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Trade and Health: The Global Spread of Diseases and International Trade

By David P. Fidler*

Introduction

In the last twenty years, public health officials have come to recognize that the traditional distinction between national and international health has been shattered by the processes of globalization.¹ At the end of the twentieth century, sovereign States no longer can protect the health of their citizens without international cooperation.² Elsewhere I have called this phenomenon the 'globalization of public

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¹ U.S. Centers for Disease Control and Prevention, Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States, 1994, 12 [hereinafter CDC Strategy] (arguing that the "concept of 'domestic' as distinct from 'international' health is outdated"); Seth F. Berkley, AIDS in the Global Village: Why U.S. Physicians Should Care About HIV Outside the United States, Journal of the American Medical Association, vol. 268, 1992, 3368, 3369 (arguing that the distinction between domestic and international health is obsolete); George A. Gellert et al., The Obsolescence of Distinct Domestic and International Health Sectors, Journal of Public Health Policy, vol. 10, 1989, 421, 421 (arguing that "traditional and historical bases for differentiating domestic and international health in Western nations have . . . lost meaning"); James W. LeDuc, World Health Organization Strategy for Emerging Infectious Diseases, Journal of the American Medical Association, vol. 275, 1996, 318, 318 (proposing that national health has become an international challenge).

² National Science and Technology Council Committee on International Science, Engineering, and Technology Working Group on Emerging and Re-Emerging Infectious Diseases, Infectious Diseases — A Global Health Threat, 1995, 11 [hereinafter CISET Rep.] (arguing that
health'. The scope of global health problems is staggering and frightening. Not only does the world face a global crisis in emerging and re-emerging infectious diseases but also in global pandemic of chronic diseases caused in many cases by the consumption of tobacco products. The massive health threats from pathogenic microbes and tobacco consumption are bad enough but are not the end of the global health crisis at the end of the twentieth century. Recently the World Health Organization (WHO) reported that the world also confronts an obesity epidemic, the impact of which "is so diverse and extreme that it should now be regarded as one of the greatest neglected public health problems of our time with an impact on health which may well prove to be as great as that of smoking."6

A major factor in the development of the globalization of public health is international trade. Pathogenic microbes move about the world as hitchhikers in international commerce. Cigarettes and other tobacco products reach new markets through international trade. The growth of the global market, and the role of international trade in creating and maintaining that market, has helped create more sedentary lifestyles and unhealthy eating habits in many countries. Each of the infectious disease, tobacco-related disease, and obesity examples underscores the powerful connection between trade and health.

The linkage between trade and health has, however, been overshadowed in international trade literature until recently by the more famous linkage of 'trade and environment'. 'Trade and health' issues have often been subsumed in the 'trade and environment' discourse, but the 'trade and health' linkage should be separated from its more well-known relative. In many ways, 'trade and health' is the oldest linkage between national and international public health indicates. See sources cited supra (note 1).

3 David P. Fidler, The Globalization of Public Health: Emerging Infectious Diseases and International Relations, Indiana Journal of Global Legal Studies, vol. 5, 1997, 11, 12. The concept of the 'globalization of public health' is not original to me as the recognition of the breakdown in the distinction between national and international public health indicates. See sources cited supra (note 1).

4 See infra Part I.A.

5 See infra Part I.B. Hiroshi Nakajima, Message from the Director-General, in: World Health Organization, The World Health Report 1997: Conquering Suffering, Enriching Humanity, 1997, v ("In the battle for health in the 21st century, infectious diseases and chronic diseases are twin enemies that have to be fought simultaneously on a global scale.").


cause it originates in the mid-nineteenth century. It, thus, pre-dates by over a century the 'trade and environment' controversy of the last fifteen years. The trade-health linkage has, over the course of a century and a half, had an impact on more than international trade law, as evidenced by the development of International Health Regulations (IHR), which are administered by the WHO. The dynamics of this linkage can be analyzed through two different areas of international law: international health law, represented by the IHR and its historical antecedents, and international trade law, represented by the General Agreement on Tariffs and Trade and its evolution into the World Trade Organization (WTO). In addition, the current WHO proposals to develop an international framework convention on tobacco regulation promises to showcase the trade-health linkage in a brand new area of international health law.

In analyzing the different ways that international health law and international trade law have handled the trade-health linkage, we can identify the special dynamics of this linkage. At its heart, the dynamics derive energy and friction from the tension between two objectives: (1) the protection of public health through the exercise of sovereignty, which I refer to as 'public health sovereignty'; and (2) the promotion of trade through the limitations on the exercise of public health sovereignty. Since the mid-nineteenth century, the story of the linkage has been the repeated attempts by States to strike a balance between public health sovereignty and trade disciplines on the exercise of such sovereignty. The great protagonist of this story is science because States have repeatedly turned to science to provide the guidance needed to balance health and trade interests. But the story does not end with science slaying the twin dragons of trade-damaging sovereignty and health-wrecking trade. Recent episodes including the saga of 'mad cow' disease in the European Community (EC), the WTO panel decision in the Beef Hormones Case (Hormones Panel Report) and the WTO Appellate Body's decision on this case (Hormones Appellate Report), and the

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8 See infra Part II.
10 See infra Part I.B.
11 See Case C-180/96R, United Kingdom v. Commission, [1996] 3 CMLR 1 (European Court of Justice rejecting Britain's application for the annulment of the EC Commission's decision imposing a worldwide ban on the export of British beef and beef products).
new United States policy to improve the food safety of imported food products suggest that the trade-health linkage has a future as controversial as its past.

In this article, I explore in depth the 'trade and health' linkage in five steps. First, I examine the globalization of public health by providing some background to the global health crises of emerging infectious diseases and tobacco-related diseases. Second, I provide a historical perspective on the trade-health linkage by exploring the development of this linkage since its first explicit recognition in international diplomacy in the mid-nineteenth century. Third, I explore the dynamics of the trade-health linkage in the areas of international health law and international trade law and show the development in both areas of what I call the 'science paradigm'. Fourth, I discuss the concerns that currently exist about the science paradigm in international health and trade law. Finally, I speculate on the future of the trade-health linkage in both international health law and international trade law and offer some suggestions for improving how the linkage will be handled in the future.

I. The Globalization of Public Health:
Global Health Crises in Infectious and Tobacco-Related Diseases

Two great threats cloud the future of global health: the crisis in emerging infectious diseases and the crisis in non-communicable diseases caused by tobacco consumption. The WHO has recognized both of these crises as world health priorities that require international cooperation and action. National governments, particularly in the United States and Western Europe, also recognize the threats posed by emerging infectious diseases and tobacco-related illnesses. In Part I, I explore each of these public health crises briefly and analyze them as progeny of the globalization of public health.

1. Emerging Infectious Diseases

International and national public health agencies define 'emerging infectious diseases' (EIDs) as "diseases of infectious origin whose incidence in humans has increased within the past two decades or threatens to increase in the near future." This defini-
tion encompasses both new diseases that humans had never identified before, like HIV/AIDS and Ebola hemorrhagic fever, as well as old diseases familiar to humans but now re-emerging as health threats, such as tuberculosis and malaria.\textsuperscript{17}

International and national public health officials have identified EIDs as one of the most serious global health threats confronting humanity in the late twentieth century. According to the WHO, infectious diseases are the world’s leading cause of death, killing at least 17 million people — most of them young children — every year.\textsuperscript{18} Up to half the 5,720 million people on earth are at risk of many endemic infectious diseases.\textsuperscript{19} The WHO has called the emergence and re-emergence of infectious diseases a global crisis that requires global cooperation.\textsuperscript{20} Key public health and medical agencies and institutes in the United States have identified EIDs as an international threat to American public health.\textsuperscript{21} Global actions plans are being developed to deal with the EID crisis that involve international and national efforts.\textsuperscript{22}

The reasons why the world confronts an EID crisis are complex, and elsewhere they are explored more thoroughly.\textsuperscript{23} Central to many of the factors behind the emergence and re-emergence of infectious diseases are the processes of globalization:

Infectious diseases spread through the links created by an interdependent world. Globalization provides infectious diseases with opportunities to infect human populations across the planet almost as easily as infecting the family next door. Just as companies today create global strategies, public health authorities must view the health of their citizens from a global perspective.\textsuperscript{24}

A key aspect of globalization that helps pathogenic microbes spread is international trade, particularly trade in food and food products. The United States Institute of Medicine has observed that "[i]nternational trade has become so pervasive that it is

\textsuperscript{17} A United States interagency governmental working group identified the emergence of 29 new diseases and the re-emergence of 20 older diseases since 1973. CISET Rep. (note 2), 14 - 15.

\textsuperscript{18} World Health Rep. 1996 (note 16), 1.

\textsuperscript{19} Id.


\textsuperscript{21} CDC Strategy (note 1); Institute of Medicine, Emerging Infections: Microbial Threats to Health in the United States, 1992 [hereinafter IOM Rep.]; CISET Rep. (note 2).

\textsuperscript{22} For a detailed analysis of proposed global action plans, see David P. Fidler, Return of the Fourth Horseman: Emerging Infectious Diseases and International Law, Minnesota Law Review, vol. 81, 1997, 771, 819 - 832.

\textsuperscript{23} Id., 785 - 800 (analyzing factors behind EIDs). See also CDC Strategy (note 1), 7 (listing factors behind EIDs); IOM Rep. (note 21), 34 - 112 (discussing factors behind EIDs); and CISET Rep. (note 2), 10 (discussing factors behind EIDs).

\textsuperscript{24} Fidler (note 22), 774 - 775.
virtually impossible to screen most of the food entering the country for known microbial hazards, let alone for new microbial threats." Up to seventy percent of fruits and vegetables consumed in some U.S. states today is imported from the developing world. It is precisely this threat from pathogenic microbes hitchhiking on world food and food products trade that stimulated the Clinton administration in early October 1997 to launch a policy initiative to improve the safety of food imported into the United States.

2. The Global Tobacco Pandemic

National and international public health officials have long considered smoking and other forms of tobacco consumption to be very hazardous to human health. Smoking kills by causing "heart disease, stroke, chronic bronchitis, emphysema, and cancer, especially lung cancer." American anti-tobacco efforts began in the mid-1960s after release of the first U.S. Surgeon General's report on the adverse health consequences of smoking. The WHO has, since 1970, been active in advocating that its member States undertake anti-tobacco campaigns. Such longstanding WHO involvement in this issue suggests that tobacco consumption has long been an international public health concern. The global circumstances of tobacco consumption have, however, changed dramatically since 1970, which has caused the WHO to launch a new effort to deal with the impending global tobacco pandemic.

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25 IOM Rep. (note 21), 68.
26 Emerging Infections: A Significant Threat to the Nation's Health: Hearings Before the Senate Committee on Labor and Human Resources, 104th Cong. 1, 1995, 44 (statement of Dr. Michael Osterholm).
27 See Bennet (note 14), A1.
In the recent past, tobacco consumption was a priority public health concern in developed countries, where "[c]igarette smoking... is one of the largest causes of preventable death worldwide and is the leading cause of premature death in developed countries." Successful anti-smoking campaigns in developed countries have, however, forced declines in demand for tobacco products. The giant tobacco conglomerates, which are mainly American or British, have turned their attention away from developed countries towards "developing and expanding new markets in Africa, Asia, Latin America, Eastern Europe, and the former Soviet Union, where tobacco regulation is limited." As Lown put it, "[t]he struggle against tobacco is not being won, it is being relocated." Tobacco exports play a key role in entering new emerging tobacco markets. Both the tobacco conglomerates and the governments of developed countries have vigorously supported tobacco exports to the developing world, often employing national trade law weapons, such as Section 301 of the U.S. Trade Act of 1974, and international trade law in the form of the GATT to open markets for their tobacco exports. Western tobacco conglomerates have hit the jackpot with these private and government-supported efforts: The evidence of this success is staggering. Worldwide cigarette consumption has increased 75% in the last few decades. American cigarette exports alone have more than trebled in the

31 Id., 260 - 261. The WHO reports that research estimates show just how devastating the tobacco epidemic in developed countries has been over the last half of the 20th century. Between 1950 and 2000, about 62 million people will have died in these countries from tobacco use, most (52 million) of these men, with the majority (38 million) dying in middle age (35 - 69 years). On average those killed by tobacco in this age group lose more than 20 years of life expectancy. World Health Organization, Mortality from Smoking in Developed Countries, 1950 - 2000, Tobacco Control, vol. 4, 1995, 102, 102.

32 Taylor (note 30), 262.

33 Id. See also Lown (note 28) (the tobacco industry's long range global strategy is to maintain sales roughly constant in industrialized countries, while investing mammoth resources to increase market share in the Third World, in the former Soviet Union and in Eastern Europe.").

