

**Testimony to the Ways and Means Committee
U.S. House of Representatives**

US-Australia Free Trade Agreement:

Implications for Prescription Drug Prices in the US and Australia

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**Center for Policy Analysis on Trade and Health
CPATH**

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EXECUTIVE SUMMARY

Provisions of the US-Australia Free Trade Agreement (FTA) could result in higher prescription drug prices for U.S. and Australian consumers. The Agreement could block legislation authorizing reimportation of less expensive drugs into the U.S. New requirements for independent review of federal agency decisions about listing and pricing for drugs could lead to higher drug prices for the Medicaid program and for Veterans Administration health services, and necessitate changes to US law and current practices. The vagueness of key provisions places these important programs at risk. These concerns should be addressed, and Congress should ensure that U.S. consumers, including veterans and Medicaid beneficiaries, are adequately protected, in these areas:

1. The Agreement could block reimportation of less expensive drugs from other countries, including future legislation that would authorize such “parallel importation,” preempting Congressional debate.

2. Vulnerable populations served by Medicaid and Medicare could face higher drug prices. These programs would have to establish an **undefined “independent review process”** for any recommendations or determinations regarding “listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals.” This **could delay or alter decisions about providing drugs and establishing affordable prices.** It could require changes to current U.S. law. It is unclear how this requirement would apply to private companies that administer the new Medicare Part D.

3. Veterans could face higher drug prices. Federal programs such as the Veterans Administration, and possibly state programs, would also have to provide new review processes for drug listing and pricing decisions. Technical standards that guide drug purchasing decisions could not be “unnecessary obstacles to trade,” but these terms are not defined. These provisions are different from current practice. **They can delay procurement decisions, and allow companies to pressure agencies for higher prices.**

4. The many vague provisions of the Agreement will be interpreted and enforced by international dispute panels, which are not guided by or subject to U.S. law. Government agencies that appeal the many unclear provisions of the Agreement after it is enacted have no guarantee of prevailing. Trade panels can impose financial sanctions to achieve compliance.

5. Many Australian health professional associations oppose the FTA, and have stated that it will raise drug prices in Australia, which are currently closely controlled. The U.S. pharmaceutical industry claims that it is necessary to raise drug prices in Australia and other developed countries, to fund innovation in research, and eventually lower drug prices in the U.S. Public funding for research and development in the U.S. reflects concern for innovation, and **patent laws that protect products from competition for 20 years permit drug companies to recoup their investments.** But the 15% of revenues the industry spends on research increasingly focuses on copycat drugs that present little if any additional therapeutic value, while treatments for important health conditions are not explored. Prices are unaffordable for many. Companies are obliged to respond to shareholder expectations for the highest possible profits, and the industry’s return on revenue is already among the highest in the U.S. **It is unclear how higher profit levels could lead the industry to offer more affordable prices. The crisis in the industry’s complex business model will not be successfully resolved by undermining price controls abroad.**

US-AUSTRALIA FREE TRADE AGREEMENT: IMPLICATIONS FOR PRESCRIPTION DRUG PRICES IN THE US AND AUSTRALIA

Provisions Related To Setting Prices For Drugs

Paragraph 17.9.4 of the Agreement could block reimportation of less expensive medicines from other countries, termed “parallel importation.” Additional rules that extend the terms of patents are included in Chapter 17 on Intellectual Property. The Agreement grants additional rights to drug patent holders that are likely to delay the entry into market of competitive generic drugs, and delay the resulting reduction in drug prices. These include “data exclusivity,” the right not to release drug trial data to generic companies.

Annex 2-C, Pharmaceuticals, establishes rules for transparency and for independent review of decisions for government agencies that create lists of drugs and set prices for drugs, but do not directly procure them, such as Medicaid and Medicare.

Agencies that procure drugs directly, including the Veterans Administration, the Department of Defense, and the Indian Health Service, are covered by Chapter 15, Government Procurement.

