10. Public Health and Medicine Policies

Thomas Faunce and Ruth Townsend

This chapter examines the extent to which the proposed Trans-Pacific Partnership Agreement may impact on public health and medicines policies in the countries party to the agreement. Its predictions are based chiefly on a critical analysis of two sets of submissions from influential US health and medicines-related corporations and industry bodies to the US Trade Representative (USTR) in 2009. The first set of submissions was on the TPPA itself and the second arose in relation to the Section 301 Trade Watch List. The submissions sought TPPA provisions that fell into four broad categories: (1) impeding the market entry of generic medicines and increasing the monopoly privileges of patented medicines; (2) restricting the capacity of governments to operate evidence-based systems that assess the cost-effectiveness of health technologies; (3) creating committee mechanisms for ongoing lobbying of governments on these issues; and (4) including investor-state dispute settlement procedures that would allow foreign corporations to sue governments if their investments are impeded, for example, by public health legislation.

When the first formal round of TPPA negotiations was held in Melbourne from 15–19 March 2010, health and medicines issues were not phrased in the above terms. Instead, the brief official memorandum released afterwards to the public stated that future negotiations were officially set to include investor-state dispute settlement, ways to promote ‘regulatory coherence’ and how to ensure small-to-medium corporate enterprises (SMEs) are able to benefit from the agreement.¹

Naturally, the communiqué did not present these issues as reflecting a US industry agenda for health and medicine policy that would in effect be pushed onto the other parties. Yet, this is exactly what is likely to happen, if only because no TPPA nation except the US has a powerful health industry sector with the capacity to influence the negotiation agenda so strongly. This is partly a function of the size of the respective economies, but it also reflects a protracted and fundamental lack of vision and organisation among the
non-US governments and trade negotiators. Indeed, watching bilateral and regional trade negotiations involving the US often becomes a disheartening exercise in observing nations pay timid obeisance to US free market ideology regardless of the deleterious impacts on their own industry development, as well as the national and global public good.

This chapter evaluates the proposals the USTR is likely to raise in the TPPA so as to influence other nations’ health and medicines policies, particularly focusing on investor–state dispute settlement. It concludes by suggesting an alternative approach that aims to reconcile legitimate public health objectives with industry incentives in a twenty-first century trade agreement that reflects a balance of private and public interests.

**TPPA Health and Medicines Provisions**

Free trade agreements were initially designed to reduce tariffs or taxes placed at the border on goods coming from one country to another. In time, however, various US industry groups have successfully transformed US-led trade agreements into opportunities to facilitate their monopoly advantage by influencing the legislation and policies that other countries can implement, under threat of trade sanctions. This happened particularly in areas of intellectual property rights (IPRs, now also referred to as intellectual monopoly privileges or IMPs) such as copyright, trade marks and patents (especially pharmaceutical patents).

Multilateral trade agreements that have impacted on domestic public health and medicines policies include the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (which required, for instance, increased pharmaceutical patent terms) and the General Agreement on Trade in Services (GATS) (which created a mechanism, for example, whereby signatories could agree to prevent barriers to foreign ownership of hospitals). The investor–state dispute provisions that appeared in the 1994 North American Free Trade Agreement (NAFTA) between the US, Canada and Mexico have also been used to challenge health and medicines policies in the signatory states, as illustrated below.²

At the bilateral level, US trade agreements have included a variety of provisions restricting market entry for generic medicines. Notably, the Australia–US Free Trade Agreement (AUSFTA) also contains potentially precedent-setting provisions that required changes to Australia’s constitutionally supported system where scientific assessment of the cost-effectiveness of a new prescription medicine is a necessary precursor to the Federal government subsidising most of its cost to patients.³

The extent to which US corporate interests have been paramount in framing such issues and how TPPA provisions resulting from them may impact on health and medicines policies is made clearer in the following section.
**Submissions on the TPPA**

The USTR sought submissions on the proposed TPPA in 2009. Members of PhRMA, the influential US patented pharmaceutical research and manufacturing lobby group, duly lodged a detailed ‘wish-list’ of proposals. It should be noted that members of PhRMA often interchange employment with, and are highly influential upon, the USTR, so this TPPA submission offers useful insights into the USTR's probable TPPA negotiating agenda in the health and medicines-related sector.