34 Lown (note 28).


last ten years. In this decade, tobacco consumption is expected to fall by 17% in developed countries and to rise by 12% in developing countries and Eastern Europe.\textsuperscript{37}

The public health consequences of this shift in global tobacco consumption patterns are grim. Taylor captures the scenario unfolding:

The enormous growth in smoking throughout the world in recent years has increased the global risk of tobacco related diseases at an alarming rate. . . . The already high prevalence of smoking in developing countries is likely to rise further as economic development makes tobacco more affordable. WHO predicts that if the current trend in developing countries persists over the next thirty years, seven million inhabitants of developing countries will die annually from smoking related diseases, accounting for 70% of tobacco related deaths worldwide. Hence, within the next thirty years, smoking will be not only the leading cause of premature mortality in developed states, but also the leading cause of premature death worldwide.\textsuperscript{38}

The looming global public health catastrophe of tobacco-related diseases has fueled renewed efforts at the WHO to address tobacco consumption. In May 1995, the World Health Assembly asked the Director-General to report to it on the feasibility of developing a treaty on international tobacco control.\textsuperscript{39} In November 1995, the Director-General delivered his report in which various options for an international instrument on tobacco control were discussed.\textsuperscript{40} International legal analysis and advocacy, led by Dr. Allyn Taylor, gave the idea of an international treaty on tobacco control more substance and momentum.\textsuperscript{41} In May 1996, the World Health Assembly instructed the Director-General to begin developing a framework convention on international tobacco control.\textsuperscript{42} At the 10th World Conference on Tobacco or Health held in August 1997, the WHO Director-General vividly described the global tobacco pandemic as "a fire in the global village"\textsuperscript{43} and urged WHO member States to "sup-

\textsuperscript{37} Taylor (note 30), 266.

\textsuperscript{38} Id., 267 - 268. See also Christopher J. L. Murray/Alan D. Lopez (eds.), The Global Burden of Disease: Summary, 1996, 38 ("By 2020, the burden of disease attributable from tobacco is expected to outweigh that caused by any single disease. . . . This is a global health emergency that many governments have yet to confront.").


port transforming WHO's recommendations for comprehensive tobacco control into international law.  

The global tobacco pandemic is also, like the EID crisis, the progeny of globalization because of the critical importance of international trade in the spreading of tobacco consumption. The transnational tobacco companies view the world as a single, global market; and the existence of borders and sovereignty seems not to constitute much of an obstacle to their strategies. Globalization is forcing States interested in controlling the tobacco threat to their populations to realize the need for international cooperation:

The tobacco pandemic vividly demonstrates the ever increasing interdependence of national efforts to protect public health. This global health challenge is international in origin, has international repercussions, and necessitates collaborative, multilateral action to encourage and assist countries in the development and implementation of effective national and international action.  

3. The Globalization of Public Health: Health v. Trade?

This overview of the infectious disease and tobacco-related disease crises could easily lead one to conclude that the contemporary architecture of international trade is dangerous to human health. The growth in the volumes of international food and tobacco trade — the conduits for diseases — flows from the opportunities opened by international trade law. The health dangers of international trade could be augmented by noting the severe pressures global economic competition places on governments, which are forced to be austere in, among many areas, their public health and health care budgets. States, thus, face great public health problems with inadequate resources and commitment. The danger is especially obvious in the developing world. The great burden of EIDs will fall primarily on the developing world, as will the future health disaster caused by tobacco consumption. Those most vulnerable to the health threats posed by globalization are those most unable to protect themselves from such threats and the international trade forces that exacerbate them. These

44 Id.
45 Taylor (note 30), 278.
46 David P. Fidler, Globalization, International Law, and Emerging Infectious Diseases, Emerging Infectious Diseases, vol. 2, 1996, 77, 78 (noting that "the development of the global market has intensified economic competition and increased pressure on governments to reduce expenditures, including the funding of public health programs, leaving states increasingly unprepared to deal with emerging disease problems.").
48 See Taylor (note 30), 267 - 268 (providing statistics on the future burden of tobacco-related diseases for developing countries).
conclusions seem to point to a Faustian bargain at work for States in the globalization of public health: support international trade and its modern rules and institutions and lose the ability to protect public health.

Such simplistic conclusions are misleading descriptively and normatively. The trade-health linkage is not, and never has been, an avoidable Faustian deal. It arises from the structure of the international system and the nature of human diseases. Historically, States have developed ways to try to strike an appropriate balance between trade interests and health objectives that cannot be dismissed without some objective analysis. These developments do not necessarily mean that the perfect balance has been struck in any historical moment, but the on-going process reveals a complicated and necessary balancing act taking place on a global scale. Normatively, seeing the trade-health linkage as a zero-sum game contains an archaic (and chaotic) vision for the future: we restrict international trade to accommodate national health. States set out to refine this type of thinking approximately 150 years ago in order that health-based restrictions on international trade had a rational basis grounded in science. While fraught with many difficulties, as this article will explore, this science-connected approach makes progress away from the ‘trade v. health’ mentality to one that sees, and works to develop further, trade and health as permanently intertwined objectives in the global village.

II. The Oldest Linkage: Trade and Health in History

While the globalization of public health is the source of great angst today, few people appreciate that it is not a new phenomenon. In fact, the globalization of public health is perhaps one of the oldest aspects of globalization. The link between trade and health is ancient, as trade and travel have been the major sources for spreading diseases since the dawn of human civilizations.49 Diamond observes that a bonanza for infectious diseases "was the development of world trade routes, which by Roman times effectively joined the populations of Europe, Asia, and North Africa into one giant breeding ground for microbes."50 The conscious linking of trade and health is also very old, dating back to at least the fourteenth century when Italian city-states began to develop quarantine systems as measures against the importation of the disease that became known as the 'Black Death' — bubonic plague.51 Although without any clue about how bubonic plague was transmitted or how it infected humans, the leaders of late fourteenth Italian city-states had the belief that the Black Death came

49 See generally William H. McNeill, Plagues and Peoples, 1976, for a study of the importance of diseases in the development of human societies.
to them through trade. By the nineteenth century, most European States had implemented quarantine systems based on the linkage between trade and health.

International cooperation on the trade-health problem did not appear until the mid-nineteenth century. National quarantine systems still dominated the European approach to the trade-health relationship in the first half of the nineteenth century, but changes in the nature of international trade forced States to confront the inadequacy of national quarantine. National quarantine systems had long been a burden on international commerce because they often subjected ships, cargo, and crew to measures and treatment that were not only economically wasteful but also "cruel to the point of barbarity." As international trade began to increase in both volume and speed in the first half of the nineteenth century, the ramshackle collection of national quarantine systems in Europe began to impose, especially for the British, an almost intolerable cost on international trade. These rising frustrations with national quarantine were peaking simultaneously with the early cholera epidemics in Europe, which caused great death and fear across Europe. Quarantine systems had not protected European populations from the ravages of cholera, so their value to national health was questioned.

Both the trade and health concerns of European nations surrounding quarantine led directly to the convening in 1851 of the first international sanitary conference. This conference represents the recognition by European States that they could not deal with disease threats moving through international trade without formal international cooperation. We see in this conference the first recognition of the phenomenon of the globalization of public health. The negotiations in 1851 on an international convention to harmonize national quarantine regulations also constitute the first multilateral cooperation on the trade-health linkage in history.

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52 Id., 31.
53 Id.
54 Id., 34.
55 Norman Howard-Jones, The Scientific Background of the International Sanitary Conferences 1851-1938, 1975, 11 (noting that "what governments found most irksome were the often disastrous hindrances to international commerce, and it was this concern that finally prompted the European nations to meet to discuss to what extent these onerous restrictions could be lifted without undue risk to the health of their populations.").
56 Goodman (note 51), 38 (discussing early European epidemics of cholera, "a new and terrifying disease to the western world").
57 Id. (noting that quarantines seemed impotent to stop spread of cholera in Europe).
58 For a description of the first international sanitary conference, see Howard-Jones (note 55), 12 - 16.
59 For more on the 19th century emergence of the globalization of public health, see Fidler (note 3), 24 - 25.
The trade-health linkage proved so strong and compelling in the latter half of the nineteenth century that European States, with occasional participation by the Ottoman Empire and later the United States, convened no less than ten international sanitary conferences to try to create international conventions to balance national health protection and international trade interests.60 For the most part, these international sanitary conferences failed to make progress until the early 1890s, by which time scientists such as Louis Pasteur and Robert Koch had demonstrated that the 'germ theory' of diseases was the correct theory.61 In other words, little headway was made in balancing trade and human health objectives until science had developed sufficiently to provide a more accurate understanding of infectious diseases.62 The scientific breakthroughs created the conditions that produced four international sanitary conventions in the 1890s—the first international legal instruments and rules created in nearly fifty years of international sanitary conferences.63

Not only had science broken the diplomatic impasse in the trade-health problem but it also began to re-orient national policies on public health protection. It became more and more apparent that quarantine systems, as traditionally organized, had little effect on preventing the importation of infectious diseases. Science pointed to the need for surveillance and public health policies driven by the epidemiological nature of the pathogen in question. Wonderfully, the scientifically-based measures needed to protect public health better resulted in fewer and less onerous restrictions on international trade. The international sanitary conventions of the first half of the

60 These ten international sanitary conferences were held in Paris (1851), Paris (1859), Constantinople (1866), Vienna (1874), Washington, D.C. (1881), Rome (1885), Venice (1892), Dresden (1893), Paris (1894), and Venice (1897). For descriptions of all these conferences, see Howard-Jones (note 55), 12-80.

61 The scientific work of Pasteur and Koch is described for general audiences in Paul de Kruif, Microbe Hunters, 1926, 54-177.

62 In 1878, Austria, France, Germany, Portugal, and Switzerland concluded a treaty to protect plant life and health that sought to reduce the threat to wine vineyards from a plant louse. See Convention Respecting Measures to be Taken Against Phylloxera Vasterix, 17 September 1878, 153 Consolidated Treaty Series 247. Charnovitz claims that this agreement is the "earliest treaty to use trade measures for a health/environment purpose." Steve Charnovitz, Trade Measures and the Design of International Regimes, Journal of Environment & Development, vol. 5, 1996, 168, 176.

twentieth century attempted to harmonize national public health measures on disease importation in a way that served both health and trade.64

The trade-health synergy made possible by scientific progress can be seen clearly in the fundamental objective of the WHO's International Health Regulations (IHR), originally adopted in 1951. The IHR consolidated and updated the rules in the various international sanitary conventions of the pre-World War II period with the objective of providing the maximum protection against the international spread of disease with minimum interference with world traffic.65 This fundamental objective continues to drive the IHR today as the WHO prepares to revise it to deal with the EID crisis.66

The IHR were not the only international legal rules to recognize the trade-health linkage immediately after World War II. The General Agreement on Tariffs and Trade (GATT), the first great multilateral trade agreement, recognized the trade-health link in 1947 by allowing contracting parties to derogate from GATT obligations if such derogation was necessary to protect human, animal, or plant life or health and was not applied in a way that constituted unjustified discrimination or a disguised restriction on international trade.67 The spirit of this GATT provision

64 The major international sanitary conventions of the first half of the twentieth century were the International Sanitary Convention of 1903, 3 December 1903, 1 Bevans 359; the Pan-American Sanitary Convention of 1905, 14 October 1905, 1 Bevans 450; the International Sanitary Convention of 1912, 17 January 1912, 4 LNTS 282; the Pan-American Sanitary Code of 1924, 14 November 1924, 86 LNTS 43; the International Sanitary Convention of 1926, 21 June 1926, 78 LNTS 229; and the International Sanitary Convention for Aerial Navigation of 1933, 12 April 1933, 161 LNTS 65. The International Office of Epizootics was also founded during this period, in 1924, to address sanitary measures relating to the export and import of animals and animal products. International Agreement for the Creation of an International Office of Epizootics, 25 January 1924, 57 LNTS 135.

65 Int'l Health Reg. (note 9), 5.

66 Fidler (note 22), 851 (noting that WHO continues to embrace this fundamental objective as it revises the IHR).

67 General Agreement on Tariffs and Trade, 30 October 1947, 55 UNTS 187, as amended by the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, 33 ILM 1125 (1994) [hereinafter GATT], Art. XX(b). The trade-health link appeared earlier in international trade law than GATT. See, e.g., the 1878 Convention Respecting Measures to be Taken Against Phylloxera Vasterix (note 62). Charnovitz has also identified a number of treaties concluded in the first half of the 20th century that directly address the trade-health linkage. See Charnovitz (note 62), 78-79 (describing five treaties that employed trade measures for health purposes); Steve Charnovitz, Green Roots, Bad Pruning: GATT Rules and Their Application to Environmental Trade Measures, Tulane Environmental Law Journal, vol. 7, 1994, 299, 327 fn. 150 (describing 1929 plant protection treaty). These six treaties were: the Convention Relating to Liquor Traffic in Africa, 10 September 1919, 8 LNTS 11; Convention to Safeguard Livestock Interests by Prevention of Infectious and Contagious Diseases, 16 March 1928, Mexico-United States, 106 LNTS 481; International Conven-
echoes the fundamental goal of the IHR: to balance health and trade requirements of States in the international system. As explored in more detail in Part III, how the GATT system strikes the balance has undergone some radical refinement.

