

**Trade and Health:**  
**Reformulating Global Governance**  
**to Advance Public Health**

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**INDEX**

<b>Introduction and Executive Summary</b>	p. 3
<b>I. Overview: Trade and Health</b>	
A. Public health, medical care, indicators of health	p.10
B. International commitments and covenants on health	p.12
C. Health and wealth: what determines outcomes?	p.13
D. Global trade and trade agreements: Trade liberalization, trade barriers, and economic growth	p.15
E. The privatization debate: Should countries move cautiously to liberalize health services? What models work to improve health services?	p.18
<b>II. Health and Trade: Links, Policy Implications, and Outcomes - Toward Convergence or Conflict?</b>	
A. Public health perspective - principles for trade and sustainable development	p.23
B. Trade perspective - the WTO and international trade agreements	p.24
C. Trade agreements related to health; Trade disputes and health examples	p.25
D. Public health comments on the effects of trade policies and agreements on health - Calls for alternatives	p.31
<b>E. Towards Policy Convergence: A Public Health Policy Framework</b>	p.33
<b>III. Global Governance 1: Democratic participation in establishing and enforcing trade rules</b>	p.34
A. The institutions: WTO, WHO, national and regional health policy	p.35
B. Alternative proposals for harmonizing policy objectives: break down the silos; reexamine global governance; create parallel health-based agreements	p.37
<b>IV. Global Governance 2: Trade Agreements, and Nations' Rights to Regulate In the Interest of Public Health</b>	p.38
A. The right to regulate, trade dispute decisions, and health	p.39
B. GATS Domestic Regulation rule	p.41
C. Alternative proposals	p.42
<b>V. Trade Agreement Provisions Regarding the Organization, Financing and Delivery of Public Health and Medical Care Services</b>	p.42
A. GATS and health care services	p.43
B. Alternative policies	p.48
<b>VI. Trade Agreement Provisions and Clinician Migration: Mode 4 of GATS</b>	p.48
A. Overview: the Problem - Clinician shortages	p.49
B. Proposals for addressing clinician migration from a public health perspective	p.50
C. Clinician shortages and trade: GATS proposals	p.50
D. Critique of using GATS Mode 4 to harmonize standards and facilitate immigration for health professionals	p.51
E. Promoting alternative trade and health policy and negotiating objectives	p.51
<b>VII. Trade agreements, Intellectual Property, and Access to Affordable Medicines</b>	p.52
A. TRIPS, TRIPS-Plus, and access to medicines	p.52
B. Proposed Alternatives	p.56
Alternatives to TRIPS and "TRIPS-Plus" rules	p.56
Alternatives for research and development of pharmaceuticals	p.57
Promoting alternative trade and health policy and negotiating objectives	p.57
<b>VIII. CONCLUSION</b>	p.58

## INTRODUCTION AND EXECUTIVE SUMMARY

Public health principles prioritize achieving and protecting the health and wellbeing of individuals, communities and populations, which in turn requires economic and social equity and justice, democracy, and equitable access to health-related services.<sup>51,89,90,95,110</sup> Leaders internationally have vowed to “place people at the center of development and direct our economies to meet human needs more effectively.”<sup>97</sup> Yet widespread threats to global health persist, coexisting with both unprecedented wealth and economic inequality.

Global health policies and global economic policies appear to be running on divergent tracks. International trade agreements illuminate these potentially conflicting policy priorities and regulatory regimes. Proponents claim that trade agreements, by eliminating government laws and regulations, such as financial tariffs and import quotas, that act as trade “barriers,” will encourage businesses to produce more in order to take advantage of more easily accessible foreign markets.<sup>76</sup> This will generate economic activity, jobs and growth, and make more products and services available at lower prices. Critics assert that the present rules for international trade, however, fail to achieve these economic benefits.<sup>21,38,103</sup>

The policies of global financial and trade institutions frequently conflict with or subordinate public health policies that prioritize the achievement of human health and wellbeing of populations.<sup>46,99,103</sup> Over the last decade global trade institutions and agreements have expanded their reach to setting international rules in new areas of services that affect health, including health care, water provision, and education. Multilateral and bilateral (nation-to-nation) trade agreements present particular barriers to global progress in health.<sup>1,6,12</sup> Current trade negotiations seek to extend trade rules related to health, but there has been little or no assessment of their impact on health and health care services.<sup>2,12,35,38</sup>

Trade dispute panels have at times determined that laws and regulations that protect or promote population health are impermissible barriers to trade.

These developments raise key questions for health: To what extent are trade policies and rules consistent with public health principles? What are the consequences of conflicts between trade and health policies for the health of the world’s people? What are the prospects for and possible benefits of policy coherence between these approaches? What policy alternatives have been proposed to bridge the divide between trade and health? What are the barriers to implementing these alternatives?

We aim to address these questions and to present information in a format accessible to general readers, while framing issues that are particularly relevant to public officials, health policy decision-makers, and professional and non-professional workers in the fields of public health and health care services.

We focus the discussion within a **global public health policy framework** that is centered on the goal of achieving global health. Such a framework **prioritizes the achievement and protection of health** and wellbeing of individuals, communities and populations. It aims to **foster progressively greater international cooperation**, the development of an interdependent model **to address international health issues**, and **global rules that promote health and access to health-related services**, as well as advance each nation’s public health and medical care

systems. It entails **promoting conditions of economic and social equity and justice, democracy, and equitable access to health-related services.**<sup>51,89,90,95,110</sup>

**Sustainable development** is an important element of the framework. This means that **economic decisions are interdependent and integrated with health and environmental concerns** to promote healthy and productive lives for human beings equitably in the present “without compromising the ability of future generations to meet their own needs.” This necessarily includes effective protection, conservation and restoration of the environment, and prudent use of natural resources.<sup>25</sup> Eradicating poverty is “an indispensable requirement for sustainable development,” to decrease the disparities in standards of living and better meet the needs of the majority of the people of the world, according to the Rio Declaration of 1992.<sup>82</sup>

We begin by offering background in both trade and in public health, for two reasons. First, the influence of trade agreements on health is a relatively new issue. Public health advocates in developed countries, for example, may not be fully acquainted with the important implications of trade agreements for domestic policy as well as for foreign countries. While international health agencies such as the World Health Organization and the Pan American Health Organization have given consistent and valuable attention to these issues, awareness within national ministries and health advocacy organizations is far less developed. There is also striking variation among countries; the debate in the U.S., for example, is still in its infancy. It is likely that assertions of interest from health advocates at the national level will be necessary to motivate consideration of these issues.

Second, trade policy and health policy analysts tend to work in separate silos, relying on different concepts, analytical methods, standards of evidence, and assumptions, for example, about the role of popular participation, and the value of epidemiology, statistics, and economic analysis for problem-solving, as well as the implications of each realm for the other.

Therefore, in order to provide a context for these discussions, we first explore essential elements of public health policy and of global trade, and the relationships between them. We discuss current economic and trade policies that influence health and health related services.

We then review relevant trade agreements, the evolution of the World Trade Organization and the role of trade dispute mechanisms in enforcing the agreements, and known critiques of trade agreements from the public health perspective. The background information in this section provides a grounding for considering the policy alternatives that follow, for those who may find it useful.

We then identify several policy areas currently addressed by trade agreements that have important implications for health. We explore how the expanded scope of trade policies and rules are likely to influence the health of the world’s people and public health policy, present critiques of those trade policies and their consequences, and note alternative options for global rules that promote health and access to health-related services. These key areas include:

- Global governance of institutions and policies that affect health, democratic representation within governance processes, and tensions between global governance of international trade and international health.
- The rights and ability of nations to exert sovereignty over domestic health regulations that promote health and that protect populations from harmful substances such as tobacco, alcohol, and food additives, and from environmental and occupational hazards;

- The financing and provision of health care and health-related services, and effects on the public and private sectors;
- The migration of health care professionals, including standards for credentialing professionals, assuring their fair treatment, and creating ethical standards for recruiting from resource-poor nations; and
- Intellectual property rules that affect access to affordable medicines.

The discussion is particularly timely. The relatively recent inclusion of health care services in international trade agreements has called new attention to the wide-ranging implications of these agreements for health. On the international level, an ongoing round of discussions on trade in services through the General Agreement on Trade in Services (GATS) is scheduled to conclude in May, 2005. There are numerous trade negotiations at the regional and bilateral levels involving virtually every area of the globe: the Americas, Europe, Africa, the Middle East, Asia, and Oceania. International trade negotiations offer key entry points to reframe the debate on trade and health, and to present public health policy alternatives.

We have tried to provide enough information on each perspective to stimulate a discussion. We hope the information is applicable to readers internationally, but have not aimed to describe comprehensively the great variety of global health experiences. We approach this paper as a prototype that may lead to subsequent reports focused more specifically on the conditions relevant to particular regions or countries.

**In summary, we present and discuss for consideration the following global health problems, the aspect of trade agreements that bear on that problem, and public health policy alternatives:**

### **I. Overview: Trade and Health.**

Public health, the global economy, international trade and sustainable economic development are linked, although rarely discussed in a common vocabulary. The public health field can and should contribute actively to the debate on trade and health.

There are broad questions regarding the global economy and international trade that are relevant and of interest to public health. These broad issues include: whether and under what circumstances open trade across borders as opposed to internally developed industries best advances economic growth; the equitable distribution of wealth, and sustainable development; and the relationships between economic growth, wealth, health, and other factors such as democratic and accountable governments and social infrastructure.

This section also briefly explores the debate about market forces in health care and health-related services, privatization of health care services, and alternative approaches to expanding access to affordable, high quality care, including the primary care movement, and the health systems approach. Well-functioning services based in the public or private nonprofit sectors can be disrupted by privatization, and are hard to reassemble if for-profit private providers default.

Although these issues are sometimes presented in polarized terms, it is appropriate for public health officials and policymakers to explore them. However, public health officials do not need to resolve these questions before taking positions and intervening effectively on more specific public health issues raised in the context of trade negotiations, including those noted below.

## **II. Health and Trade: Links, Policy Implications, and Outcomes - Toward Convergence or Conflict?**

New and widespread threats to global health present new challenges to advancing the health of the world's population. Expansion of the scope of international trade rules presents potential conflicts with public health priorities. Enforcement of trade agreements through the powerful regulatory regime of the WTO presents additional challenges to public health, including nations' ability to regulate in the interest of health.

This section examines international trade agreements and specific trade dispute decisions related to health, suggesting the trade and health policy may be on a divergent and conflicting path. It offers an alternative public health policy framework, one which calls for a shift toward global cooperation and achieving health and human wellbeing, and away from a focus on achieving purely microeconomic and macroeconomic objectives. Current international trade negotiations offer entry points for offering such an alternative policy framework.

## **III. Global Governance 1: Democratic Participation in Establishing and Enforcing Trade Rules.**

Global health problem: In a global economy, accountable governments must be able to cooperate to protect populations from cross-border hazards such as infectious diseases and environmental degradation, and to assure that the activities of transnational corporations contribute to population health and sustainable development.

Health-related trade problems: The regulatory "police" powers of public health have often conflicted with commercial interests.<sup>29</sup> Trade agreements prioritize commercial interests over public health concerns, rather than striking an effective balance.

Public health officials are generally excluded or only peripherally involved in negotiating trade rules and agreements.<sup>89</sup>

Trade dispute panels that enforce trade agreements do not adequately rely on or prioritize public health standards.

Public health policy alternatives: Public health representatives should be included in trade negotiations and dispute resolution proceedings, and public health principles accorded greater priority. Alternative, cooperative mechanisms for global governance that prioritize health goals and protect health could play a useful role. Leaders and civil society organizations at the national level can play an important role in motivating such mechanisms.

In order to protect and advance health, public health policies and administrative mechanisms need to recognize and address changes in the global economy, in particular the increased pace and volume of international trade in finances, goods and services, and increasing economic integration among nations.

## **IV. Global Governance 2: Trade Agreements, and Nations' Rights to Regulate in the Interest of Public Health.**

Global public health problem: Exposure to a range of environmental and workplace hazards, and to hazardous products, can result in harm from unsafe food, infant formula, and tobacco and alcohol products, among others. Public health measures legitimately provide protection from these hazards and the marketing of unsafe products; and set affirmative standards for the safety and quality of goods and services. These protections are sometimes under attack from affected

domestic commercial interests, and from efforts to restrict government enforcement of accountability generally.

Trade-related public health problem: Both trade dispute decisions, and trade rules such as the Domestic Regulation rule, present challenges to nations' right to regulate in the interest of public health.<sup>9,38,73</sup> These decisions can provide protections for foreign corporations, but may also indirectly benefit domestic interests in conflict with public health rules, as well as interfere with governments' rights to enact and implement public health protections. A number of recent trade dispute decisions have challenged public health protections from exposure to environmental health standards and to other health-related threats.<sup>46,99,123</sup>

Public health policy alternatives: Trade rules and alternative health rules can prioritize and protect the public's health, and better balance health priorities with commercial concerns.

## **V. Trade Agreement Provisions Regarding the Organization, Financing and Delivery of Health Care and Health-Related Services.**

Global public health problem: Millions lack access to affordable health care services; 2.4 billion people have inadequate access to safe drinking water and sanitation.

Private for-profit corporations can provide needed cash to expand services, but unless held accountable by an effective regulatory environment can undermine equity and divert profits away from services.

Trade-related public health problem: The terms of trade agreements can bind countries to exposing health-related services to privatization, commodification and deregulation.<sup>26,35,49</sup> They penalize countries for reversing decisions to privatize, and discourage creation of new services based in the public sector.

The agreements undermine the regulatory environment required to hold corporations accountable.

Provisions regarding health-related services can be traded off against other economic goods and services in the context of trade negotiations.

Public health policy alternatives: Countries can and do choose to make policy choices about how to finance and deliver health-related services, including the role of market forces in health care and health-related services and the privatization of health care services, without the additional pressure and unintended consequences related to internationally binding and enforceable trade commitments.

Countries need to be well-informed about the trade-offs involved in treating health-related services as globally traded commodities.

Alternative approaches to expanding access to affordable, high quality health care include a focus on primary care and health systems.

## **VI. Trade Agreement Provisions Regarding Clinician Migration: Mode 4 of GATS.**

Global public health problem: Shortages of nurses and other health professionals are caused in part by the failures of fragmented and underfinanced health care systems in both developed and

developing countries, sometimes exacerbated by austerity in government spending for health care. The resulting “brain drain” of nurses from developing to developed countries causes dislocations, as well as some benefits, at both ends.<sup>16, 71</sup>

Trade-related public health problem: Trade negotiations may consider clinician migration as a discrete issue, for example proposing to ease credentialing standards for clinicians who migrate temporarily, without monitoring the impact of such changes on the quality and availability of care, the domestic workforce, or the wellbeing of immigrants.<sup>113</sup>

Public health alternatives: Proposals suggest ethical standards for recruiting health care personnel from under-staffed low-income nations, and the ethical treatment of immigrant workers. There should be better tracking and evaluation of health professional migration. The underlying structural problems that lead to clinician migration require stronger national health systems and greater cross-border cooperation. It is not clear whether trade negotiations offer a constructive framework for this undertaking.

## **VII. Trade Agreements, Intellectual Property, and Access To Affordable Medicines.**

Global public health problem: Unaffordable drug prices result in lack of access to essential medicines in developing countries. For example, of 38 million people with HIV/AIDS, 5.8 million globally could benefit now from effective pharmaceutical treatments, including antiretroviral therapies, drugs preventing mother-to-child transmission, and the control of related opportunistic infections. Only about half a million of these people in the developing world are receiving treatment.

High prices are also a barrier to prescription drugs in developed countries which lack regulatory mechanisms to address drug pricing, such as the United States.

Few useful innovative drugs are being developed, despite substantial revenue from drug sales. There is insufficient research into therapies for conditions prevalent in low-income countries.

Trade-related problems: Trade agreements enforce, extend, and progressively strengthen intellectual property rules internationally, such as patents that offer monopoly marketing rights to pharmaceutical companies which therefore exert tremendous influence over prices. While trade rules have been used to block the provision of lifesaving drugs in developing countries, the recent Doha Agreement on public health seeks to overcome this obstacle.<sup>6, 117</sup> In the future, trade rules, including intellectual property rules, can discourage the production of generic equivalents and the distribution of essential medicines in developing countries. Trade rules could also block the reimportation of affordable brand-name patented drugs from one developed country to another. Alternatively, trade rules may encourage the production and distribution of essential medicines and generic equivalents, if the Doha Agreement on public health is fully implemented.<sup>117</sup>

Proponents of intellectual property rules assert that extending patent laws will stimulate pharmaceutical innovation and production in new countries, and that using trade agreements to raise drug prices in developed countries will more fairly share the burden of research and development. They further maintain that intellectual property rules and patents do not restrict access to life-saving drugs in developing countries.<sup>7</sup> Critics contend that patent laws have raised drug prices and stifled innovation in developed countries by encouraging the industry’s dependence on “blockbuster” copycat drugs.<sup>5</sup>

Public health alternatives: Some proposals address easing or modifying how intellectual property rules are applied to production and distribution of generic drugs in developing countries, fully recognizing and implementing the Doha Agreement flexibilities, and eliminating parallel importation rules that could block reimportation of drugs into developed countries. More far-reaching proposals address the underlying causes of high drug prices and flagging innovation, such as reformulating patent rules to incentivize innovation.