1. The Agreement would block reimportation of less expensive drugs from other countries.

Chapter 17.9.4 on parallel importation could be used to block reimportation of lower priced drugs into the U.S from any country. Reportedly other language in the Agreement prohibiting reimportation was removed earlier. However, this provision in the current the version of the Agreement posted on the U.S. Trade Representative website would have the same effect:

Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.

Many members of Congress and the public have expressed interest in reimportation; this Agreement would preempt a debate on the subject. There is no provision that allows future laws passed by the U.S. Congress to supersede this Agreement. Under Chapter 13, each country is allowed to identify current laws that do not conform with the Agreement and will remain exempt, and also areas where future domestic legislation can differ from the Agreement. There is no reference in this chapter or its related schedules and annexes to parallel importation of drugs, or to pharmaceuticals.

2. Transparency and independent review requirements for Medicare, Medicaid, and perhaps others.

Annex 2-C, Pharmaceuticals, applies transparency requirements to “federal healthcare authorities [that] operate or maintain procedures for listing new pharmaceuticals or indications for reimbursement purposes, or for setting the amount of reimbursement for pharmaceuticals, under its federal healthcare programs.” In the case of the U.S. this would apply to Medicare and Medicaid, which are both federal programs. (A claim that Medicaid is not a federal program because it is administered by states would likely be referred to an international trade dispute panel if challenged.) It would also apply to Australia’s Pharmaceutical Benefits Scheme, which determines the list of available drugs and negotiates prices.

The independent review process is not defined. It suggests a decision-making process “independent” of government authorities, that will allow the industry (referred to as “applicants”) to go beyond current adequate negotiation processes, and appeal for higher prices for more products.

The requirements are stated in Paragraph 2(a) – (f), Transparency, listed below.

- (a) ensure that consideration of all formal proposals for listing are completed within a specified time;
- (b) disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;
- (c) afford applicants timely opportunities to provide comments at relevant points in the process;
- (d) provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;
- (e) provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
- (f) make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.**

Questions:

2a. Since international trade law and trade panels govern this Agreement, and since the independent review process is not clearly defined, how can agencies assure that they will retain the final authority to assure appropriate lists and affordable prices for their vulnerable populations?

2b. For U.S. federal health care authorities that do not currently comply with paragraphs (a) – (f) above, what legislative or regulatory change would be required for compliance?

2c. Since international trade law and trade panels govern this Agreement, how can agencies be certain regarding whether they are covered by this provision?

3. Technical specifications and independent review requirements for federal and state health care agencies that establish formularies and engage in procurement of pharmaceuticals: VA, DoD, IHS

Government programs that directly procure drugs, including the Veterans Administration and Department of Defense, are covered by requirements to establish **technical standards and independent review** for drug purchases in Chapter 15 on Government Procurement. **Specifically, Article 15.6 states that technical specifications cannot have the “purpose or effect of creating unnecessary obstacles to trade.”** (See relevant provisions in **Attachment #1.**)

Article 15.11 describes the two levels of independent review that government procurement bodies must make available in the case of challenges to their decisions. This goes beyond the requirements of the World Trade Organization’s Government Procurement Agreement, to which the U.S. is a party. The differences are detailed in **Attachment #2** below.

A footnote in Annex 2-C states: “Pharmaceutical formulary development and management shall be considered to be an aspect of government procurement of pharmaceutical products for federal healthcare agencies that engage in government procurement. Government procurement of pharmaceutical products shall be governed by Chapter 15 (Government Procurement) and not the provisions of this Annex.”

The second sentence of the footnote refers broadly to “Government procurement of pharmaceutical products,” and does not limit the application merely to federal agency activity. This suggests that **state drug formulary programs could be subject to the Agreement.**

Question 3a. Since international trade law and trade panels govern this Agreement, how can the VA and other agencies be assured that technical standards for setting formularies and prices will be considered acceptable, and do not constitute unnecessary obstacles to trade?

