# Advancing Global Public Health Standards: A Precarious Balance Five Pivotal WTO Cases

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#### Abstract

This paper examines five World Trade Organization (WTO) disputes and their related settlements to explore the primacy of public health concerns in trade-related matters. It asks first, whether the WTO successfully manages the interface between trade-related questions and global public health concerns? Second, we explore if the WTO decisions reflect strong and effective public health standards? The five cases considered include the French asbestos ban, the EU and US' restriction of world access to generic drugs, the US-Indonesia dispute related to clove cigarettes, the US-EU disagreement over hormones in beef and Thailand's attempts to introduce plain packaging for alcohol products. This paper concludes that, despite moments of hope that the WTO might be more than just a trade organisation, the WTO's major focus is trade, with public health occupying a very small role in its decision making in judicial culture. Even when a world consensus exists among scientific and policy experts that a product is detrimental to human well-being, member states' trade interests are given greater weight than the immediate need to protect citizens' health and raise global health standards - access to generic drugs, protection against carcinogenic material such as asbestos and restriction on cigarette packaging. WTO decisions appear to be made in a legal "black hole" without linkage to human rights legal protection of the individual and the collective. Because the WTO jurisprudence is decided on the case by case basis, frequently the decisions of WTO panels while technically correct they fail to have a larger view of global public health issues. The paper concludes that the WTO is in need of rebalancing its trade vs. health foci, and of heightening the importance placed on public health, in order to address the needs of a 21<sup>st</sup>-century world and to gain global citizens' trust. Against a weak trade vs global health regulatory regime, the paper illustrates how compliance with WTO decisions in the area of global public health leaves a great deal of room for foot dragging by governments which emboldens big Pharma and other global actors to use the WTO's commercial norms to armour plate themselves against progressive change. Hence progress towards strengthening global health standards is unlikely to come from the WTO's current culture of jurisprudence.

## Advancing Global Public Health Standards: A Precarious Balance Five Pivotal WTO Cases

In 2001, the World Trade Organization (WTO) took the unprecedented step of allowing the French government to ban the importation of asbestos. This ban occurred under the little-used Article XX of the General Agreement on Tariffs and Trade (GATT), which allows exceptional public health restrictions on trade. Just two years later, the head of the World Health Organization (WHO) launched an amendment to the Agreement on Trade-Related Intellectual Property Rights (TRIPS), to allow poorer countries with insufficient capacity for pharmaceutical production to import generic medicines under compulsory licensing provisions. These decisions raised global publics' hope that public health concerns would predominate over trade-related interests. This early optimism receded, however, in the face of other decisions less friendly to establishing global public health standards.

Many experts see the WTO as *more than just a trade organisation*, since it can take public interest issues such as health, the environment and standard setting into account in decisions of its dispute resolution panels. So its mandate is more than being the world's global governance institution charged with strictly advancing a far-reaching trade agenda. There are many grey areas that give the opportunity for the WTO to give leadership and direction to the global public health trade liberalization interface. Morals, for example, were taken into account recently in the dispute over Canadian seal products. In 2009, the EU banned the promotion and marketing of seal products, leading to a WTO dispute with complainants Norway and Canada. The Panel and Appellate Body agreed, albeit for different reasons, that some of the ban's elements were discriminatory, but deemed the measure to be "nevertheless provisionally justified under the public morals exception" (Howse, Langille & Sykes, 2014). But given that moral concerns are deemed reasonable exceptions to WTO regulations, why are so few considered under Article XX(a)? There is no definitive answer to this highly pertinent question. But boldly, is it not morally and commercially wrong to sell cigarettes – a product that kills around six million people per year, and half of all its users (WHO, 2015b) – as though they are ordinary consumer goods?

The upholding of the French asbestos ban establishes that trade issues can be debated from a wider public health lens. In order for concerns of health impacts on the one hand, and trade interests on the other, to be treated more evenly, however, the WTO must change its approach – yet for this to happen, major public support is needed. Unfortunately, the WTO's legal culture is far from taking the first steps necessary to elicit such a change. The puzzle is that, as Trebilcock, Howse and Eliason (2012) and Labonte (2014) espouse, the WTO does not have an independent view of public health standards: as framed by its founding documents, it merely mediates disputes based on individual complaints advanced by member states. This leaves a very large grey area for corporations and governments to sidestep the heart of the matter, namely striking a new balance between trade and health linkages.

We review five cases and their related WTO decisions to explore the primacy of public health concern in trade-related matters.<sup>1</sup> These cases include the French asbestos ban, the EU and US' restriction of world

<sup>&</sup>lt;sup>1</sup> From a methodological perspective, we examined all cases during the last 20 years that touched upon health. The five cases chosen are most illustrative of the adjudicative challenges that the WTO faces in managing health-related issues. The criteria that informed our choice include jurisprudential importance, scale of public benefits and/or harms, and current relevance to ongoing debate and discussion. Initially we examined 13 cases. While other experts' choices would likely differ, many of our top five would likely call appear on their list as well.

access to generic drugs, the US-Indonesia dispute related to clove cigarettes, the US-EU disagreement over hormones in beef and Thailand's attempts to introduce the plain packaging of alcohol products. These five cases are identified in Figure 1.

In revisiting these cases, we examine the costs-and benefits associated with each WTO decision and assess whether we are making progress in terms of the importance placed on health in WTO judgments. We explore the following questions. First, does the WTO successfully manage the interface between trade-related questions and global public health concerns? Second, do WTO decisions reflect strong and effective public health standards?

# Public Health v. Trade: Five Major WTO Cases

Figure 1, below, briefly outlines the five cases that we will examine.

# Figure 1

	Pitting Public Health Against Trade: Five Major WTO Cases							
Case Name and No.	Date (Request for Consultations, Panel Report & Appellate Body Report - MM/DD/YYYY)	Complainant	Respondent	Topic/Issue	General Discussion			
Measures Affecting Asbestos and Products Containing Asbestos <u>DS135</u>	RfC: 05/28/1998 PR: 09/18/2000 ABR: 03/12/2001	Canada	European Communities	Asbestos	<ul> <li>Impact of the asbestos ban in Europe</li> <li>Asbestos use in developing countries</li> <li>Contradictory Canadian asbestos policy</li> <li>Limited policy success re. international asbestos trade</li> </ul>			
Measures Affecting the Production and Sale of Clove	RfC: 04/07/2010 PR: 09/02/2011 ABR: 04/04/2012	Indonesia	United States	Smoking	• WTO push to liberalise trade v. international consensus that cigarette use should be reduced			