Notably absent from the preceding analysis has been any mention of tobacco. Tobacco does not figure in the trade-health linkage until well after World War II.68 Infectious diseases dominate the linkage from its first appearances in late fourteenth century Italian city-states. Two points should, however, be noted. First, tobacco has been actively traded internationally since its first cultivation by Europeans in the Americas.69 Thus, the tobacco-international trade connection is very old. Second, the GATT framework established in 1947, and refined thereafter, applies to trade in many products, including tobacco.70 The tobacco-international trade law connection has, at least implicitly, been around since the founding of GATT. These two observations combine to show that the conditions have been ripe for many years for tobacco to figure more prominently in the trade-health linkage. What was missing was the scientific evidence that tobacco consumption caused human diseases. Just as science launched international health law in the late nineteenth century, scientific advancement would propel tobacco to the forefront of the trade-health linkage in the latter half of the twentieth century.71

68 The connection between tobacco imports and health was not lost on King James I of England, who was so alarmed by the increasing use of tobacco that he published in 1604 "A Counterblaste to Tobacco", in which he criticized smoking as "A custome lothsome to the eye, hateful to the Nose, harmefull to the braine, [and] dangerous to the Lungs." Quoted in Mark S. Gold, Tobacco, 1995, 19. The English poet Swinburne also expressed an appreciation of the tobacco-health connection by remarking that King James was a bad king "but I love him, I worship him, because he slit the throat of that blackguard [Sir Walter] Raleigh, who invented this filthy smoking." Quoted in Victor G. Kiernan, Tobacco: A History, 1991, 15. Raleigh did not invent smoking, but he played an instrumental role in bringing tobacco consumption from the New World — where indigenous peoples had long smoked tobacco (id., 8 - 12) — to the Old World. Id., 12 ("Raleigh is agreed to have been the first to bring smoking into fashion" in England).

69 "Tobacco was, in fact, the first export from the New World, thus launching the economic juggernaut that has, to this day, continued almost unchallenged." Gold (note 68), 18.


71 Karl Fagerström et al. describe the current state of medical and scientific research on tobac-
This brief history of the trade-health linkage demonstrates not only its considerable age but its continued importance across hundreds of years of human activity. The recognition of the role of international trade in the spreading of diseases produced national regulatory action in the form of quarantine systems from the late fourteenth to the nineteenth centuries. The growing burdens of the national quarantine systems on international trade stimulated international cooperation on harmonizing national quarantine measures in the mid-nineteenth century. Scientific advances in the late nineteenth century created the necessary conditions for the development of the first rules of international law regulating the trade-health relationship. After World War II, at the dawn of a new international order, the trade-health linkage was embedded in two important realms of international law: international health law (IHR) and international trade law (GATT).

### III. The Dynamics of the Trade-Health Linkage: The Development of the Science Paradigm

The trade-health linkage has produced a set of dynamics in both international health law and international trade law that emphasizes science. The basic conflict in the trade-health linkage is between the sovereign right to protect national health and the interests of other States in international trade. Trade-restricting national public health measures have created international friction and have led States into international negotiations on balancing public health sovereignty and international trade. International negotiations have tended to strike the balance by using science for guidance because science tells us what is necessary medically to protect public health. Trade restrictions are more acceptable when they are based on science. Science becomes, then, the standard against which national measures are evaluated under international law and the standard set for international harmonization of public health measures through international law. The role of science medically and legally becomes institutionalized in international organizations responsible for international health and international trade. These international organizations bear the responsibility for maintaining the integrity of the use of science in the attempts to balance public health sovereignty and international trade. This set of dynamics I call the 'science paradigm'. In Part III, I explore the development of the science paradigm in international health law and international trade law.

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co consumption: "Tobacco smoking is no longer regarded as just a habit. The two most recent decades of research have resulted in its classification as a drug addiction on par with other so-called hard drugs and as a consequence, the United States Food and Drug Administration, has proposed regulations to control the promotion, sale, and distribution of cigarettes and smokeless tobacco." Karl O. Fagerström et al., Nicotine Dependence Versus Smoking Prevalence: Comparisons Among Countries and Categories of Smokers, Tobacco Control, vol. 5, 1996, 52, 52.
1. International Health Law and the Science Paradigm

a) Infectious Diseases

As noted in Part II, progress in the development of international health law in the nineteenth century did not occur until science had advanced sufficiently to give people a more accurate understanding of pathogenic microbes. Once the 'germ theory' of diseases had been developed and accepted by the international scientific community, international health law began to develop rapidly. One of the key aspects of the development of international health law was the attempt to harmonize national quarantine measures on scientifically-based regulations. The international sanitary conventions of the first half of the twentieth century established the maximum measures against certain infectious diseases that State parties could take. These maximum measures were based on a scientific understanding of the diseases in question. For example, the International Sanitary Convention of 1903 provides that "[n]o merchandise is capable by itself of transmitting plague or cholera. It only becomes dangerous when contaminated by plague or cholera products." Such scientific understandings of infectious diseases allowed States to harmonize national public health measures in a way that was less restrictive of trade and more protective of public health.

The important role science had come to play in the development of international health law is apparent from the creation of the WHO and the IHR after World War II. The inclusion in the WHO Constitution of powers under which the World Health Assembly could adopt binding regulations on "sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease" was, at the time adopted, thought a great advance in international health law because "[t]he authority to issue regulations supposedly gave the WHO the ability to keep the IHR up-to-date regarding scientific advances without having to proceed through the cumbersome treaty process." Science is also important in explaining two other novel features of the IHR. First, under the WHO Constitution, the IHR and any revisions of them are binding on all WHO member States unless they conceal

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*International Sanitary Convention of 1926* (note 64), Art. 15 ("The measures as provided in this Chapter must be regarded as constituting a maximum within the limits of which Governments may regulate the procedure to be applied to ships on their arrival."). *See also* Int'l Health Reg. (note 9), Art. 23.


*Fidler* (note 22), 836.
tract out' by notifying the Director-General within a specified period of time of their rejection of the IHR or any revision to them. The scientific basis for the IHR gives them a legitimacy that supports reversing traditional international legal practice from 'contracting in' to 'contracting out'. Second, any reservations made to the IHR or any revisions to them have to be approved by the World Health Assembly. Given the universality of scientific conclusions, the sovereign power to make reservations to international agreements is subject to restriction in order to preserve harmonization through scientifically-based regulations.

In the various manifestations of international health law, science allows States to agree to scientifically-grounded restrictions on the exercise of public health sovereignty. The international sanitary conventions and later the IHR created very detailed regulatory regimes driven by the scientific requirements of preventing the spread of certain infectious diseases. These regulations constitute the maximum measures that governments may apply to people and products flowing in international trade. In the IHR, the responsibility for updating the regulations as science advances rests with an international organization, the WHO. The science paradigm clearly plays a dominant role in the conceptualization and implementation of traditional international health law.

b) International Tobacco Control

The science paradigm also occupies an important role in the WHO’s recent efforts to create a framework convention on international tobacco control. The impetus behind this new initiative in international health law arises, of course, from (1) the scientific evidence that smoking and other forms of tobacco consumption are dangerous to human health, and (2) the rapid growth of tobacco use in the developing world. As in the IHR’s infectious disease context, science legitimates international cooperation and the development of international law. The proposed WHO framework convention, it is hoped, will lead to more specific protocols on particular regulatory issues, like tobacco advertising and cigarette warning labels. Science provides the basis for these anticipated efforts at harmonizing tobacco regulatory regimes in WHO member States. The role of science and the need for science-based harmo-

76 WHO Const. (note 74), Art. 22.
77 Int’l Health Reg. (note 9), Art. 88(1).
78 Taylor/Roemer (note 41), ii ("An international instrument for tobacco control is justified by an incontrovertible science base demonstrating that tobacco use is the largest single cause of preventable, premature death and disease.").
79 Taylor (note 30), 294 - 299 (discussing the framework-protocol approach to the tobacco pandemic).
80 Id., 286 (noting that "tobacco control shares the characteristic of ‘scientific certainty’ that
nization of national tobacco regulations will be institutionalized in the framework-protocol regime, which will provide WHO member States with an on-going forum for refining and shaping international tobacco control efforts. Thus, the features that mark traditional international health law on infectious diseases are appearing as well in nascent form in the international strategy on tobacco regulation.

2. International Trade Law and the Science Paradigm

The science paradigm also comes to dominate international trade law on sanitary and phytosanitary measures (SPS measures), but it was not dominant in the first few decades of GATT. As noted in Part II, GATT Article XX(b) allows contracting parties to impose SPS measures if such measures are necessary and do not constitute unjustified discrimination or a disguised restriction on international trade. This GATT provision makes no explicit mention of science, but Charnovitz argues that GATT preparatory documents suggest that ‘necessary’ meant "necessary in a scientific sense." In the Uruguay Round, GATT contracting parties agreed to place science at the center of the new regime for SPS measures — the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). In this Part III.2, I discuss (a) the history of Article XX(b) in GATT, and (b) the place of science in the SPS Agreement. This analysis will demonstrate the rise of the science paradigm in international trade law.

a) A Short History of Article XX(b)

Article XX(b) represents a balancing of public health sovereignty and trade: GATT contracting parties are allowed to derogate from the GATT rules, such as the prohibition on quantitative restrictions on imports, for public health reasons, as long as the SPS measures applied satisfy certain disciplines. Article XX(b) applies three disciplines to SPS measures: the SPS measure must (1) be ‘necessary’ to protect animal, plant, or human life or health; (2) not be an unjustified discrimination on

has galvanized international action in some realms of environmental law, including acid rain and the ozone layer.

81 Id., 295 ("The success of other international organizations in using periodic meetings of contracting parties to forge international consensus indicates that this process should be included as a basic provision of an international convention on tobacco control.").

82 Charnovitz (note 67), 326.


84 GATT (note 67), Art. XI.

85 Id., Art. XX(b).
international trade;\textsuperscript{86} and (3) not be a disguised restriction on international trade.\textsuperscript{87} Only the necessary requirement is specific to SPS measures because the other two trade disciplines apply to all exceptions contained in Article XX of GATT.

The first thing to note about Article XX(b) of GATT is that it does not, like the IHR, attempt to harmonize national SPS measures through international rules. GATT contracting parties can enact whatever SPS measures they desire as long as they meet the necessary requirement and are applied in a way that does not violate the most-favored-nation treatment principle (i.e., the ‘unjustified discrimination’ rule) or the national treatment principle (i.e., the ‘disguised discrimination’ rule). The central question becomes, then, what does ‘necessary’ mean in Article XX(b). This is the question that has generated the controversy in the history of Article XX(b).

aa) GATT Controversies Not Referred to Dispute Resolution Panels

GATT documents reveal a number of controversies over contracting parties appealing to Article XX(b) that, for whatever reasons, never went to a dispute resolution panel.\textsuperscript{88} A key feature of a number of these disputes is the complaint that the SPS measures in question had no scientific or public health basis. Contracting parties brought complaints to the GATT Council about the application of SPS measures by other contracting parties and cited statements or resolutions of the WHO that the measures being applied had no public health justification.\textsuperscript{89} In other words, the SPS

\textsuperscript{86} Id., Art. XX (chapeau).

\textsuperscript{87} Id.


\textsuperscript{89} In complaining about the EC's import ban imposed after the nuclear accident at Chernobyl, Hungary supported its argument that the EC's ban was arbitrary and unjustified by noting the WHO's recommendation "according to which there was no public health justification to ban imports from East European countries." European Economic Community — Suspension of Food Imports from Certain East European Countries, in GATT Doc. No. C/M/198, para. 14, 29. Peru also complained about the unjustified measures other countries took against its exports after it suffered a cholera epidemic in 1991. See Restrictions on Exports from Peru Following the Cholera Epidemic, GATT Doc. No. C/M/248, para. 12, 29 (Peruvian representative arguing that restrictions on Peruvian exports violated, inter alia, WHO recommendations); Restrictions on Exports from Peru Following the Cholera Epidemic, GATT Doc. No. C/M/250, para. 18, 44 (Peruvian representative illustrating inconsistency between restrictions on Peruvian exports and WHO conclusions that such restrictions are not justified on public health grounds); Restrictions on Exports from Peru Following the Cholera Epidemic — Communication from Peru, GATT Doc. No. L/7038, 24 June 1992 (attaching letter from Director of the Pan American Health Organization stating that "none of the available analytical information relating to controls imposed on food exports and/or imports showed any evidence that the spread of cholera is related to the commercial export of food.").
measures were not necessary to protect human, plant, or animal health or life because they had no effect on or relevance to the health danger present. Although not the way these episodes were handled by the GATT Council, one could read into these controversies the requirement for a scientific basis for SPS measures as part of the 'necessary' discipline. The unsatisfactory way in which these Article XX(b) controversies arose and were handled provided impetus for the development of the new approach to SPS measures in the SPS Agreement.90

A particularly high profile controversy that never made it before a GATT panel was the dispute between the United States and the EC over the latter's ban of meat raised with growth hormones. A major feature of this trade dispute was the American claim that the EC had no scientific justification for its import ban. The United States tried to use the then-existing Standards Code91 to have a GATT Committee on Technical Barriers to Trade establish "a Technical Expert Group to examine the scientific judgment involved in the EC's decision to ban the importation of meat treated with growth hormones."92 The EC was, however, successful in blocking the formation of this Technical Expert Group and thus in shielding its import ban from scientific scrutiny. This long-running beef hormones saga played a prominent role in the negotiation of the SPS Agreement in the Uruguay Round.

bb) Dispute Panel Interpretations of the 'Necessary' Requirement

Two GATT panels93 and one WTO panel94 have interpreted the 'necessary' requirement in Article XX(b) as part of resolving specific disputes. The interpretations follow a consistent pattern, which could be considered the GATT jurisprudence on Article XX(b). First, the burden is on the State invoking Article XX(b) to demonstrate that the SPS measure in question is necessary within the meaning of GATT.95 Second, the dispute panels have asked whether the SPS measure in question falls

90 Patterson (note 88), 94 (noting that "[i]n 1986, the trade ministers of GATT member countries officially recognized the need for strengthened GATT disciplines to prevent the use of health-related measures as unjustified trade barriers and set this as a major goal of the Uruguay Round.").