The PhRMA submission suggests that the TPPA negotiations could serve to address ‘market access barriers, [and] remedy inadequate consultative mechanisms and transparency concerns in countries like New Zealand, for which no US FTA currently exists … [Doing so] would ensure that patients throughout the TPP region receive safe, effective and innovative medicines’ (emphasis added to highlight the replacement of ‘cost-effective’ with ‘effective and innovative’). By way of preliminary explanation, drug regulatory authorities in Australia and New Zealand (like those in many European nations, South Korea and China) in assessing ‘innovation’ consider not only the safety (toxicity), efficacy (whether they work) and quality (standard of manufacturing) of medicines, but also their comparative cost-effectiveness (compared to existing products). The latter is an important addition designed to facilitate value for public expenditure and affordable access to ‘best value’ medicines by patients in those countries.

The PhRMA submission also advocates provisions expanding the IMPs (or IPRs) that increase the monopolistic advantage of its members:

A lack of commitment to protect US IP around the world could impair future R&D investment and could discourage the capital investments. … A strong IPR framework should not be undermined by other government pricing and regulatory mechanisms that significantly devalue IP protection, or in some cases render it of little economic value.

PhRMA’s subsidiary recommendations for TPPA provisions include pro-monopolistic ‘linkage evergreening’ provisions that would require regulators of prescription drug quality, safety and efficacy (in TPPA nations that are not already so obligated) to notify a patent-holder of an impending generic entrant to the market. These obligations have already been imposed on Australia under the AUSFTA and have the aim of reducing competition and maintaining high prices for patented pharmaceuticals. PhRMA is further seeking ‘data exclusivity’ TPPA protections that prevent generic companies from using drug safety research data on patented medicines even after a patent has expired, thus again restricting generic entry to the market and therefore limiting consumer access to cheaper medicines. Such provisions may also have the effect of hindering the ability of governments to license
compulsorily a medicine for generic manufacture (at a low but reasonable compensation to the patent-holder) in a public health emergency.

The submission to the USTR by the US patented pharmaceutical company Novartis reiterates PhRMA’s sentiments in hoping that the TPPA could promote ‘cooperation among TPP signatories to ensure the quality, safety and efficacy of medicines’, and that the TPPA could lead to ‘enhanced cooperation among the TPP participants’ respective drug authorities’ as a way of preventing the entry of substandard medicines onto the market. There is again no mention of promoting enhanced cooperation or achieving ‘regulatory coherence’ on cost-effectiveness amongst TPPA participants, despite increased interest in promoting health technology cost-effectiveness assessment at the Federal level in the US.

Novartis also seeks TPPA provisions that require a drug manufacturer to provide regulatory certification of compliance with Good Manufacturing Practices (GMP). It wants a Medical Devices and Pharmaceuticals Working Group established to facilitate ongoing lobbying of other TPPA governments on issues affecting drug quality, safety and efficacy, including post-marketing pharmaco-vigilence, as well as a private sector advisory body.8

PhRMA and the USTR Special 301 Watch List
PhRMA’s submissions here also provide valuable insights on the USTR’s likely TPPA demands in the health and medicines sector. Section 301 of the US Trade Act of 1974, as amended,9 is ‘the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate, or deny U.S. rights or benefits under, trade agreements, or are unjustifiable, unreasonable or discriminatory and burden or restrict U.S. commerce’.10 PhRMA continues to recommend that, because of concerns about allegedly inadequate patent protection and pharmaceutical cost-effectiveness regulation, the governments of Australia, Chile, New Zealand, Peru and Vietnam be placed on the USTR’s Special 301 Watch List.11

These recommendations (set out below) signal PhRMA’s dissatisfaction with the already extensive concessions to pharmaceutical IMPs that the USTR has secured on its behalf in the raft of existing US FTAs. Their implications for the TPPA negotiations therefore need to be analysed against the backdrop of those agreements and the public health controversies that they created. Unless the non-US TPPA nations take a more positive pro-domestic industry or pro-public-good stance, their position on its health and pharmaceutical-related provisions is likely to be both defensive and disadvantageous.