There is an analytical gap in discussions of pharmaceutical policies between developed and developing countries. Better understanding the links between these policies could lead to better alternatives, and more unified support for them.

## **I. Overview: Trade and Health**

### **I.A. Public health, medical care, indicators of health.**

When many people think about health policy, they think of medical care: treatment for people who are already sick with an acute or chronic illness, through hospitals, doctors, emergency rooms, and prescription drugs. This care may be financed and delivered by public, non-profit private, for-profit private and/or community sources. Access to affordable medical care is a critical issue, and most health-related funds in the U.S., for example, are allocated to this realm of health services.<sup>51</sup> However, the broader field of public health considers and addresses a wide range of factors that influence people's health.

In 1854, renowned English physician John Snow ushered in a new era in public health by tracing a cholera epidemic in London to a contaminated water pump. Snow's findings contributed to the development of government policies and other organized efforts to prevent, monitor and control disease, and to maintain and prolong life in entire populations.<sup>37</sup>

The U.S. Institute of Medicine, the World Health Organization, the United Nations Universal Declaration of Human Rights, and the UN Commission on Economic, Social and Cultural Rights have defined central elements of public health, and enshrined international commitments to achieving it.<sup>51,90,95,110</sup>

The U.S. Institute of Medicine (IOM) has defined public health as “what society does collectively to assure the conditions for people to be healthy.”<sup>51</sup> The objective of public health efforts is to achieve “population health (also referred to as the health of the population, or the public's health) as measured by health status indicators” such as life span, infant mortality, and quality of life. The IOM noted “the well-supported hypothesis” that:

the health of populations and individuals is shaped by a wide range of factors in the social, economic, natural, built, and political environments. These factors interact in complex ways with each other and with innate individual traits such as gender and genetics. Approaching health from such a broad perspective takes into account the potential effects of social connectedness, economic inequality, social norms, and public policies on health-related behaviors and on health status.

Health care services and biomedical technologies can generally only address the immediate causes of disease—for instance, controlling high blood pressure to prevent heart attacks—and do so on an individual basis. Preventive approaches that focus on populations are likely to have broader impact. Such approaches may include ‘healthy’ policies that support education, adequate housing, a living wage, or clean air.<sup>51</sup>

The World Health Organization (WHO) is the United Nations specialized agency for health, established in 1948. WHO's Constitution states its objective as “the attainment by all peoples of the highest possible level of health,” defined as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”<sup>110</sup>

In 2000, recognizing the dramatic change in the world health situation in the latter part of the 20<sup>th</sup> century, the UN Committee on Economic, Social, and Cultural Rights called for consideration of resource distribution and gender differences as determinants of health, as well as such socially-related concerns as violence and armed conflict, new diseases such as AIDS,

increasingly prevalent conditions such as cancer, and the rapid growth of the world population as obstacles to realizing the right to health. The statement recognizes that the participation of the population in all health-related decision-making at the community, national and international levels is important.<sup>92</sup>

Population health generally improved in the 20<sup>th</sup> century, but suffered significant reversals during the 1990s. According to the IOM, in the U.S.:

In the past century, infant mortality declined and life expectancy increased. Vaccines and antibiotics made once life-threatening ailments preventable or less serious, and homes, workplaces, roads and automobiles became safer. In addition to the many health achievements facilitated by public health efforts, such as sanitation and immunization, unparalleled medical advances and national investment in health care have also contributed to improvements in health outcomes.

But life expectancy plummeted in a number of nations during the 1990s due largely to the AIDS pandemic, particularly in Africa. During the '90s, rates of infant mortality and maternal mortality increased in countries such as India, reversing earlier gains.<sup>28</sup>

### **Disparities in health**

Some health conditions strike people disproportionately based on attributes such as gender, race and ethnicity, income, education or age. These differences may be due largely to biological factors, such as conditions related to older age. However, in many other cases the reasons for the differences are complex, reflecting inequalities in economic and social status and in power. These inequalities can in turn affect the health of communities and individuals' health-related behaviors, and are also associated with poorer access to adequate health care. Differences which are related to economic, social and political inequalities are referred to as disparities.<sup>83</sup> Disparities in health are seen as obstacles to sustainable development.<sup>82</sup>

The IOM reports that, "Despite leading the world in health expenditures, the United States is not fully meeting its potential in health status and lags behind many of its peers," due to several factors. "For example, the vast majority of health care spending, as much as 95 percent by some estimates, is directed toward medical care and biomedical research, [despite] strong evidence that health care is just one of several determinants of health." Further, many lack health insurance or access to health care services.<sup>51</sup>

There are tremendous differences in health within nations, and also among them.<sup>23,95</sup> A CPATH report noted that in Latin America, the region of the world with the greatest disparities between rich and poor, differences in health indicators between rich and poor within countries are also especially notable.<sup>82</sup> The Americas provide striking examples of inequalities in health resources and outcomes:

Table 1. Income, Expenditures on Health, Infant Mortality in the Americas, 1998.<sup>82</sup>

<i>Country</i>	<i>Gross National Income Per cap. Current U.S.\$<sup>1</sup></i>	<i>Expenditures Per cap. On Health Services, Latest Year, Current U.S.\$<sup>3</sup></i>	<i>Health Expenditures % of GDP<sup>2</sup></i>	<i>Infant Mortality Per 1,000 Births</i>
<b>1 Developed</b>				
Canada	21,130	1,847	9.3	6
United States	34,100	4,055	12.9	7
<b>2 Developing</b>				
Antigua & Barbados	9,440	498	1.9	17
Argentina	7,460	667	8.4	19
Bahamas	14,960	778	4.3	18
Belize	3,110	170	2.7	35
Bolivia	990	53	6.5	66
Brazil	3,580	320	6.5	36
Chile	4,590	369	5.9	11
Columbia	2,020	226	9.4	25
Costa Rica	3,810	245	6.7	14
Cuba	*	138	9.1	7
Dominican Republic	2,130	126	4.8	43
Ecuador	1,210	59	3.6	30
El Salvador	2,000	164	7.2	30
Guatemala	1,680	78	4.4	41
Guyana	860	45	5.4	58
Haiti	510	16	4.2	91
Honduras	860	56	8.6	33
Jamaica	2,610	159	5.5	10
Mexico	5,070	234	5.3	28
Nicaragua	400	53	12.5	39
Panama	3,260	255	7.3	18
Paraguay	1,440	120	5.2	27
Peru	2,080	100	6.2	43
St. Kitts and Nevis	6,570	349	5.8	30
St. Vincent & Grenadines	2,720	170	6.3	(not available)
Suriname	1,890	140	6.3	28
Trinidad & Tobago	4,930	248	4.3	16
Uruguay	6,000	697	9.1	16
Venezuela	4,310	200	4.2	21

1. Developing countries – Economic Policy – 2001. World Bank.

<http://devdata.worldbank.org/external/dgcomp.asp?rmdk=110&smdk=473880&w=0>

2. <http://who.int/whr/2001/main/en/annex/Annex5-en-WEB.xls>. 1998

3. <http://www.socwatch.org.uy/indicators/query.htm>. 1998

\* GNI per cap is not presented for Cuba in the World Bank's table, Developing countries – Economic Policy – 2001. No explanation is provided for this missing information.

## I.B. International commitments and covenants on health

There is international support for policies and programs that can alleviate disparities in health. The Institute of Medicine comments, "If assuring the conditions that support population health is an important social and political undertaking, ...the government and its partners must be committed to a broad array of activities in order to change the conditions for health."<sup>51</sup>

United Nations Conventions that define and establish the human right to the enjoyment of the highest attainable standard of health also generally establish steps governments must take to ensure the right to health.

The United Nation's Universal Declaration of Human Rights, adopted by the General Assembly in 1948, commits all nations to achieving certain enumerated rights and freedoms. Article 25 asserts that all people have "the right to a standard of living adequate for the health and well-being" of themselves and their families, "including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond" their control.<sup>90</sup>

Additional treaties have reinforced the concept of health as a matter of basic dignity and rights. The right to health is set out in a number of international treaties to which most countries are parties. These treaties include: the International Covenant on Economic, Social and Cultural Rights (ICESCR); the Convention on the Rights of the Child (the Children's Convention); the Convention on the Elimination of All Forms of Discrimination Against Women (the Women's Convention); the Convention on the Elimination of All Forms of Racial Discrimination (Race Convention); the Protocol of San Salvador to the American Convention on Human Rights; and Convention 169 of the International Labor Organization.<sup>82</sup>

A CPATH review of these international instruments makes it clear that "the right to health as it is enshrined in international law extends well beyond health care services. Fulfillment of the right to health has been interpreted as implying multi-sectoral action to provide basic conditions necessary for health such as water and sanitation, [food and nutrition, housing] and environmental [and occupational] health and safety; popular participation in decisions regarding their health, such as the organization of insurance systems; and recourse in the event of violations."<sup>82</sup>

In 2000, heads of state convened at the World Summit for Social Development in Geneva to review the principles adopted in 1995 in Copenhagen. They committed to "give the highest priority to the promotion of social progress, justice and the betterment of the human condition," to create a framework for action to "place people at the center of development and direct our economies to meet human needs more effectively," and to "promote equitable distribution of income and greater access to resources through equity and equality of opportunity for all." They made specific commitments which included a global drive to "create an economic, political, social, cultural and legal environment that will enable people to achieve social development." At the international level, the leaders called on international financial institutions to integrate these objectives into their policy programs and operations.

### **I.C. Health and wealth: what determines outcomes?**

During the 1980's and 1990s, prevailing policies emphasized market-driven economic growth as key to poverty alleviation, which in turn would lead to improvements in health and human welfare. Public spending on social welfare was generally reduced to achieve macroeconomic goals such as deficit reduction.

There is no doubt that poverty is directly related to poorer health.<sup>63h</sup> But evidence suggests that economic growth in itself is not sufficient to improve health. Spending on social welfare is also

necessary. Social policies that ensure a more equitable distribution of wealth also contribute substantially, such as policies on employment, health care coverage, and child care. Furthermore, health and spending on social welfare programs are key components of economic growth.

DeMel has summarized the shift in these views. According to de Mel,<sup>63e</sup> a view of development in the late 1970s held that high incomes were both necessary and sufficient for poor countries to raise social indicators such as health. The example of Sri Lanka, a poor country with excellent health indicators, challenged that view. In 1981 Amartya Sen found that if health achievements were based on income levels, the life expectancy of Sri Lanka corresponded to a country that generated 20 times more wealth in terms of per-capita GDP. Sen and Paul Isenman argued that Sri Lanka's achievements were due at least in part to high and effective social spending. However Bhalla and Glewwe argued in 1986 that although the levels of social indicators were high relative to income, the improvement in these levels were not exceptional. They proposed that the focus on social spending over investment was actually retarding further progress in the social indicators.

Subsequent work in the 1990s by Anand and Kanbur and by Anand and Ravallion helped to resolve this question by demonstrating, with regard to infant mortality rates, that:

1. Both income growth and welfare spending matter for the improvement of social indicators, but welfare spending matters more.
2. Income growth matters primarily through creating the means to increase welfare spending (i.e. income growth matters indirectly).

Aturupane, Glewwe and Isenman in 1994 made a useful cross country analysis of data that helped to forge a consensus:

	<b>Reduced Income Growth</b>	<b>Increased Income Growth</b>
<b>Better Infant Mortality Rate (IMR) Indicators</b>	Many Latin American countries	Many East Asian countries
<b>Worse IMR Indicators</b>	Many African countries	Many South Asian countries

The conclusion was that statistically, income growth is seen to be positively correlated with Infant Mortality Rate indicators, meaning that there is a valid association between higher income and lower infant mortality. But income growth is neither *necessary* nor *sufficient* for this relationship to hold. The efficacy of income growth for improving health and wellbeing, then, depends on additional factors.

In addition, improvements in health are an important component of economic growth and development. The contribution of health to economic growth gained world-wide attention in 2002, after the release of a report by the Commission on Macroeconomics and Health (CMH), commissioned by the World Health Organization and prepared by leading international figures in the field.<sup>23</sup> The CMH report argues that not only does poverty produce ill-health but disease produces poverty, especially because early ill-health affects future productivity. It concludes that in order to provide essential medical goods and services to the 2.5 billion people who do not have access to them currently will require an annual investment of \$163 billion by 2007. It points out that these sums represent a justified and manageable increase in annual donor funding by developed nations. The CMH report estimates that the investment proposed could not only save 8 million lives a year by the end of the decade but that the savings in morbidity and mortality would equal an economic gain of \$186 billion a year.

## **I.D. Global trade and trade agreements: Trade liberalization, barriers to trade, and economic growth**

There are broad questions regarding the global economy and international trade that are relevant and of interest to public health. These broad issues include: whether and under what circumstances open trade across borders as opposed to internally developed industries best advances economic growth; the equitable distribution of wealth and sustainable development; and the relationships between economic growth, wealth, health, and other factors such as democratic and accountable governments and social infrastructure.

Does trade liberalization increase economic growth, social welfare investment, and health? In this section, we review key trade concepts, a brief history of trade liberalization, and the implications for health.

### **Trade policy and sustainable development objectives**

Global trade and the integration of cultures have a long history, including nomadic conquests and Marco Polo's Silk Road trade route between Europe, the Middle East and Asia.<sup>23</sup> Trade among nations has promoted innovation, and international cooperation on the terms of trade could increase prosperity and political harmony.

The preamble of the 1994 agreement that established the World Trade Organization (WTO) to govern global trade identifies the objectives for "free" or liberalized trade policies. These included "higher standards of living, steady growth of real income, full employment and economic growth patterns compatible with sustainable development." Even the least developed countries were projected to share the benefits of global production and trade in goods.<sup>91</sup>

But there is controversy about whether the present rules for trade meet these stated WTO goals or achieve the conditions for sustainable development, including eliminating poverty, and establishing equity, transparent and democratic decision-making, and accountable governance.<sup>30</sup>

Developed and developing countries may adopt complex positions regarding international trade agreements, and constituencies within those countries are likely to hold differing views. For example, government and civil society organizations in many developing countries may resist applying trade rules to health and medicines, while supporting other aspects of trade as part of an economic development agenda.

### **History: protectionism vs. liberalization**

World economic history has long been characterized by cycles—or pendulum swings—between freer trade (or trade liberalization), and protectionism, according to Rosset.<sup>76</sup> Swings toward trade liberalization are sometimes referred to as "economic integration"—as in integrating the economies of Canada, the US and Mexico via the North American Free Trade Agreement (NAFTA). In the period of European colonialism, the economies of the colonies were integrated into the increasingly global economies of Europe.

Many presently developed countries were able to grow in the 1800s and early 1900s in part by "protecting" domestic industries. The emergence of new "free" trade policies would now deprive newly developing, postcolonial nations of this option.<sup>24</sup>

Following World War II, economically developed nations, through a series of conferences at Bretton Woods, created the World Bank and the International Monetary Fund (IMF), to encourage coordination on exchange rates and measures of national financial stability. The nations were not ready to agree to an institution that would set rules for trade, but established a series of ongoing international negotiations on trade in the form of the General Agreement on Trade and Tariffs (GATT). As described below, the World Trade Organization (WTO) emerged from the GATT process in 1995.

In the 1970s, according to Rosset, businesses in the United States and Europe began to confront crises brought on by rising wages at home and excess productive capacity. They found themselves with the ability to produce more than their home markets could absorb, and needed access to markets in developing countries to move their excess production. This brought the issue of protectionism by developing nations' governments to the fore.

At the same time, the governments in many developing nations became enmeshed in a debt crisis. As a result, they sought renegotiation of their debt through the World Bank and the International Monetary Fund (IMF). The World Bank and IMF offered debt restructuring, and new interest-bearing loans, contingent on the adoption of Structural Adjustment Programs (SAPs) by developing nations' governments. SAPs required steep cuts in government spending, including support for social services, and the privatization of many government services and enterprises. They also called for trade liberalization, including lower tariffs and quotas. This provided outlets for US and European products.

In the past two to three decades cross-border financial transactions and exchanges among interconnected multinational corporations, facilitated by advances in communication, technology, and transportation have occurred at an accelerated pace. This process is sometimes referred to as economic globalization. These conditions have motivated transnational corporations to seek production facilities and labor, as well as markets, overseas. In order for these corporations to continue to increase their overseas activity and their profits, they have influenced governments to adopt "free" trade policies, or trade liberalization.

### **Trade liberalization: removing barriers to trade**

Rosset describes trade liberalization as the process of removing barriers to trade.<sup>76</sup> International trade agreements aim to facilitate cross border trade, by eliminating trade "barriers" in the form of government laws and regulations, such as financial tariffs and import quotas, and government subsidies which distort market forces.<sup>66</sup> Doing so, proponents assert, would create incentives globally for businesses to produce more because they would have easier access to foreign markets. This increased economic activity would increase jobs and growth, while global competition would make more products and services available at lower prices.