91 Agreement on Technical Barriers to Trade, 12 April 1979, 1186 UNTS 276.


93 See Thai Cigarette Case (note 36); and United States — Restrictions on Imports of Tuna, unadopted, 3 September 1991, 30 ILM 1594 (1991) [hereinafter Tuna-Dolphin Case].


95 Tuna-Dolphin Case (note 93), para. 5.22.
"within the range of policies designed to protect human, animal or plant life or health." Third, the panel will look to see whether the SPS measure in question is applied in an extrajurisdictional manner. In the Tuna-Dolphin Case, the GATT panel noted that Article XX(b) allowed each contracting party to set its own human, animal, or plant life or health policies but that it did not allow contracting parties to force other countries to adopt its health policies through trade restrictions. Fourth, the panels have analyzed whether the SPS measure in question is ‘necessary’; and the panels have interpreted ‘necessary’ as follows: a SPS measure is not necessary if an alternative measure is available that achieves the same public health objective and is consistent with GATT obligations or is less inconsistent with such obligations. Thus, a SPS measure must be the least trade-restrictive measure possible to be considered ‘necessary’ to protect human, animal, or plant life or health under GATT. Fifth, the SPS measure in question also must pass the ‘no unjustified discrimination’ and ‘no disguised restriction’ on international trade disciplines.

Combining the Article XX(b) analysis from the controversies that did not go before dispute panels and from the panel decisions, we can make the following observations. First, the controversies that did not go before dispute panels suggested that the sovereign right to enact SPS measures was not adequately balanced by the Article XX(b) disciplines. The lack of a scientific basis for many of these measures raised the question whether ‘necessary’ should be read to mean ‘scientifically necessary’. Second, the dispute panel decisions involving Article XX(b) suggest that ‘necessary’ also has a trade aspect in that SPS measures have to be the least trade-restrictive measures possible in the circumstances of the particular case. In other words, even a scientific justification (e.g., as in Thailand’s scientific justification for concern about Thai tobacco consumption) does not give a State complete freedom to enact whatever measure it deems fit. Scientifically-based SPS measures must still (1) be the least trade-restrictive measure possible, (2) not constitute unjustifiable discrimination on international trade, and (3) not represent a disguised restriction on international trade. Article XX(b) could, thus, be seen to impose in theory both a science-based discipline and trade-related disciplines on public health sovereignty.

96 See Thai Cigarette Case (note 36), para. 73 (determining that import ban fell within scope of Article XX(b)).
97 Tuna-Dolphin Case (note 93), para. 5.27.
98 Thai Cigarette Case (note 36), para. 75 (interpreting ‘necessary’ requirement in Article XX(b)); Tuna-Dolphin Case (note 93), para. 5.28 (interpreting ‘necessary’ requirement in Article XX(b)); and U.S. Gasoline Case (note 94), para. 6.24 (following the Thai cigarette panel ruling on the interpretation of ‘necessary’ in Article XX(b)).
99 The GATT panel in the Thai Cigarette Case ruled that the Thai import ban on American cigarettes was not necessary because it was not the least trade-restrictive measure available. Thai Cigarette Case (note 36), para. 81.
b) The SPS Agreement

During the Uruguay Round, the GATT contracting parties realized the inadequacy of Article XX(b) in disciplining public health sovereignty by drafting the SPS Agreement. In the SPS Agreement, we see the full flowering of the science paradigm in international trade law.

While the SPS Agreement confirms the trade-related disciplines in Article XX(b), it places science at the center of SPS measure policy making for WTO member States. The SPS Agreement requires all SPS measures to be based on scientific principles and evidence. This provision makes explicit the implied scientific element of the 'necessary' requirement in Article XX(b). It also echoes the practice under international health law of basing national public health measures on scientifically-sound principles.

The SPS Agreement also follows the harmonization strategy long used in the international health law area by requiring that WTO member States base their SPS measures on international standards set by international organizations. The SPS Agreement differs from the IHR in that the harmonized standards are not the maximum measures that may be applied but are instead 'safe harbors' in which the national measures are presumed to be in conformity with GATT. WTO member States can apply SPS measures that are more stringent than international standards; but such higher standards have to be based on scientific principles and evidence, as well as survive the trade-related disciplines.

Finally, the SPS Agreement institutionalizes the role of science in international trade law in two ways: (1) through reference to international standards created by other international organizations, such as Codex Alimentarius; and (2) by bringing disputes arising within the SPS Agreement under the WTO dispute settlement system. In these two ways, the SPS Agreement institutionalizes at the international level both the use of science in setting standards and the review of scientific justifications for national SPS measures. As Charnovitz has observed, the SPS Agreement's scientifically-based standards impose "new disciplines that have never before been imposed in GATT... disputes."

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100 SPS Agreement (note 83), Art. 2.2.
101 Id., Art. 3.1.
102 Id., Art. 3.2.
103 Id., Art. 3.3.
104 Id., Art. 2.3.
The importance of the science paradigm in the SPS Agreement appears clearly in the Beef Hormones Case, which contains the first WTO panel and Appellate Body rulings to interpret the SPS Agreement. In this case, the WTO held that the EC's ban on the importation of growth hormone-treated meat and meat products violated the SPS Agreement because it was not based on scientific principles or evidence. The EC bore the burden of demonstrating that its ban, which was stricter than the international standards set by Codex Alimentarius for five of the six hormones in question, was scientifically justified. The WTO ruled that the import ban was put in place without being based on a scientific risk assessment as required by the SPS Agreement and that the scientific evidence relied on by the EC did not support an import ban.

Science dominates the Beef Hormones Case. The legal findings of the panel and Appellate Body flow from its analysis of the EC's scientific evidence for the import ban. The EC import ban clashed fundamentally with the science paradigm in the SPS Agreement because it was not based on scientific principles and was maintained without sufficient scientific evidence. Without such a basis or evidence, the EC could not maintain a measure more stringent than relevant international standards established by the appropriate international organization. The institutionalization of science appears in (1) the role accorded the standards set by the Codex Alimentarius on the use of growth hormones, and (2) the interpretation of the SPS Agreement's science provisions by the panel and Appellate Body under the WTO dispute resolution system.


109 Hormones Panel Report (note 12), paras. 8.124, 8.129, 8.134, and 8.139; Hormones Appellate Report (note 13), paras. 197 - 199. The Hormones Panel Report and the Hormones Appellate Report are not identical in all respects as the latter reverses a number of important holdings of the former. These differences are analyzed infra in Part IV.

110 SPS Agreement (note 83), Art. 2.2 ("Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific evidence and is not maintained without sufficient scientific evidence . . .").
IV. Science Rules? Concerns About the Science Paradigm

While the science paradigm prominently appears in traditional international health law concerning infectious diseases, the new efforts to create international health law on tobacco regulation, and international trade law on SPS measures, this prominence has attracted some critical attention. In Part IV, I examine some of the concerns that arise in connection with the science paradigm in the trade-health linkage.

1. Whose Science Rules?

Science is attractive in the trade-health linkage because it promises an objective way to balance public health sovereignty and international trade interests. When irrational politicians and greedy merchants fall out over the trade implications of public health measures, we turn to the people in white lab coats to cut the Gordian policy knot. Science in the laboratory is not, however, science in the midst of diplomacy. The reliance on science in various areas of international law raises questions that erode the image of scientists as dispensing Solomonic wisdom in trade-health controversies. The structure of the international system, and the importance of power in such an anarchical structure, force us to ask questions that relate science to power. As Atik has observed, once science leaves the laboratory and enters the world of the diplomat, power considerations inevitably follow.111

The first science-power question is this: why appeal to science in the trade-health linkage? The answer to this might seem obvious: science has plenty to tell us about the human health consequences of pathogenic microbes and tobacco consumption. The thrust behind the question, which is also implicit in the 'obvious' answer, raises the issue of the cultural importance of science. Historically, Western, developed States have been the champions of science and technology.112 Science and its development is intimately linked with the faith in human reason nurtured by the Enlightenment. The development of the science paradigm in international legal areas constitutes yet another example of the prevalence of European ideas and approaches to human problems that may not be as deeply rooted in non-European cultures.

A second science-power question confronts the direct relationship between science and power: is it not the case that those advocating the science paradigm are also those

111 Jeffrey Atik, Science and International Regulatory Convergence, Northwestern Journal of International Law & Business, vol. 17, 1997, 736, 752 ("To assert the presence or absence of a scientific basis for a proposition will become a political act with international significance.").

that have the lion's share of trade power in the international system? Atik observes that the world's "centers of scientific authority correspond, not accidentally, to the major players in the world trading system." Science power and trade power are linked, and science power can be used by developed countries to open more trading opportunities for their companies through challenges to developing countries' SPS measures. The ability to mount a successful challenge to an SPS measure under the SPS Agreement requires certain scientific capabilities and resources that many countries might not possess. While scientific truths may apply universally (e.g., tobacco kills without discrimination on the basis of nationality or economic status), scientific power is not dispersed widely in the international system, which may be a cause for concern in how the science paradigm operates.

2. Political Science? The Freezing of Science in International Organizations

A great irony of the science paradigm is that the elevation of science in the policymaking process tends to have a chilling effect on State behavior in connection with the trade-health linkage. In the IHR, for example, the WHO was supposed to keep these Regulations relevant and up-to-date as scientific knowledge of infectious diseases progressed. While some changes were made to the IHR since 1951, most notably in the removal of typhus and smallpox from the list of diseases subject to the Regulations, the IHR became more and more anachronistic in only applying to the pestilential diseases of the past — yellow fever, cholera, and plague. The EID crisis has revealed how ill-suited the IHR are for international infectious disease threats in the late twentieth century. The WHO is currently preparing a revision of the IHR to bring it up to speed with current conditions, but the intervening decades since 1951 until the present reveal a reluctance on the part of the WHO member States to keep international health law in step with scientific understandings about the international spread of infectious diseases. In the IHR, the science paradigm was frozen because it focused on three diseases that did not constitute the greatest threats to human health. The IHR's rules on yellow fever, cholera, and plague are scientifically-informed; but the political, economic, and social relevance of these three diseases in the late twen-

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113 Atik (note 111), 749.
tieth century exposes science's continuing vulnerability to international politics, particularly the jealous guarding of sovereignty by States.

In the international trade law context, the de facto binding nature of international standards, guidelines, and recommendations made by, among others, the Codex Alimentarius, may produce a similar freezing of science in international organizations. The nature of the process through which international standards — the bases for harmonization — are set will change now that the standards will have legal significance through the SPS Agreement. Since 1962, Codex Alimentarius has "quietly established 249 international food standards." After the SPS Agreement and the Beef Hormones Case, Codex Alimentarius will no longer operate quietly in obscurity. After the Hormones Panel Report, the EC Farm Commissioner argued that Codex Alimentarius is paralyzed because the WTO now relies on its decisions. The panel's holding heightened the importance of international standards by interpreting the right to adopt higher than international standards found in Article 3.3 of the SPS Agreement as an exception to the general requirement to base SPS measures on international standards found in Article 3.1. The Appellate Body reversed the panel on the relationship between Articles 3.1 and 3.3, arguing that the panel's interpretation makes international standards promulgated by Codex Alimentarius obligatory in force and effect. The Appellate Body argued that the "right of a Member to establish its own level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right and not an 'exception' from a 'general obligation' under Article 3.1." Although the Appellate Body attempted to counter the notion that international standards, which technically are only recommendations, become de facto binding through the SPS Agreement, the requirement that higher than international standards must be scientifically justified through a risk assessment under Article 5.1 still elevates both the political and legal importance of international standards. Ironically, science-based harmonization may lead to the international standard-setting process freezing up because States become reluctant to adopt new standards because they become, if not necessarily legally binding, significant obstacles to the exercise of public health sovereignty.

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116 Alison Maitland, EU Farm Chief Hits at WTO Over Meat Row, Financial Times, 4 September 1997, 26 (reporting EC Farm Commissioner blaming "the WTO sanitary and phyto-sanitary agreement for 'paralysing' progress in adopting higher food standards.").


118 Hormones Appellate Report (note 13), para. 165.

119 Id., para. 172.
These examples of science at the mercy of international politics explode any illusion that the appeal to science in the science paradigm escapes politics. Science not only is embedded in a particular power framework in international relations but also is subject to the political decisions made by States. Science in the science paradigm is really 'political science'.