Cigarettes <u>DS406</u>					<ul> <li>WTO decision against the clove cigarettes ban v. the FCTC goal of protecting people from tobacco use</li> <li>Debate about "like" products</li> </ul>
Generic Drugs and Restrictions by Major WTO Members <u>DS 408/409</u>	RfC: 05/11/2010	Brazil, India, Egypt	European Union, The Netherlands, US	Generic Drugs	<ul> <li>Patent and intellectual property rights</li> <li>Tentative and limited WTO push towards greater generic drugs access</li> <li>Contradictory US and EU stance on generic drugs</li> </ul>
Measures Concerning Hormones in Meat and Meat Products <u>DS26</u>	RfC: 01/26/1996 PR: 08/18/1997 ABR: 01/16/1998	United States, Canada	European Communities	Meat	<ul> <li>"Ideal" level of scientific standards for food products</li> <li>US/Canadian refusal to follow the precautionary principle</li> <li>Where the onus of proving higher standards should lay</li> </ul>
Thailand Alcohol Warning Labels	The WTO was never formally engaged in this dispute	Australia, EU, and others	Thailand	Alcohol	<ul> <li>Thailand's attempt to introduce warning labels on alcohol</li> <li>Protectionism from countries like Australia</li> </ul>

# Case 1. Asbestos Asbestos: A 'Win' for Public Health

2001 marked a significant period in regards to international trade: in this year, public health policy was given an unusually auspicious place in the settling of a world trade dispute when the Appellate Body of

the WTO upheld a 1998 French ban on asbestos under Article XX(b) of GATT 1994, deeming the ban "necessary to protect human...life or health" (WTO, 2015b). The World Health Organisation (WHO) acknowledges asbestos as one of the most prevalent occupational carcinogens, estimating that well over 100,000 people die per year of asbestos-related diseases, or ARDs (Asbetstos Timeline, 2016).

The French ban on the importation and use of asbestos, while a salute to public health, ignited disputes amongst asbestos-producing countries in the EC and Canada. The EC and Canada fought the ban within the Dispute Settlement Body of the WTO between 1999 and 2001. The EC's and Canada's case revolved around the issue of "like products," with regards to asbestos chrysotile, polyvinyl alcohol fibres (PVA) and cellulose fibres. In yet another gesture towards protecting health, the Appellate Body disagreed that the products were "like." It upheld France's ban, and evoked the conditions of Article XX(b) of GATT 1994 in so doing.

The Appellate Body's decision was seen by many as a landmark victory in the fight to uphold public health concerns in global trade debates. Indeed, it was the first time that Article XX had been effectively used to protect public health in a trade infringement matter. Further, new applications of all forms of asbestos were officially banned across the EU on January 1<sup>st</sup>, 2005, and a further 28 countries worldwide upheld some form of the ban (Kazan-Allen, 2015a). While the ban has successfully reduced asbestos' production and use within the EU's member states, however, it has not led to the complete demise of the EU asbestos market (Vogel, 2005). If anything, the market and demand for asbestos continues to grow annually. And due to the nature of asbestos, there are long-running consequences that are still felt today. We examine the nature of the asbestos ban "victory" by considering its effects within the EU and whether the EU ban has affected asbestos use on a global scale.

#### Success Stories in the Battle for Global Standards

Significantly, international asbestos trade norms and agreements rose out of domestically placed bans challenging producers rights, forcing many producers to close operations or dramatically reduce production Some initial embargos were introduced long before the WTO dispute, with the first successful asbestos-related lawsuit occurring in 1967 in the UK (Asbestos Timeline, 2016.). Denmark banned all forms of asbestos, with certain exceptions, in 1980. Tougher asbestos policies were also introduced by Canada, US and France in the 1980s onward (Kazan-Allen, 2015b). Johns Mansville was forced into bankruptcy by successful class action law suits by former employees. Initial consumer and worker battles for restitution and compensation based on scientific evidence succeeded in convincing legislators to ban asbestos domestically. These hard-fought decade-long legal battles in domestic US courts particularly against Johns Manville in 1982 and other companies were key to establishing the international norms that are recognised today, such as the EU-wide prohibition of asbestos use.

The lack of a fully enforceable international agreement remains an international failure in eliminating asbestos-related disease .In the global South such as India and China as well as Russia, asbestos is widely used in construction and in buildings. So while progress has been made in the global North, asbestos sales and exports continue without restriction in much of the globe.

### Seeking Global Consensus: Other Examples

The battle to ban asbestos use across more nations remains a priority. In the public mind asbestos is an issue that has clear class aspect to it exposing men and women in the construction and demolition trades. This does not mean that comprehensive and legally enforceable international agreements in support of public health are impossible. The Stockholm Convention on Persistent Organic Pollutants (POPs), for instance, is a prime example of a successful fight for global standards (Stockholm Convention, 2008). The 2001 Stockholm Convention, which has 152 signatories, was established after a large number of countries banned DDT – a chemical that is highly destructive for human and animal health – in the 1970s and 80s (UNIDO, 2004). It is seen as victory over neoliberal economic policies that minimize the need for international global governance health protection. This international norm includes restrictions on the use of the insecticide, with DDT only permitted for specific usage. While DDT is still used in some countries, such as North Korea, India and China, mainly to control malaria-carrying mosquitos, its application has decreased dramatically as a result of the convention. In this case, beneficial international norms developed in response to a groundswell of domestic bans.

Voluntary multilateral agreements are not always effective, however, as is evidenced by the International Whaling Commission's (IWC) attempts to control whale hunting. The IWC has 88 members. It has struggled, however, to stem the global hunting of whales. Russia and Japan, for example, continue to hunt and kill these mammals (Hurd, 2012). The IWC's aims are targets rather than standards. Ultimately, when international agreements are unenforceable "buy-ins" rather than mandatory targets, countries may see them as a luxuries requiring excessive effort and resources to be achieved. Optional voluntary international agreements preferred by global multinationals often result in lax, sometimes non-existent, policing and compliance. For many experts such as the American Conference of Industrial Hygienists (ACGIH), compulsory standards are more effective in terms of producing a consensus on global standards. but they require political will, time and leadership as well as luck that is highly difficult to achieve and only infrequently. (Foundation for Occupational Health and Safety, 2016)

#### The EU and the WTO at Loggerheads

It is widely agreed among occupational and environmental health professionals that there is a compelling case for a worldwide ban on asbestos. According to a recent EC statement, up to 47,000 EU citizens will die yearly from asbestos-related diseases (ARDs). This number is 50% higher than previously thought (European Economic and Social Committee, 2015). Indeed, Kameda et al. (2014) state that "Europe can thus be characterized as the historical global centre of asbestos use and the current global centre of reported asbestos-related diseases" (para. 18). They also reveal that 14 of the 17 countries analysed that used high or very high levels of asbestos between 1920 and 1970 have experienced similarly augmented asbestos-related mortality rates (Kameda et al., 2014).

It was hoped that the implementation of the French ban, and the fact that it was upheld by the WTO, would lead other states to follow suit. Indeed, Bill Jordan, General Secretary of the International Confederation of Free Trade Unions, stated that "The EU's action will encourage unions in many other countries to press for similar measures to phase out the use of white asbestos" (Kazan-Allen, 2000, para. 2). Unfortunately, this has not been the case, and many developing states are using asbestos at higher levels than ever before. While most key asbestos markets of the 19<sup>th</sup> and 20<sup>th</sup> centuries, such as Europe,

the US and Canada, have registered a massive decrease or outright ban of asbestos in buildings, this reduction has been offset by growing asbestos consumption in developing countries such as China, India and Thailand (Vogel, 2005).