Accordingly, nations could expect to benefit by their increased ability to export their goods and services to other countries, where their products will be no more expensive than domestically produced products because trade barriers such as domestic tariffs and quotas will have been removed. Every country is supposed to benefit from liberalized trade, according to the theory of comparative advantage, because each country would produce what it is best suited to produce, whether it be coffee or cars. This is less than clear in practice however, and a global controversy has emerged as to whether this approach to economic development is on the right track. Critics assert that the present rules for international trade fail to achieve expected economic benefits.<sup>21,38,105</sup>

When governments remove barriers to trade (such as import tariffs and quotas), they are opening their markets to foreign competitors. In doing so, they are taking the risk that if the resulting imports are too cheap, domestic producers may be driven out of business. If, under the theory of comparative advantage, the exporting country can produce the same good more cheaply because of pure comparative advantage, such as climatic conditions, it would be better for the importing country to produce something else, where it has a true comparative advantage. In practice, however, cheaper products are rarely cheaper because of pure comparative advantage. Rather, it is because of distortions, such as the effect of market concentration, or occasionally due to subsidies to large producers of steel or agricultural products. For a typical developing country, comparative advantage at home may be a lower paid, more exploited workforce.

Under international trade rules, barriers to trade can include any policy measures that alter—or distort—the uninhibited flow of trade. Barriers can take the form of tariffs (taxes on imports), as discussed above. In this context, tariffs and other measures employed by countries to protect their domestic production from the competition of cheap imports, are portrayed as “protectionism.” In addition to tariffs, trade barriers can take many other forms; as a group they are called “non-tariff” barriers. Non-tariff barriers can be import quotas, local content requirements, production subsidies and price supports (because they make local products cheaper and therefore more competitive than unsubsidized imports), export subsidies (because they confer an artificial advantage to foreign products in importing countries), and others.

For example, rules orienting governments to purchase locally or to support local or minority owned businesses generally intend to encourage local economic development, and in some cases to redress historical inequalities. Such domestic rules can be construed as barriers to trade and as such can thus conflict with international trade rules.

In the case of services, laws and regulations that protect health, or set standards for the quality of services, can also be considered “disguised” barriers to trade.

GATT rules promote competition among businesses at the international level, and impose requirements for foreign and domestic goods to be “treated equally.” Practices such as tariffs that “protect” national industries from foreign competition were considered barriers to international trade, and discouraged by GATT rules.<sup>103</sup>

Many criticize the basic assumptions of the GATT, as well as their later manifestations.<sup>24,41,58,103</sup> The GATT was shaped by the interests of the economically powerful participants. It was created against a backdrop of inequalities in international economic development and political power, and a history of colonialism. The sharp and persistent divide between economically developed, developing and transitional economies, and unequal distributions of wealth both within and among nations, raise questions about their fundamental soundness.

### **Does trade liberalization increase economic growth?**

Several reports suggest that trade liberalization and trade agreements have not produced the promised results for economic growth or job creation. The Center for Economic and Policy Research (CEPR) report, “Poor Numbers: The Impact of Trade Liberalization on World Poverty,” found that “gains to developing countries from trade liberalization are smaller in reality than the numbers that have been widely cited in the public debate. At the same time, the costs to developing countries of complying with commercial agreements such as the WTO are

often ignored. This leads to a lot of misunderstanding regarding the potential impact of trade liberalization and the conditions that are attached to it."<sup>105</sup>

Ten years of experience with NAFTA, a regional trade agreement between Canada, Mexico, and the United States, provides additional insights. The Environmental Health Coalition, in their report, "Globalization at the Crossroads: Ten Years of NAFTA in the San Diego/Tijuana Border Region," notes that "increasing economic instability, poverty, worker and environmental injustice have resulted in the San Diego/Tijuana border region during the ten years since the North American Free Trade Agreement took effect." The report calls for replacing the NAFTA model of free trade with "fair trade agreements that include enforceable environmental protections, protect labor rights, hold corporations accountable, defend democracy and reduce inequality."<sup>38</sup>

An assessment by the Carnegie Endowment for International Peace found that NAFTA did not create new jobs as promised in the United States, and that in Mexico it drove out millions more jobs in agriculture due to increases in imports compared with the jobs created by export manufacturing.<sup>21</sup>

### **I.E. The privatization debate: Should countries move cautiously to liberalize health services? What models work to improve health services?**

Should countries move cautiously to liberalize health services? This section briefly explores the debate about market forces in health care and health-related services, privatization of health care services, and alternative approaches to expanding access to affordable, high quality care, including the primary care movement, and the health systems approach.

There is an wide array of arrangements among countries for organizing, financing and delivering public health and medical care services. They achieve varying levels of success in offering access to high quality of care at an affordable cost, according to international measures and domestic assessments. (In this case, we refer to public health services as those that monitor, analyze, protect and promote population health, and to medical/health care services as those that treat illness. Prevention of illness can fall into both categories.)

Most developed countries experimented with a variety of approaches to providing a set of social services during the nineteenth and twentieth centuries. They moved between combinations of public sector and private sector responsibilities for organizing, financing, delivering and providing oversight for firefighting, water supply and sanitation, health care, education, physical infrastructure such as roads, and utilities such as energy and telecommunications. In the 1930s and 1940s, the United States diverged from most other nations in veering toward private financing, organization and delivery of health care services; as a result, the largest health insurance companies, and some of the largest private hospital corporations, are based in the U.S. In contrast, England and some Scandinavian countries rely on health service systems, in which the government pays for health care through taxes and directly provides services by operating hospitals and employing clinicians. Other European nations, Canada, Japan, and other developed countries rely on social insurance systems, in which the government assures universal coverage through a mix of public and private funding sources, and the delivery system is also mixed. The comprehensiveness of systems varies, ranging from full coverage for social and preventive services, to partial coverage for some services such as in-hospital nursing care.

Two trends of importance for health care services converged in the 1990s. International financial pressures on governments to reduce social spending, as well as periodic financial shocks, caused governments in Europe, Canada and Japan, as well as middle-income developing countries, to question and reduce the extent of their investments in predominantly publicly financed health care systems. At the same time, the growing crisis in health care costs and the number of uninsured in the U.S. was addressed through private sector policies, after the failure of the Clinton Administration's health care reform proposal. The financial and political strength of the health insurance and pharmaceutical industries increased, and policy proposals for universal coverage based on public sector solutions virtually evaporated in the U.S.

For-profit corporations greatly increased their activity in health care during the 1990s, in both financing and delivering health care services. For-profit health insurance plans, including managed care plans, mushroomed in the U.S., outstripping traditional non-profit insurers and health maintenance organizations. In addition, for-profit hospital chains became widespread. These corporations offered cash infusions for expanding and operating health systems, as well as the potential for earnings for some professionals in managerial or ownership positions, without the restrictions faced by nonprofit and public systems. This financial advantage depended on the corporations' ability to earn profits for investors, an imperative sometimes at odds with providing needed care to vulnerable populations and others with a high demand for services, and that led in some cases to misuse of funds. While a number of nonprofit health systems work internationally, for-profit health insurance companies and hospital chains have been more aggressive about entering foreign markets.

The U.S. is the only developed country without universal financial coverage for health care. At 15% of GDP, U.S. per capita health care spending is the highest in the world. The use of most health care services including doctors' visits is lower in the U.S. than in many other countries, including the majority of countries that rely to a greater extent on public financing. Popular policies emphasize individual incentives on the "demand" side to control costs – encouraging individual users to choose less expensive services or forego them entirely – although these are less effective than "supply side" measures that exert leverage by government or other group purchasers over the health care system.<sup>67</sup>

At the same time, the AIDS pandemic has illustrated that there is a severe shortage of both public health and medical care services available in much of Africa, as well as in much of Asia and parts of Latin America.<sup>44,104</sup>

In developing and transitional countries, Koivusalo and Mackintosh report that Asian transitional economies developed well-distributed primary care networks, while African nations built primary care systems in the post-colonial period as a part of nation-building.<sup>85e</sup> In a number of developing and transitional countries, where government-financed or provided health care has not kept pace with the need for services, there is pressure to turn to the private sector for a solution.<sup>20,106e</sup>

The interest in privatization has been fanned by some significant failures in health care systems.

During the Cold War period, as developing nations emerged from the constraints of colonialism, the superpowers supported a number of inefficient and corrupt governments that failed to provide adequate health care and other services. In a range of countries, health care professionals created hierarchies that relegated nurses and other allied health care workers to positions of lower status, authority and pay, and also substantially excluded users of services

from knowledge and decision-making about their care. Combined with the incentives of health care industries to profit from expensive or high-volume products associated with acute care such as hospital equipment and prescription drugs, the result has been escalating payments for care with known deficiencies in outcomes, and in some systems an over-emphasis on acute, technology-driven care as opposed to prevention, primary care, and public health systems.

### **Do countries pay too much for health care?**

Privatization advocates claim that access to services is inadequate because the services are too expensive, and that market forces are needed to control costs, rather than deliberate plans and programs to assure access to appropriate care. However, critics note that cutting spending for health and education, privatizing public assets, deregulating the economy and allowing multinational companies to compete with local firms, have often led to the loss of local purchasing power and greater unemployment, and discontent with resulting cutbacks in services. There are competing claims regarding the successes in expanding access, controlling costs.<sup>20</sup>

The general charge that countries pay “too much” for health care bears closer examination. Developed countries pay between 5% and 15% of GDP for health care. Countries at the lower end of the scale, such as the UK, have acknowledged that they probably don’t spend enough, and have begun financing at a higher level of care. But the drive for cost containment in health care in the 1980s coincided with the growth of multinational corporations and the resulting retreat by employers from their commitment to the social welfare of the domestic workforce, and also with the neoliberal prescription for general reductions in government spending of all sorts.

As summarized in one report, “As governments cut budgets, the quality and reputation of public services suffered. (Public sector unions are fond of calling this process ‘defund, defame, and privatize.’) As a result, consumers came to favor private alternatives. In many cases, however, these private providers neglected vulnerable consumers, charged much higher prices, or further contributed to the diminishing of public budgets through obtaining tax breaks, incentives, or even government bailouts.”<sup>15</sup>

Revelations that hospital care in the U.S. produces up to 100,000 deaths annually due to preventable errors in care called attention to real problems in quality. Since hospital care is the most expensive element of medical care, there is a legitimate question about whether payers are getting their money’s worth. The growing rate of preventable hospitalizations for chronic conditions better treated through primary care such as asthma and diabetes suggests system failures. And the high costs of care at the end of life are receiving deserved examination. These factors, though, do not suggest that competitive market forces will necessarily set the cost equation straight. Koivulsalo and Mackintosh suggest an industrial approach to the organizational features of hospitals and health care systems would be useful, rather than relying on a microeconomic approach to financial incentives.<sup>98e</sup>

Proposals for increasing access to health care services, controlling costs, and improving quality, though private sector, microeconomic solutions, are still contested in both developing and developed countries. European countries have generally retreated from experiments with market incentives such as private financing, while private insurance companies have made significant inroads in parts of Latin America.<sup>77,52,87</sup>

### **Coverage for health care**

Financing universal coverage is rarely possible without strong participation by the public sector, which must either set the rules for financing and coverage, or pay directly.

Universal coverage is an important element of health services, as it creates a uniform risk pool. While everyone will eventually get sick, no one can predict when, to what extent, or what the cost will be. People without financial coverage are just as likely to experience the major expenses associated with a major illness. The resulting financial burden is felt mostly by the individual patient, but also by any health care provider who is not compensated for care, and by the residual “safety net” system. Like fire fighting, it is a classic case that demands universal coverage.

Health insurance can be a lucrative enterprise, particularly if companies can segment and cover relatively healthy populations. There is therefore commercial pressure from insurance companies to gain access to public social insurance funds that finance care. Private health insurance programs may improve access for some segments of the population for some services, but usually the changes are not distributed equitably.<sup>52,60</sup> Additionally, as Koivusalo and others point out, in the event of failures, it is difficult to reconstruct a universal risk pool once it has been segmented.<sup>98c</sup>

### **Privatizing delivery of services**

In the area of delivering services, through institutions such as hospitals and clinics, or by individual clinicians such as doctors and nurses, a wide variety and mix of public, private (nonprofit and for-profit) and community-based owners and administrators have been successful (and also not successful) in offering high quality, affordable care. While health care delivery is less profitable than health insurance, there is still pressure from private companies to allow entry.<sup>60</sup> The critical question, in cases where public sector delivery is successful, is what private providers will contribute. Where public sector delivery is not successful, the critical question is whether the public sector has the resources and organizational wherewithal to hold private companies accountable for performance.<sup>124</sup>

There is little consensus on the advantages and disadvantages of private, public and community-based coverage and service delivery, but there are strong arguments on all sides.

A World Bank online discussion group offers insight into the debate. One online moderator asserts that Singapore’s private health insurance system has offered all of the advantages and none of the drawbacks of a public health insurance system. A resident responds that the system seems to work well because most residents don’t use it, and some travel abroad for major episodes of care.<sup>107a</sup>

A forum sponsored by the Friedrich Ebert Stiftung and the Carnegie Council on Ethics and International Affairs in April, 2003, posed the question: Privatization and GATS: a Threat to Development? The report of the debate between “market skeptics and privatization proponents” on approaches to the reform of public services notes,

Ten years ago, as the communist regimes collapsed and market-oriented economics began a lengthy period of robust growth, the wisdom of open trade, capital market liberalization and privatization went largely unquestioned. A decade later, however, there is widespread concern that economic liberalization has failed to deliver its promised results. Sagging economic growth and corporate scandals in the United States and Europe, in addition to the recent financial crises in Latin America, Russia and Asia, have only intensified these concerns. Moreover, the privatization of state-owned enterprises – once thought to be a crucial measure of development – has delivered mixed results.

While privatization of traditionally competitive sectors shows evidence of increased productivity and profitability, the privatization of natural monopolies, especially water and energy, has engendered more disturbing outcomes. **Indeed, ...the observation that privatization has often led to soaring prices, denial of access, and mismanagement cannot plausibly be denied.**<sup>20</sup>

The report notes that while the private sector has an important role in economic development, the key question is how services can be delivered to best meet development goals, including poverty alleviation and social equity.

While acknowledging that government services throughout the developing world are often inadequate and inefficient, leaving multitudes without basic services or only intermittent access, it notes that privatization is also increasingly unpopular, where privatization has led to corruption, job losses, and higher prices.

The Carnegie/Ebert report notes the concern that subjecting services to GATS rules would impose a single model of corporate-led development on all WTO members.

### **Commodification and fragmentation of health services**

Koivulsalo and Mackintosh point out that in the case of health care, the issue is not only whether ownership or control is in public or private hands, but also the commodification of health service units that can be sold on the market, and the commercialization of all aspects of the complex health care system.<sup>98e</sup> This contributes to fragmented care delivery systems, which cause users to access different providers to treat several different health conditions that exist within the same person, for example, or a shortage of necessary services that are less remunerative. The application of competitive market forces to determine coverage and therefore access, to decide the distribution and nature of health care services, and to evaluate the performance of the system, has excluded many from care and created an unsustainable system.

In practice, this means a separation of preventive, primary and acute health care, and supportive social services, when in fact ready access to a range of integrated services provides higher quality at a lower cost. In the U.S., there is an oversupply of specialist physicians and an undersupply of primary care physicians, and cyclical shortages of nurses.

### **Alternative Approaches: Primary Care, and Health Systems**

From sources as disparate as the Partners in Health Project in Haiti to the U.S., analysts have called for a focus on assuring primary care, and a shift to more integrated models of health care.<sup>91, 42</sup> Primary care can signify the basic level of health care services that most people need to prevent the progress of disease and maintain chronic conditions. It can also imply a type of system in which users of services participate in decisions about the system and their treatment, there is continuity of care, and different providers coordinate the care of a single patient.

A health systems approach relies on assessing the needs of a population and planning the range and types of services appropriate to particular communities.

An example of this model exists in Brazil, where a national system has controlled the spread of HIV/AIDS relatively successfully. A coordinated system of care involves pharmacists, doctors, nurses and community health workers in preventing and treating the illness, through an integrated system of care. Community campaigns advocate prevention. The country assures

universal distribution of antiretroviral drugs to everyone in need. Brazil manufactures some of its own drug treatments for AIDS, and negotiates low prices for those it imports.

Cuba's planned system of public health, supplemented by primary, secondary and tertiary medical care, is regarded internationally as a model. It is credited, in part, for Cuba's low rates of infant and maternal mortality. A doctor and nurse are located in each community, and community and specialty acute hospitals are distributed regionally based on population density. Medical care is available in schools and workplaces.

In response to a major address calling for a health systems approach in the developed world,<sup>57</sup> critical authors responded that such a vision is "pie in the sky."<sup>45</sup> Indeed, there are powerful and profitable advocates for the status quo. However, the prospect of further voluntary and nearly irreversible progress toward the commercialization of health care services through GATS is an important occasion to reconsider the prospects for envisioning and implementing alternatives.

## **II. Health and Trade: the Links, Policy Implications, and Outcomes – Toward Convergence or Conflict?**

### **II.A Public Health Perspective - Principles for Trade and Sustainable Development**

New and widespread threats to global health present new challenges to advancing the health of the world's population. Expansion of the scope of international trade rules presents potential conflicts with public health priorities. Enforcement of trade agreements through the powerful regulatory regime of the WTO presents additional challenges to public health, including nations' ability to regulate in the interest of health.