Question 3b. How can the VA and other agencies assure that they will retain the final authority to determine lists and prices of drugs, in the interest of assuring appropriate lists and affordable prices, and that “independent” review panels will not assume this authority?

Question 3c. What is the complete list of federal and state health care agencies in the U.S. that engage in pharmaceutical formulary development and management?

Question 3d. Of these government health care agencies, to what degree do current procurement methods differ from the provisions of Chapter 15 of the US-Australia FTA? (See Attachment #1.) What legislative and/or regulatory change(s) would be required to ensure compliance with the provisions of Chapter 15?

4. Trade agreements are interpreted by international panels which are not guided by or subject to U.S. law. Several provisions of the Agreement are ambiguous, including the definitions of the kinds of agencies covered, technical specifications, and independent review. The Government Procurement section (see above), for example, requires countries to prove that technical specifications on which they base their decisions do not have the “purpose or effect of creating unnecessary obstacles to trade.” Countries involved in trade disputes have frequently been surprised at the types of technical standards that trade dispute panels find acceptable. Government agencies that appeal these provisions in the event of a challenge, including by asserting that they are exempt, have no guarantee of prevailing.

5. The FTA is intended to lead to higher drug prices in Australia. It is not clear that this will be likely to lower drug prices in the US.

The Agreement applies the same requirements for transparency and independent review, described above, to Australia’s Pharmaceutical Benefits Scheme, including consulting with applicants (which would include pharmaceutical companies), and providing independent avenues for appealing decisions about listing and pricing drugs. It also establishes a Medicines Working Group, intended to “promote discussion and mutual understanding of issues relating to this Annex (except those issues covered in paragraph 4, including the importance of pharmaceutical research and development to continued improvement of healthcare outcomes,)” consisting of “officials of federal government agencies responsible for federal healthcare programs and other appropriate federal government officials.”

Several U.S. policymakers have stated that it is the explicit intention for this Agreement to raise drug prices in Australia. A recent submission to the Australian Senate Select Committee on the US-Australia Free Trade Agreement presented concerns that these provisions will indeed raise drug prices there. Relevant sections of this report are reproduced below in **Attachment #3**.

Assuring the development of beneficial new drugs, and making them available at an affordable price, are essential concerns. In the U.S., these concerns have led to substantial public contributions, in funding and other resources, for research and development, and to patent laws that protect products from competition for 20 years to allow drug companies to recoup their investments. Nevertheless, innovation increasingly focuses on copycat drugs of uncertain therapeutic value, while treatments for important health conditions are not explored. Prices are unaffordable for many. It is among the most profitable industries in the U.S., earning a 19% return on revenue, or \$72.6 billion in profits in 2002. **It is unclear how higher profit levels could lead the industry to offer more affordable prices in the U.S.** The industry has no track record of voluntarily reducing prices, without competition following expiration of patents, and is obliged to respond to shareholder expectations for the highest possible profits. **The current complex business model for the U.S. pharmaceutical industry appears to be at a crossroads, one that will not likely be successfully navigated or credibly addressed by undermining price control systems abroad.**

SUMMARY

The U.S.-Australia Free Trade Agreement contains a number of provisions related to pharmaceutical products that are likely to interfere with current efforts to achieve or maintain affordable prescription drug prices in the U.S. and in Australia. The Agreement preempts important rights of governments. Resolving international concerns about drug prices and availability will involve careful consideration of complex issues by a range of stakeholders. To the extent that these issues can be usefully addressed in trade agreements, multilateral settings are likely to be more productive than bilateral agreements. The provisions noted should be reconsidered, and should not serve as a precedent for future agreements.

ATTACHMENT #1: PROVISIONS ON TECHNICAL SPECIFICATIONS AND INDEPENDENT REVIEW FOR GOVERNMENT PROCUREMENT

ARTICLE 15.6 : INFORMATION ON INTENDED PROCUREMENTS

Technical Specifications

3. A procuring entity may not prepare, adopt, or apply any technical specification or prescribe any conformity assessment procedure with the purpose or the effect of creating unnecessary obstacles to trade between the Parties.