### **Every Country for Itself**

What good is the French ban if other countries are ignoring it? Part of the issue is that, despite the WTO's ruling, there are still no set international standards regulating asbestos production and use. This allows countries to set their own rules, permitting certain states to continue consuming asbestos despite the fact that its carcinogenesis effects are well-established by scientist. As Le et al. (2011) contend, "...the 'lessons' of other countries are not easily learned" (para. 18). Such lessons have clearly not been taken into account by many developing countries that still produce and/or consume a considerable amount of asbestos. Figure 2 and 3 shows this hazardous product's top five consumers and producers, and their rates of consumption and production:

Asbestos Consumption by Country (Metric Tons)								
Country 1995		2000	2005	2010	2012			
China	447,000	382,315	515,000	614,000	531,000			
India	115,739	145,030	255,000	426,000	473,000			
Russia	649,580	449,239	315,000	263,000	196,000			
Brazil	182,129	172,560	139,000	189,000	168,000			
Indonesia	50,231	42,877	23,300	124,000	162,000			

# Figure 2

Source: United States Geological Survey (http://minerals.usgs.gov/minerals/pubs/commodity/asbestos/)

#### Figure 3

Asbestos Production by Country (Metric Tons)								
Country         1995         2000         2005         2010         2012								
Russia	685,000	750,000	925,000	1,000,000	1,000,000			
China	511,835	315,000	520,000	400,000	420,000			
Brazil	210,352	229,332	195,000	302,257	306,500			

Kazakhstan	160,829	233,200	355,000	214,100	241,200
Canada	524,392	309,719	200,000	100,000	-

Source: United States Geological Survey (http://minerals.usgs.gov/minerals/pubs/commodity/asbestos/)

The tables above make for disturbing reading: outside of Russia and Brazil, asbestos consumption by states increased from 1995 to 2012. Indonesia tripled, while India quadrupled, its use of this toxic material. A similar pattern emerges when asbestos production is considered: while Canada and China reduced their production levels considerably, Russia, Brazil and Kazakhstan increased theirs, with Russia's production rates rising dramatically. Clearly, the WTO decision had little impact upon the consumption and production rates of a number of countries other than Canada. The statistics above demonstrate that the widespread hope that the EU ban on asbestos, as well as the WTO's support of this decision, would reduce global asbestos use was unfounded.

## Winners and Losers: Still a Zero-Sum Game

As an asbestos producer, Canada historically exported the majority of its asbestos to developing countries in Asia and Latin America. In Canada asbestos has been barred from use in construction (Vogel, 2005). It is clear that, while Canada recognizes the dangers of asbestos exposure, as reflected in its policy of limiting and regulating the product's domestic use, it was only recently during the PQ Government in Quebec that the remaining asbestos mine was closed in 2012.

Although the Government of Canada recognizes that "...breathing in asbestos fibres can cause cancer and other diseases" (Government of Canada, 2015; Carex Canada, 2015), this country played a key role in preventing asbestos from being placed on Annex III of the 2011 Rotterdam Convention, which would have forced exporting states to warn importing countries of the product's associated health hazards (Rennie, 2011). Ottawa is actively considering a ban on use of asbestos in federal construction industries while domestic pressure is mounting to place a ban on all asbestos products (Grant, 2016).

List of Countries That Have Banned Asbestos							
Algeria	Denmark	Israel	Netherlands	Slovenia			
Argentina	Egypt	Italy	New Caledonia	South Africa			
Australia	Estonia	Japan	Norway	Spain			
Austria	Finland	Jordan	Oman	Sweden			
Bahrain	France	Korea (South)	Poland	Switzerland			

### Figure 4

Belgium	Gabon	Kuwait	Portugal	Turkey
Brunei	Germany	Latvia	Qatar	United Kingdom
Bulgaria	Greece	Lithuania	Romania	Uruguay
Chile	Honduras	Luxembourg	Saudi Arabia	
Croatia	Hungary	Malta	Serbia	
Cyprus	Iceland	Mauritius	Seychelles	
Czech Republic	Ireland	Mozambique	Slovakia	

<sup>1</sup> Exemptions for minor uses are permitted in some countries listed; all countries listed, however, have banned the use of <u>all types</u> of asbestos.

Source: International Ban Asbestos Secretariat (http://ibasecretariat.org/alpha\_ban\_list.php)

Upholding France's asbestos ban has proven a localized success for the EU, as well as states around the world that want to maintain high public safety standards. The WTO's decision gives states the opportunity to ban asbestos without infringing upon trade rights the classic trade-off under global neoliberalism. Countries who have joined the ban (Figure 4) will continue to experience the ramifications of previous asbestos exposure and the longer latent effects for ARDs. Countries that continue using asbestos will face their own slow epidemic of ARDs, and little can be done to stop them except domestic pressure. Despite the precedent with the EU, the WTO appears powerless to independently extend GATT Section XX protection by prohibiting exports, or restricting asbestos imports for the citizens of asbestos-consuming nations. As yet there is no enforceable precedent-setting global standard with respect to the exporting of asbestos. So far there is no resolution of how public health controls might be implemented without limiting the commercial rights of countries to sell without restriction. Today there is still no global ban on the production, use and sale of the asbestos.

# Case 2. Cigarettes US v. Indonesia: The Battle Over Clove Cigarettes

Tobacco consumption presents significant health risks. It is estimated that tobacco's toll in the 20<sup>th</sup> century is 100 million deaths and one billion deaths are projected for the 21<sup>st</sup> century (Reddy, 2013). These enormous risks have led international organisations to attempt to reduce cigarette and tobacco use across the globe. This push for tighter smoking restrictions, however, inhibits the free trade of tobacco products, and subsequently leads to WTO involvement. In this section, we focus on attempts by international organisations to implement higher public health standards related to smoking. We consider a WTO case from 2010, involving the US and Indonesia, that illustrates this organisation's involvement in the cigarette dispute.

Unlike many other products under WTO scrutiny, smoking provides no health benefits. Malone (2010) refers to cigarettes as being among the deadliest consumer products, while the WHO states that tobacco products are the only legally available commodities where up to half of users can be killed when they consume them as regularly as suggested by the producer (WHO, 2015c). Understandably, international organisations have increasingly pushed to usher in the "tobacco endgame".

A smoke-free world is the tobacco endgame's ultimate goal, as embraced by a small but growing number of countries, including Finland, New Zealand and Bhutan, the latter of which banned the sale of all tobacco products in 2004. But reaching this target involves a number of smaller interim objectives. These goals include de-normalising tobacco use, rendering the tobacco industry more liable and reducing its profitability (Reddy, 2013).