3. National Science? Sovereign Expressions of Science

Science is supposed to transcend national boundaries as an endeavor that produces universal truths. Yet, controversies in the international trade area suggest that science can be very national. The 'mad cow' dispute between the United Kingdom and the EC over the scientific justification for the EC's ban on British beef exports, the long-running dispute between the EC and the United States over the use of growth hormones in beef production, and recent U.S.-EC trade squabbles over meat, pork, and poultry inspection systems all involve scientific clashes as well as trade conflicts. Atik argues that "[w]e can anticipate many cases where scientific consensus is split along national lines." This, of course, raises the specter of trade interests corrupting the scientific process and pre-determining scientific evidence. In the science paradigm, science is supposed to act as a neutral arbiter between public health sovereignty and trade interests. If trade interests in fact drive, or are perceived to be driving, science, then the attractiveness of the science paradigm wanes considerably.

The convenient tailoring of scientific theories to national economic interests is an old phenomenon, dating back at least to the nineteenth century. The international sanitary conferences of the nineteenth century, up to the breakthrough conferences of the 1890s, were plagued by the great scientific debate over the nature of diseases. The opponents of national quarantine systems, led by the British, favored the 'miasma' theory of diseases, which posited that cholera and other diseases were not contagious and thus not carried through the channels of international trade but arose

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120 Atik (note 111), 748 (noting that in the 'mad cow' crisis, "the United Kingdom had maintained that the European's Union ban on exports of British beef was entirely without scientific justification.").

121 See Fidler (note 3), 34, fn. 104 for description of this U.S.-EC trade controversy.

122 Atik (note 111), 748.

123 Atik cautions that "we need not reach the cynical view that one group of scientists (say, the Europeans) is corrupted by the economic interest of its country to account for the division of opinion."). Id. Scientific uncertainty could also account for the division of science along national lines; but, even in a situation of scientific uncertainty, why does the division fall along national lines?

124 Howard-Jones (note 55), 26 ("Both the contagionists and anti-contagionists made up their minds first and then selected the facts that seemed to fit their theories.").
from bad air or soil where the diseases actually occurred.\textsuperscript{125} If miasma theory was correct, then the troublesome system of European quarantine regimes that frustrated British trade was unnecessary. The British dismantled their quarantine system and developed an approach that mirrored provisions later adopted in the international sanitary conventions.\textsuperscript{126} Those countries that wanted to keep their quarantine systems for health and political (e.g., anti-British) reasons favored the contagionist theory, which argued that diseases were spread between human populations through trade and that quarantine, thus, was a rational strategy. This 'great debate' took place in a morass of scientific ignorance until the work of \textit{Pasteur} and \textit{Koch} proved contagionist theory to be correct. In the end, the British did all the right things for the wrong reasons, and the quarantine-favoring countries did all the wrong things for the right reason. The whole episode serves to illustrate the intertwining, for better or worse, of science and national interest in the trade-health linkage.

The vulnerability of science to economic interests is also well illustrated in the scientific controversies surrounding tobacco consumption. The major American tobacco companies have waged a 'scientific' battle for nearly thirty years by producing research that found no link between smoking and ill-health.\textsuperscript{127} The effort of the tobacco companies to deny the dangerous nature of smoking by using science ultimately failed and was exposed as fraudulent. The ultimate triumph of 'good science' in the tobacco situation does not, however, remove concerns that the entire episode reveals about the ability of powerful interests, be they companies or governments, to manipulate science for particular economic and political objectives.

The role of science in international environmental law is also illustrative of problems facing the science paradigm in the trade-health context. According to \textit{Susskind}, science has not played a very strong role in the formulation of international environmental law since 1972.\textsuperscript{128} While science helped international negotiations on acid rain, ozone depletion, and biodiversity, \textit{Susskind} argues that science "was secondary or irrelevant in shaping the terms of the treaties dealing with whaling, hazardous waste trade, tropical deforestation, Antarctic mineral exploitation, . . . trade in African elephant ivory . . . ocean dumping, world heritage, wetlands and migratory species

\textsuperscript{125} \textit{Goodman} (note 51), 38 (discussing doctrine of miasma).

\textsuperscript{126} \textit{Howard-Jones} (note 55), 56 (noting that "paradoxically, the measures of sanitary control advocated and practised by the British were completely in line with the thinking and practice of today, as exemplified in the International Health Regulations.").

\textsuperscript{127} \textit{See Philip J. Hilts}, Smoke Screen: The Truth Behind the Tobacco Industry Cover-up, 1996 (analyzing tobacco industry's disinformation machine and tactics).

\textsuperscript{128} \textit{Lawrence Susskind}, Environmental Diplomacy: Negotiating More Effective Global Agreements, 1994, 63 ("A review of most of the international treaties negotiated since the 1972 Stockholm conference shows that scientific evidence has played a surprisingly small role in issue definition, fact-finding, bargaining, and regime strengthening.").
protection, and rewriting the Law of the Sea." In addition, science becomes very politicized in international environmental negotiations because the complexity of these issues produces uncertainty that allows politics to dominate the discussions. A battle is presently being waged over the science of global warming that reveals the vulnerability of environmental science to politics. The use of science by States in the environmental context also shows how science is subordinate to concepts of national interest and power.

The science paradigm is premised on science not becoming coopted into the normal dynamics of international politics. Realism — the dominant international relations theory since Thucydides — informs us that all aspects of international politics are about power. In Hans Morgenthau's famous phrase, statesmen think and act in terms of interest defined as power. In the realist's world, science is no different from other instruments, such as morality, that are harnessed by sovereign States in their pursuit of power. While the realist theory is by no means universally accepted, its dominance over time, and its continued existence, provide one theoretical angle with which to think about the phenomenon of 'national science'.

4. Science According to Non-Scientists?
The Interpretation and Enforcement of Science-Based Rules of International Law

Another problem with the science paradigm is how science-based rules of international law will be interpreted and enforced. The lack of authoritative interpretative mechanisms is sometimes considered a general weakness of international law.  

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129 Id.

130 Id. (noting that "there will always be self-interested actors willing to exploit scientific uncertainty for their own ends, arguing against any global action (that would hurt them) on the grounds that a fuller understanding is required before a clear course of action can be charted. When scientists acknowledge uncertainty, they allow political actors greater control over decision making.").

131 See, e.g., J. D. Mahlman, Uncertainties in Projections of Human-Caused Climate Warming, Science, vol. 278, 1997, 1416, 1417 ("Characterizations of the state of science of greenhouse warming are often warped in differing ways by people or groups with widely varying sociopolitical agendas and biases.").

132 Susskind (note 128), 65 ("When its purposes are served (and we are not alone in this), the United States uses scientific evidence to argue for the actions it favors. When we prefer to take a different political course, we attack the available data as insufficient, regardless of the strength of the worldwide scientific consensus.").


135 See H. L. A. Hart, The Concept of Law, 1961, 209 (arguing that international law lacks "a
Similarly, enforcement is sometimes considered the great black hole for international law, into which its finely crafted rules are sucked into non-existence. Thus, discussing the interpretation and enforcement issues in the trade-health context should come as no surprise. But, at least in terms of international trade law, the interpretation and enforcement problems are not the classical concerns. In this Part IV.4, I explore the interpretation and enforcement issues confronting both international health law and international trade law.

a) International Health Law

Commentators have frequently observed that the IHR suffer from frequent non-compliance by WHO member States. Member States of the WHO often do not report outbreaks of diseases subject to the IHR and often impose measures against other member States suffering outbreaks that go beyond the maximum measures provided in the Regulations. The WHO historically has shown no interest in monitoring or enforcing the IHR. This reluctance is explained by the powerful non-legal ethos at WHO and by the unwillingness on the part of WHO member States to empower WHO against themselves.

The non-enforcement of the IHR’s rules seriously erodes the effectiveness of the science paradigm. The scientifically-informed rules of the IHR are not observed, which means science is not driving WHO member State behavior in the IHR context. The science paradigm in the IHR seems irrelevant to State behavior, which is contrary to the purpose of using science to balance sovereignty and trade interests.

b) International Trade Law

A key difference between the SPS Agreement and the IHR is that the former is plugged into a powerful dispute resolution system in the form of the WTO’s dispute settlement regime. WTO member States accused of violating the SPS Agreement cannot prevent the complaining State from bringing the dispute before a WTO dispute

unifying rule of recognition specifying 'sources’ of law and providing general criteria for the identification of its rules.


See Allyn L. Taylor, Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health, American Journal of Law and Medicine, vol. 18, 1992, 301, 303 (WHO’s unwillingness to use law and legal institutions "stems, in large part, from the organizational culture established by the conservative medical professional community that dominates the institution.")
resolution panel. The science paradigm in the SPS Agreement has, as a result, a sophisticated and public mechanism for interpreting, monitoring, and enforcing its rules.

While avoiding the problems that have plagued the IHR, the dispute settlement system linked to the SPS Agreement raises other important concerns. The two most prominent are: (1) the interpretation of scientific evidence by WTO dispute resolution panels, and (2) the application of the trade-related disciplines to scientifically-justified public health measures.

aa) The Interpretation of Scientific Evidence by WTO Dispute Resolution Panels

As demonstrated by the Beef Hormones Case, in SPS Agreement cases the WTO will have to decide whether a member State has scientifically justified a challenged SPS measure. In essence, a panel of non-scientists will be making scientific determinations. This situation raises concerns about the competence of WTO dispute panels to make scientific judgments when rival scientific cases are made. The SPS Agreement attempts to address this in allowing WTO panels to have access to scientific experts to help it through the thickets of scientific controversy. Where an international standard has been set, then worries about the competence of the WTO panel might be less sharp because ostensibly an authoritative scientific body has evaluated the evidence. But competence issues might remain: how does the WTO panel determine whether the challenged State has provided a scientific justification for a measure that is more stringent than international standards? In appealing the Hormones Panel Report, for example, the EC argued that the WTO panel "disregarded and distorted the evidence with regard to both the... hormones at issue supplied by the Panel's experts, as well as the scientific evidence presented by the European Communities."

The competence concern boils down to a question of deference: how much deference is a WTO panel going to give to the scientific evidence and arguments of a

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138 David A. Wirth, The Role of Science in the Uruguay Round and NAFTA Trade Disciplines, Cornell International Law Journal, vol. 27, 1994, 817, 843 ("An additional issue arises when decision-makers in an adjudicatory setting, such as members of GATT panels, are lay persons and not technical experts who are specially trained in the scientific discipline to a particular dispute."); Charnovitz (note 105), 490 (noting that "the use of science in judicial review is a rapidly evolving field — one that ad hoc GATT panels would seem ill-equipped to handle.").


140 Hormones Appellate Report (note 13), para. 17.
WTO member State? Another way to think about this is formulating a standard of review for scientific evidence: will WTO panels use a standard like 'rational review' or 'heightened scrutiny' or a more rigorous 'cost-benefit analysis'? Wirth has argued that WTO and NAFTA panels have to accord national regulatory authorities deference on scientific issues.\textsuperscript{141} He believes that dispute resolution panels should conduct a procedural rather than a substantive review of the scientific evidence presented and only look for a "minimal level of scientific evidence."\textsuperscript{142} In appealing the Hormones Panel Report, the EC similarly argued "that WTO panels should adopt a deferential 'reasonableness' standard when reviewing a Member's decision to adopt a particular science policy or a Member's determination that a particular inference from the available data is scientifically plausible."\textsuperscript{143}

The SPS Agreement appears to require, however, WTO panels to apply a standard of review that is more critical than a rational review approach, Wirth's procedural approach, or the EC's deferential 'reasonableness' standard but not as stringent as a cost-benefit calculus or a \textit{de novo} standard of review because it requires a showing of 'sufficient scientific evidence' supporting SPS measures.\textsuperscript{144} In addition, the Appellate Body in the \textit{Beef Hormones} Case pointed out that, under Article 11 of the WTO Dispute Settlement Understanding, panels should make an objective assessment of the facts in all cases.\textsuperscript{145} The Appellate Body held that an objective assessment of the facts involved more than deference and less than \textit{de novo} review of the facts.\textsuperscript{146} In the Hormones Panel Report, the panel took a heightened scrutiny approach by (1) using individual scientific experts to assist its deliberations on scientific matters,\textsuperscript{147} and (2) closely examining the EC's scientific case supporting the import ban.\textsuperscript{148} In addition, Codex Alimentarius had set international standards for five of the six growth hor-

\textsuperscript{141} Wirth (note 138), 854 - 855.
\textsuperscript{142} Id., 856.
\textsuperscript{143} Hormones Appellate Report (note 13), para. 14.
\textsuperscript{144} SPS Agreement (note 83), Art. 2.2. \textit{Atik} comments that "[t]he requirement that a SPS measure be premised on a scientific basis represents a middle-ground between a more searching cost-benefit analysis that introduces international economic values and the quite liberating rational relationship test."\textit{Atik} (note 111), 745. \textit{Barceló} argues that the European Court of Justice uses a cost-benefit balancing test in its rulings on measures taken to protect public health that restrict intra-EC trade. \textit{John J. Barceló III, Product Standards to Protect the Local Environment — the GATT and the Uruguay Round Sanitary and Phytosanitary Agreement}, Cornell International Law Journal, vol. 27, 1994, 755, 771 - 772.
\textsuperscript{145} Hormones Appellate Report (note 13), para. 116.
\textsuperscript{146} Id., para. 117.
\textsuperscript{147} Hormones Panel Report (note 12), para. 8.7.
\textsuperscript{148} Id., paras. 8.117 - 8.159. As Charnovitz observed, "[t]he panel accorded no deference to the Commission's factual findings." Charnovitz (note 106), 1785.
mones in issue in the case, which provided the WTO panel with an independent scientific foundation against which to evaluate the EC measures. It also helped the WTO panel that none of the scientific studies cited by the EC supported its position at all, suggesting that the EC import ban would not have survived even a rational review standard. The Appellate Body upheld the standard of review applied by the panel.