The World Health Organization has noted that existing international rules, institutional mechanisms, and forms of organization need to evolve in order to respond to new challenges of globalization and to ensure that the benefits of globalization are broadly shared. Detailed analysis is needed to better inform policy makers concerned with shaping global health governance in the future.<sup>111</sup>

These challenges call for a shift toward global cooperation, and a shift from a focus on achieving microeconomic and macroeconomic objectives to achieving health and human wellbeing. Current international trade negotiations offer entry points for offering such an alternative paradigm.

A global public health policy framework prioritizes the achievement and protection of health and wellbeing of individuals, communities and populations, in the context of sustainable economic development. Such a framework would foster progressively greater international cooperation, the development of an interdependent model to address international health issues, and global rules that promote health and access to health-related services, as well as advancing each nation's public health and medical care systems. It entails promoting conditions of economic and social equity and justice, democracy, and equitable access to health-related services.<sup>51,89,90,95,110</sup> We discuss this framework and its implications beginning on p. 33.

## **II.B. Trade Perspective - The WTO and International Trade Agreements**

During the 1980s, politically powerful nations, particularly the U.S. and U.K., increasingly took the view that government budgets should be decreased, that state regulations affecting industries should be minimized in favor of unfettered competitive market forces, and that government social programs should be reduced and reshaped according to models that address individual consumers rather than populations and communities. (Government functions that provide economic stability and rights for corporations, as well as private sector subsidies, were not targeted.) The political agenda known as the Washington Consensus contributed to the tendency in this period to emphasize market based policies and to diminish the public sector's role in providing social services and protections.

Also during this period, U.S. President Ronald Reagan and British Prime Minister Margaret Thatcher began planning to expand the GATT to cover new realms of economic activity: services, intellectual property rights, agriculture, and investments. These priorities were implemented during the 1986-1994 round of GATT negotiations, known as the Uruguay Round (because the initial meetings took place in Uruguay).

At the conclusion of the Uruguay Round, the GATT was succeeded by the World Trade Organization (WTO) which came into effect on January 1, 1995 with 76 member countries; since then membership has almost doubled and now includes 148 countries.

Based in Geneva, with 550 non-elected staff, the WTO oversees international trade agreements. Nations can elect to join the WTO, in return for which they are expected to comply with all existing WTO trade agreements. (The Government Procurement Agreement is an exception; it is "plurilateral," meaning only some WTO members are parties to the agreement.)

Recent WTO ministerial meetings, including meetings in Seattle in 1999 and Cancun in 2003, have drawn global attention for the conflicts and protests they engender.<sup>81</sup>

The breaking points have generally been the "new issues," which developing countries generally view as disadvantageous to their interests – investment, agriculture, intellectual property and services, and competition policy. These topics, added to the trade agenda during the Singapore Round in 1995, identify new frontiers that developed countries have sought to harmonize through trade agreements. A number of developing countries have expressed opposition to addressing these issues, or to particular proposals advanced by the "Quad" bloc: the United States, the European Union, Canada and Japan. While many developing nations are eager for economic growth and the potential benefits of international trade, many are also deeply concerned about the global imbalance in wealth and power. They believe that retaining control over these issues is key to their economic future. They have organized into various negotiating blocs of their own, including the African, Caribbean and Pacific (ACP) nations, and the Group of 21 that brought the 2003 WTO ministerial in Cancun to a standstill. While the membership of this Group has varied, China, India, Brazil and South Africa have provided a powerful counter-balance to the Quad nations.

### **Trade disputes: Enforcement of trade rules, and “investors’ rights”**

WTO agreements are enforced by financial fines and trade sanctions in the case of violations. For this reason, they have proven to be the most effectively enforced international agreements. The WTO is set as the unequivocal arbiter of trade rules. Countries that believe their companies are being barred from trade by another country for reasons that violate WTO rules can file a dispute with the WTO. Disputes among nations are resolved by panels appointed by the WTO. The panels are not accountable to national governments or courts. The panels can authorize countries to impose trade sanctions, financial penalties and the boycott of products against other countries, as compensation for violations or for failure to comply with trade panel decisions.

Chapter 11 of NAFTA provides an “investor’s rights” provision that allows individual foreign corporations (referred to as investors) to directly sue any of the three participating national governments. Companies can sue for the loss of current or future profits, even if the loss is caused by a government agency’s prohibiting the use of a toxic substance.<sup>31,99</sup> Prior to NAFTA, regional trade agreements only permitted country-to-country enforcement by governments. This was a major elevation of the rights of corporations, and an important blow to national sovereignty. Subsequent regional and bilateral agreements negotiated by the US include the investor’s rights provision. Objections by the Intergovernmental Policy Advisory Committee to the USTR, composed of state and local public officials, contributed to keeping this provision out of the U.S.-Australia Free Trade Agreement.

### **II.C. Trade agreements related to health**

Upon the establishment of the WTO in 1995, a host of new trade agreements applied GATT rules to services, intellectual property, agriculture and investments. A number of the agreements directly affect health, food and environmental safety, and labor standards. These include the General Agreement on Trade in Services (GATS), discussed in Sections III and IV below, the Agreement on Agriculture, the Agreement on Trade-related Aspects on Intellectual Property Rights (TRIPS), the Agreement on the Application on Sanitary and Phyto-Sanitary Standards (SPS), the Agreement on Technical Barriers to Trade (TBT), and the Agreement on Government Procurement.

#### **Trade in Services**

The services market is a new frontier in global commerce and is considered to be highly profitable by multinational service corporations and their host governments, which have identified and begun to pursue new export markets in services.<sup>31</sup> World trade in commercial services accounted for around one fifth of world exports of goods and services, reaching \$7 trillion in 1998.<sup>40</sup> Nearly 90% of all merger and acquisition purchases in developing countries were in the services sector in 1999, mostly resulting from the privatization of state enterprises.<sup>54</sup> Furthermore, services now account for 60-70% of Gross Domestic Product and employment in industrialized countries, including traditionally private commercial enterprises such as banking and insurance, as well as traditionally public sector services, including telecommunications, health care, water and sanitation, education, and corrections.

Possible or actual adverse consequences for health of some key agreements are described in Tables 2 (multilateral agreements) and 3 (regional agreements).

Table 2 – Multilateral Trade Agreements

Trade Agreement	Objective/Scope	Health-Related Issues	Potential Consequences
<p><b>General Agreement on Trade and Services (GATS)</b> <sup>105</sup></p>	<p>Like other agreements, GATS seeks to reduce nations' internal barriers to such international trade, and to harmonize international standards, where variation among countries could present a barrier. GATS extends WTO rules to services, including advertising, packaging, retailing and distribution of services. The rules are designed to increase commercial competition by private corporations, operating across national boundaries. It identifies a list of both commercial/ financial services, and traditional social services, as subject to international trade rules.</p>	<p>Countries have committed and others may consider committing their <b>hospital services and health facilities including community health centers</b> to coverage under GATS rules, including direct ownership, management and operation by contract of hospitals on a "for fee" basis.</p> <p><b>Health insurance</b></p> <p><b>Distribution of wholesale goods, including: Tobacco products and Alcohol products</b></p> <p><b>Medical, dental, veterinary, midwives, nurses, physiotherapists and paramedical personnel</b></p>	<p>Where such commitments have been made, a range of national hospital funding and performance laws and regulations could be subject to challenge under GATS.</p> <p>Programs and rules that could be challenged as violations of GATS rules include: federal and subfederal insurance programs; extending coverage for health care (restricting the number of competing insurers); restrictions on genetic and gender discrimination, and patient protection laws.</p> <p>Countries that have restricted the application of GATS market access rules regarding tobacco and alcohol distribution can respect community efforts to limit the number of liquor stores in local communities, and enforce federal and subfederal laws on tobacco distribution. The EC has requested, for example, that the U.S. remove such restrictions.</p> <p>Immigration and licensing standards for clinicians are important quality concerns. Increased hiring of immigrant nurses in the US, for example, may mask poor working conditions, and drain important clinical resources away from countries of origin. These issues should be examined in a process driven by a concern for health, not by commercial trade.</p>
<p><b>Agreement on Trade-Related Aspects of</b></p>	<p>TRIPS, finalized in 1995, governs patents for pharmaceuticals, and copyrights.** It protects the exclusive</p>	<p>TRIPS rules, including the patenting of</p>	<p>Has been used to uphold patent protections for pharmaceutical companies, limiting access to</p>

<b>Intellectual Property (TRIPS)</b> <sup>101</sup>	monopoly rights of producers to control the terms of sales for their products, preventing market entry by competitors for at least 20 years after the original brand name product is introduced to the market.	pharmaceuticals, govern production and distribution of essential medicines, including generic derivatives.	essential medicines, delaying production and access to generic medicines, and prohibiting drug reimportation. Could limit farmers' control of seed exchange and access to agricultural inputs. <sup>4,32</sup> TRIPS protections for trademark holders (such as tobacco brand names) could be used to block health warnings on cigarette packages. <sup>10***</sup>
<b>Trade Agreement</b>	<b>Objective/Scope</b>	<b>Health-Related Issues</b>	<b>Potential Consequences</b>
<b>Agreement on the Application of Sanitary and Phytosanitary Measures (SPS).</b>	Reduces barriers to trade that derive from governments' regulations and laws designed to protect the health of humans, animals, and plants. Requires measures to be scientifically justified.	Regulatory safeguards for health must comply with SPS trade rules.	Directly affects regulatory safeguards for health. Can restrict application of the precautionary principle.
<b>Technical Barriers to Trade (TBT)</b> <sup>10</sup>	Encourages the use of international standards as the basis for technical regulations that affect trade. Internationally recognized standards, such as those of the International Standards Organization (ISO), are presumed not to be unduly burdensome to trade; unlike SPS, the TBT does not require measures to be scientifically justified. Applies to standards developed by the Codex Alimentarius Commission.	Public health measures must comply with TBT trade rules. In the absence of internationally recognized standards, public health measures are subject to challenge under this agreement.	It is possible that if public health measures become recognized as international standards (for example, tobacco control measures in the Framework Convention on Tobacco Control), these measures may enjoy the presumption that they are "necessary" and "least restrictive" to trade under the TBT agreement.
<b>Agreement on Government Procurement</b>	A "plurilateral" agreement that to date includes only 28 developed countries. It states that governments cannot favor local companies or service suppliers, or impose technical specifications if they pose "unnecessary" barriers to trade. The rules apply to purchases over certain income levels. Governments can apply "restrictions that promote general environmental quality," but only "as long as such restrictions are not disguised barriers to trade." The provisions apply to governments at the national level, and also to state and local levels, with their agreement. <sup>****</sup>	Local hiring and other practices that favor sustainable economic development are required to comply with rules of this agreement. Government contracts which call for and enforce medical and financial privacy rules must comply with rules of this agreement.	May limit governments' ability to use government procurement practices to implement public policy, in areas including standards for quality and performance, environmental protection, public health and safety, gender and racial equity, labor practices, and human rights.

\* Public services are excluded if they are "provided in the exercise of government authority" and if they are "supplied neither on a commercial basis nor in competition with one or more service suppliers." Since many public services are also provided in the private sector, or at least have

commercial relationships with private suppliers, it is unlikely that many services would actually be exempt under this definition.

\*\* Technological changes have made it far easier for global competitors in developing countries to reproduce engineering advances pioneered in developed economies. Through TRIPS, the entertainment, computer software and pharmaceutical industries developed a basis for protecting their inventions and therefore profits from international competition.

\*\*\* The issue of TRIPS and access to medicines is discussed in depth in Section VII.

\*\*\*\* Local, state and national governments use procurement practices and contracts as important instruments for enacting public policy, including public health and safety.

**Table 3 – Selected Key Regional Trade Agreements\***

<b>Trade Agreement</b>	<b>Objective/Scope</b>	<b>Health-Related Issues</b>	<b>Potential Consequences</b>
<b>North American Free Trade Agreement (NAFTA)</b>	Enacted in 1994, this agreement reduced trade barriers between Canada, the United States and Mexico. Includes an investors' rights provision granting private corporations that right to file trade challenges directly against government policies and regulations of partner nations.	Government policy and regulations, including public health, environmental safety, occupational safety and health must comply with NAFTA trade rules.	Landmark trade disputes filed under NAFTA have challenged environmental safety and occupational health and safety rules. <sup>12,37,86</sup>
<b>Free Trade Area of the Americas (FTAA)</b>	The FTAA would extend NAFTA to the remaining 34 nations of the western hemisphere, excluding Cuba, affecting 800 million people. <sup>71</sup> The FTAA includes an investors' rights provision. Pending negotiations are scheduled to conclude by 2005. However, as disagreements among nations are surfacing, reaching this deadline is unlikely. The U.S. has turned to increasing its bilateral (nation-to-nation) negotiations with other countries.	Health-related areas included in the FTAA are: hospitals; medical clinics; health insurance; the services of health professionals including doctors and nurses; access to essential medicines; the distribution of alcohol, tobacco and food; water provision and sanitation; education; energy; and telecommunications.	FTAA rules could be used to find that health protections are unnecessary barriers to trade.  Intellectual property provisions may result in severely limiting access to essential medicines.  Both private and public services may be subject to the FTAA. **
<b>Central America Free Trade Agreement (CAFTA)</b>	Agreement between United States and Central American nations of Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua, as well as the Dominican Republic. If enacted by their legislatures in 2005, more than 80 percent of US exports to consumers and industrial products to Central America will be duty-free immediately upon entry into force of the Agreement, and all remaining tariffs will be eliminated within ten years. The agreement applies to advertising, intellectual property and services.	Very similar to FTAA.	CAFTA rules could be used to find that health protections are unnecessary barriers to trade.  Intellectual property provisions may result in severely limiting access to essential medicines.

\* A number of regional and bilateral agreements are being pursued, particularly since WTO processes became bogged down in 2003. They include or exceed WTO provisions. Developed nations generally have superior economic and political bargaining leverage in these negotiations.

\*\* Public services are excluded if they are “provided in the exercise of government authority” and if they are “supplied neither on a commercial basis nor in competition with one or more service suppliers.” Since many public services are also provided in the private sector, or at least have commercial relationships with private suppliers, it is unlikely that many services would actually be exempt under this definition.

There are numerous other regional trade alliances, including MERCOSUR and the Andean Pact in South America, which may develop mutually beneficial trading rules. Negotiations between the European Free Trade Association (EFTA) - Switzerland, Norway, Iceland and Liechtenstein (which are not members of the European Union) - and the Southern African Customs Union (SACU) are proceeding because the Europeans have agreed not to seek

additional intellectual property rules affecting pharmaceuticals, or on investment and government procurement. The SACU member countries expressed interest in first harmonizing their own trade policies with each other on these issues.<sup>61</sup>

### **Trade and Health Policy Divergence – Trade Disputes and Health Policy: Selected Examples**

Nations have successfully brought challenges before trade tribunals claiming that public health measures violate trade rules. Health and quality standards and labeling requirements have sometimes been construed by the World Trade Organization as barriers to trade. From a public health perspective, standards for labeling genetically modified foods or protecting dolphins from becoming snared in commercial fishing nets are important protections for human and animal health, and the environment. But businesses have found these standards cumbersome, and therefore barriers to trade.

The following present some trade dispute cases with negative implications for health. As is typical of such cases, the health argument did not substantially prevail.

- **Banning Beef Treated With Artificial Hormones**

The European Union's ban on the sale of beef from cattle treated with artificial hormones was ruled an unfair trade barrier by a WTO panel after complaints from the US. The ban was applied in a nondiscriminatory manner to both domestic and imported beef, as required by the WTO rules on national treatment. There is evidence of risk to humans from artificial hormones. However, there is not yet a precise scientific conclusion quantifying the risk from residual artificial hormones in beef. To justify its ban, the EU relied on the precautionary principle, an important basis for public health policy, which asserts that potentially dangerous substances should be proven safe before they are marketed. The WTO ruled that the ban was illegal under the terms of the Agreement on Sanitary and Phyto-Sanitary Measures (SPS), in part because it did not rely on a risk assessment method approved by the WTO. The tribunal authorized the US to retaliate with sanctions against European goods.<sup>103</sup>

- **Health and Safety Under NAFTA**

During the debate on enactment of NAFTA, supporters suggested that the regional agreement could provide a mechanism for improving working conditions. The Maquiladora Health and Safety Support Network reviewed 28 cases filed through the related North American Agreement on Labor Cooperation, and found that seven were related to workplace safety and health. However, they found that in each case, there was no change in enforcement of the country's own regulations, and no change in the regulations themselves. Workers were not involved in the dispute resolution process. There was no timeline for decisions.<sup>15</sup>

- **Closure of a Toxic Waste Disposal Site**

In a landmark environmental case filed under NAFTA Chapter 11, a NAFTA tribunal awarded the U.S.-based Metalclad Company \$16.7 million in its suit against Mexico. The state of San Luis Potosí had refused permission for Metalclad to re-open a waste disposal facility, in the face of a geological audit showing the facility would contaminate the local water supply and resulting opposition by the local community. Metalclad claimed that this local decision constituted an expropriation of its future potential profits and successfully sued Mexico.<sup>99</sup>

- **Eliminating Toxic Gasoline Additive**

The Methanex Corporation of Canada sued the United States for approximately \$1 billion, because the state of California banned the use of methyl tertiary butyl ether (MTBE), a gasoline

additive. Though introduced to reduce air pollution, MTBE was found to be carcinogenic when it leaked into the water supply. Methanex produces methanol, a component of MTBE. This case remains under consideration by a closed appeal tribunal. Due in part to the possible sanctions resulting from this case, MTBE remains in use within California.<sup>46</sup>

- **Chilling Effect on Public Health Measures**

The possibility of a WTO trade challenge has chilled some developing countries with limited budgets from pursuing laws that protect public health and wellbeing. In 1988, a Guatemalan law upheld the WHO-UNICEF Infant Formula Marketing Code, and prohibited companies from using advertising labels that made infant formula appear to be healthier than breast milk. The US-based Gerber Products Company conducted a four-year campaign opposing the law, and refused to comply. In 1995, Gerber won support from the US to challenge the law before the WTO. To avoid the dispute, the Guatemalan government ruled that imported baby food products are exempt from the infant health laws.<sup>103</sup>

- **Protection from Hazardous Substances: Thai Tobacco Case**

In 1990, Thailand's prohibition of cigarette imports was found unjustified, even though the WTO trade panel recognized that chemicals and other additives in U.S. cigarettes may have been more harmful than those in Thai cigarettes.<sup>13</sup>

#### **II.D. Public Health Comments on the Effects of Trade Policies and Agreements on Health; Calls For Alternatives**

National and international organizations have commented on the effects of trade on health during the last several years, expressing concern about potential adverse impacts, and recognizing the need for coherence of policy priorities and global governance to protect and promote health and other human rights.