Australia
PhRMA’s 301 Watch List submission clearly outlines its TPPA intentions
PhRMA and its member companies are concerned that: (1) Actions during the ongoing implementation of the AUSFTA have weakened intellectual property provisions; and (2) Existing and emerging issues affecting patient access to new medicines have not yet been adequately addressed.

PhRMA stated that the reforms undertaken under the AUSFTA were welcomed, but that there was ‘a range of remaining issues with the Australian Government’:

PhRMA notes that there is some disagreement between PhRMA member companies and the Australian Government regarding the likely impact of statutory price reductions on the listing of new, innovative medicines on the PBS, identified in a recent report to the Minister for Health and Ageing from the separate joint Government-Industry Access to Medicines Working Group which was created as part of the PBS reform process. PhRMA encourages the Australian Government to pursue policy solutions which will ensure that innovative medicines are not adversely affected by the PBS reforms.

The manner is which Australia’s cost-effectiveness assessment system for medicines was significantly altered as a result of USTR demands under the AUSFTA provides valuable lessons for other TPPA nations. Australia is unlikely to reopen those negotiations, as to do so will create regulatory confusion with AUSFTA provisions and significant public backlash. An analysis of how Australia’s PBS works will also provide valuable insights into one argument that US TPPA negotiators may make about ‘regulatory coherence’, linking the notion to prior attempts (such as the AUSFTA) to undermine regulatory systems that promote scientific assessment of health technology innovation.

The first point to note in confirmation of this argument is that the AUSFTA attempted to change the Australian PBS system fundamentally, despite the fact that the latter has unquestionable democratic legitimacy. The PBS (in its pre-AUSFTA form) was one of the few pieces of public policy in Australia that had been approved in a constitutional referendum by a majority of citizens in a majority of states. It had survived challenges to its implementing legislation in the High Court of Australia and been improved by a series of Federal governments over more than fifty years of intense health policy debate.

The core regulatory component of the PBS system remains Section 101: 3A and 3B of the Commonwealth National Health Act 1953. This, in broad terms, requires that pharmaco-economic experts on the Pharmaceutical Benefits Advisory Committee (PBAC) recommend PBS listing of a pharmaceutical submitted by its manufacturer after a positive determination of its comparative cost-effectiveness (or ‘health innovation’) in relation to alternative therapies (whether or not those involve drugs).
Australia’s PBS (even post the AUSFTA) remains highly respected nationally and internationally as a successful articulation of a scientific approach to ensuring maximum public benefit from government expenditure on medicines. Now solidly based on principles of the National Medicines Policy, it has been operating for over half a century to provide evidence-based, cost-effective and equitable access to health care for Australians.

Before a newly patented drug is listed under the PBS, it must obtain safety, quality and efficacy marketing approval from the Australian Therapeutic Goods Administration (TGA). Once this is done, the supplier may apply to have it listed on the PBS. That listing is determined by an independent statutory committee – the Pharmaceutical Benefits Advisory Committee established under the authority of the National Health Act 1953. The PBAC is required to consider applications against certain criteria set out in the legislation. Under Section 101 3B(a) of the National Health Act 1953, the PBAC cannot recommend a new drug for listing if it is ‘substantially more costly than an alternative therapy’ unless it ‘provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies’.

Yet, as a result of the AUSFTA, in August 2007 (after minimal parliamentary debate lasting no more than two weeks for both houses combined), the National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007 was passed, amending key provisions of the National Health Act 1953. The legislation effectively created two PBS pricing formularies: F1 comprises single brand, mostly patented and ‘innovative’ drugs, and F2 comprises multiple brand, mostly generic medicines. Reference pricing no longer occurs between the two formularies. Although these F1–F2 legislative changes to the PBS ostensibly facilitate lower-cost generic medicines into Australia, they appear substantially to reflect the position on the PBS articulated by US negotiators during the AUSFTA negotiations (and in the AUSFTA Medicines Working Group) on the ‘elimination’ of PBS reference pricing mechanisms.