The tobacco industry's liability has, in fact, increased. A prime example of this is a 2008 lawsuit filed against RJ Reynolds by Cynthia Robinson, whose husband died of lung cancer in 1996. Robinson's case was based on her view that her husband's death was caused by his cigarette use and that RJ Reynolds "...was negligent in not informing him that nicotine is addictive and smoking can cause lung cancer." Robinson was originally awarded \$23.6 billion by RJ Reynolds in 2014 (Capelouto & DiGiacomo, 2014). This court decision that found RJ Reynolds liable indicates that tobacco companies are starting to be held accountable for their actions, or inaction, and for the impact their products have on public health.

## **Cigarettes and Public Health: Setting a Legal Standard**

A number of countries are attempting to achieve the endgame goal. New Zealand and Finland, for example, are aiming for a smoke-free country by 2025, and a tobacco-free country by 2040, respectively (Reddy, 2013). Bhutan as noted above, banned all tobacco products in 2004 and has implemented tough anti-tobacco laws, including jail time for those caught breaking the law (Parameswaram, 2012).

The pursuit of a tobacco-free world is supported by the presence of the WHO's 2008 Framework Convention on Tobacco Control (FCTC) bitterly fought by big tobacco corporations. The FCTC was created by WHO members who recognised the dangers of smoking and tobacco use, and, for the first time, used the WHO's treaty-making powers to implement a public health agenda (Brundtland, 2009). Even if it is only hortatory and regarded by many legal experts as soft law, it represents a significant step forward. The convention is important none the less because it has at its centre the idea of harm reduction. The FCTC is the first international tobacco control treaty created under the jurisdiction of the WHO, with Article 3 stating that "the objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke" (WHO, 2005). With 168 signatories to the agenda, it is clear that the FCTC's messages and goals have gained worldwide support at a time were deregulation and minimal global governance standards is often seen as the norm.

The FCTC has helped countries implement policies that restrict cigarette and tobacco consumption. China, which banned tobacco advertising and smoking in public places, provides a good example. According to Jacobs (2014), the FCTC supported China in this country's creation of gender-specific policies, where women and men are targeted differently in order to effectively reduce tobacco use. China experimented with advertising bans in the 1990s, but had little success until 2010 with the implementation of the "Protect Women from Tobacco Marketing and Smoke" initiative. This initiative banned advertisements that implied a link between female beauty and smoking. It also prohibited smoking in public places: because 97% of smokers are men, it was deemed that women faced undue risk and exposure to second-hand smoke (Jacobs, 2014). The FCTC's successful attempts to realize the tobacco endgame demonstrate that there is a public health consensus in regards to tobacco use and control. Multinational tobacco corporations, of course, are not part of this consensus and have become global adversaries with deep pockets.

#### **Smoking Bans and Trade**

China's abovementioned domestic bans, which do not prohibit tobacco products at the level of trade or infringe upon patent restrictions, are fairly safe from the long arm of the WTO's high court. China is at the beginning of ginger phase of banning smoking in public places including restaurants. So while they still have a long way to go it is clear that in railway stations and airports and many restaurants Chinese are complying slowly to the new regulator. Policies that infringe upon importation or the trade rights **of** tobacco producers, however, will probably face WTO action. So far in advanced economies big tobacco has been losing in the courts. This is come about because of the of the comprehensive tobacco control measures associated with associated with the FCTC and strong de-normalizing measures at the domestic level. Plain packaging has a clear message of being labelled a socially pariah kind of activity.

The WTO, as a trade-based organisation, weighs public health concerns lightly and only through the lens of trade. This means that national treatment and the principle non-discrimination are fundamental precepts that cannot be encroached upon for reasons of public health, however valid they may be as policy goals. Consequently, WTO regulations could prevent or weaken attempts to implement policies that help achieve health-related goals with regards to tobacco. This is clear from the clove cigarettes ban dispute between the US and Indonesia.

In the US v. Indonesia case, the US banned clove flavoured cigarettes, but not menthol, in an attempt to reduce youth smoking (WTO, 2014). This case centred on the issue of whether menthol and clove cigarettes are "like products." The US argued that they are not like products because they are meant for different markets, claiming that adults trying to satisfy nicotine addiction use menthol cigarettes, while younger people smoke clove cigarettes for experimentation (WTO, 2014, p. 5-6). The US believed the ban should be upheld, and argued that restrictions on clove cigarettes would reduce youth smoking.

Both the WTO Panel and the Appellate Body found, for different reasons, the products to be "like." They therefore found the US measures to ban clove cigarettes were discriminatory and sided with Indonesia (WTO, 2014) effectively a decision to liberalize the importation of tobacco products. Ultimately, the US asked that the WTO Dispute Settlement Body (DSB) refer the matter to arbitration consistent with Article 22.6 of the Dispute Settlement Understanding, which is consistent with the WTO approach to adjudicating trade disputes. The US and Indonesia went to negotiate a "side" agreement, whereby clove cigarettes' importation into the US was restricted in exchange for US concessions to Indonesia in other trade areas. This does not negate the fact, however, that the WTO decided against a public health measure

in favour of trade which would increase the supply of cigarettes. The case illustrates that the WTO, missed an opportunity to strengthen global public health standards. In this particular instance both parties to the agreement came to a settlement that let everyone continue smoking and nothing to restrict the trade in cigarettes and tobacco products.

In the case of clove cigarettes, protectionism and self-interest were paramount. The US banned clove, but not menthol, cigarettes. The US also claimed that it was initiating the ban uniquely for health purposes. It is worth noting, however, that the main producer of clove cigarettes was Indonesia, while the majority of menthol cigarettes are produced in the US (WTO, 2014). Further, if the aim was purely to promote health, then why did the US not ban menthol cigarettes as well? The US claims that it had not conducted the appropriate research to ban this product, yet it is fairly well known that menthol cigarettes, like non-menthol cigarettes, are dangerous to public health. So American tobacco interests prevailed in minimizing any further restriction on the sale and consumption of cigarettes. In fact, on March 13<sup>th</sup> of 2012, Brazil successfully banned menthol cigarettes along with all other flavoured tobacco products, thereby avoiding WTO opprobrium (Framework Convention Alliance, 2012). The US ban on clove, but not menthol, cigarettes represents a protectionist move for multinational tobacco companies, rather than a priority on the health of the American public. It is hard to reconcile the effective interventions of the US Surgeon General on the dangers of smoking with the pro-business posture of the US Trade Representative to the WTO on behalf of big tobacco.

## **Case 3. Generic Drugs**

# The 2003 Decision to Limit Trade-Related Aspects of Intellectual Property Rights (TRIPS), and the 2010 Dispute Between India, the EC and the Netherlands

The generic drugs debate highlights a fundamental paradox within the WTO in regards to public health. It is difficult to reconcile the objectives of neo-liberal trade liberalization and patent protection with the promotion and protection of health. In October 2015 MSF issued this statement related to the TPP trade related negotiations: "MSF expresses its dismay that TPP countries have agreed to US government and multi-national drug company demands that will raise the price of medicines for millions necessary by unnecessarily extending monopolies and further delaying price lowering generic competition." The trade-focused WTO fosters a system in which it is difficult to obtain life-saving or sustaining drugs, due to tough patent regulations and legalized monopoly enjoyed by big Pharma. In a recent report the United Nations highlighted the growing medical crisis in the global South because so little research and money is spent by Western pharmaceutical giants on finding medical solutions to common global South diseases such as Guinea worm disease.