4. In prescribing the technical specifications for the good or service being procured, a procuring entity shall:

- (a) specify the technical specifications, wherever appropriate, in terms of performance and functional requirements, rather than design or descriptive characteristics; and
- (b) base the technical specifications on international standards, where such exist and are applicable to the procuring entity, except where the use of an international standard would fail to meet the procuring entity's program requirements or would impose greater burdens than the use of a recognized national standard.

5. A procuring entity may not prescribe technical specifications that require or refer to a particular trademark or trade name, patent, copyright, design or type, specific origin, producer, or supplier, unless there is no other sufficiently precise or intelligible way of describing the procurement requirements and provided that, in such cases, words such as "or equivalent" are included in the tender documentation.

6. A procuring entity may not seek or accept, in a manner that would have the effect of precluding competition, advice that may be used in the preparation or adoption of any technical specification for a specific procurement from a person that may have a commercial interest in the procurement.

7. Notwithstanding paragraph 6, a procuring entity may:

- (a) conduct market research in developing specifications for a particular procurement; or
- (b) allow a supplier that has been engaged to provide design or consulting services to participate in procurements related to such services, provided it would not give the supplier an unfair advantage over other suppliers.

ARTICLE 15.11 : DOMESTIC REVIEW OF SUPPLIER CHALLENGES

1. In the event of a complaint by a supplier of a Party that there has been a breach of the other Party's measures implementing this Chapter in the context of a covered procurement in which the supplier has or had an interest, the Party of the procuring entity shall encourage the supplier to seek resolution of its complaint in consultation with the procuring entity. In such instances the procuring entity shall accord timely and impartial consideration to any such complaint.

2. Each Party shall maintain at least one impartial administrative or judicial authority that is independent of its procuring entities to receive and review challenges that suppliers submit, in accordance with the Party's law, relating to a covered procurement. Each Party shall ensure that any such challenge not prejudice the supplier's participation in ongoing or future procurement activities.

3. Where a body other than an authority referred to in paragraph 2 initially reviews a challenge, the Party shall ensure that the supplier may appeal the initial decision to **an impartial administrative or judicial authority that is independent of the procuring entity** that is the subject of the challenge.

4. Each Party shall ensure that the authorities referred to in paragraph 2 have the power to take prompt interim measures, pending the resolution of a challenge, to preserve the supplier's opportunity to participate in the procurement and to ensure that the procuring entities of the Party comply with its measures implementing this Chapter. Such interim measures may include, where appropriate, suspending the contract award or the performance of a contract that has already been awarded.
5. Each Party shall ensure that its review procedures are conducted in accordance with the following:
- (a) a supplier shall be allowed sufficient time to prepare and submit a written challenge, which in no case shall be less than ten days from the time when the basis of the complaint became known or reasonably should have become known to the supplier;
 - (b) a procuring entity shall respond in writing to a supplier's complaint and provide all relevant documents to the review authority;
 - (c) a supplier that initiates a complaint shall be provided an opportunity to reply to the procuring entity's response before the review authority takes a decision on the complaint; and
 - (d) the review authority shall provide its decision on a supplier's challenge in a timely fashion, in writing, with an explanation of the basis for the decision.