The inclusion of USTR demands in the AUSFTA resulted in many other statutory changes and policy influences that impact on Australian pharmaceutical regulation. These may become templates for what the USTR seeks to obtain in other nations through the TPPA. One problematic area for the US, however, was the potential influence on pharmaceutical policy of the definitions of pharmaceutical ‘innovation’ inserted in AUSFTA Annex 2C.1. The Australian Minister for Trade at the time (Mark Vaile) stated in relation to Annex 2C of the AUSFTA that ‘the core principle that we both agree on in this area ... is recognising the value of innovation’. This begged the question as to what the term meant. Annex 2C.1 contained two competing definitions of pharmaceutical innovation. The first definition required valuing pharmaceutical innovation through competitive markets (the US approach). The second definition permitted the valuing of pharmaceutical innovation
through the operation of objectively demonstrated therapeutic significance (the Australian approach). It is to be hoped (should the issue arise) that Australian TPPA negotiators recommend a joint adoption of the Australian science-based definition of pharmaceutical innovation.

Fortunately the changes to the PBS arising from the AUSFTA did not alter the four key pillars of the National Medicines Policy. These are:

- timely access to the medicines that Australians need, *at a cost that individuals and the community can afford*;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

PhRMA also complained about Australia’s anti-evergreening legislation that was passed as a condition of AUSFTA implementation legislation coming into force. PhRMA additionally protested against the possibility that the Australian Patents Act 1990 might be amended to allow the manufacture of generic medicines for export to international markets where relevant patents have expired. Such a reform would provide support for the weakening Australian domestic generic manufacturing market and would not contravene TRIPS. PhRMA likewise claims that Australia’s data exclusivity protections are weak, although they are precisely what is required by the AUSFTA and by TRIPS.

**Chile**

It may be a telling foretaste of the USTR’s TPPA arguments that, according to PhRMA’s 301 Watch List submission, Chile has failed to establish an adequate system to protect proprietary pharmaceutical data as required by Article 17.10.2 of the US–Chile Free Trade Agreement. In particular, PhRMA considers that Chile has not moved far enough to protect ‘patent linkage’ and ‘data exclusivity’ requirements (explained in Chapter 11). PhRMA, for example, claims that a new sanitary decree issued by Chile’s Health Ministry for public comment in April 2008 would, if enacted, definitively foreclose ‘linkage evergreening’ because it stated explicitly that the Public Health Institute lacks authority to consider intellectual property – or any other criterion apart from safety and efficacy – in granting sanitary registrations. In comments to *El Mercurio* on 25 April 2008, Economy Minister Hugo Lavados noted that the government was ‘not happy about being on this list’, but added that ‘we’ve seen recently that views within the United States on this subject aren’t as strong as they were a while ago’.

**New Zealand**

New Zealand has a lot to lose in relation to health and medicines policies under the TPPA, having not yet been exposed to any US bilateral trade deal that contains anti-generic medicines or anti-cost-effectiveness provisions.
In its submission to the 301 Watch List Report regarding New Zealand, PhRMA states:

New Zealand’s Pharmaceutical Management Agency (Pharmac) continues to impose stringent cost containment strategies, and operate in a non-transparent, unpredictable manner, creating an unfavourable environment for innovative medicines ....

This is lobbying rhetoric, of course, as the Pharmac system is only about ensuring value for public expenditure of money on medicines by transparently rewarding medicines that are scientifically proven to possess ‘health innovation’ over comparable marketed products. The Pharmac system is a cost-effectiveness and government subsidy system for pharmaceuticals similar to Australia’s PBS. Scientific advice on comparative cost-effectiveness of new medicines is provided by the Pharmacology and Therapeutics Advisory Committee (PTAC). The Pharmac system has additional public health advantages through its closed-bid competitive tender process (a set amount, for example, being offered to the lowest bidder to provide medicines for a specified programme).

