requires health authorities to "permit a manufacturer… to apply for reimbursement of additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy." There is no such provision in 340B or Medicare Part B.[7] Indeed; Federal regulations do not allow manufacturers to request that these programs cover additional indications that are not approved by the FDA (so-called "off-label" indications).

Article 5.2(b) requires health authorities to "ensure that the Party's determination, if any, of the reimbursement amount for a pharmaceutical product or medical device… is based on competitive market-derived prices," or else to "appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides." These are vague standards that are not defined in the agreement. It is at least plausible that a pharmaceutical company could challenge 340B or Medicare Part B reimbursement prices as not being "market-derived" since they are constrained by mandatory discounts and penalized for increasing market prices.[7]

Hon. Patrick Leahy, Senator for Vermont
Hon. Peter Welch, Representative for Vermont