At the fourth trade ministerial of the **Summit of the Americas** (the San Jose Ministerial) in March, 1998, ministers called upon the Free Trade Area of the Americas (FTAA) trade agreement to contribute to raising living standards, to improve the working conditions of all people in the Americas, and to protect the environment.<sup>82</sup>

In addressing the Third Ministerial meeting of the World Trade Organization (WTO), in 1999, the **UN Committee on Economic, Social and Cultural Rights** recognized the advantages of an international trading system – envisioned in the preamble to the 1994 Agreement Establishing the World Trade Organization (WTO) – which acknowledges the importance of sustainable development. The Committee urged the WTO to review:<sup>91</sup>

the full range of international trade and investment policies and rules in order to ensure that these are consistent with existing treaties, legislation and policies designed to protect and promote all human rights. Such a review should place the highest priority on assessing the impact of WTO policies on the most vulnerable sectors of society and on the environment. The Committee...emphasized that the realms of trade, finance and investment are in no way exempt from human rights principles and that 'the international organizations with specific responsibilities in those areas should play a positive and constructive role in relation to human rights.'

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<sup>††</sup> Avafia, Tenu. The potential impact of US-SACU FTA negotiations on public health in southern Africa. Trade Law Centre for Southern Africa. Working Paper No. 6. November 2004. <http://www.tralac.org/scripts/content.php?id=3114>

In the course of monitoring nations' compliance with their obligations under the International Covenant on Economic, Social and Cultural Rights (the Covenant), "the Committee had become increasingly aware of the extent to which international economic policies and practices affect the ability of States to fulfill their treaty obligations."

Accordingly, the Committee strongly endorsed the call from the United Nations Sub-Commission on the Promotion and Protection of Human Rights in Resolution 1999/30, on August 26, 1999, to take steps "to ensure that human rights principles and obligations are fully integrated in future negotiations in the World Trade Organization," and to undertake a study of the "human rights and social impacts of economic liberalization programmes, policies and laws."

The Committee also called for a comprehensive review to assess the impact that trade liberalization may have on the effective exercise of human rights, especially those enshrined in the Covenant. In light of impending additional rounds of trade liberalization negotiations and the inclusion of new areas for international trade negotiations, such a review was urgently needed. The Committee noted the strong warning signaled by the UNDP Human Development Report 1999 against the negative consequences of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), "particularly on food security, indigenous knowledge, bio-safety and access to health care... The wave of economic and corporate restructurings undertaken to respond to an increasingly competitive global market and the widespread dismantling of social security systems have resulted in unemployment, work insecurity and worsening labour conditions giving rise to violations of core economic and social rights..."

The Committee expressed the view that the WTO contributes significantly to and is part of global governance reform. Such reform, in the view of the Committee, must be driven not only by macroeconomic considerations, but by a concern for the individual. Moreover, international economic policy must be shaped by human rights norms, in order to ensure that the benefits for human development of the international trade regime be equitably shared by all, in particular the most vulnerable sectors.

The Committee cautioned that trade liberalization be understood as a means, not an end. While recognizing that trade liberalization may have the potential for wealth generation, the Committee also recognized that trade and investment liberalization neither necessarily creates nor leads to an environment which favors the realization of economic, social, and cultural rights. Human well-being should be the objective of trade liberalization, according to the Committee, as it is the objective expressed legally in international human rights instruments. At the Third WTO Ministerial Meeting, the Committee made note that at the World Conference on Human Rights held in 1993 in Vienna, 171 States declared that the promotion and protection of human rights is the first responsibility of Governments.

In 2001, the **American Public Health Association (APHA)** passed a resolution that addressed global health and equity, the General Agreement on Trade in Services (GATS) and the Free Trade Area of the Americas (FTAA). The resolution calls for action to advance the interests of population health including: the establishment of a commission with the mandate to explore the impact of free trade agreements on population health and the public health infrastructure before further liberalization of trade through GATS, FTAA, or bilateral agreements; alternative proposals such as the Fair Trade Agreement of the Americas to promote trade agreements that advance the interests of population health; including international labor rights and safe working

conditions; and encouraging the alliance of public health professionals and affiliates across international borders to advance such alternatives.<sup>4</sup>

In June 2004, the **American Medical Association (AMA)** issued a report on international trade agreements. The report concluded that the complex provisions of international trade agreements may be far-reaching, and that it is important to increase awareness of the potential implications of these agreements for medical services and public health. The report recommended that the AMA monitor developments on U.S. international trade agreements that involve the provision of medical services, and the distribution and advertising of alcohol and tobacco, and collaborate with other professional organizations to provide advice to the U.S. Trade Representative on trade issues that could affect the provision of medical services.<sup>3</sup>

### **II.E. Toward Policy Convergence: A Public Health Policy Framework**

The statements cited above suggest the value of a public health policy framework, that articulates public health priorities and suggests points of coherence with trade and economic policies. Developing consensus among policymakers and international governance institutions on such a framework can be a step towards implementing change.

A public health policy framework could guide global governance of health-related services, and shape global political and economic policy making. It would promote sustainable development, meaning that economic decisions are interdependent and integrated with health and concerns to promote healthy and productive lives for human beings equitably in the present would be addressed “without compromising the ability of future generations to meet their own needs.” This necessarily includes effective protection, conservation and restoration of the environment, and prudent use of natural resources.<sup>30</sup>

Principles for a public health policy framework could include:

- Enjoyment of the highest attainable standard of health, i.e. of physical, mental and social well-being, including the absence of disease or infirmity.
- Universal access to affordable, accessible, high quality medical care.
- Support for socio-economic and related determinants of health: safe food and nutrition, housing, safe and potable water and adequate sanitation, safe and healthy working conditions, healthy environment, equitable distribution of resources, and protection from discrimination based on race and gender, with particular emphasis on the most vulnerable in society.
- Effective, accountable public health systems that monitor population health status, promote health, and prevent illness through measures implemented on the individual, community, national and international levels.
- Equitable sharing of the benefits of sustainable economic growth and development with particular emphasis on poverty alleviation.
- Respect, protection, and fulfillment of human rights, with effective state enforcement of human rights obligations, and full integration of human rights principles and obligations in WTO multilateral, and bilateral trade negotiations.
- Respect for civil and political rights: to life, freedom of assembly, democratic participation in civic affairs, and decision-making which is conducive to transparency and democratic accountability.

Points of convergence between public health policy, and trade and economic policy, could include:

- Improving the wellbeing of the world's people is a central goal.
- Improvements in material wellbeing are interdependent with improvements in people's health, investments in public health infrastructure and social programs, and democratic political participation in decision-making.
  - For example, the simple project of assuring universal access to safe water and sanitation and to primary health care would immensely improve disease-free life span and economic productivity
- Sustainable economic development benefits both developed and developing nations.
- Alleviating poverty, and addressing imbalances in political and economic power among nations, are important priorities.

Structural and institutional shifts are also necessary to achieve health and human wellbeing. These include:

- Achieving health should be a key focus of political and economic international governance structures.
- Existing health and human rights principles and obligations should be incorporated into WTO multilateral, as well as bilateral negotiations.
- Existing global health regimes and international covenants should be strengthened and/or modified to address international health issues, and support each state's public health and medical care systems.

Progressively greater international cooperation in developing an interdependent model to address global health challenges and strengthen public health and medical care systems may involve:

- Strengthening policy and enforcement powers of international bodies dedicated to improving health, such as the World Health Organization
- Reallocating enforcement power that now resides with the WTO, World Bank and International Monetary Fund, toward the WHO and/or other bodies that prioritize health.
- Assuring that such decision-making bodies include and reflect democratic participation.
- Coordinating governance of economic functions and health-related services.
- Effective enforcement of state obligations to respect, protect and fulfill human rights.
- Blocking measures that promote "low road" as opposed to sustainable economic development and therefore adversely affect health, as expressed in international trade agreements and other policy instruments.

### **III. Global Governance 1: Democratic Participation and Transparency in Establishing and Enforcing Trade Rules**

In a global economy, accountable governments must be able to cooperate to protect populations from cross-border hazards such as infectious diseases and environmental degradation, and to assure that the activities of transnational corporations contribute to population health and sustainable development.

Both public health and trade authorities have legal enforcement powers. Public health authorities, for example, have the right to quarantine infected individuals,<sup>112</sup> trade officials to regulate imports. Health and commercial interests may conflict, as when regulations restrict the distribution of tobacco and alcohol, or exposure to toxic industrial pollutants. Deaton suggests that in past centuries, commercial interests have often prevailed, as in the case of moderating restrictions on travel during epidemics of the middle ages.<sup>29</sup> In the current era, protecting population health is an important policy priority, as an important component of sustainable

economic development as well as a benefit to individuals and nations.<sup>27</sup> On the other hand, at a time when health care itself is a commercial enterprise, and government regulation in itself conflicts with the prevailing market-based economic agenda, a fair balance in global governance between health and trade organizations is particularly challenging.

Numerous agencies at the regional, national and local levels assume primary responsibility for promulgating and enforcing regulations related to public health and medical care.

This section reviews the major international public health and trade organizations, and finds that public health is poorly represented in trade institutions, with negative consequences for democracy. We recommend that public health organizations take on greater presence in international trade negotiations and in trade policies, with the intent of introducing public health concepts as priorities.

### **III.A. The institutions: WHO, WTO, national and regional health policy**

#### **The World Health Organization (WHO)**

The World Health Organization (WHO) is the United Nations specialty agency on health. Several other UN agencies such as UNICEF (Children’s Fund), UNCTAD (Conference on Trade and Development), UNDP (Development Program), and UNHCHR (High Commission on Human Rights) share responsibility for functions we have defined as linked to public health, including increasing access to health-related services such as water and sanitation, protection from violence, and encouraging sustainable economic development. WHO is the central repository for health policy, and international health surveillance and monitoring. WHO is governed by representatives from each of WHO’s 192 Member States through the World Health Assembly. The main tasks of the World Health Assembly are to approve the WHO program and the budget for the following biennium and to decide major policy questions.<sup>109</sup> While each nation has one vote, wealthy nations like the U.S. contribute disproportionately to the WHO budget, and therefore hold great influence over its policies.

The WHO is in the process of reviewing the International Health Regulations, which are designed to “ensure the maximum security against the international spread of diseases *with minimum interference with world traffic.*”<sup>112</sup> (emphasis added) Its origins date back to the mid-19th century when cholera epidemics overran Europe between 1830 and 1847. These epidemics were catalysts for intensive infectious disease diplomacy and multilateral cooperation in public health, starting with the first International Sanitary Conference in Paris in 1851.

“Between 1851 and the end of the century, eight conventions on the spread of infectious diseases across national boundaries were negotiated. The beginning of the 20th century saw multilateral institutions established to enforce these conventions, including the precursor of the present [Pan American Health Organization \(PAHO\)](#).”

“In 1948, the WHO constitution came into force and in 1951 WHO Member States adopted the International Sanitary Regulations, which were renamed the International Health Regulations in 1969. The regulations were modified in 1973 and 1981. The IHR were originally intended to help monitor and control six serious infectious diseases: cholera, plague, yellow fever, smallpox, relapsing fever and typhus. Today, only cholera, plague and yellow fever are notifiable diseases.”<sup>112</sup>

The present era of international trade and its potential implications for health has prompted the WHO to address trade and health policy coherence. The WHO’s Department of Ethics, Trade,

Human Rights and Health Law (ETH) in the Sustainable Development and Health Environment Cluster (SDE) “works to achieve greater coherence between international trade and health policy by building the knowledge base and strengthening capacity in member states and in WHO itself to recognize and act on the public health implications of trade rules.”<sup>96</sup>

The office on Globalization, Trade and Health (GTH) is located within the ETH, and works to bring a health dimension to international economic policies. Recognizing that trade agreements may present both opportunities and risks for population health, GTH aims to ensure that trade and globalization improve the health of the poor and disadvantaged populations. The GTH program coordinates with related agencies, including the WTO, Organization for Economic Cooperation and Development, and UN Development Program.<sup>111</sup>

A substantial part of the work and the resources of GTH is focused on supporting WHO regional offices and developing countries “in their efforts to analyze, monitor and track the implications of multilateral trade agreements for population health. This evidence is used by countries to inform ongoing trade negotiations, the crafting of trade policy as well as the process of crafting other necessary complementary domestic policies to meet national growth, income distribution and health targets.”<sup>111</sup>

WHO sponsors regional offices in Africa, the Americas, South-East Asia, Europe, the Eastern Mediterranean, and the Western Pacific. The Pan American Health Organization (PAHO) has been particularly active in encouraging national health ministers to become involved in trade issues, and has sponsored a book on the topic.<sup>36</sup>

In its publication, *Global Public Goods for Health*, WHO authors point out, “This concept identifies where a ‘good’ or service (such as knowledge of an infectious disease outbreak) which would be of benefit globally will not be produced or disseminated if left to ‘the market’, because of a lack of incentive: no-one can be excluded from accessing the good, no charge can be levied for use and no costs recouped. Nationally, the production of these goods is usually assured by government intervention, but at the global level there is no ‘global government’ to undertake this role. The global public good concept therefore extends the economic analysis of public goods to this international level.”<sup>85</sup>

WHO has commented on the recognized need for evolution of existing rules, institutional mechanisms, and forms of organization “to better respond to the emerging challenges of globalization and ensure that globalization benefits those currently left behind in the developing process.” Global Health Governance has been identified as a key issue which requires further detailed analysis “to better inform policy makers interested in shaping the future ‘architecture’ for global health.”<sup>111</sup>

### **World Trade Organization (WTO), U.S. Trade Representative, and Public Health Representation**

As noted above, the World Trade Organization, based in Geneva, functions with 550 staff. The staff and funding of the WTO far outstrip those of the WHO. Each of the 148 member countries (usually referred to in trade agreements as Parties) has a vote in changes to WTO agreements. The WTO is supposed to act by consensus.

The WTO employs health economists, and has published several works advancing proposals for trade liberalization in health-related services. The WTO and WHO have collaborated on a major

joint publication, *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat*.<sup>124</sup>

WTO trade tribunals, which can authorize countries to impose effective financial penalties on trade rivals who lose trade disputes, operate behind closed doors. The public cannot observe or participate. Trade tribunal members are required to be experts in trade law and economics, but have no knowledge of public health scientific methods, standards or principles.

WHO staff and officials have no official role in WTO deliberations and negotiations. WHO has “observer” status in WTO proceedings, a role similar to that of other nongovernmental organizations.

The weak participation of health agencies with the WTO reflects in part the division of economic and political power within nations. Health ministries are rarely involved or consulted in trade issues. However, partly due to PAHO’s work, some Latin American health ministers have recently played an active role in debates on access to medicines and intellectual property rules.

A recent analysis of trade advisory committees in the U.S. by CPATH found significant participation by industries that affect health, including pharmaceutical, tobacco, alcohol, health insurance, processed foods, and chemicals. There are no representatives from public health.<sup>11</sup>

For example, the U.S. Government Accountability Office has reported that the official advisory bodies that consult with the U.S. Trade Representative – which negotiates trade agreements on behalf of the U.S. – have significant influence over trade proposals. CPATH, other health policy organizations, and members of the U.S. Congress have called for adding public health representation to existing trade advisory committees, and creating a new advisory committee representing a range of health concerns. In order to democratize the executive branch’s policymaking process, CPATH has also recommended establishing an independent Congressional advisory committee on public health, to educate and advise Congress on pending trade negotiations.

### **III.B. Alternative proposals for harmonizing policy objectives: break down the silos; reexamine global governance; create parallel health-based agreements**

At a time with increased threats to global health, complicated by potentially divergent and conflicting international trade and health policy, the global governance structures for prioritizing and achieving improvements in population health should be strengthened. In the case of health-related goods and services, new or existing public health agencies at the national and international levels could assume the lead role for coordinating trade and economic functions. Public health principles and public health agencies should play a greater role in determining health-related policies. Both organizational and educational efforts can better harmonize policies in trade and in health.