The New Zealand arm of the patented pharmaceutical industry has already begun lobbying the public in that nation to believe that the TPPA will offer New Zealanders ‘quicker access to new and expensive medicines’. A Researched Medicines Industry Association of New Zealand (RMI) newsletter has stated that the association expected that any trade deal between New Zealand and the US would entail reforms at Pharmac, ‘to align practices in New Zealand with other trade agreements’. This would be an unfortunate interpretation of ‘regulatory coherence’ under the TPPA as it would mean imposing on New Zealand the kinds of restrictions on rapid access to generic medicines and interference with the cost-effectiveness assessment of new patented prescription drugs that were strongly opposed in earlier US bilateral trade agreements (like the AUSFTA) as contrary to public health.

The RMI has Pharmac’s process of closed-bid competitive tendering particularly in its sights, because of its capacity to facilitate genuine competition and a realistic understanding of the marginal cost of production of newly patented pharmaceuticals. Will New Zealand be able to stand up to such pro-monopolistic pressure from the USTR in the TPPA negotiations? New Zealand Prime Minister John Key has already indicated that something significant will have to be traded for alterations to Pharmac as that is ‘not something we are looking at getting rid of’. If such a trade is made, however, will the New Zealand public be told exactly what was gained for each component of the Pharmac system that is altered?

**Peru**

PhRMA’s Section 301 Watch List submission demands that Peru have a five-year data exclusivity provision and the evergreening trade deal provisions
that link drug safety to patents status evaluation. The United States and Peru signed a US-Peru Trade Promotion Agreement in 2006, which PhRMA does not consider a model for future trade agreements. This is partly because it does not contain patent linkage provisions. The Andean Court of Justice (ACJ) has already issued several legal opinions forcing Andean Community members to refuse recognition of peripheral patents that in fact constitute ‘evergreening’ ploys to prolong royalties from a medicine by strategic claims of additional patent life (for example, over scientifically dubious second uses or new packaging or stabilising ingredients) when the main patent over its active pharmaceutical ingredient is about to expire.

Vietnam
In its Section 301 submission for Vietnam, PhRMA argues that:

Even with the significant reforms Vietnam has undertaken in recent years, there are still several areas which are of great concern to PhRMA, namely weak intellectual property protection, the absence of data exclusivity, patent linkage legislation, overly-stringent product registration and clinical trial requirements, a lack of legal status, and government reference pricing.

Vietnam’s failure to implement data exclusivity protections is said by PhRMA to be contrary to paragraphs 5 and 6 of Article 9 of Chapter 11 of the US-Vietnam Bilateral Trade Agreement. On the evergreening tactic of patent linkage, Vietnam has stated that ‘it is not appropriate to inject patent enforcement procedures into regulatory procedures’, and that ‘it is impossible to issue administrative rules or procedures to administrative agencies to enforce patents’.

PhRMA’s Watch List submission also attacks Vietnam’s mandatory system based on the Certificate of Pharmaceutical Product (CPP) or a Free Sales Certificate (FSC) and certification for Good Manufacturing Practices, as well as its requirements for quality tests for all new batches of vaccines and biological products before they are imported into the country. It further objects to the requirement that multinational companies conduct local clinical trials prior to registration of medicines.

Investor-State Provisions and Health Policy
The TPPA may have serious implications for public health in one particular area in addition to pharmaceutical regulation. This involves investor-state dispute resolution procedures. For example, Philip Morris, the tobacco company, lodged a submission with the USTR about the TPPA that outlined its concerns over Australia’s move toward plain packaging of cigarette packets. Philip Morris stated in this submission that the adoption of plain packaging of cigarettes would amount to expropriation of intellectual property rights in its trade mark, as well as ‘limit the freedom of commercial free speech,
significantly restrict competition and breach Australia’s obligations under the WTO TRIPs Agreement’. The tobacco company’s submission sought, as a response, an investor–state dispute settlement provision that would allow the company to sue governments for introducing tobacco regulation that it believed reduced the commercial value of its investment.