Other, more difficult, cases are likely to present themselves under the SPS Agreement in which the WTO panel's competence to make scientific determinations will be more questionable. Atik observes that "[e]ven more challenging would be cases... where affirmative scientific justifications can be argued both for the regulation and for its removal." Atik cites the EC's muesli case as an example. Sandoz produced muesli cereal enhanced with vitamins to promote good health, and such vitamin supplementation was legal in Germany and Belgium. The Netherlands, on the other hand, banned the importation of such muesli because it might be harmful to human health by encouraging the consumption of fat-soluble vitamins. Other products might also have mixed health effects in a population that could be regulated in ways that trigger SPS Agreement scrutiny. It is not clear at this point how WTO panels will approach such difficult scientific determinations. The Appellate Body clearly held in the Beef Hormones Case that the Dispute Settlement Understanding mandates that the heightened scrutiny approach embodied in the 'objective assessment of the facts' standard be applied by WTO panels, but how such a standard of review operates in cases with more complicated scientific controversies than the Beef Hormones Case remains to be seen.

If the experience of American federal courts in dealing with scientific evidence is any guide, the WTO panels attempting to make scientific determinations in the SPS Agreement context are in for a controversial future. The handling of science in American federal court litigation may point to problems that WTO panels will face in SPS Agreement disputes. The major controversy has been the standard of admissibility for scientific evidence. The 'general acceptance' test prevailed in federal courts

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150 Id., para. 8.137.
151 Charnovitz (note 106), 1785 (noting that "[f]rom the panel's perspective, there wasn't much to accord deference to.").
152 Hormones Appellate Report (note 13), para. 119.
153 Atik (note 111), 757.
154 Id., 754. See Case 174/82, Criminal Proceedings Against Sandoz BV, 1983 ECR 2445.
155 See Atik (note 111), 757 (noting that "SPS measures present many of these difficult cases" and referring to pharmaceutical products that have both harmful and healthful effects).
156 Charnovitz (note 106), 1785 ("Whether panels should accord deference remains an unresolved issue in WTO jurisprudence.").
from 1923 until 1993. Under this test, federal courts admitted scientific evidence from the litigants if the evidence was generally accepted as reliable by the appropriate scientific community. In 1993, the U.S. Supreme Court noted that the general acceptance test has "been much debated, and scholarship on its proper scope and application legion." In the same case, the U.S. Supreme Court held that the Federal Rules of Evidence, not the general acceptance test, governed the admissibility of scientific evidence in federal courts. Under the Federal Rules of Evidence, all relevant evidence is admissible; and expert witnesses may provide testimony on scientific evidence if it will assist the trier of fact. The Supreme Court held that nothing in the Federal Rules of Evidence indicates that they incorporate the general acceptance test. Under the Federal Rules of Evidence, the federal trial judge "must ensure that any and all scientific testimony admitted is not only relevant, but reliable." The trial judge is to act as a 'gatekeeper' by screening scientific evidence for its relevance and reliability. The foci of the gatekeeper approach set out in Daubert is "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." In short, American federal courts have moved from a standard that focused on the end results of scientific inquiry (the general acceptance test) to a standard that focuses on the reliability and relevance of the methodology of the scientific inquiry (the gatekeeper approach).

The gatekeeper approach has, however, come under fire from both judges and commentators. Kesan has, for example, noted that "[m]any judges have expressed discomfort at having to review methodologies and techniques that undergird scientific evidence presented in courts." The results produced by the gatekeeper approach have contradicted the U.S. Supreme Court’s confident prediction "that federal judges..."

157 Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923) (holding that for scientific evidence to be admissible it "must be sufficiently established to have gained general acceptance in the particular field to which it belongs.").  
159 Id., 587.  
161 Id., 588.  
162 Id., 589.  
164 Daubert (note 158), 592 - 593.  
possess the capacity to undertake this review."\textsuperscript{166} Kes\textsuperscript{a}n writes: "The result of these gatekeeping exercises is a tortured landscape of post-\textit{Daubert} decisions, which are non-uniform, inconsistent, and irreconcilable."\textsuperscript{167}

Within the \textit{Beef Hormones} Case, a similar shift from a general acceptance test to a gatekeeper approach may have occurred as the case moved from the panel to the appellate stage. The Appellate Body took issue with the panel over its handling of the 'substantive requirements' of the risk assessment required by Article 5.1 of the SPS Agreement. In the opinion of the Appellate Body, the panel wrongly interpreted Article 5.1 to require that the scientific conclusions reflected in the relevant SPS measure must conform to the scientific conclusions of the risk assessment.\textsuperscript{168} The Appellate Body explicitly rejected the notion, implicitly fostered by the panel's interpretation, that Article 5.1 incorporates a general acceptance test: "Article 5.1 does not require that the risk assessment must necessarily embody only the view of the majority of the relevant scientific community."\textsuperscript{169} In addition, the Appellate Body rejected an implication it sensed in the Hormones Panel Report that the risk assessment required by Article 5.1 mandated "a certain magnitude or threshold level of risk be demonstrated."\textsuperscript{170} In other words, the SPS Agreement does not require that a risk cross a minimum threshold of probability to support a SPS measure.\textsuperscript{171}

All that is required by the Article 5.1 risk assessment is that a reasonable relationship exist between the SPS measure and the risk identified in the risk assessment.\textsuperscript{172} While acknowledging that States base most SPS measures on "'mainstream' scientific opinion,"\textsuperscript{173} the Appellate Body argued that "equally responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources."\textsuperscript{174} The Appellate Body has rejected a general acceptance approach to scientific evidence in favor of a test that looks to the reliability and relevance of such evidence — does it come from

\begin{thebibliography}{99}
\bibitem{daubert} \textit{Daubert} (note 158), 593.
\bibitem{kesan} Kes\textsuperscript{a}n (note 165), 251.
\bibitem{hormones} Hormones Appellate Report (note 13), paras. 193 - 194. See Hormones Panel Report (note 12), para. 8.137 (arguing that "the scientific conclusion reflected in the EC measures in dispute . . . does not conform to any of the scientific conclusions reached in the evidence referred to by the European Communities.").
\bibitem{hormones2} Hormones Appellate Report (note 13), para. 194.
\bibitem{id1} Id., para. 186.
\bibitem{id2} Id. ("To the extent that the Panel purported to require a risk assessment to establish a minimum magnitude of risk, we must note that imposition of such a quantitative requirement finds no basis in the SPS Agreement.") See also id., para. 184.
\bibitem{id3} Id., paras. 193 - 194.
\bibitem{id4} Id., para. 194.
\bibitem{id5} Id.
\end{thebibliography}
a 'qualified and respected source' and does it reasonably support the SPS measure at issue?

One interpretation of the Hormones Appellate Report is that the Appellate Body has mandated an approach to scientific evidence that is even more liberal than the Daubert gatekeeper standard in U.S. federal courts because it did not specifically require WTO panels to examine the methodology underlying the scientific reasoning. The approach of the Appellate Body makes clear, however, that WTO panels should examine whether the reasoning or methodology underlying the evidence applies to the facts of the case. The Appellate Body noted, for example, that much of the scientific literature produced by the EC did not evaluate the carcinogenic potential of the relevant hormones when used for animal growth promotion. The Appellate Body has, in essence, mandated that WTO panels be Daubert-like gatekeepers for scientific evidence presented in future SPS Agreement cases by WTO member States.

In one important respect, however, a WTO gatekeeper approach is different from the Daubert standard. Under Daubert, the scientific evidence is still subject to jury deliberations after having been admitted by the gatekeeper. The jury may reject the evidence and the legal claims flowing from it. Under the Hormones Appellate Report, if the scientific evidence is relevant and comes from reliable sources, then the SPS measure at issue will in all likelihood bear a rational relationship to the evidence, which means that the WTO member State has satisfied its science-based legal obligations under the SPS Agreement. A panel could not, at that point, reject the evidence as not in conformity with mainstream scientific knowledge — as could a domestic jury. Under the Hormones Appellate Report, once the evidence is past the panel gatekeepers, legal consequences automatically result. Just as under Daubert it is easier for a litigant to get scientific evidence admitted, under the gatekeeper approach crafted in the Hormones Appellate Report it will be easier for a WTO member State to satisfy the science-based disciplines of the SPS Agreement than under a WTO version of the general acceptance test.

In the Beef Hormones Case, the EC could not even satisfy the WTO gatekeeper standard because it did not produce relevant scientific evidence that rationally supported its import ban. Although the WTO gatekeeper approach appeared to work in the Beef Hormones Case, trouble may still be looming ahead, if U.S. federal court travails with the Daubert test are any indication. WTO panels may confront harder cases than the Beef Hormones Case. In fact, the EC proclaimed victory when the Appellate Body released its decision because it believed it had succeeded in achieving

175 Id., paras. 199 - 200.
176 This distinction between Daubert and the WTO flows from the fact that under the SPS Agreement and Dispute Settlement Understanding all evidence is admitted to the ultimate decision makers (i.e., the panel members) for consideration, whereas under Daubert a federal judge may not allow certain scientific evidence to reach the jury.
legal interpretations that would allow it to satisfy the science-based discipline of the SPS Agreement. Apparently the EC is at work on a new risk assessment that it believes will pass muster under the Appellate Body’s interpretations of the SPS Agreement. More generally, WTO gatekeeping exercises might evolve into a tortured landscape of post-Beef Hormones Case decisions that are non-uniform, inconsistent, and irreconcilable because the gatekeeper approach will not prove any easier to use within the WTO than in U.S. federal courts.

The role WTO panels will play in interpreting scientific evidence also raises the question about the quality of the international standards on which they will lean for scientific support. The Beef Hormones Case illustrates this problem. In this case, the EC argued that the vote in the Codex Alimentarius on the international standards in question was very close (33 votes for, 29 against, and seven abstentions), suggesting that the international standards established in the Codex process did not represent a clear scientific victory for the United States’ position. The WTO panel ruled that whether an international standard is adopted by a wide or narrow margin is not relevant because of the unambiguous command in Article 3.1 of the SPS Agreement that WTO member States base their health protection measures on existing international standards.

Narrow votes in international standards-setting organizations clearly raise, however, scientific and legal concerns. Does a close and controversial vote mean that there is no scientific consensus? Does the close and controversial vote mean that politics has infiltrated what is supposed to be a scientific, technical endeavor? Despite the Appellate Body’s effort to disparage the notion that international standards become legally binding through the SPS Agreement, the Beef Hormones Case raises the stake of each and every vote in standard-setting international organizations, perhaps contributing to the politicization and paralyzation of these processes. More importantly, it suggests that international standard setting does not escape the problems haunting the science paradigm.

Other aspects of the Beef Hormones Case raise questions about the operation of the science paradigm in international trade disputes. For example, the Appellate Body held that the panel erred as a matter of law in allocating the evidentiary burden of proof to (1) the member State that imposes a SPS measure as a general matter, and (2) the member State that imposes a SPS measure that is more protective than relevant international standards. Interestingly, the Appellate Body held that the SPS Agree-

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177 Trade Disputes: Big Beef, The Economist, 24 January 1998, 71 (noting that both the U.S. and EC proclaimed victory after the Appellate Body released its decision).

178 Id. (noting that the "EC can keep the ban in place for another 15 months while it studies the alleged risks all over again.").


180 Id., para. 8.69. The Appellate Body did not address this issue in its decision.

181 Hormones Appellate Report (note 13), para. 253(a).
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ment differs from the traditional relationship between GATT obligations and Article XX(b) claims. Under GATT, the party relying on Article XX(b) bears the burden of satisfying the conditions laid out in that Article. But, under the SPS Agreement, the Appellate Body held that the complaining member State bears the burden of establishing through evidence and legal arguments a prima facie case that the member State imposing the SPS measure has violated the SPS Agreement. So, the Appellate Body determined "that the United States and Canada have to make a prima facie case that these [SPS] measures are not based on a risk assessment." The Appellate Body's allocation of the burden of proof to the complaining member State may make challenging SPS measures more difficult and certainly accords more deference to public health sovereignty than the allocation of the burden of proof under Article XX(b) of GATT.

In addition, it raises questions about the relationship between Article XX(b) and the SPS Agreement. In the Hormones Panel Report, the panel held that the SPS Agreement stands alone and does not require the existence of a prior violation of GATT in order to be violated by a member State. But, the panel also held that "if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement." Under traditional Article XX(b) analysis, the State invoking Article XX(b) bears the burden of establishing that the measure meets the trade-related disciplines in the chapeau of Article XX and the necessary requirement in Article XX(b) itself. If the panel must look to the SPS Agreement to interpret the validity of an Article XX(b) claim, the Appellate Body appears to reverse the onus of the burden of proof by placing it on the complaining party not the party invoking Article XX(b). Such a result would constitute a radical departure from prior Article XX(b) jurisprudence.