ATTACHMENT #2: DIFFERENCES BETWEEN WTO GOVERNMENT PROCUREMENT AGREEMENT AND US-AUSTRALIA FTA ON INDEPENDENT REVIEW

<u>Issue</u>	<u>WTO Government Procurement Agreement</u>	<u>U.S.-Australia Free Trade Agreement</u>	<u>Difference</u>
Levels of review	<p><i>Article XX</i> <i>Challenge Procedures</i></p> <p>1. In the event of a complaint by a supplier that there has been a breach of this Agreement in the context of a procurement, each Party shall encourage the supplier to seek resolution of its complaint in consultation with the procuring entity. In such instances the procuring entity shall accord impartial and timely consideration to any such complaint, in a manner that is not prejudicial to obtaining corrective measures under the challenge system.</p>	<p>ARTICLE 15.11 : DOMESTIC REVIEW OF SUPPLIER CHALLENGES</p> <p>1. In the event of a complaint by a supplier of a Party that there has been a breach of the other Party's measures implementing this Chapter in the context of a covered procurement in which the supplier has or had an interest, the Party of the procuring entity shall encourage the supplier to seek resolution of its complaint in consultation with the procuring entity. In such instances the procuring entity shall accord timely and impartial consideration to any such complaint.</p> <p>2. Each Party shall maintain at least one impartial administrative or judicial authority that is independent of its procuring entities to receive and review challenges that suppliers submit, in accordance with the Party's law, relating to a covered procurement.</p>	<p>WTO requires impartial review by the procuring entity.</p> <p>Australia requires a second level of review, and empowers an independent authority to review the procuring entity's decision.</p> <p>This provides opportunities to delay procurement decisions.</p>

<u>Issue</u>	<u>WTO Government Procurement Agreement</u>	<u>U.S.-Australia Free Trade Agreement</u>	<u>Difference</u>
Challenge of procurement decision.	7. Challenge procedures shall provide for: (a) rapid interim measures to correct breaches of the Agreement and to preserve action may result in suspension of the procurement process. However, procedures may provide that overriding adverse consequences for the interests concerned, including the public interest, may be taken into account in deciding whether such measures should be applied. In such circumstances, just cause for not acting shall be provided in writing; (b) an assessment and a possibility for a decision on the justification of the challenge; (c) correction of the breach of the Agreement or compensation for the loss or damages suffered, which may be limited to costs for tender preparation or protest. commercial opportunities. Such	4. Each Party shall ensure that the authorities referred to in paragraph 2 have the power to take prompt interim measures, pending the resolution of a challenge, to preserve the supplier's opportunity to participate in the procurement and to ensure that the procuring entities of the Party comply with its measures implementing this Chapter. Such interim measures may include, where appropriate, suspending the contract award or the performance of a contract that has already been awarded.	1. The WTO requires only that interim corrective measures preserve commercial opportunities generally; US-Australia gives specific rights to the complaining supplier for interim measures. 2. The WTO calls for procedures that can provide for interim measures (such as delaying a procurement decision). US-Australia gives that power to the independent review authority, which is separate from the procuring entity. 3. The WTO has an exception for the public interest; US-Australia has no such exception.

ATTACHMENT #3: AUSTRALIAN SUBMISSION ON THE FTA AND DRUG PRICES

THE FTA AND THE PBS

A submission to the Australia Senate Select Committee on the US-Australia Free Trade Agreement

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THE PBAC APPEALS PROCEDURE

Under the FTA, Australia has undertaken to “make available an independent review process” by which a manufacturer can challenge PBS listing decisions made by the key committee, the Pharmaceutical Benefits Pricing Authority.

The government has repeatedly promised that this would not be able to set aside or overturn PBAC decisions. However, the realities of the FTA are that Australia is likely to face very large sanctions under the dispute resolution and enforcement sections of the FTA if it does not provide an appeals process that the US and its drug makers find acceptable. Any process that does not have the power to reverse decisions, and which merely returns a submission to the committee for further consideration, will not represent any advance for the American side or the US companies. According to several statements from the industry and the American side, an appeals process without power is not what they think they have secured.

Such a process will seriously compromise the negotiating position of the PBAC. At present, the committee commissions sophisticated economic evaluations of each new drug and decides whether the price requested by the company represents fair value in terms of the health benefits the drug is likely to provide. If the answer is no, companies must reduce their price or find new data to justify the price they want. Often, the price comes down.

If, rather than re-submitting to the PBAC, sponsor companies could go to an alternative forum to have the PBAC’s decision overturned or changed, the committee would find it far more difficult to enforce price discipline on major drug makers.