Investor–state provisions have now become a controversial part of bilateral investment treaties and investment chapters of FTAs; as of 2008, over 300 investor–state dispute settlement cases have been decided. Such provisions grant investors covered by them a right to initiate dispute-settlement proceedings for damages against foreign governments in a variety of different fora, including international arbitration proceedings and domestic courts. These proceedings can be commenced without having to exhaust local remedies. The lawyers appointed to such arbitral proceedings are appointed and paid at the behest of the parties, fostering a pro-plaintiff jurisprudence. Foreign investors can use this mechanism to undermine government legislation promoting, for example, sustainable development, environmental protection, and human health and medicines policy. For this reason it was vigorously resisted by Australia and excluded from the AUSFTA.

In its submission to the USTR on the TPPA, Philip Morris’s case for a multilateral investor–state provision maintained:

Notwithstanding PM’s general support for the TPP initiative, we are very concerned about the excessive legislative proposals pending in Australia and Singapore that threaten to violate existing bilateral and multilateral agreements with the US .... PM considers that availability of an investor state dispute settlement mechanism including the right of investors to submit disputes to independent international tribunals, is a vital aspect of protecting its foreign investments.

As the following examples show, moves to introduce a multilateral investor–state provision into the TPPA would have a potentially deleterious impact on the capacity of signatory nations to pass legislation implementing the precautionary principle in relation to public health risks.

**Investor–State Disputes on Health and Medicines Policy**

Investor challenges against government regulation have occurred under investor–state dispute settlement processes across a spectrum of public health and environmental legislation, including tobacco controls and packaging, toxic chemical bans, toxic gasoline additives, water protection, garbage disposal, food security, and hazardous waste disposal.

Of particular concern in the health policy context for many TPPA nations is the NAFTA investor–state dispute brought by the US firm Centurion Health Corporation for US$160 million alleging that ‘Canada is an unfair competitor in ways detrimental to US private sector companies in [its] monopolized health
Centurion claims the Canadian government is in breach of NAFTA Articles 1502 and 1503, which limit ‘state enterprises’ and ‘government monopolies’, and for which they are asking to be compensated. If this claim is successful, it will set an adverse precedent for those states that maintain a universal health-care system and uphold a public-health system ideology. A notice of arbitration was lodged in early 2009.

Not all NAFTA health and medicines-related investor–state claims have been made by US corporations. Apotex Inc., a Canadian generic pharmaceuticals firm, has brought a claim against the US under Chapter 11 of NAFTA alleging that a US court decision in favour of the Pfizer drug company violated NAFTA Article 1102 (national treatment) and Article 1105 (minimum standard of treatment under international law). The company also alleged under NAFTA Article 1110 that the decision expropriated Apotex’s investments in generic versions of the antidepressant Zoloft and was manifestly unjust. Apotex relied on the doctrine that a manifestly unjust domestic legal decision breaches international law and can be viewed as a substantive denial of justice. It further argued that the US had ‘no public purpose’ for interfering with its property rights and sought a total of US$8 million in compensation. Apotex has brought a similar claim involving US regulatory provisions concerning an abbreviated new drug development application for Pravachol and patents allegedly held by Bristol Myers Squibb. The US Department of State said that it will defend the case ‘vigorously’.

Investor–State Claims and the Precautionary Principle
The precautionary principle emerged in German regulatory policy during the 1970s and rapidly spread through the international policy arena as a philosophical challenge against policies that demanded an often unrealistic level of scientific certainty about risks before recommending or implementing public health and environment protection measures. One well known international enunciation of the precautionary principle is found in Principle 15 of the Rio Declaration on Environment and Development (1992): ‘Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.’ The Australian Intergovernmental Agreement on the Environment (IGAE) includes an almost identical definition of the precautionary principle in Section 3.5.1. The manner in which the precautionary principle applies often depends on the correlation between evidence of the nature and seriousness of the risk, as well as the kinds of remedies to be made available.