The Appellate Body also held that the panel erred as a matter of law in bifurcating risk analysis into 'risk assessment', which involves only scientific factors, and 'risk management', which can involve non-scientific factors. Under the SPS Agreement, risk assessment is the only requirement; and member States can factor into risk assess-

182 Id., para. 104.
183 Id.
185 Id., para. 197, fn. 180.
186 The Appellate Body did determine that the U.S. and Canada had both made the necessary prima facie case that the EC's import ban was not based on a risk assessment. Id., para. 197, fn. 180.
188 Id., para. 8.42.
ments "not only risk ascertainable in a science laboratory operating under strictly
controlled conditions, but also risk in human societies as they actually exist, in other
words, the actual potential for adverse effects on human health in the real world
where people live and work and die." The Appellate Body broadened the scope of
risk assessment from the narrow, purely scientific process envisioned by the panel.
While this broadening did not affect the outcome of the Beef Hormones Case, it
creates more flexibility for public health sovereignty because risk assessments may
examine and evaluate all "risks for human health whatever their precise and imme-
diate origin may be."

The Appellate Body also reversed the panel on an issue relating to the harmoniza-
tion element of the science paradigm. As noted earlier, the panel held that Article 3.3
of the SPS Agreement is an exception to the general obligation in Articles 3.1 and 3.2
to harmonize SPS measures on international standards. Thus, a failure to justify
scientifically a higher than international standard under Article 3.3 also triggered a
violation of Article 3.1's harmonization duty. The Appellate Body interpreted the
relationship between Articles 3.1, 3.2, and 3.3 differently. First, the Appellate Body
reversed the panel's holding that 'based on' international standards in Article 3.1 was
the same as 'conform to' international standards in Article 3.2. This interpretation
produces two harmonization strategies: (1) national SPS measures can be based on,
but not identical to, international standards (Article 3.1); and (2) national SPS meas-
ures can conform to, or be identical to, international standards (Article 3.2). Only
national SPS measures that conform to international standards enjoy the benefit of
the presumption that such measures are consistent with the SPS Agreement and
GATT. But, under the burden of proof ruling, a member State challenging a SPS
measure based on but not conforming to international standards must show a prima
facie case that the measure is either not based on an international standard or in-
consistent with the risk assessment obligations.

As for member States imposing higher than international standards under Article
3.3, the Appellate Body stressed that the right to adopt such higher standards "is an
autonomous right and not an 'exception' from a 'general [harmonization] obligation'
under Article 3.1." A violation of Article 3.3 resulting from a failure to provide a

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190 Hormones Appellate Report (note 13), para. 187.
191 The Appellate Body held that the EC did not provide an assessment of the risks "arising
from the failure of observance of good veterinary practice combined with problems of control
of the use of hormones for growth promotion purposes." Id., para. 208.
192 Id., para. 206.
193 Id., paras. 163 - 166.
194 Id., para. 170.
195 Id., para. 171.
196 Id., para. 172.
scientific justification for a higher standard does not, in the Appellate Body’s view, also produce a violation of the harmonization provision in Article 3.1.\textsuperscript{197} The Appellate Body’s interpretation of Articles 3.1, 3.2, and 3.3 does not, however, adversely affect the harmonization element of the science paradigm because two of the three options involve harmonization strategies (Articles 3.1 and 3.2) while the non-harmonization option (Article 3.3) remains subject to the science disciplines of the SPS Agreement.

bb) The Application of the Trade-Related Disciplines to Scientifically-Justified SPS Measures

Another concern about the WTO dispute settlement system involves the application of the trade-related disciplines (i.e., the necessary requirement, the no unjustified discrimination requirement, and the no disguised restriction on trade requirement) to scientifically-justified SPS measures. Having a scientific basis for a SPS measure does not end the analysis under the SPS Agreement because all SPS measures must also satisfy the trade-related disciplines. Of the three trade-related disciplines, the most controversial is the necessary requirement, which many people argue has been interpreted in such a narrow fashion that legitimate sovereign health concerns are subordinated to trade interests.

aaa) Discrimination and Disguised Restrictions

The requirement that a SPS measure not constitute arbitrary or unjustified discrimination\textsuperscript{198} flows from the most-favored-nation principle that is a pillar of GATT law.\textsuperscript{199} The prohibition on SPS measures constituting disguised restrictions on international trade\textsuperscript{200} derives from the GATT principle of national treatment.\textsuperscript{201} Given the importance of the most-favored-nation and national treatment principles in GATT, the application of these trade-related disciplines is not surprising and is relatively uncontroversial. Banning the importation of a product from one country because of a perceived health risk but not the like product from another country posing exactly the same health risk does not make public health sense since the risk is the same. Similarly, banning an imported product with a health risk while allowing a like

\textsuperscript{197} Id., para. 253(h).
\textsuperscript{198} GATT (note 67), Art. XX (chapeau); SPS Agreement (note 83), arts. 2.3 and 5.5.
\textsuperscript{199} GATT (note 67), Art. I.
\textsuperscript{200} Id., Art. XX (chapeau); SPS Agreement (note 83), arts. 2.3 and 5.5.
\textsuperscript{201} GATT (note 67), Art. III.
domestic product with the same risk to be sold and consumed raises questions about the public health sincerity of the government's action.

The controversy over Thailand's banning of imported cigarettes while allowing the sale of domestic cigarettes raised these very questions. In attacking the Thai cigarette import ban, the United States believed that Thailand was using public health as a smokescreen for protectionism.²²² Leading scholars also viewed the Thai cigarette import ban as protectionism rather than a legitimate public health measure.²²³ Charnovitz argued that the Thai panel "reached the right conclusion but for the wrong reason" by basing its holding on the necessary requirement rather than on the disguised restriction to trade prohibition.²²⁴ The facts of the Thai Cigarette Case demonstrate, however, that it can make public health sense to ban an imported product posing a health risk while allowing a like domestic product with the same risk to be consumed. Thailand's import ban represented a key element in its overall effort to reduce smoking. In addition to the import ban, Thailand had banned cigarette advertising, imposed a requirement for warning labels on cigarette packages, and reduced its own cigarette exports.²²⁵ Given the evidence that cigarette consumption increased in other markets after being forced open by the United States,²²⁶ the Thai import ban was not clearly a protectionist measure disguised as a public health policy.

The Beef Hormones Case also contains some interesting arguments and holdings concerning the 'discrimination' and 'disguised restrictions on trade' disciplines. The SPS Agreement imposes both these disciplines generally in Article 2.3 and then more specifically in Article 5.5.²²⁷ Neither the panel nor the Appellate Body interpreted Article 2.3 in detail in the Beef/Hormones Case. The controversy came in interpreting Article 5.5. Article 5.5 prohibits member States from having SPS measures that contain arbitrary or unjustifiable distinctions in measures designed for different situations if such distinctions result in discrimination or a disguised restriction on international trade.²²⁸ The Appellate Body held that a member State complaining of a viola-

²²² In 1990, the U.S. Trade Representative argued that "I don't see how health concerns can enter the picture if the people are smoking their own cigarettes . . . . They smoke a whole lot of their own cigarettes." Quoted in Suthiphon Thaveechaiyagarn, Current Developments: The Section 301 Cigarette Case Against Thailand — A Thai Perspective, Law and Policy in International Business, vol. 21, 1990, 367, 384.

²²³ Charnovitz (note 67), 326 fn. 145 (arguing in connection with the Thai import ban that "[i]t is difficult to imagine a clearer example of a 'disguised restriction' on trade.").

²²⁴ Id.

²²⁵ Thaveechaiyagarn (note 202), 374, 375 fn 56.

²²⁶ Id., 377.

²²⁷ SPS Agreement (note 83), arts. 2.3 and 5.5.

²²⁸ Id., Art. 5.5.
tion of Article 5.5 has to show (1) that the accused member State has adopted SPS measures against risks in several different situations; (2) that the levels of protection exhibit arbitrary or unjustifiable distinctions in their application in different situations; and (3) that the arbitrary and unjustified distinctions result in discrimination or a disguised restriction on international trade. What this construction of Article 5.5 means is that there is no violation if the distinctions in levels of SPS protection are only arbitrary and unjustified. While the Appellate Body agreed with the panel that one distinction in EC levels of protection was unjustified, it reversed the panel's holding that the unjustifiable distinction constituted a discrimination or a disguised restriction on international trade. The panel based its holding on prior Appellate Body rulings on the meaning of the trade-related disciplines in the chapeau of Article XX, but the Appellate Body did not believe that these rulings could simply be imported to interpret Article 5.5 of the SPS Agreement. In other words, the trade-related disciplines in Article 5.5 do not mirror those in the chapeau of Article XX. The question that arises from the Hormones Appellate Report is whether proving violations of the trade-related disciplines in Article 5.5 is more difficult than under Article XX of GATT. The unjustifiable distinction combined with the significant size of the discrepancy in levels of protection was not enough to support a finding that the EC ban was a disguised restriction on international trade. The weight of those considerations was counterbalanced, according to the Appellate Body, by the depth and extent of the anxieties experienced within the European Communities concerning the results of general scientific studies, the dangers of abuse of hormones and other substances used for growth promotion and the intense concern of consumers within the European Communities over the quality and drug-free character of the meat available in its internal market.

In this case, good faith irrationality fueled by consumers shielded the EC from being found in violation of the trade-related disciplines in Article 5.5.

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210 Id., para. 215 (arguing that "both the second and third elements must be found.").
211 Id., para. 235. The Appellate Body reversed the panel's rulings that some distinctions were arbitrary and unjustified. See id., paras. 219 - 235.
212 Id., para. 246.
214 Hormones Appellate Report (note 13), para. 239. This is another example where the Appellate Body distances the SPS Agreement from Article XX jurisprudence.
215 Id., para. 240.
216 Id., para. 245.
The Necessary Requirement

More controversial historically in the area of the trade-related disciplines is the interpretation of the necessary requirement. In the *Thai Cigarette* Case, the GATT panel ruled "that the import restrictions imposed by Thailand could be considered to be 'necessary' in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives." This interpretation of the necessary requirement in Article XX(b) has also been followed by the GATT panel in the *Tuna-Dolphin* Case and the WTO panel in the *U.S. Gasoline* Case. The SPS Agreement appears to follow this GATT jurisprudence because (1) Article 2.2 states that "Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health; and (2) Article 5.6 requires that SPS measures be "not more trade restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility." A SPS measure is more trade-restrictive than required if "there is another measure, reasonably available taking into account technical and economic feasibility, that achieves the appropriate level of sanitary or phytosanitary protection and is significantly less restrictive to trade."

Forcing States to adopt the least trade-restrictive policy possible has come under criticism as a standard that unduly favors trade over health and that represents an unwarranted restriction on public health sovereignty. The United States has, for example, expressly rejected the least trade-restrictive interpretation of the necessary requirement in the interpretation of the necessary requirement found in NAFTA

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217 *Thai Cigarette* Case (note 36), para. 75.
218 *Tuna-Dolphin* Case (note 93), para. 5.28.
219 *U.S. Gasoline* Case (note 94), para. 6.24. The WTO panel in the *Beef Hormones* Case did not interpret the necessary requirement in the SPS Agreement. The United States and Canada appealed to the Appellate Body that the panel should have addressed this issue by interpreting Articles 2.2 and 5.6 of the SPS Agreement. Hormones Appellate Report (note 13), para. 74. The Appellate Body upheld the panel's decision not to interpret Articles 2.2 and 5.6. *Id.*, para. 250.
220 SPS Agreement (note 83), arts. 2.2 and 5.6.
221 *Id.*, Art. 5.6, fn. 3.
222 Jeffrey Dunoff argues that "[a]s the *Thai Cigarette* and *Tuna-Dolphin* cases demonstrate, in practice it is almost impossible to meet the requirement that a trade measure be the least GATT inconsistent remedy reasonably available." Jeffrey L. Dunoff, Institutional Misfits: The GATT, the ICJ & Trade-Environment Disputes, Michigan Journal of International Law, vol. 15, 1994, 1043, 1063.
SPS provisions. In the scholarly literature, Schoenbaum argues that the least trade-restrictive interpretation of the necessary requirement in Article XX(b) relates to the protection of living things not to whether the measure is a necessary departure from GATT obligations. Schoenbaum advocates that a SPS measure that has a scientific basis should then only be judged against the discrimination and disguised restriction of trade disciplines. He argues that "in deciding what is 'necessary', WTO panels should employ a 'rule of reason' approach that allows some freedom of action to member states." In other words, a scientifically-based SPS measure does not have to be the least trade-restrictive measure possible, which creates more room for public health sovereignty in selecting policy options. A scientifically-based SPS measure will only be ruled incompatible with GATT law if it imposes an unreasonable burden on international trade or if it is applied in a discriminatory manner in violation of the most-favored-nation or national treatment principles.

One way to work through this rule of reason approach is to apply it to the facts of the Thai Cigarette Case, which is the source of the traditional interpretation of 'necessary' in Article XX(b). In this case, the GATT panel ruled that the Thai import ban, which violated Article XI of GATT, was not necessary because the Thais had alternative measures available that could have been applied consistently with GATT obligations. To meet its goals of ensuring the quality of cigarettes consumed in Thailand and of reducing the quantity of cigarettes sold, Thailand could have instituted (1) strict, non-discriminatory labeling and ingredient disclosure regulations and a ban on unhealthy additives to address the quality concern, and (2) a ban on cigarette advertising of both domestic and foreign brands to deal with the quantity concern.