To create a greater role for public health representation in trade agreements, there should be official public health participation in trade negotiations, deliberations, and dispute resolution processes, including officials such as the WHO and national health ministers, and representatives of civil society.

Environmentalists have created examples of parallel or alternative international agreements that address both the environment and trade. The experience with multilateral environmental

agreements is new and still unfolding. This could suggest creating parallel or alternative international agreements that specifically address health issues, including trade-related aspects of health.

Public health could also campaign to implement and enforce existing UN covenants that prioritize health and human rights.

Interdisciplinary programs could break down the silos between experts and policymakers in trade and in public health. These silos consist of different concepts, analytical methods, standards of evidence, and assumptions about the role of popular participation. Epidemiology, statistics, and economic analysis can offer different contributions to problem-solving; public health contributions deserve greater weight. It is likely that assertions of interest from health advocates at the national level will be necessary to motivate a realignment.

For example, in the summer of 2004, public outcry called attention to provisions of the U.S.-Australia Free Trade Agreement (FTA), which could have blocked popular Congressional proposals to permit reimportation of prescription drugs from Canada into the U.S. Previously, trade policy was delegated to Congressional staff with expertise in trade, while health staff were marginalized. Following the Australia FTA debate, Senate health staff convened a significant meeting with trade staff, during which both sides acknowledged and debated their various perspectives. In the House of Representatives, trade and health staff similarly realigned their discussions, and health staff have continued to exert greater authority in health-specific trade discussions.

#### **IV. Global Governance 2: Trade Agreement Provisions and the Nations' Rights to Regulate In the Interest of Public Health**

Exposure to a range of environmental and workplace hazards, and to hazardous products, can result in harm from unsafe food, infant formula, and tobacco and alcohol products, among others. Public health measures legitimately provide protection from these hazards and the marketing of unsafe products; and set affirmative standards for the safety and quality of goods and services. These protections are sometimes under attack from affected domestic commercial interests, and from efforts to restrict government enforcement of accountability generally.

While commercial activities in medical care and pharmaceuticals can play a constructive role in the project of advancing health, there is disagreement about whether predominant economic and international trade policies detract from health. Policies which emphasize the primacy of corporate rights, the free flow of capital and goods, and minimal public involvement in social services, have particular consequences for health and for health-related services.

Nations' rights to regulate in the interest of public health are challenged by trade rules in two ways.

First, trade dispute resolution mechanisms supersede national decision-making. The principles for determining disputes give health concerns secondary importance.

Secondly, the specific wording of the "domestic regulation" trade rule in the General Agreement on Trade in Services reinforces the history of trade dispute decisions which favor commercial over public health principles. This language is under negotiation for purposes of GATS, but is

being introduced and incorporated as boilerplate language into bilateral and regional agreements.<sup>118,121</sup>

Particularly troubling, according to the Domestic Regulation rule as currently written, national measures that set standards for quality, but which WTO trade dispute panels consider to be more burdensome to trade than necessary, could be found to violate trade agreements. This could be true even if those measures do not discriminate in any way between domestic and foreign businesses. This is a departure from previous trade rules, and a potentially more intrusive role for trade rules in setting domestic policy.

#### **IV.A. The Right to Regulate, Trade Dispute Decisions, and Health**

##### ***Trade rules – Are health protections barriers to trade?***

Trade rules raise a key question: do trade agreements safeguard nations' right to regulate in the interest of health?

Trade agreements comprise myriad complex rules governing trade, and are intended to reduce or eliminate barriers to trade. A key problem is that the barriers to international trade in health care services are at least in some cases the same laws and regulations that nations have devised to protect and promote the health of their populations, and also to assure coverage, access, affordability, accountability and quality of health care services. (In international trade terms, these laws and regulations are referred to as “non-tariff” barriers to trade.)<sup>73</sup> The policies of global trade institutions frequently do not prioritize the achievement of human health and wellbeing of populations.<sup>46,99,103</sup>

The GATT and subsequent trade agreements, including those under negotiation such as GATS (addressed in Section V) and the FTAA, provide an exception that allows nations to adopt and enforce measures (laws, regulations, standards, actions) necessary to protect human, animal, or plant life or health. This exception, however, requires that such measures not be applied in a manner which would arbitrarily or unjustifiably discriminate between countries or be a disguised restriction on international trade.<sup>118</sup> In comparison, nations have the right to exempt any measures they consider necessary for peace and security. There are no qualifications to this right.

Historically, when nations have asserted that their regulations are exempt from trade agreement rules because they are necessary to protect human, animal, or plant life or health, they have had to shoulder the burden of proof. The introductory clause, or “chapeau,” of Article XX requires that a health measure, even if “necessary” to protect human life, may be rejected if it was passed with an intent to discriminate against imported products. For example, as noted above, the WTO trade panel found that Thailand's prohibition of cigarette imports was found unjustified, even though the panel recognized that chemicals and other additives in U.S. cigarettes may have been more harmful than those in Thai cigarettes.<sup>13</sup>

This means that in defending their health measures, nations have had to meet a two-tiered test:

1. Necessity. They must show that the health or environmental measure is necessary, i.e., that it is effective, and that no less trade restrictive measures to achieve the same public health purpose were available. For example, a nation that imposes tariffs on tobacco imports may be challenged to “prove” that tariffs on tobacco products are “necessary” for tobacco control, and that tariffs are less restrictive on trade than, e.g., consumer health warnings.<sup>18</sup>

2. **Intent.** Even if they prove the measure is necessary, nations must also show that the proposed public health measure does not constitute a “arbitrary or unjustifiable discrimination,” or a “disguised restriction on international trade” or intentional discrimination against imported products or services.<sup>13</sup> According to the US-based Campaign for Tobacco-Free Kids, “This requires a difficult inquiry into the state of mind of policymakers. Health groups believe that the expected public health consequences of a measure should be the overriding concern of any inquiry regarding tobacco products.”<sup>19</sup>

### **Critique**

A number of WTO rulings have applied the “necessity” test. On only one occasion was justification found to uphold the public health measure. The rare WTO decision that favored health, in a case involving asbestos, has served largely to illustrate the problems with the system. A participant in adjudicating this case reported that although the WTO economists on the dispute panel accepted the public health justification for banning asbestos, for which there was well-grounded evidence, they did so despite a complete lack of expertise in science, medicine or public health. More troubling, if the standard of evidence required in the asbestos case were used as a precedent for bans on toxic substances, it could be more difficult to defend the regulation of other toxic exposures for which harm is less well-established.<sup>81</sup>

A key question then becomes: when is a protective health regulation actually a pretext by a national government to discourage trade by a foreign corporation; and when is it a legitimate protection? In cases where a conflict is alleged, who should decide whether the regulation should be permitted to prevail, and according to what standards? What is the democratic process by which nations agree that this abrogation of their sovereignty is warranted by the resulting benefits?

### ***Trade rules – Impact on Health Care Services***

In the realm of health care services, rather than creating systems designed to achieve health, trade rules enforce trends that promote: the privatization, deregulation, and decentralization of health care services; dismantling of the public health infrastructure, public funding for health care, and cross-subsidization; and the fragmentation of risk pools and services. These policies lead to higher expenses without resulting improvements in access to services, quality of care or health status.<sup>20,98c,98f</sup>

### ***Enforcement of trade rules shapes nations’ social policies***

In practice, this means that the democratic decision-making rights of governments at all levels – local, regional and national – are subordinated to WTO decisions on matters that it deems are related to trade. WTO decisions can also have a chilling effect on regulatory protections. Trade disputes have increasingly affected protections for health, the environment, and working conditions. While countries may justify barring the import or marketing of certain products for protection of health, for example tobacco or infant formula, the WTO can see this as a pretext for limiting trade.

These conflicts have suggested that the WTO should pursue a more limited mandate, and alter or abandon its approach to these new issues.

## **IV.B. The Domestic Regulation Rule and the Right to Regulate**

**The Domestic Regulation rule** makes domestic laws and regulations, including those which protect the public's health and safety, subject to challenge and possible elimination if they are determined to be "unnecessary barriers" to trade, or more "burdensome than necessary to assure the quality of a service" (GATS Article VI.4).<sup>118</sup> It proposes to apply these standards to "measures relating to qualification requirements and procedures, technical standards and licensing requirements."

The "barriers" to international trade in services, which GATS seeks to remove, consist of a vast array of local, state, and national laws, regulations, rules, procedures, decisions, or administrative actions on rights, the quality of services, professional licensing, and privacy, that protect safety, the environment, working conditions, and health, and can include public subsidies for vital human services such as health care and water. Protections for human, animal and plant life are permitted, but can be challenged if they conflict with the trade rights of foreign corporations.

The United States Coalition of Services Industries, the major lobbying group representing services industries in the United States, has explicitly identified "restricting licensing of health care professionals and excessive privacy and confidentiality regulations" as serious barriers to trade in health care services.<sup>25</sup> In administering other trade agreements with similar language, WTO panels have defined terms like "burdensome" and "necessary" in favor of commercial interests, at the expense of public health, as described above.

### **GATS and Services Disputes**

Only four disputes have been adjudicated under GATS. The decisions suggest that GATS rules are extremely complex, and even sophisticated trade negotiators may be unaware of the domestic regulatory prerogatives they are surrendering to global trade rules. In the first, the trade panel rejected a Mexican decision to retain certain telecommunications surcharges, and also rejected Mexico's arguments that development objectives have to be considered in weighing whether a developing country is meeting its GATS commitments.<sup>119</sup>

According to the WTO trade panel:

Mexico argues that commitments made by developing country Members have to be interpreted in the light of paragraph 5 of the preamble to the GATS, and GATS Article IV which recognize that these Members need to 'strengthen their domestic services capacity and efficiency and competitiveness'. However, we note that these provisions describe the types of commitments that Members should make with respect to developing country Members; they do not provide an interpretation of commitments already made by those developing country Members. (WTO Mexico, para 7.214)

On November 10, 2004, the World Trade Organization released the full text of the decision in Antigua and Barbuda's 2003 claim that U.S. laws prohibiting Internet gambling violate trade obligations under the GATS. The decision, which implicates both federal and state laws in the U.S., could have consequences for local oversight and control of gambling. The United States has indicated it will ask for a review of the panel decision. The panel stated, "Members' regulatory sovereignty is an essential pillar of the progressive liberalization of trade in services, but this sovereignty ends whenever rights of other Members under the GATS are impaired."<sup>123</sup>

### **Critique**

The Domestic Regulation rule gives greater weight to commercial concerns than to health, noting that measures that protect health comply with the rule only if they do not conflict with trade. The final rule may be even more intrusive to domestic policy-making, invalidating measures that

can be shown to be less than essential, even if those measures treat both foreign and domestic corporations the same. This is a violation of public health principles that recognize the importance of popular participation in setting health policies, the complex balance between trade and health imperatives, and the fact that it is appropriate for public health standards to reflect varying local customs and conditions.

#### **IV.C. Alternative Proposals**

Current GATS Objective on Domestic Regulation: In current GATS negotiations, Member States are called upon intensify their efforts to conclude the negotiations on rule-making under GATS Articles VI:4, X, XII, and XV, in accordance with their respective mandates and deadlines, which includes the Domestic Regulation rule.

Alternative Policy: Reexamine the Domestic Regulation clause to privilege health priorities and promotion of universal access before commercial concerns. Specific alternative trade and health policy objectives regarding this GATS objective may include:

1. To seek the reduction or elimination of barriers that limit or deny parties to trade agreements from safeguarding access to affordable, high quality health care, water, education and other essential human services;
2. To domestic measures as “necessary” if they support and promote enforceable commitments to advancing population health, and to achieving universal access to health care, affordable medications, and safe, affordable water; and seek parallel provisions in trade agreements.
3. To recognize the jurisdiction of state, national and international health organizations, including professional associations and the World Health Organization, over health care policies, and to encourage effective international collaboration in improving the effectiveness of public health and medical care systems.

### **V. Trade Agreement Provisions, and the Organization, Financing and Delivery of Public Health and Medical Care Services**

Services, broadly defined to include finance, banking, retail and wholesale sales, distribution, and construction, as well as social services, such as health care and water, became a growing sector of international economic activity during the 1980s and 1990s, and the largest sector of economic activity in developed countries.

Since the 1980s, there has been increasing commercial activity in services considered vital to public health, including health care, water provision and sanitation, and education, as well as other services such as energy and telecommunications often provided by public or quasi-public agencies and which can affect people’s health. International financial institutions and some national governments have advanced policies that rely on market forces to provide access to these services and to control their costs. The market approach is controversial, and the inclusion of health-related services in trade agreements has generated considerable debate.

The implications of trade agreements for public health and medical care services offer an important case in point. We address health services, clinician migration, and prescription drugs as discrete topics, for the purpose of discussing the trade agreement rules and provisions that apply to them. In practice, and in terms of an integrated approach to public health, these issues are inextricably linked. Several commentators and advocates have addressed the importance of an alternative framework that integrates these topics.<sup>13, 47, 58</sup>

Cross-border trade in health services can offer benefits. A PAHO report in 1994 noted that under the right circumstances, developing nations could benefit from increased revenues for treating foreign patients, and for training health professional students.<sup>34</sup> Such trade could also enhance the supply, quality and technological development of health services for the domestic population. The temporary migration of doctors, nurses, dentists and other health professionals could improve skills and cross-border cultural competencies, help fill periodic shortages, establish ongoing relationships with patients who might travel in the future, and generate remittances to home countries in foreign exchange. Border areas in particular could benefit from easier rules for the flow of finances and personnel.

In practice, problems as well as benefits have emerged. It is questionable, even if countries wish to pursue such trade, whether making legally binding commitments to all of the provisions of international trade agreements is superior to simpler country-to-country negotiations. International cooperation through international health organizations and professional associations could also accomplish many of the desired objectives, with fewer negative consequences.

The terms of trade agreements can bind countries to exposing health-related services to privatization, commodification and deregulation. Countries can and do choose to make these policy choices without the additional pressure of trade commitments. A joint WHO/WTO report suggests that accountable government oversight is key to assuring access to affordable, high quality health care services, whether offered by public, private and community-based providers. Accountability is particularly critical for assuring that private health insurance companies and health care service providers perform as promised.<sup>124</sup>

In this section, we look specifically at the case of health care services and trade agreements, beginning with the General Agreement on Trade in Services (GATS). First, we review how GATS works, and the process of “committing” health care services to certain GATS rules. Secondly, we present issues countries can consider when deciding whether or not to make such commitments, and rely on WHO recommendations to proceed with caution. Countries face important questions about how best to provide health care services, whether or not they choose to make GATS commitments on health care. In Section I.E., we addressed the merits of approaching health-related services as commercial, private enterprises, or public goods, and the debate on whether privatization offers greater efficiency and access at lower cost, or greater fragmentation of services and access, with higher costs that are redistributed to lower-income people.

## **V.A. GATS and Health Care Services**

Health care services in some countries are already subject to privatization, commodification and deregulation, due to Structural Adjustment Programs, independent decisions made by local and national officials, and the influence of health care industries. Countries now have a choice about whether or not to include health care services under certain GATS rules, through the process described below. Doing so would facilitate participation by private corporations in health care services, and GATS trade rules make it more difficult for governments to reverse decisions to privatize, or to establish new public health services, referred to as “monopolies” under GATS. Canada’s respected Romanow Commission, which prepared a national report on the future of Canada’s health care system in 2003, has projected that GATS rules could undermine and reverse some countries’ government-sponsored health coverage systems.<sup>21</sup>

The World Trade Organization has set a new deadline of May, 2005, for country proposals on the General Agreement on Trade in Services (GATS). At the same time, the United States is pursuing a number of regional and bilateral trade agreements that duplicate or expand GATS provisions.

These events present an imperative for nations to prepare well-grounded policy as a basis for negotiating positions for advancing global health, and improving access to health care services. They also offer the opportunity to raise broader questions about fundamental policy goals for global governance of health and health care services, the venues best suited to exploring the routes to achieving these goals, and the constituencies who must be involved.

### **How GATS Works: Requests and Offers**

GATS consists of a number of **“unconditional” rules** that automatically apply to all of the listed services for which GATS applies. GATS rules apply to all WTO nations.

The Domestic Regulation rule, described above, is an unconditional rule. Once its language is finalized, all services of all nations will be subject to its restrictions, which presently require that all laws, regulations, and administrative procedures related to qualification requirements, technical standards, and licensing be no more burdensome than necessary, and not disguised barriers to trade.

While the WTO claims that the GATS respects each country’s right to regulate, the proposed GATS Article VI, Paragraph 4, on Domestic Regulation, as noted above, places all national, state, and regional government laws, regulations, rules, procedures, decisions, or administrative actions that may affect trade in services under scrutiny, as well as some local government measures.

Under other provisions, protections for human, animal and plant life are permitted, but can be challenged if they conflict with the trade rights of foreign corporations.

Because many nations have responded with caution to the proposal to open both their commercial and social services to international trade, with the prospect of lesser degrees of national regulation and control, GATS also includes additional **“conditional” rules**. Nations can choose whether or not they wish to cover any of their services under these conditional rules.

GATS states that nations are expected to progressively add to the list of services covered by the conditional rules, meaning foreign private corporations would have greater opportunity to offer those services. Presumably, all social services could eventually be covered by these rules.