Approximately 40 per cent of legal challenges made under NAFTA’s Chapter 11 investor–state provisions have been against Canadian governmental legislation which can be viewed as applying the precautionary principle in relation to risks to public health and the environment. Examples include
Canada’s payment of US$13 million to the Ethyl Corporation because Canada banned the importation and inter-provincial trade on the suspected neurotoxin, MMT.48 Similarly, on 25 August 2008, Dow AgroSciences LLC, a US corporation, initiated Chapter 11 NAFTA proceedings for losses allegedly caused by a Quebec ban on the sale and certain uses of lawn pesticides containing the active ingredient 2,4-D.49 In March 2009 a notice of investor-state arbitration was lodged, with Dow alleging that there was no scientific evidence to support the ban on their product and challenging the Quebec government’s use of a ‘precautionary approach’ to managing environmental health issues as merely a political reaction rather than one based on empirical evidence. Dow is claiming damages of not less than US$2 million, plus costs.50

Investor-state claims are usually framed in terms of insufficient scientific evidence being available to justify public health or environmental legislation that has allegedly interfered with corporate investments. Yet such a situation of scientific uncertainty in the face of a threat to public health is exactly what the precautionary principle was created to deal with. If the standard of proof required to activate the precautionary principle was expressly recognised in the TPPA as lower than that required to activate the investor-state clause, then that may offer some mechanism for at least alleviating the ‘chilling effect’ that the threat of an investor-state dispute can have on public health and environmental protection legislation.

**US and Australian Politics on Investor-State Provisions**

Whilst the industry’s submissions to the USTR have sought a multilateral investor-state provision in the TPPA negotiations, senior figures in both the US and Australian governments seem not to support this. As Lori Wallach and Todd Tucker report in Chapter 3, President Obama is on record as saying that he intends to restrict investor-state claims through US-related trade deals. Obama also promised that he ‘will ensure that foreign investor rights are strictly limited and will fully exempt any law or regulation written to protect public safety or promote the public interest’.51

As Wallach and Tucker explain, US Democrats have also drafted an alternative trade agreement model (Bill H.R 3012), otherwise known as the Trade Reform, Accountability, Development and Employment Act of 2009 (the Bill). This has not yet been debated by the Congress. However, analysis of the Bill suggests that many of the concerns about public health and medicines policy that Australia and other nations in TPPA negotiations are likely to raise with the US (including the negotiation of investor-state provisions) would be addressed if this legislation were adopted. Amongst other things, the Bill reaffirms the WTO Doha Declaration on TRIPS and Public Health (adopted by the US in 2001). To date, however, the trade and investment policies of the Obama administration remain unclear.

The Australian Labor government has raised similar doubts. In answer to
an opinion editorial piece about the TPPA by the authors of this chapter in March 2010, the Australian Trade Minister at the time, Simon Crean, wrote:

There is an urgent need to correct the record after the publication of the article, ‘Big pitfalls and fewer freedoms in the new trade agreement with the US’ (Canberra Times March 15, pg9) by Thomas Faunce and Ruth Townsend … [T]he Trans-Pacific Partnership talks … are being held in Melbourne this week …. The goal of the negotiations is to find a pathway to a Free Trade Area of the Asia-Pacific. It is not a reopening of the FTA with the US that came into force in 2005 …. It is wrong to suggest that we are about to re-open obligations in relation to the Pharmaceutical Benefits Scheme that were settled in 2005. If there are to be any changes to the scheme in the future, it would be part of a domestic policy debate in Australia. It does not concern me what the US drug companies are pushing for because decisions about the scheme are made in the national interest by the Australian Government. The article also argues there is a threat to Australia from the introduction of an investor–state dispute settlement provision through the TPP. We will give our negotiating partners a chance to pitch their case on the issue, but let me say we have serious reservations about the inclusion of investor–state dispute settlement provision in this agreement. We do not want new layers of red tape under the guise of trade liberalization. Australian negotiators will make this clear at the Melbourne meeting which concludes today. Simon Crean, Minister for Trade, Parliament House

Conclusion
The PhRMA submissions on the TPPA and the Section 301 Trade Watch List analysed above show that the US pharmaceutical industry, through the USTR, will be seeking a variety of provisions related to public health and medicines policy that are monopolistic and protectionist in nature. No other TPPA nation appears to have an industry group likely to be pushing for countervailing proposals in the health and medicines sector. The US industry also aims to inhibit market entry for generic medicines by tying up the drug safety regulatory agencies of other nations in red tape, as well as undermining the evidence base of cost-effectiveness pricing schemes.