In theory compulsory licensing permits countries to sidestep patent laws under conditions of national emergency, as per the WTO's 2001 Doha Declaration (Odell & Sell, 2006). The Doha Declaration on Trips and Public Health confirms that countries are free to determine the grounds for granting compulsory licenses for a public health emergency. The US wanted to limit the list of diseases that were subject to compulsory licenses. The 2001 Doha Declaration, however, which emphasized the ability of TRIPS member countries to access necessary medications despite patent rights and did not specify diseases that were or were not exempt (Abott, 2005). The Declaration's broad language and lack of specificity

ultimately meant that it lacked applicability. Additionally, compulsory licensing was only permitted in a country's domestic market, meaning that generic drugs could not be imported under the regulation (Odell & Sell, 2006). Unless a country had the capacity to produce its own drugs, it could not take advantage of the measure.

A second issue with the compulsory licensing measures was that even countries that could manufacture the drugs domestically were limited due to sanctions promoted by the measures' opponents. This is highlighted by Thailand's 1997/98 attempt to use compulsory licensing to produce AIDS drugs (Odell and Sell, 2001). Succumbing to US sanctions, Thailand abandoned its efforts. This demonstrates the limited nature of the WTO's support for broader generic drug production and trade. It also shows how the push for trade liberalisation led to increased patent protection for brand named drugs. In the recently concluded TPP, for instance, global pharmaceutical companies use the negotiations to increase patent protection for themselves. The generic drugs debate reveals the power of big Pharma to restrict access to lower-priced generic drugs despite the role of NGOs such as Oxfam and others in mobilization of public opinion to broaden access to these life-saving drugs.

Another significant event in the generic drugs debate was the 2005 permanent waiver to Article 31(f) of the TRIPS Agreement: this waiver allowed WTO members to issue compulsory licences to export patented medicines to countries that did not have the capacity to produce the drugs themselves (Vandoren & Eeckhaute, 2005). The waiver's limitations, however, are significant: how much has it impacted, for example, the issue of countries being deterred through the implicit or explicit threat of sanctions. Mitchell and Voon (2009) point out that by 2009, only Rwanda had taken advantage of the new compulsory licensing regulations. Reichman (2009) adds that the regulations were only used once due to "...cumbersome procedures" instituted by some governments, as well as with the WTO (p. 5). In hindsight, this landmark battle over generic drugs, like other hard-fought WTO disputes against the top-down strictures of global neoliberalism, in retrospect seems to be only a symbolic rather than a substantive course changing victory.

Indeed, the new compulsory licensing measures, in several ways, present more of a cost than an opportunity. Many countries do not invoke compulsory licencing out of a fear of compromising relations with aid-giving countries (Richey & Haakonsson, 2007). The US, for example, pressures countries to refrain from using the updated regulations to access generic drugs by threatening to place these states on its "Watch List" (Mitchell & Voon, 2009). McGill (2009-2010) mentions that in 2002, Egypt granted the rights to produce Viagra to a local drug manufacturer two months after Pfizer entered this country to produce the same product. A Pfizer agent stated that Egypt's action would scare away foreign investors, which it ultimately did: Foreign Direct Investment (FDI) in this country saw a reduction from \$948 million in 1987 to \$509.4 million by 2002 (McGill, 2009-2010). Such external pressures highlight why compulsory licensing has been used so little, even with measures added to make it more accessible. In fact, it has barely been invoked until now: India has filed to produce generic anti-cancer drugs, and it will be interesting to see how this situation evolves. Overall, compulsory licensing has not led to the acquisition of important medications by those who need them.

## An Elusive Goal: Drug Access for the Poor

The growing push toward tougher Free Trade Agreements (FTAs) is worrying with regards to generic drug access. A number of US FTAs increase the longevity of patents to compensate for "...unreasonable delays in the Party's issuance of patents," while including a number of other measures intended to secure patent protection (Mitchell & Voon, 2009, p. 592). The TRIPS framework states that countries can have more extensive rules than TRIPS, as long as these regulations do not infringe upon TRIPS provisions (Mitchell & Voon, 2009). By creating their own rules, powerful countries like the US can restrict access to generic drugs: the TRIPS framework's allowances do not match with the WTO's stated commitment to ensuring "...access to medicines for all" (WTO, 2001, p. 1).

The most prominent WTO pharma dispute occured when Dutch officials seized generic drugs being shipped from Brazil to India (Mercurio, 2012). This situation did not go to the dispute settlement body (DSB) within the WTO however, as a mutually agreed upon solution was reached, this case highlights the tension regarding generic drugs and trade. In December 2008, a ship carrying 570 kg of Losartan Potassium, a drug prescribed for high blood pressure, was seized en route to Brazil from India due to a complaint from the patent holder, the Netherlands (Mercurio, 2012). There was no sense that the drugs in question were substandard with respect to quality, and the drug was not subject to compulsory licensing. Mercurio (2012) mentions that multiple other seizures occurred after this, which inevitably led to the heightening of tensions between Brazilian, Indian and European leaders, as well as NGOs and the public in general.

## Patent Protection, Access and Affordable Drugs

The EU justified the seizure of the abovementioned drugs by claiming that it suspected that they violated intellectual property rights. Council Regulation (EC) No. 1383/2003 guides European border control measures and allows border authorities to take action when goods infringe upon intellectual property rights ("Council Regulation," 2003). This incident highlights different states' views about patent protection, with the EU trying to protect drug patents, and India and Brazil trying to make these drugs more accessible for those in need. As Baker (2012) notes, the EU seizure infringed upon the core features of international rules regarding generic drugs.

On the surface, the generic drugs dispute appears to pertain to the quality of the drugs in question. In 2015, the EU banned approximately 700 generic drugs produced in India, and cited concerns about the safety and integrity of these drugs as the reason ("EU Bans 700 Generic Drugs," 2015). Admittedly, this large-scale ban on generic drugs appears to have been based on health-related data: notably, the electrocardiograms of the generic drug companies' studies. It has been suggested, however, that the drug companies' data were manipulated. The EU ban, then, could be based upon this allegedly falsified data, or it could be a cover to discriminate against generic drugs ("EU Bans 700 Generic Drugs," 2015).

There are some interesting inconsistencies regarding the use of generic medicines. The US and EU are known to be two of the most ardent supporters of intellectual property rights, yet generic drugs make up a considerable amount of their domestic drug usage. According to the European Generic and Biosimilar Medicines Association (EGA), generic drugs in Europe account for 55% of dispensed medicines ("Factsheet," 2014). Similarly, the Generic Pharmaceutical Association (GPhA) points out that generic medicines make up 80% of prescriptions dispensed in the US (2013).