**A basic unconditional rule** – one that already automatically applies to all WTO nations – is **most favored nation (MFN)**. The MFN rule requires that countries must treat foreign corporations from all other countries the same. This means that if Country A allows companies from any other country to operate, it must offer the same terms of operation to the companies of any other foreign country. Under this rule, Country A can still distinguish between how it treats its own domestic companies, and foreign ones, such as giving certain preferences to domestic companies. But once any other Country B is allowed to do business there, Country A must offer the same terms to all other foreign businesses. For example, if the U.S. imports soccer balls from Hungary, and refuses to import soccer balls from Pakistan for any reason (including concerns about labor conditions), the U.S. could be subject to a trade violation charge based on the MFN rule. Country A could choose to close a particular service from competition by all foreign

corporate competitors, and reserve it as a strictly domestic service. This is rare in commercial services, but could well be the case for some social services.

A related rule, but one that is **conditional**, is **“national treatment.”** This takes the MFN rule a step further. The national treatment rule requires that all foreign private service providers receive the same treatment as *domestic* service suppliers. Because it is a conditional rule, countries can decide whether or not to commit health care services and other services to coverage under this rule. However, once Country A chooses to commit a particular service under the national treatment rule, it can no longer choose to completely close off foreign competition in that service. Once it has made this commitment, Country A is required to treat foreign and domestic companies equally, even if there are no foreign companies presently doing business there. In this way, it operates somewhat differently from the MFN rule, which only applies once a country already has foreign companies present. Because it is a conditional rule, countries can decide whether or not to commit health care services and other services to coverage under this rule. National or local governments that wish to give preference to local health service providers for any number of domestic policy reasons could be challenged if they agree to cover health care services under this rule.

A second key **conditional rule** to which nations can commit these services is **“market access,”** which limits the right to regulate the number and types of service providers. This could have implications, for example, for rules that restrict the density of liquor stores in a neighborhood, or requiring needs-based standards for establishing specialty acute care health facilities.

Further, GATS presents the option to commit any service to these conditional rules (national treatment and market access) in each of **four “modes” of commercial transactions:**

**Mode 1:** Delivery of services across borders. **Example:** Telemedicine.

**Mode 2:** Providing services to foreign consumers who travel to use them.

**Example:** Niche hospital specialty services that market to foreign patients.

**Mode 3:** Commercial presence, including foreign direct investment in the services of another country.

**Example:** Hospital ownership by a foreign company.

**Mode 4:** Movement of natural persons, including rules related to the temporary immigration of personnel.

**Example:** Migration of nurses.

Of these modes, developing countries have expressed greatest interest in mode 4, the movement of natural persons. They see their supply of skilled and unskilled labor as a potential source of international competitive advantage. This is a particularly salient issue regarding the migration of nurses and other clinicians, as discussed below.

### **Should countries commit health services under GATS?**

A WHO report recommends caution to countries considering including health services in trade agreements.<sup>35</sup> It points out that decisions to commit are entirely at a country’s discretion, and that if a country is unsure about the effects of making specific commitments, it is fully within its rights to decline to make legally binding commitments to liberalize their health services.

However, international trade negotiations still involve trade-offs and balancing of priorities. In this case, the first set of negotiations may be within a country’s own administration. Trade negotiators and health policymakers are unlikely to be familiar with each other’s policy framework. Trade offices have primary responsibility for trade agreements, and may not consult on a regular basis with health officials; health ministries may not be aware of trade negotiations or fully prepared to participate effectively. While health care services are often a significant

portion of the national budget, health constituencies can be less persuasive in resisting demands from a foreign country for concessions on health services, if the other country is offering in return concessions that domestic commercial interests want, whether in other services such as transportation or construction, or in agriculture or textiles.

Users of health care services, health care professionals, and health policymakers therefore have the added responsibility of assuring that a country's internal trade policies are harmonized to address all of its national objectives, including health priorities, in a context of sustainable economic development. National policymakers and trade officials also have the responsibility for bridging the silos between trade and health, and to assure that all parties are involved in assessing trade-offs that could affect health.

The WHO report identifies the following opportunities and risks in making commitments in the following areas:

<b><u>Supply Mode</u></b>	<b><u>Opportunity</u></b>	<b><u>Risk</u></b>
Mode 1: Cross-border supply of services	Increased care to remote and under-served areas (telemedicine, e-health)	Diversion of resources from other health services, such as primary care
Mode 2: Consumption of services abroad (patients traveling abroad for treatment)	Generates foreign exchange earnings for health services of importing country	Crowding out of local population and diversion of resources to serve foreign nationals
Mode 3: Commercial presence (establishment of health facilities in other countries)	Creates opportunities for new employment, funding for services and access to new technologies	Development of two-tiered health system, diversion of funds away from domestic priorities.
Mode 4: Presence of natural persons (doctors or nurses practicing in other countries)	Economic gains from remittances of health care personnel working overseas; ability to fill staff shortages; cross-cultural exchanges, especially at border areas.	Permanent outflow of health personnel, with loss of investment in educating and training such personnel; undermining credentialing and working conditions in destination country; fair treatment of immigrants.

Private and government health insurance plans have also identified barriers to payment across borders for treating foreign patients, and have considered that trade agreements could resolve this problem.<sup>34</sup>

WHO recommends the following “Health Policy Principles to Guide Liberalization of Health-Related Services:”

- Liberalized trade in health-related services should lead to an optimal balance between preventive and curative services.
- Involvement of both private industry and civil society is important to ensure that liberalization of health-related services promotes participatory health policy towards achieving national goals.
- Improving access and affordability of health-related services should be a goal of liberalization of trade in health-related services.
- Developing countries, and least-developed countries in particular, deserve special consideration in the process of liberalizing trade in health-related services.
- The status of health as a human right should inform and guide proposals to liberalize trade in health-related services.
- Before making any specific commitment under GATS, governments should ensure they have thoroughly assessed the implications of opening health systems to foreign services and the potential costs and benefits of making legally binding commitments. Countries may wish to experiment through autonomous liberalization of certain health related services, and only make commitments under GATS after a careful assessment of its effects.

Questions policy-makers should ask include:

- To what extent is the sector already open to foreign service providers, and what have been the regulatory concerns posed by existing foreign competition?
- Do the commitments fit the strategies and directions identified by national health policy?
- What effect would the commitments have on government-provided health-related services?
- What regulatory burdens would the commitments create for the government in health-related sectors?
- Would the commitments eliminate or weaken regulatory approaches necessary for the protection and promotion of health?
- What scientific and public health evidence and principles can be brought to bear to analyze the possible effects of the commitments?
- Can the commitments be crafted both to protect health policy and to liberalize trade progressively?

WHO recommends that countries take the following steps regarding GATS commitments in health:

- Identify a focal point for trade in health-related services within the Ministry of Health.
- Establish contacts and systematic interactions (e.g., a GATS working group) with trade and other key ministries and with representatives from private industry and civil society.
- Collect and evaluate relevant information on the effect of existing trade in health-related services within the country.
- Obtain reliable legal advice not only on GATS but also on other international trade and investment agreements (e.g., bilateral investment agreements) that may affect trade in health-related services.
- Develop a sustainable mechanism for monitoring the impact of trade in health-related services generally and the GATS 2000 process specifically.
- Utilize the information and technical assistance provided by WHO on matters concerning trade in health-related services.
- Subject all requests for, and offers of, liberalization of trade in health-related services to a thorough assessment of their health policy implications.

Numerous health advocacy groups have endorsed the following steps, including CPATH, the American Public Health Association, and the American Nurses Association:

1. Assure that health takes priority over commercial interests.
2. Assess the impact of trade agreements on population health, and assure based on such assessment that these agreements do not have an adverse impact on health.
3. Exclude vital human services such as health care and water, and intellectual property rules that affect affordable medications, from trade negotiations and challenge under the FTAA.
4. Include public health representatives in the negotiating advisory process, and promote transparency and democratic accountability at all levels of trade negotiations.
5. Support enforceable commitments to advancing population health, and to achieving universal access to health care, affordable medications, and safe, affordable water.

## **V. B. Alternative policies**

1. Countries can pledge not to make offers or requests for health-related services through GATS. (The European Union has pledged not to make either new requests or new offers in health care services. There are some existing commitments in professional and health services.)

2. The World Commission on Social Dimensions of Globalization recommends aiming to achieve policy coherence among sectors.<sup>108</sup> They suggest that economic and health goals, for example, are most likely to be achieved if both the goals and related policies are integrated at best, and at least not in conflict. In particular, they will be most successful if they integrate goals for economic growth with those for human wellbeing. For example, economic policies intended to create growth, investment, and employment creation can be designed also to achieve:

Gender equality

Education, health, and food security

Human settlements

More accountable institutions with greater democratic participation, to include nations, legislatures, businesses, labor, civil society

More rapid development in lower income countries

3. Create alternative modes in GATS that integrate a social welfare policy approach with economic development and opportunities, as suggested by Mkandawire and Rodriguez:<sup>98f</sup> For example, where countries now commit to limiting regulations in “modes” such as cross-border trade and foreign direct investment, they could also commit to strengthening regulations (or opportunities generally) in modes such as:

Economic opportunity in trade in services

Democracy in regulating and providing services

Workforce

Improving systems, universality, quality

4. Current GATS Objective: Targeted technical assistance should be provided with a view to enabling developing countries to participate effectively in the negotiations.

Alternative Policy: Specific alternative trade and health policy objectives regarding this GATS objective may include:

To recognize the jurisdiction of state, national and international health organizations, including professional associations and the World Health Organization, over health care policies, to

encourage effective international collaboration in improving the effectiveness of public health and medical care systems, and to provide technical assistance to strengthen the capacity of nations to respond equitably to the GATS objective regarding services.

## **VI. Trade agreement provisions and Clinician Migration: Mode 4 of GATS**

Trade rules under GATS address the temporary migration of health care workers. The migration of health care professionals, including nurses and doctors, presents serious challenges to public health. The causes are rooted in health care systems, as well as the traditional push/pull factors: social, economic and political pressures at home; the promise of a better life elsewhere.

This section reviews the nature of the clinician shortage, and presents proposed remedies for ameliorating the clinician crisis. We then explore how GATS rules regarding temporary migration might apply to health care professionals, the drawbacks of the GATS approach, and alternative GATS language that would advance public health goals. We suggest that the WTO may provide a useful forum for airing the issues, but caution that policy decisions should be guided by the ultimate goal of improving health care systems and population health, and arguably led by national and international level agencies that prioritize health.

### **VI. A. Overview: The Problem - Clinician shortages**

The shortage of nurses in developed and developing nations is recognized as a crisis.<sup>16,65,71,94</sup> Developed nations are finding that domestically trained nurses are in short supply, a problem that is intensifying as the nursing population ages, training for new nurses is not keeping pace with the need to replace nurses who retire, and the aging of the population signals that the demand for nursing care in institutional and community settings will continue to increase. Health care employers are recruiting highly skilled nurses from developing countries on a routine basis to fill some positions.

This has several consequences for those developing countries and regions that serve as the greatest sources of nursing personnel, which include the Philippines, the Caribbean, India, and South Africa. On the positive side, many emigrant nurses send payments back to families in their home countries, providing hard currency and financial support for developing economies; many return home to retire, and bring further financial resources. Domestic unemployment is reduced. On the other hand, the “brain drain” leaves many developing country health care systems with their own severe scarcity of nurses, in a context of relatively greater need for health services. Developing countries often invest public funds in education of nurses and other health personnel, to find their most skilled personnel recruited away.

The resulting shortages are particularly devastating in parts of Africa where HIV/AIDS has struck hardest, and where health personnel are scarce.

In developed countries that recruit foreign nurses, the consequences are not entirely positive. Immigrant nurses are often highly competent, and offer the added benefit of cultural competence in certain immigrant communities. They may however be subject to exploitation, and unaware of their rights. Further, their availability can mask fundamental health care system problems that are causing the nurse shortage in the first place, including excessively demanding working conditions in hospital settings, inadequate pay or professional rewards, hierarchical working relationships, and inadequate training programs. These problems can undermine the quality of patient care.

The problem is less severe in the case of physicians and other medical personnel, at least at present. However, some economists have noted that importing lower paid foreign physicians would be one quick fix for escalating health care costs in the U.S.<sup>63g</sup>

Hospitals have already begun to send medical transcription and radiology work offshore to lower paid workers in India and elsewhere. The issue of accountability, and which nation's laws apply, came to public attention when a contractor to the University of California at San Francisco neglected to pay a subcontracted medical transcriptionist in India. She threatened UCSF that she would release confidential patient medical records online unless the hospital took responsibility for her payment.

### **VI. B. Proposals for addressing clinician migration from a public health perspective**

Several organizations have developed guidelines for addressing the shortages and migration of health professionals from a public health perspective. They proceed from the goal of improving the health of populations, and improving health care systems. The International Council of Nurses, based in Geneva, and Physicians for Human Rights, among others, have proposed standards that respect the rights of nurses, as well as the importance for population health of creating health systems that adequately deploy and remunerate health professionals. Those principles are not yet widely implemented. They include:

- Regulate to prevent devastation of emigrant home country workforce, avoid exploitation of immigrant clinicians, and ensure qualifications.
- Convene international decision-making process on standards for nurse migration with participation of health care users and providers, unions, professional associations), health ministries, trade ministries
- Adjust remittance systems to achieve public goals, e.g.
  - Contribute portion of employer-paid retirement fund taxes to country of origin
  - Dedicate portion of remittances to fund public health infrastructure
- Reform developed country health care systems to assure adequate workforce, working conditions, and compensation

### **VI. C. Clinician shortages and trade: GATS proposals**

As described above, GATS presents several categories or “modes” of international trade. Mode 4 relates to measures on the temporary immigration of workers in the service sector; technically it is called the movement of natural persons. The Domestic Regulation rule, in Article VI of GATS, states that licensing procedures should not in themselves act as a restriction on the supply of the service. When the language of Article VI is finalized, it will apply to all services for all WTO member countries. Countries can choose whether or not to subject health professional services to the GATS conditional rules on market access (measures relating to the number and type of services, in this case the number of foreign clinicians) and national treatment (measures requiring the same standards for foreign and for domestic services). In effect, countries that make a commitment for nursing services under Mode 4 are agreeing to alter their standards for entry of foreign nurses, which could mean changes in the number permitted to enter, as well as changes in training and performance requirements.

The WTO has promulgated the first set of international standards for recognition of training and licensing of professionals under GATS Mode 4. The standards apply to accountants. In March,

2004, the WTO convened representatives of the legal and nursing professions, among others, to explore how the standards might be extended to apply to them.

Several developing countries have expressed serious interest in using flexibilities in GATS Mode 4 to facilitate issuing visas for their health care professionals. (“GATS visas” are envisioned as authorizing temporary, not permanent, immigration, for business purposes; time periods however can be extended.) While this position is somewhat controversial within countries, for “brain drain” and other reasons, India has already advanced a proposal to the United States under GATS Mode 4 for full recognition of physician licensing based on training in India.

#### **VI. D. Critique of using GATS Mode 4 to harmonize standards and facilitate immigration for health professionals**

An overarching question is whether the WTO is the proper forum for discussing the harmonization of health professional standards, and the immigration of health professionals, given the WTO’s understandable focus on commercial rather than health system priorities. It is probably fair to suggest that it should not be the only organization, or the leading one, to convene such a discussion, sort through policy proposals, and administer decisions.

During the WTO conference on Mode 4 and professional standards in March, 2003, some participants questioned whether the parameters for establishing international standards for training and licensing are sufficiently broad to accommodate health system concerns. For example, draft language in Article VI of GATS, currently under negotiation, states that licensing procedures should not in themselves act as a restriction on the supply of the service. This frames the discussion of international standards for training and licensing health professionals within the constraints of not restricting the commercial supply of a service. It shifts the goal from reaching international agreement on standards to promote quality health care universally, to lessening the burden on private commerce, with the potential outcome of loosening and potentially downward harmonization of standards.

The WTO workshop presentations focused on whether current rules for accounting should apply to lawyers and nurses, rather than how to resolve health system problems more broadly. This suggests the importance of health-driven venues and agendas.

#### **VI. E. Promoting Alternative Trade and Health Policy and Negotiating Objectives**

Health professional associations and legislators should become aware of the emerging phenomenon of GATS negotiations, and develop policy approaches. There is great potential for international exchanges on standards for health professional training and practice. Internet resources as well as the relative ease of international travel make communications on curriculum, and international training opportunities, increasingly accessible. There could be an important role for international health agencies and professional societies in developing these approaches, which could then guide or replace the GATS processes.

GATS negotiating objectives for May, 2005 follow, along with alternative policy proposals to promote health.

Current GATS Objective: With a view to providing effective market access to all Members and in order to ensure a substantive outcome, Members shall strive to ensure a high quality of offers, particularly in sectors and modes of supply of export interest to developing countries, with

special attention to be given to least-developed countries.

Current GATS Objective: Members shall aim to achieve progressively higher levels of liberalization with no a priori exclusion of any service sector or mode of supply and shall give special attention to sectors and modes of supply of export interest to developing countries. Members note the interest of developing countries, as well as other Members, in Mode 4.