DISPUTE RESOLUTION AND ENFORCEMENT

Often, when trade negotiators cannot finalise contentious points of detail, they produce a text that is deliberately unclear on these matters and that can be sorted out later. These “constructive ambiguities” abound in those elements of the FTA that affect the pharmaceutical market and the PBS. These ambiguous clauses allow each side to claim a “win” and to secure endorsement from each nation’s legislatures. But further consultation and dispute resolution processes will be put in place to sort these matters out later, outside of public and parliamentary scrutiny.

Two such processes are included in this FTA: a consultative Medicines Working Group, and the overall disputes resolution processes.

The **Medicines Working Group** will comprise federal officials from each country. Decisions will effectively be binding on Australia unless the draconian provisions of the FTA’s enforcement processes are to be risked. The Australian parliament is being asked to endorse an agreement that does not specify what will happen to key elements of one of its central national health programs, the PBS; and that gives immense power to a non-Australian group meeting behind closed doors, with no published agenda and no accountability to the Australian people, parliament or press.

Matters likely to be discussed by the Medicines Working Group include the PBAC appeals procedure, crucial technical aspects of PBAC economic evaluations, involvement of companies in PBAC decision-making, whether the Australian government will still be able to remove drugs from the PBS and demands

about speed of listing. Most of these matters would potentially diminish the negotiating position of the PBS in dealing with overseas drug companies and would lead to higher drug prices.

If Australia does not comply with US demands, or does not change its laws, regulations and processes to put into effect the FTA and the judgments of the Medicines Working Group, the **disputes resolution and enforcement** processes will come into force. These involve the establishment of committees and working groups that “seek the advice of non-governmental persons or groups” – a measure that brings the industry and its lobbyists directly into the processes of administering and enforcing the FTA.

If Australia is found to be in breach, a fine can be set of up to 50 percent of the value of the benefit Australia is calculated to have gained by its breach. As some single drugs cost the PBS more than \$100 million a year, these fines are likely to be very large indeed. Ongoing penalties of up to \$US15 million may also be imposed for each instance of each breach.

And “benefits under the agreement” may be suspended. This means the US could deny Australia any or all of the access achieved under the FTA to its market for any Australian product, including primary products such as beef and lamb.

PRESSURES ON THE PBAC

As discussed above, the PBS listing process is a combination of valuation followed by negotiation, built on objective economic and clinical evaluation of their products. The PBS does not attempt to gain the lowest possible price: rather, it attempts to pay what it believes, based on the evidence of clinical safety and efficacy, is fair and consistent with what is paid for other medicines. It is a sophisticated and very successful program that has been copied by other countries. The PBS has provided Australia with very competitive drug prices. Local branch offices of global drug companies are under immense power from their overseas head offices to achieve prices closer to those ruling in the US; therefore, anything that weakens the power of the PBAC to reject unsatisfactory prices, and to hold out for better value, will inevitably cause costs to rise and add to the long-term problems of financial sustainability facing the PBS.

Australia’s ban on direct-to-consumer advertising of prescription medicines will become easier for companies to circumvent. This will add to the pressure on the PBAC to make new drugs available whatever the cost. It will also increase total cost as patients are induced to switch to new, expensive drugs from older, cheaper ones or from no drug at all.

Company representatives will become involved in the actual meetings of the PBAC and its technical sub-committees, and will be able to make personal sales pitches to the meetings deciding on the value of their products. The FTA will reinforce companies’ ability to seek higher prices for already-listed drugs, but there will be no capacity for the PBS to review prices downwards if (as often happens) drugs perform less well in the “real world” of actual clinical use than they did in the original clinical trials.

The combined pressures of all these measures on the PBAC and its members will be enormous and extraordinarily difficult to resist. The committee will effectively be under siege: the number of interests attacking any negative decision will have multiplied both in number and in strength. Despite its present powers under the *National Health Act*, it is difficult to see how the committee will be able to continue serving the public’s interest properly under such conditions.