# **Generic Drugs: The Preferred Option for Many Governments**

Generic drugs are important to health markets around the world. Even within Canada and the US, two ardent supporters of intellectual property rights, this represents a truism. Canadian provincial leaders have recently worked together to set lower prices for six widely used generic drugs in the hopes of saving up to \$100 million (Council of the Federation Secretariat, 2013). Figure 5, below, shows the noteworthy growth of the generic drugs industry within Canada between 2006 and 2014:

	Canadian Generic Prescription Drug Sales (Billion \$)								
Year	2006	2007	2008	2009	2010	2011	2012	2013	2014
Total	17.86	18.96	20.65	21.98	22.35	22.16	22.17	22.29	23.27
Generic Drugs	3.26	3.89	4.70	5.27	5.72	5.43	5.40	5.22	5.27
Generic Market %	18.25	20.52	22.76	23.98	25.59	24.50	24.36	23.42	22.65

# Figure 5

Source: CGPA (http://www.canadiangenerics.ca/en/resources/market\_trends.asp)

According to the Canadian Generic Pharmaceutical Association (2015), while generics accounted for only 22.65% of drug purchases within Canada in 2014 in monetary terms, they represented over 67% of all Canadian prescriptions. Further, a 2014 Generic Pharmaceutical Association annual report notes that, within the US, generic drugs, both branded and unbranded, accounted for 86% of all dispensed retail prescriptions. Clearly, the importance of generic drugs within the US and Canada – countries that are typically opposed to these products' easy dissemination in other countries – cannot be underestimated. Canadian generic drug sales are expected to grow further as governments continue to adopt reference-based pricing. A similar level of growth is expected in biosimilars, for the treatment of cancer and other conditions, which are likely to be manufactured by countries such as India. Contradictions permeate the generic drugs debate.

Even where generic drugs are available, however, access can prove difficult due to the medications' price. WHO statistics show a difference between generic HIV drug prices between North America and Sub-Saharan Africa: the median price of these drugs in North America is \$98.60 per year, whereas the median price in Sub-Saharan Africa is \$93.93 per year (WHO, 2011).

While the drugs' price is cheaper in Sub-Saharan Africa, an examination of typical incomes in each country reveals a problem. According to World Bank data (2015), the Gross National Income (GNI) per

capita for Sub-Saharan Africa is \$3,562 (PPP), whereas for the US and Canada, GNI (PPP) is \$55,200 and \$51,690, respectively. Looking at the proportional differences between the cost of HIV treatments and the incomes for those living in Sub-Saharan Africa versus North America highlights the problematic issue of drug pricing – and the ability of some, but not others, to afford life-saving medications.

The debate regarding intellectual property rights and generic drug access is both important and divisive. As such, it will continue long into the future. The dispute is fraught with contradictions, notably, the simultaneous WTO push rhetorically to make access to drugs easier, and the attempts by the US and the EU to protect intellectual property rights by restricting accessibility through explicit or implicit threats. Big pharmaceutical companies who favour market fundamentalism and highly protectionist policies protecting their monopoly position in markets are determined to limit access and keep prices high. They play a very active role in this debate. The levy of over \$13 billion dollars in fines associated with fraudulent pharmaceutical marketing practice by a number of companies in the US underlines the importance of price (ProPublica, 2014). These contradictions cause confusion and difficulties when it comes to finding solutions.<sup>2</sup>

# Case 4. Beef Hormones EU v. US and Canada, and the Fight to Protect National Standards

Food and agricultural product safety is a common topic of dispute within the WTO. The threat of diseases affecting meat and other food items leads to international caution when trading these commodities. Sanitary standards can also lead to disputes, given that different countries hold differing views as to the desired levels of sanitary safety. We will examine the 1996 beef hormones debate in this part of our paper.

The 1996 beef hormones dispute between the EC, Canada and the US is an important event in regards to public health and food safety. A negative view of hormone use has arisen in Europe, largely due to German consumers' refusal to accept American beef products with higher hormone levels (Josling, Roberts & Hassan, 2012). The EC placed a ban on the meat of animals that had been subjected to hormone treatment, in order to protect public safety (Josling, Roberts & Hassan, 2012). The US and Canada objected to the ban, due to the impact it would have on the international trade of their beef products. The EC's decision was seen by the US and Canada as a clear example of market protectionism.

In front of the Panel, the US argued that the European ban was not based upon scientific evidence, which is required under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS rules). The EU maintained that there was insufficient evidence supporting the safety of hormones in beef (Josling, Roberts & Hassan, 2012).

## The Precautionary Principle as a Scientific Standard

The EU argued its point by invoking the "precautionary principle" of public health, that incomplete evidence or scientific uncertainty of harm should not prevent action from being taken to protect human

 $<sup>^2</sup>$  The Affordable Care Act in the US counterintuitively prohibits the use of cost-effectiveness evaluation to assess the health benefits per unit cost of medications, as a basis for establishing the drug price that the government will reimburse.

well-being (Canadian Chamber of Commerce, n.d., p. 1). The EC did not present evidence that supported the EU argument that precautionary action should be taken to support human health. It argued instead that the studies conducted were faulty (Josling, Roberts, Hassan, 2012). The Panel reported that the EC's actions violated Articles 3.1, 5.1 and 5.5 of the SPS Agreement (WTO, 2009). The Panel found that the EC ban was not based on an appropriate risk assessment in regards to Article 5.1, that it was not compliant with international standards for Article 3.1, and that the measures lacked supportive scientific evidence in line with Article 3.3 (Josling, Roberts & Hassan, 2012). Ultimately, the Appellate Body upheld the Panel's decision, and the EC measures were deemed to restrict trade. This dispute emphasized that, despite the EC's pro-health stance, the precautionary principle is not part of general international law and, as the Appellate Body stated, Articles 5.1 and 5.2 take precedence over it (Josling, Roberts & Hassan, 2012).

An important aspect of the Panel and Appellate Body's decision was that the precautionary principle does not constitute a legitimate reason to implement higher standards. The fact that the onus is on the defender, in this case the EC, to prove that human health is at risk, and that higher standards should exist, rather than on the complainant to prove that the lower standards will not adversely affect consumers, gives the accuser an advantage. Definitive evidence, often difficult to acquire, is needed to improve safety standards. The WTO's approach, then, makes it difficult to implement higher standards. While this is to be expected of the WTO, given the fact that it is a trade organisation that aims to liberalise trade and minimize regulatory approaches committed to standard setting, it is still disappointing with regards to the protection of public health.

#### **Do SPS Rules Favour Lower Standards?**

The WTO recognizes the sanitary standards set by the Codex Alimentarius and World Organisation for Animal Health (OIE) (WTO, 2015c; OIE, 2015a). The regulations found in the Codex and the OIE's "Terrestrial Animal Health Code" aim to improve animal welfare and set standards for the international trade in animals and animal products (2015a; 2015b).