In the TPPA negotiations, the USTR is likely to meet strong resistance from the public in Australia and New Zealand to any inclusion of their democratically supported systems for assessing the cost-effectiveness of medicines.

In the interests of regulatory coherence and promotion of the legitimate business interests of their small and medium enterprises (such as biotech start-ups and generic medicine firms), the non-US nations negotiating the TPPA should instead demand reciprocal changes in the US system for regulating medicines. One such example would be to require the US medicines regulatory system to recognise (as the USTR did in Annex 2C
of the AUSFTA) that pharmaceutical innovation can and should be based on scientific assessment of comparative cost-effectiveness as well as on the operation of competitive markets (the latter requiring strong anti-monopoly laws). Non-US TPPA negotiators should likewise demand, in the interests of regulatory coherence, the inclusion of a provision that requires the US to support the establishment of a Federal agency to advise on the cost-effectiveness of medicines and remove any legislative provisions that inhibit the creation of a Federal PBS-type system for assessing the cost-effectiveness of health technology in the US. This would create a level playing field for the entry of generic manufactured pharmaceuticals produced by non-US small and medium enterprises into the US market.

Non-US TPPA negotiators should also argue for a provision that, even if a drug is in patent in their countries, it can be manufactured for sale in other TPPA countries where it is out of patent. This, too, would greatly assist non-US small and medium enterprises in the generic medicines sector. The TPPA should expand the compulsory licensing exceptions that allow drug patents to be broken (with reasonable compensation) in a public health emergency. Non-US TPPA negotiators should demand that the TPPA permit and require the US Federal government pass laws to reintroduce the research use exemption that allows publicly-funded university researchers to experiment with the chemistry of drugs that are in patent without having to pay royalties.

Some general recommendations can also be made about the process to be followed in the negotiations. First, all the stakeholder groups involved in and representing public health and medicines interests, including consumer advocates, should be informed and invited to participate in the process beyond just the opportunity to supply a written submission. Second, it is critical that detailed minutes be kept and published, recording TPPA health and medicines-related negotiations, including what was traded off for what. These could be particularly important in later dispute resolution proceedings.

Finally, the right of investors to use investor-state dispute mechanisms to directly challenge the right of democratically elected governments to protect their own public health, environment and medicines policy undermines the sovereignty of the state and threatens its security. There must be no multilateral investor-state dispute resolution system included in the TPPA; to do so would trigger an immediate, highly controversial public debate in Australia, similar to that surrounding the AUSFTA. If an investor-state provision is included, the standard of proof required to activate it should be clearly distinguished from that applying to public health legislation based on the precautionary principle; no damages should be awardable without domestic remedies being exhausted; and arbitral decision-makers must be required to take into account domestic constitutional and legislative public health protections. If necessary, non-US TPPA nations should make unilateral interpretative declarations to this effect before signing a TPPA.

10. PUBLIC HEALTH AND MEDICINE POLICIES

7 Submission of PhRMA to USTR, Docket ID: USTR-2009-0041, p. 5.
13 Mark Vaile, Deputy Prime Minister and Minister for Trade, Joint press conference at the office of the United States Trade Representative, Washington, DC, 7 March 2006.
14 PhRMA ‘Special 301 Submission 2009, p. 115.
15 Ibid.
22 PhRMA, ‘Special 301 Submission 2009’.
April 2010.

25 Submission of Philip Morris International to USTR TPPA submissions.


33 Submission of Philip Morris International.


42 Ibid.


46 Ibid.


52 Minister for Trade, Simon Crean, Canberra Times, 17 March 2010.

53 PhRMA, Special 301 Submission 2009, p. 52.