Alternative Policy: In an interdependent and collaborative process of engagement, nations can develop and advance alternative trade and health negotiating objectives. Alternative trade and health negotiating objectives to address clinician licensing, staffing, and immigration in negotiations of multilateral and bilateral trade agreements might include:

1. Nations will agree to support the development and strengthening of the public health infrastructure, particularly in developing nations, including initiatives that develop local human resources in health, and retain human resources in health by addressing quality of work and standard of living for health care workers.
2. Trade agreements will promote high quality health care through supporting the highest standards for health professional education and for clinician licensing;
3. Nations and trade agreements will promote respect for the rights of health care workers, including those who emigrate, and ensure that provisions in trade agreements do not weaken or reduce protections for health care workers who emigrate and do not promote skill drain from health systems of the country of origin. Nations and trade agreements will promote initiatives that develop local human resources in health, and generally raise quality of work and standard of living for health care workers.
4. Eliminate rules and adjudication of policies and regulations that set standards for quality of health care services from the jurisdiction of GATS, WTO, regional and bilateral trade agreements.

## **VII. Trade agreements, Intellectual Property, and Access to Affordable Medicines**

Pharmaceuticals can save lives and cure illnesses. Yet millions who need prescription drugs cannot obtain or afford them. The question of how to finance and organize the research, production and distribution of drugs is a burning political priority. Intellectual property rules, which are reinforced by trade agreements, are a central arena for the debate.

In this section we review: the problem of access to affordable prescription drugs; the role of patent and trade rules in the problem; examples of the problem and role of trade rules regarding HIV/AIDS in southern Africa, and drug reimportation in the United States; alternative proposals for financing and organizing the research, production and distribution of drugs; and trade-related alternative proposals.

### **VII. A. TRIPS, TRIPS-Plus, and Access to Medicines**

#### **The Problem**

Access to prescription drugs varies across economically developed and developing nations. Most developed nations have implemented policies that provide affordable medicines to most

residents. Governments in these countries generally leverage their purchasing power to negotiate affordable prices, even with patent-holding brand name companies. The outstanding exception is the U.S., which houses the world's largest drug companies; as a result, the escalating cost of drugs has led to outspoken protests by the elderly and other influential constituencies. The Center for Medicare and Medicaid Services estimates 2004 expenditures in the U.S at \$207 billion (more than \$700 per person).<sup>5</sup>

In the developing world, on the other hand, a few countries such as Brazil and India have developed industries that produce safe and effective "generic" versions of patented drugs (basically copycats of the original drug). Many middle-income countries and most developing countries can neither afford to manufacture nor import patented drugs, which are expensive.

The patent system is one source of the controversy. Patents grant the drug company that first produces a new drug a monopoly right to market the drug in a given country during a set time period; this time period was standardized at 20 years under TRIPS. While the drug is under patent, with limited exceptions, no other company can compete with the innovator company; it cannot copy the same product in generic form and sell it. This means the innovator company holding a patent has wide leeway to set a price. During the government-granted patent period, drug companies are known to charge prices in the U.S. that are 400 percent or more above competitive market prices.<sup>6</sup>

Patents were applied to pharmaceuticals in the 1980s. The intention at the time was to facilitate faster translation of basic research on the biological mechanisms of a disease, into a marketable prescription drug that could treat it. The twenty-year patent right promised high financial rewards to originator companies. On the other hand, by placing a time limit on the monopoly patent right, it allowed generic companies to develop, since they were also promised a market at a time certain.

This system, however, has revealed serious distortions that have impeded innovation, maintained high prices and obstructed access.<sup>3</sup> It offers companies economic incentives to produce "blockbuster" drugs that will return the highest possible profits. This means that companies neglect conditions such as tuberculosis and malaria, which are prevalent in developing countries which cannot pay as much as the lucrative markets in developed nations. Companies also neglect research on conditions prevalent in the North, but which don't promise the greatest possible financial returns, such as new antibiotics for drug-resistant infections; if the profit potential is higher for yet another slightly modified version of a drug for allergies, partly because research costs are far lower, corporations will invest there.

Marketing and administration costs exceed the amount of money spent on research, as firms seek to pursue the monopoly profits associated with patent protections. And companies have concealed research findings in ways that impede the progress of research, preventing health professionals and the public from becoming aware of evidence that some drugs may not be effective, or could even be harmful.

Trade rules increasingly act to constrain the ability of governments at each level of economic development from offering affordable drugs, for example by preventing middle- and low-income countries from producing, importing or exporting affordable generic versions of patented drugs. For example, the U.S.-Australia Free Trade Agreement could obstruct U.S. efforts to reimport drugs from other developed nations, whose own policies effectively lower drug prices.

Authorizing generics would provide competition to patent-holding drug companies, and make lifesaving drugs affordable to millions. In this case, however, patent-holding drug companies would lose some of the income they might have garnered from middle-income countries. In addition, while many developing countries could neither pay brand-name prices nor compete by producing generics, allowing less expensive drugs to be marketed there could destabilize high prices in wealthier countries. This could occur if cheaper drugs find their way back through gray market or approved reimportation routes. Even if this does not occur, the evidence that lower prices are possible present the greatest concern for the pharmaceutical industry.

Angell and others are calling attention to that fact that the industry earns 19% in profits, spends 15% on research and development, and 37% on marketing and administration.<sup>3</sup>

U.S. trade legislation identifies as a negotiating objective to pressure other nations to abandon successful policies to maintain lower drug prices, for the stated purpose of increasing those countries' contributions to drug research and development.

### **The role of trade agreements: TRIPS**

Patents are protected internationally through the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). (See Table 2) Although trade agreements generally encourage international competition in order to lower prices, TRIPS is unique in protecting the rights of certain companies to protect their prices from competition through patents.

TRIPS requires all nations to impose 20 year patent terms at a minimum. Countries can exceed TRIPS provisions, that is, take more aggressive action to protect the intellectual property rights of originator companies. Prior to the emergence of TRIPS in 1995, not all countries used a patent system for drugs. Developing countries in particular asserted that they lacked the complex administrative apparatus needed to verify and coordinate drug patent claims. Most countries must be in compliance by 2005; least developed countries have until 2016.

The case of AIDS has most dramatically illustrated the problems of access in the developing world, and the barriers presented by patent and trade rules. Worldwide 38 million people are infected with HIV, the sexually transmitted virus that develops into AIDS. Ninety percent live in developing countries. An estimated 26.6 million people in southern Africa are living with HIV/AIDS.<sup>††</sup> South Africa has the highest HIV/AIDS population in the world with 5.1 million infected adults. The HIV prevalence among pregnant women is approximately 40 per cent in Botswana and Swaziland, and approximately 30 per cent in South Africa. The HIV prevalence rate among sexually active adults in Swaziland escalated from 4 per cent in 1992 to 38.8 per cent in 2004. The pandemic has slashed life expectancy in the region.

AIDS is virtually always fatal if not treated with drugs, but is not fatal if treated. The three major kinds of important treatments prevent mother-to-child transmission of the HIV virus; antiretrovirals attack the virus itself; and others treat opportunistic infectious that are associated with the illness.

The lack of affordable drugs is a key barrier to containment, although a number of additional factors contribute to the ongoing pandemic, including an inadequate public health infrastructure to diagnose and treat the disease, migratory jobs and the associated sex trade, lack of power by women to insist on protected sex, stigma, and ineffective government policies.

TRIPS allows countries to override patent rights and to provide for less expensive drugs in the interests of public health. For example, TRIPS refers to two possible avenues. One is “parallel importation.” Since manufacturers may sell patented products at a lower price in some countries than in others, someone in the lower-price country could re-sell the drug to a third country at a price that would be lower than the manufacturer’s price in the third country. A second is “compulsory licensing,” which allows a country to produce or import a generic version of a drug without the patent holder’s permission under certain conditions of national emergency or serious threat to the public’s health. Brazil used the threat of compulsory licensing to negotiate more favorable prices for importing patented antiretroviral drugs.

However, the TRIPS provisions permitting parallel importing and compulsory licensing are ambiguous, and the pharmaceutical industry has challenged them. In 1998, the Pharmaceutical Manufacturers Association of South Africa and 39 multinational pharmaceutical companies, concerned that the example of Brazil could become a pattern, brought a lawsuit to prevent the South African government from purchasing generic versions of HIV/AIDS drugs from countries such as Thailand, India and Brazil, and to enforce their patents on those drugs under TRIPS.<sup>10</sup> The suit was withdrawn in 2001, after international protest.

There have since been several attempts to clarify the circumstances under which compulsory licensing and other flexibilities are permitted. On November 14, 2001, the World Trade Organization adopted the Declaration on the TRIPS Agreement and Public Health, referred to as the Doha Declaration.<sup>117</sup> It states that the TRIPS Agreement “does not and should not prevent [WTO] Members from taking measures to protect public health.” Supporting public health involves “promoting both access to existing medicines and the creation of new medicines.” Subsequent agreements in 2003 and 2004 further commented on the rights of very low income countries that cannot produce their own generics to import them from other countries. While these measures, and the advocacy surrounding them, have resulted in lower prices for some drugs in some countries, obstacles remain.

Some of the most effective antiretroviral treatments were developed after 1995, when TRIPS was initiated, and new treatments are being developed as old ones generate biological resistance. There is concern that these newer drugs will remain expensive and unavailable. India and Brazil, which are major suppliers of generic alternatives, are compelled to abide by TRIPS patent rules as of 2005. They will be unable to produce generic versions of drugs that come under patent in 2005 or later, and therefore unable to export them to developing countries, which will not have access to them.

### **TRIPS-Plus and Drug Reimportation**

Recently negotiated bilateral trade agreements and regional trade agreements currently under negotiation include provisions that significantly increase the patent protections provided in TRIPS (referred to as “TRIPS-plus”) and do not incorporate the flexibilities agreed to in the Doha Declaration, which strengthen public health protections.

These agreements extend beyond TRIPS the scope of what may be patented. For example, TRIPS allows the exclusion from patentability of diagnostic, therapeutic and surgical methods, and plants and animals. Recent agreements, such as the US-Morocco Free Trade Agreement requires that patents be made available for plants and animals, and for new uses or methods of using a known product, including for the treatment of humans and animals. These agreements also allow pharmaceutical patent holders to extend patent extensions beyond twenty years allotted in TRIPS. In addition, “data exclusivity” and “market exclusivity” provisions grant

pharmaceutical patent holders years of extended exclusive proprietary control over use of clinical information normally used to obtain regulatory approval by documenting the bioequivalence and therefore effectiveness of generic drugs. These delays add new restrictions on bringing generic drugs to market. Collectively, these TRIPS-plus provisions limit competition among pharmaceutical companies, maintain high drug prices, and make it increasingly difficult for poor people to obtain essential medicines. These tighter restrictions in bilateral and regional trade agreements set a new floor, undercutting nations' ability to negotiate more flexible access to essential medicines multilaterally.

The U.S., for example, has promoted the use of bilateral and regional trade agreements to limit or prohibit the reimportation (or parallel importation) of less expensive drugs from one country to another. At the same time, the U.S. Congress has introduced several bills authorizing the reimportation of U.S.-made drugs back from Canada to the U.S., in order to take advantage of Canada's lower prices. Many U.S. states and cities have taken similar action.

In negotiations for a trade agreement with Australia, the U.S. included a rule that would give any patent holder the right to block drug reimportation. This provision is remarkable in that the patent holder has this right, even if the country proposing to reimport drugs is neither Australia or the U.S. This means, for example, that the government of Australia could file a trade violation against the U.S. if the U.S. took action to reimport drugs from Canada.<sup>11</sup>

The terms of the Agreement also give the pharmaceutical industry greater leverage over Australia's drug price control system.

## **VII. B. Proposed alternatives**

A number of alternatives are being proposed to facilitate access to affordable prescription drugs. In general, these alternatives address one or another major aspect of the problem: research and development of new drugs in the U.S. and other developed nations; mechanisms for purchasing and distributing affordable medicines in the developed and developing world; alternatives to particular TRIPS-plus provisions, such as those that limit compulsory licensing for generic drugs, and assuring access for generic producers to the clinical trial data used by the innovator patent-holding companies to establish the safety and efficacy of their products.

These policy alternatives are in many cases new, creative, and worthy of consideration. The longstanding economic and political power of the pharmaceutical industry has been a central obstacle to change. It is likely that unless the industry is in a position to compromise, the policy space to consider alternative proposals will be hard to find.

The pharmaceutical industry has achieved political success in the U.S. partly by tying its defense of intellectual property to the interests of the entertainment and computer software industries. The case can be made that whether or not these industries are pursuing legitimate interests of their own, e.g. to prevent pirating of movies or software in China, these concerns are on a different order of magnitude from the human devastation caused by blocking access to drugs for HIV/AIDS in Africa and Asia.

There is an analytical gap in discussions of pharmaceutical policies between developed and developing countries. Better understanding the links between these policies could lead to better alternatives, and more unified support for them.

### **Alternatives to TRIPS and “TRIPS-Plus” rules**

Alternatives to the TRIPS-Plus provisions in bilateral and regional trade agreements include the following:

1. Eliminate TRIPS-Plus provisions entirely. Require adherence to the letter and spirit of the Doha Declaration. This includes no extension of patent terms beyond 20 years.
2. Provide minimal but affordable additional payments to patent holders, so that developing countries can implement “compulsory license” rights to produce and export generic drugs to other developing countries, even while patents are in effect.
3. Assess a royalty fee to allow generic producers to use the same clinical trial and other data that patent-holders used initially to establish safety and efficacy (overcoming “data exclusivity” provisions that give patent-holders the exclusive right to this information). To address emergencies, royalties would be calibrated to the level a free market will support when cheaper generic makers emerge to supply enough drugs to meet demand generated by that emergency.

These mechanisms would permit access to inexpensive generics in developing nations, while the property rights of big pharmaceuticals are not altogether forfeited.

Robert Weissman of Essential Action in the U.S., Jean Lanjouw at the University of California at Berkeley, and others have written proposals to accomplish these goals.

### **Alternatives for research and development of pharmaceuticals**

Analysts such as Marcia Angell, Kevin Outterson and Donald Light have recently taken issue with pharmaceutical industry claims regarding the value, expenditures and framework of its research and development.<sup>3</sup> In the U.S., much basic research in pharmaceuticals is supported by public funds through the National Institutes of Health. The drug industry then develops and markets products based on this research. The pharmaceutical industry claim that other developed countries are “free riders” on U.S. R&D, and that this is the basis of their lower prices, is under examination. Some specific alternatives to financing and organizing the research and production of pharmaceuticals have been summarized by Dean Baker:<sup>8</sup>

- 1) A proposal by Tim Hubbard and James Love for a mandatory employer-based research fee to be distributed through intermediaries to researchers (James Love 2003);
- 2) A proposal by Aidan Hollis for zero-cost compulsory licensing patents, in which the patent holder is compensated based on the rated quality of life improvement generated by the drug, and the extent of its use (Hollis 2004);
- 3) A proposal by Michael Kremer for an auction system in which the government purchases most drug patents and places them in the public domain (Kremer 1998); and
- 4) A proposal by U.S. Congressional Representative Dennis Kucinich to finance pharmaceutical research through a set of competing publicly supported research centers (U.S. Rep. Dennis Kucinich 2004).

In addition, Love and Hubbard propose to direct research funds to reward innovation directly.

All of these proposals finance prescription drugs in ways that allow most drugs to be sold in a competitive market, without patent monopolies. These proposals also would eliminate many of the economic distortions created by the patent system.

### **Promoting Alternative Trade and Health Policy and Negotiating Objectives**

Alternative trade and health negotiating objectives to protect and promote affordable access to prescription drugs to prevent and treat illness and disease might include:

1. To seek to obtain the reduction or elimination of barriers that prevent affordable access by the population of parties to trade agreements to essential medicines and prescription drugs, including, any trade provisions that delay access to generic drugs through extensions of patents, extensions of data exclusivity by drug patent holders, extension of drug market exclusivity by drug patent holders, or drug importation or reimportation.
2. To seek to obtain the reduction or elimination of barriers that prevent countries from the issuance of compulsory licenses to manufacture patented pharmaceuticals to remedy excessive pricing, and to export generic versions to countries that have no or insufficient domestic pharmaceutical manufacturing capacity to increase access to essential medicines;
3. To respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001, and affirmatively promote provisions in trade agreements to this effect.

## **VIII. CONCLUSION**

International trade agreements raise fundamental questions for policymakers and the public about whether and how we will improve human health and wellbeing, and achieve sustainable economic development. The will and ability to create institutions of global governance that respect the rights of nations and individuals to participate in economic and political decisions will play an important role.

Trade rules and trade dispute decisions currently prioritize commercial interests without participation by public health advocates, or consideration for their effects on health. After a decade, WTO agreements and regional agreements such as NAFTA remain controversial, and have contributed both to an increase in economic inequality and the elimination of some public health protections.

An alternative public health policy framework elevates the priority of individual, community and international health in economic decision-making. As described on p. 33, such a framework can motivate greater convergence between public health policy, and trade and economic policy, and support structural changes required to achieve sustainable development, alleviating poverty while increasing political and social rights.

This paper has proposed alternative solutions based in public health principles, in four areas critical to public health and sustainable economic development, and which are also the subject of trade negotiations: global governance, the financing and delivery of health-related services, the

migration of clinicians, and access to affordable medicines. Some can be implemented in the near term. All merit consideration.

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