It would seem that internationally set guidelines would reduce the number of disputes over sanitary standards. This is not the situation, however, as evidenced by the abovementioned US v. EU battle concerning beef hormones. While the WTO states that members should base their standards on recommended Codex Alimentarius guidelines (2015c), it is not compulsory for governments to follow the Codex standards. This has led to conflict and debate, given the fact that WTO members have their own beliefs, needs and economic interests when it comes to acceptable standards for trade. As Josling, Roberts and Hassan (2012) assert, "the SPS rules were instituted to reduce conflict over these issues, but the complexities of scientific standards, interpretation of the rules provisions and implications for trade, health and consumer protection issues are widespread" (p. 21). The US, for example, proceeds with an activity until the activity is proven to cause harm. The EU approach, on the other hand, relies more heavily on the precautionary principle (Peterson & White, 2010). As Justice Stephen Breyer mentions in *The Court and the World* (2015), globalization has made it almost impossible to avoid engagement with foreign and international laws, with some countries or regions, such as the EU, wanting more stringent rules, and others, like the US, wanting regulations relaxed.

Such disputes beg the question of why states cannot create their own standards, so that they can regulate them as they want? Allowing states to create their own standards would benefit countries or regions that want to implement higher standards of health, such as the EU in some instances. Countries' regulations could then align with their own domestic requirements, scientific findings and national values as to what standard a product should conform to in order to protect the public and the national interest.

This independence, however, could lead to a situation where countries are setting their level of scientific standards with an eye to protecting their own products, rather than public health. As is evident in several WTO disputes involving sanitary standards, it is often alleged by some critics that protectionist measures lurk under the guise of a desire for "higher standards." Further to this, countries could put domestic public health at risk by lowering standards too much in order to obtain cheaper products. Additionally, independent standard-setting would not put an end to international disputes: some states would complain that others' standards were too high because of subsidies, and that upon commercial level playing field was no longer level.

An alternate approach from a public health perspective is to keep these international standards, but to reverse the onus in the WTO's approach to food and agriculture sanitary concerns. In order to put due attention on health concerns, the country that wishes to lower standards should be the one tasked with providing evidence to support its point, rather than the other way around. Setting sanitary regulations by this principle would benefit public health through a general rising of standards. It would not lead to a race to the bottom: regulations would be softened if proof was provided that the lower measures were not detrimental to health.

Ultimately, the WTO appears to espouse a reactive rather than proactive approach which minimizes any leadership role for global governance purposes. It also reinforces the singular focus of the WTO priority on protecting markets centric view of trade, rather than giving equal weight to global health concerns. The net effect of the evolving corpus of WTO jurisprudence is in elevating the WTO as the de facto if not de jure body for setting international health and safety standards rather than public health organizations like the WHO. This virtual jurisprudential monopoly seriously limits the potential protections afforded to global publics and has made the WTO gun shy with respect to limiting corporate intellectual property protection for patented medicines and other pharma favoured policies.

# **Case 5. Plain Packaging for Toxic Consumables Thailand's Alcohol Labels: Policy Goals and Regulatory Constraints**

Support for the plain-packaging of tobacco products has increased significantly in the last few years, and such packaging is seen as an effective way to reduce cigarette and tobacco use. Labelling changes have been considered for alcohol products as well, and notably in Thailand. This country faced significant opposition from a number of states, however, as well as the threat of a WTO dispute. Here, we look into Thailand's proposal to change the labelling on alcohol products, and discuss the international community's response. Alcohol is estimated to represent 3.8% of global deaths and 4.6% of global disability adjusted life years lost (Rehm et al, 2009).

In 2008, Thailand introduced the Alcohol Beverage Control Act, B.E. 2551, which under Section 26 (1) stated that manufactured or imported alcoholic beverages must be produced in line with the conditions set up by the Committee (World Health Organization, 2008). Under this legislation, Thailand notified the WTO in 2010 of its plans to implement new alcohol labelling rules (Eurocare, 2010).

## Setting Domestic Standards: A Sovereign Right?

According to the WTO's Committee on Technical Barriers to Trade (2010), the measure submitted by Thailand can be separated into two main parts: firstly, the product labels must not contain any word or statement that "...is likely to mislead" (p. 1) people into thinking that alcohol consumption can improve health, and secondly, pictorial labels are required on the product, rotating between six different warning labels and statements every 1,000 products. These statements include, "Drinking alcohol leads to unconsciousness and even death" and "Drinking alcohol is a bad influence on children and young people" (p. 2). The labels must also state that the sale of alcohol to those under 20 years of age is prohibited. Finally, images must cover between 30% to 50% of the label, depending on the shape of the package.

Thailand's proposed measures are undoubtedly aimed at addressing alcohol use issues within the country. Alcohol consumption levels have been rising in Thailand. A 2014 WTO report indicates that the average amount of pure alcohol consumed per capita grew by 0.3 litres between 2003 and 2005, and again between 2008 and 2010. Further, and according to the Organization for Economic Co-operation and Development (OECD, 2012), there has been a 23% increase (6.1 litres) in the consumption of pure alcohol per capita since 1990.

Thailand's proposed labelling measures led to concerns about impeded trade on the part of a number of international companies and countries. International liquor companies pressed their respective governments to take issue with these measures and, indeed, many joined the fray (Barta & Passariello, 2010). A number of countries, including the US, Australia, Argentina and the EU, complained that these measures created an image that even moderate drinking is dangerous to health. Further to this, these countries argued that the measures would require companies to produce different packaging for Thailand, thus infringing upon international trade (Barta & Passariello, 2010).

The international companies' argument – notably, that Thailand's plans infringe upon international trade because multiple labels would be required – is plainly weak. These companies already ship a variety of products, all of which require labels in different languages and styles and forms, around the world. The arguments these companies presented are reminiscent of those of any aggrieved party that feels harshly treated due to the impact that actions will have on them and their goals.

One of the most interesting aspects of this case is the comparison that can be made to Australia's 2011 switch to plain packaged tobacco products. To summarise quickly, the Australian government has led the fight against tobacco advertising, and has implemented laws dictating that tobacco packages must all be composed of large graphic images with strongly regulated fonts and colours. These measures are supported by a number of countries including the EC, New Zealand, and others.

Evidence shows that after Australia introduced the plain packaging for tobacco, which portrayed graphic health warnings (GHWs), respondents were more motivated to quit. In fact, the number of those attempting to quit rose by approximately 4%, while the number of people who found the cigarette pack to be less appealing increased by over 30% (Mitchell, 2010). Evidently, plain packaging and GHWs reduce both tobacco's appeal and levels of use (Barta & Passariello, 2010). However plain packaging and harm warnings which have successfully advanced for tobacco, although not without dispute, appear not to have been accepted for alcohol consumption for the time being. Public opinion and policy makers in the global North have not arrived at a consensus about a labelling policy to discourage the consumption of alcohol. On the other hand, the penalties facing drivers who drink and are involved in accidents have been dramatically increased throughout the EU, in some American states, Mexico and in Canada among others.

## **Restricting the Right to Advertise Smoking**

There is a paradox inherent in Australia's approach to its own cigarette packaging measures versus its approach to Thailand's attempt to plainly package alcohol: while Australia implemented the packaging changes to reduce cigarette and tobacco use and protect its citizens' health, this same country has fought Thailand's attempts to realize similar measures to reduce national alcohol consumption. Perhaps not surprising since Australia boasts a large alcohol industry, which is well known for its wine production.

Other countries that support Australia's actions and plan to follow in its footsteps by implementing their own form of plain packaging for tobacco, are also questioning the measures proposed by Thailand. The UK, for example, plans to implement plain packaging in May 2016 (Euractiv, 2015), while the BBC (2014) reports that France is also implementing plain packaging soon. Like Australia, the EU examined the Thai measures and questioned whether there were alternatives, such as education campaigns (O'Brian, 2013). This contradictory response on the part of many nations emphasizes that trade and health concerns are still a divisive topic of global debate. It also suggests that, while the importance of public health is recognized, strong commitment to its protection, which may well impede trade, is still lacking.

Both alcohol and tobacco harm health. So it is perplexing that strong prevention measures enjoy support when applied to one product, but not the other. It may simply be more closely tied to who is selling and who is buying. Even more intriguing is that Australia is trying to implement tougher alcohol labelling itself, despite criticising the Thai proposals. There is apparently "...widespread support" (Barta & Passariello, 2010) for tougher alcohol measures in Australia (Blackwell, 2013). These laws against driving and drinking have been considerably toughened and drunken drivers face severe penalties than in the past. So clearly the law is being used to deter excessive drinking rather than a labelling approach as in cigarette packaging.

## Alcohol and Tobacco Restrictions and Unanswered Legal Questions

Australia has been taken to the WTO DSB by a number of countries, all of which have challenged this nation's plain packaging actions for tobacco (Mitchell, 2010) and the tobacco discussion remains a lively topic at the WTO as the initial disputes are in process at the WTO DSB. Ultimately, if the WTO DSB allows the Australian plain packaging measure it will be a significant victory for public health. Still, a large grey area persists with respect to new measures to ban the sale of tobacco products. How public

health concerns are valued in the larger picture of settling this international trade skirmish remains elusive. Initial dispute settlement is expected in 2016 and it is entirely unclear what the implications will be for alcohol packaging.

#### Conclusion

In the introduction to this paper we posed two fundamental questions. First, does the WTO successfully manage the interface between trade-related questions and global public health concerns? Second, do WTO decisions reflect strong and effective public health standards?

There was much hope when the French Asbestos case surfaced that a greater focus on public health might emerge from WTO decision making and dispute resolution outcomes. As our five case studies illustrate, the WTO has no apparent role in setting a broader framework or corpus of principles to guide future decision making related to health. Moreover, the WTO does not operate in a framework of precedential decision making which could the trade equivalent of 'common law' to guide new cases. Its efforts lack the necessary legal muscle to establish clear and effective global health standards since it is required to continuously trade off competing interests between nation state producers and consumers of various products. The WTO made a historic decision in supporting the French ban of asbestos. While this decision helped reduce asbestos use in France and the EU, it has had no apparent effect in stemming the global production and consumption of this carcinogenic material which is on the rise in several large nations. Likewise, in the dispute over clove cigarettes, the US decided not to accept the decision by the WTO dispute resolution mechanism. Rather the US and Indonesia came to a private, bi-lateral agreement after the WTO panel rejected the American arguments of the case. If WTO decisions can be side-stepped, there is little chance they will protect public health in the face of member states' powerful trade interests.

When the WTO does decide in favour of public health, it is once again often undermined by member states. With respect to compulsory licensing of branded drugs, for example, which was aimed at helping developing countries access life-saving drugs, powerful member states actively discouraged other countries from invoking the licensing measures. Countries, such as the US, have threatened to withdraw aid should the measures be invoked.

Finally, even when a product is known to have an egregious impact on human health, like tobacco or alcohol consumables, the WTO plays a passive role in settling disputes and has not separate voice by which to stem their trade and use. In the bickering between companies and countries that are economically affected, attempts by some states to protect their citizens' health may well be met simply by competing corporate global drug manufacturers. The approach seems to preclude the making of principled, evolving health-focused decisions. This was demonstrated in Australia's resistance to Thailand's attempts to use plain packaging for alcohol products, as well as the US and Canada's resistance to EU concerns about hormones in meat products. In decisions involving toxic goods, such as cigarettes and alcohol, the WTO supports an aggressive commercial agenda minimizing the role of the state to protect the health of its own citizens on narrow legal grounds. As seen in the Indonesia v. US dispute over clove cigarettes, the test of whether "like products" are being traded most often outweighs global health interests even when the like products manufacturers are merchants of death from tobacco.

The WTO has demonstrated a weak capacity to establish standards related to global public health. This organisation weakly establishes a fragmented approach to global health standards as best illustrated by the asbestos case. The WTO also tolerates market protectionism as a side-bar solution to health issues amongst its member states, as the clove cigarette case illustrates. The WTO appears to have no independent view of when a health standard should be applied, but instead reverts to a simple resolution between states' individual disputes. The WTO reinforces a neoliberal institutionalist view of an international agency which simply trades off interests between competing nation states and the private interests within them, with a weak capacity to generate international standards (Keohane, 1989). It turns a blind eye when states adopt policies that may be harmful to global public health. Its most fatal flaw as noted earlier is that unlike common law, which is based on precedent-setting, each WTO decision stands on its own, creating a weak framework for the protection of public health in the context of a partiularistic legal culture. The absence of a cumulative corpus of principle making associated with judgments, has spurred some scholars to identify this as a "black hole" in terms of WTO jurisprudence (Drache and Jacobs, 2014, pp. 1-26).

Going forward, the WTO's influence is also now further limited by regional trade agreements, particularly in regards to intellectual patents, state investor dispute protection and very broad rules with respect to investment. The TPP is likely to have an important impact on the setting of global health standards. It has extended intellectual patent protection to eight years, which represents a hard-lobbied victory for "big pharma." Biosimilars will be subject to protectionism-oriented special interests. All in all, global drug prices are expected to continue to rise and government public health systems are facing escalating costs. Global health standards are facing relentless supply-side pressures. WTO Director General Mike Moore's promise on February 22, 2001 in the *International Herald Tribune* of "Drugs for the Poor and Patents as Well" seems to have done better on the patents than the drugs for the poor. That promise is receding on the horizon with ever higher prices set by big pharma for many drugs and veiled threats against any country challenging the interests of trade blocs with significant pharmaceutical industry to protect.

The five cases presented in this article, and their outcomes, cast a shadow over the adequacy of the WTO's adjudication of trade matters when balanced against global health interests and standards. To date, the attempt to apply the principle of unimpeded market access to establishing effective global health standards is ineffective (Labonte, 2014). The WTO will need to assume a different position with respect to supporting public health outcomes to earn the trust and meet the 21<sup>st</sup>-century needs of its member states and the world's publics.

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