The end result of the GATT panel's least trade-restrictive interpretation of the necessary requirement was the opening of the Thai market to American and other countries' tobacco exports. Since the opening of national markets to tobacco imports, smoking in Thailand and other Asian countries has increased dramatically, compounding the public health problems caused by tobacco consumption in Asian countries. This outcome in Thailand's case was entirely foreseeable. In its expert

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223 Barceló (note 144), 769 ("in interpreting NAFTA article 712(5) [which contains the requirement that SPS measures only be applied to the extent necessary] . . . the U.S. Trade Representative expressly claimed that the article does not impose a 'least-trade-restrictive' requirement.").

224 Schoenbaum (note 7), 276.

225 Id.

226 Id.

227 Thai Cigarette Case (note 36), para. 77.

228 Id., para. 78.

229 Lown (note 28) (noting that after the U.S. government successfully pressured Japan, Taiwan, South Korea, and Thailand to allow the sale of American cigarettes "smoking soared
submission to the GATT panel in the Thai Cigarette Case, the WHO "stated that the experience in Latin America and Asia showed that the opening of closed cigarette markets dominated by a state tobacco monopoly resulted in an increase in smoking." In addition, the WHO commented on the effect of advertising regulations on big tobacco companies: "Multinational tobacco companies had routinely circumvented national restrictions on advertising through indirect advertising and a variety of other techniques." The GATT panel never addressed why it believed Thailand would be successful in opening its market to tobacco imports and in reducing smoking when the opposite had happened everywhere else in the developing world where tobacco imports were allowed. Opening the Thai market to imports from the major Anglo-American tobacco companies through the least trade-restrictive interpretation of the necessary requirement in Article XX(b) directly contributed to the exponential worsening of the public health problems Thailand was experiencing because of tobacco consumption. The interpretation of 'necessary' proved a boon among young people.

230 Thai Cigarette Case (note 36), para. 55. Thailand made these facts part of its arguments: "Since the health consequences of the opening of cigarette markets constituted one of the major justifications for Thailand's cigarette import regime, Thailand deemed it necessary that the panel consult with experts from the World Health Organization (WHO) on recent experience in countries which had been made to open their markets for cigarettes. This showed that once a market was opened, the United States cigarette industry would exert great efforts to force governments to accept terms and conditions which undermined public health and governments were left with no effective tool to carry out public health policies. Advertising bans were circumvented and modern marketing techniques were used to boost sales. Hence, 'Thailand was of the view that an import ban was the only measure which could protect public health.'" Id., para. 27.

231 Id. In its submissions, Thailand also argued that, despite the import ban on foreign cigarettes, "foreign cigarette manufacturers had advertised on Thai television, in mass circulation newspapers and on billboards. Indirect advertising had also taken place and the logos of cigarette manufacturers had appeared on clothing and many other non-tobacco products." Id., para. 21.

232 Jeffrey L. Dunoff, Reconciling International Trade with Preservation of the Global Commons: Can We Propose and Protect?, Washington and Lee Law Review, vol. 49, 1992, 1407, 1449 (noting that "the Panel did not consider the relative effectiveness of the import ban as opposed to labelling and advertising regulations."). Lack of inquiry into the effectiveness of alternative, less trade-restrictive measures appears to be a feature of GATT panel analysis because "no GATT panel has required that the proposed alternative measure be as effective as the measure actually employed." Dunoff (note 222), 1063.

233 "Thailand contended that the prohibition on imports of cigarettes was justified by the objective of public health policy which it was pursuing, namely to reduce the consumption of tobacco which was harmful to health. . . . smoking lowered the standard of living, increased sickness and thereby led to billions of dollars being spent every year on medical costs, which reduced real income and prevented an efficient use being made of resources, human and natural." Thai Cigarette Case (note 36), para. 21.
to the tobacco trade but a disaster to public health. In short, a balance between public health sovereignty and foreign trade interests did not exist.

Under a rule of reason approach, the outcome in the Thai cigarette case might have been different and more beneficial to public health. Given that Thailand easily established the scientific justification for tobacco control measures, the question then becomes whether the import ban constitutes an unreasonable restraint on international trade in the circumstances of the case. A powerful argument could be made that such an import ban imposed by a developing country vulnerable to the economic power of multinational tobacco companies selling a dangerous product is a reasonable restraint on international trade from a public health perspective. The history of developing countries in Latin America and Asia experiencing worse smoking problems after market penetration by Western tobacco companies solidifies the reasonableness of the import ban as a SPS measure. Unlike the formalistic and abstract approach of the GATT panel in the 

Thai Cigarette Case, the rule of reason approach is sensitive to context; and this sensitivity gives public health policy more options and flexibility in establishing SPS measures. The rule of reason approach restores equilibrium between public health sovereignty and international trade interests.

A possible concern about the rule of reason approach to the necessary requirement in the SPS Agreement relates to the case-by-case nature of the approach. WTO panels will be in the position of fashioning a 'common law' of necessity in SPS cases. In fashioning this common law of necessity, WTO panels will have to develop guidelines in operating the rule of reason approach. Clearly one of the items WTO panels would have to consider is the likely public health effects of alternative and less trade-restrictive measures. The GATT panel in the 

Thai Cigarette Case never took such effects into consideration. If this had been a consideration in the 

Thai Cigarette Case, then the result would have been different given the overwhelming evidence from other countries that the less trade-restrictive measures suggested by the GATT panel would not have protected public health in Thailand. In addition, WTO panels should include in any rule of reason analysis consideration of the dangerousness of the product in question. The more inherently dangerous a product, such as tobacco, the WTO panel should place less emphasis on reducing trade restrictions and more emphasis on public health protection.

The facts of the Thai cigarette case and the dangerous nature of tobacco consumption may make the rule of reason approach look very attractive, but WTO panels

234 See Thaveechaiyagarn (note 202), 384 - 385.

235 Atik argues that "assuming a flow of dispute resolution decisions under the WTO and NAFTA, there may come to be a 'common law' of scientific determinations." Atik (note 111), 755. The same point applies to the interpretation of the necessary requirement in the SPS Agreement.
may confront harder cases. There may be situations where the health risks of a product might be very controversial and where the health ramifications of less trade-restrictive measures are unclear. How does the rule of reason approach work in these harder SPS cases? Should the balance be struck in favor of public health sovereignty by deferring to the State that enacted the measure or in favor of international trade by requiring a less trade-restrictive measure? In short, it may be difficult in some cases to determine whether a scientifically-justified SPS measure imposes an unreasonable burden on international trade in the particular circumstances because there are few clear parameters guiding such a decision.

Perhaps some insight can be gained by looking to the EC law principle of proportionality. Under Article 36 of the EC Treaty, EC member States can restrict the freedom of movement of goods in order to protect, among other things, public health. The European Court of Justice (ECJ) reviews trade-restricting public health measures to evaluate whether they have a disproportionate impact on intra-EC trade. While this sounds like a reasonableness standard, the proportionality principle in EC law is actually closer to the traditional GATT interpretation of 'necessary'. Under the proportionality principle, "a measure may not restrict trade between Member States more than is necessary to achieve its legitimate object." The ECJ has ruled that "[n]ational rules or practices do not fall within the exception specified in Article 36 if the health and life of humans can [be] as effectively protected by measures which do not restrict intra-Community trade so much." This formulation reminds one of the least trade-restrictive interpretation of GATT's necessary requirement. If emphasis is placed on the concept 'effectively protected' in the proportionality principle, then perhaps room for consideration of context, as suggested by the rule of reason approach, is possible. But splitting hairs in EC law interpretation probably will not get us very far given the peculiar nature of the EC project of building a single market, which is not an objective of the WTO. The ECJ historically has reviewed all Article 36 claims very strictly in terms of their impact on intra-EC trade. The same strictness may not be the proper course within the WTO, as suggested by the Thai Cigarette Case.

One way to establish a WTO rule of reason approach is to develop a presumption that a scientific justification for a SPS measure makes the trade-restrictive aspects of


\(^{238}\) Case 104/75, Adriaan de Peijper, 1976 ECR 613, 636.

\(^{239}\) Paul Craig/Gráinne de Búrca, EC Law: Text, Cases, & Materials, 1995, 605. See also Barceló (note 144), 771 - 772 (describing rigorous ECJ cost-benefit balancing test in proportionality principle).
such a measure reasonable and thus necessary in terms of GATT. The presumption could be overcome by the complaining party demonstrating that the burden of the scientifically-based SPS measure on international trade is unreasonable. This burden of proof might be satisfied by establishing that the SPS measure in question does not address any real health threat while seriously disrupting international trade flows. The costs to international trade would have to grossly outweigh speculative health benefits in the enacting State. In essence, the complaining State would have to prove that (1) the SPS measure bears no rational relationship to the health objective despite having a scientific basis, and (2) the measure seriously disrupts international trade. Rather than being a nearly impossible standard to satisfy, the 'necessary' requirement would be a less stringent standard of review. The trade-related disciplines of 'no unjustified discrimination' and 'no disguised restriction' on international trade still remain to keep SPS measures in conformity with fundamental GATT principles.

Does the Beef Hormones Case offer any support for the development of a rule of reason approach to the necessary requirement in the SPS Agreement? The incorporation of the traditional GATT interpretation of 'necessary' into Articles 2.2 and 5.6 of the SPS Agreement poses an obstacle to the development of a rule of reason approach in SPS Agreement cases. Because neither the panel nor the Appellate Body addressed Articles 2.2 or 5.6 substantively, the Beef Hormones Case offers no direct indication that the WTO is inclined to move away from the traditional GATT interpretation of necessary towards a rule of reason approach.

The Appellate Body's interpretations of risk assessment do, however, bring the controversy about the necessary requirement alive. As discussed earlier, the Appellate Body held that a member State does not have to establish any minimum magnitude of risk in conducting a risk assessment. Thus, a SPS measure can be legitimate when supported by a very small risk as long as there is "a rational relationship between the measure and the risk assessment." Interpreting the SPS Agreement not to require any threshold level of risk be established raises the question how to prevent member States from seriously disrupting international trade through SPS measures protecting against low-probability risks. The 'necessary' and 'not more trade-restrictive than required' standards in Articles 2.2 and 5.6 respectively stand as potential disciplines against measures significantly restricting international trade to protect against low-probability risks. While the facts of the Thai Cigarette Case (high-probability risk from importation of an inherently dangerous product into a developing country)
support a rule of reason approach, the *Beef Hormones* Case suggests that the traditional necessary discipline is more attractive in cases involving low-probability risks from importation of products not inherently dangerous.

Assuming that the EC's next risk assessment establishes a very low-probability risk from hormone-treated meat, the EC will have satisfied the science-based disciplines of the SPS Agreement under the Hormones Appellate Report. The question would then be whether some less trade-restrictive measure than an import ban would reasonably be available to the EC to achieve its appropriate level of health protection. Responding to United States and Canadian arguments that the panel erred in not finding the EC in violation of Article 5.6, the EC argued that only a total import ban would achieve the objective of ensuring "that consumers are not exposed to any residues of hormones used for growth promotion purposes."244 Given the lengths that the Appellate Body went to in its interpretations of Articles 3 and 5 of the SPS Agreement to emphasize the public health sovereignty of member States, it seems questionable that the WTO would apply Articles 2.2 and 5.6 as rigorously as GATT and WTO panels have applied the necessary requirement of Article XX(b). Thus, the Hormones Appellate Report could be interpreted as indirectly setting the stage for a more lenient approach to the necessary requirement in SPS cases.245

This leniency will not, however, develop necessarily into a rule of reason approach. What is more likely is the development of a standard that falls somewhere in between the rule of reason approach and the traditional, strict interpretation of necessary in Article XX(b). Such a standard would probably have to involve WTO panels paying close attention to the less trade-restrictive alternative measures allegedly available and evaluating them for their technical and economic feasibility, their potential to achieve the appropriate level of health protection, and their trade-restrictiveness. Panel deliberations of alternative measures under Articles 2.2 and 5.6 are, thus, likely to be more detailed and comprehensive than GATT panel considerations of possible less trade-restrictive alternatives under Article XX(b). The Appellate Body suggested as much in refusing to address Article 5.6 because it argued that "it cannot be assumed that all findings of fact necessary to proceed to a determination of consistency or inconsistency of the EC measures with the requirements of Article 5.6 have been made by the Panel, which Article also provides that 'technical and economic feasibility' should be taken into account."246

In sum, the likely impact of the *Beef Hormones* Case on the 'necessary' trade discipline is that WTO panels will begin to demonstrate greater sensitivity to arguments

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244 *Id.*, para. 83.

245 This analysis again points to the Appellate Body distancing the SPS Agreement from Article XX(b) of GATT. What in effect may have happened is that the Appellate Body has undertaken a radical re-interpretation of Article XX(b) through the SPS Agreement.

246 Hormones Appellate Report (note 13), para. 251.
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and counterarguments about possible less trade-restrictive alternative measures. WTO panels cannot adopt a rule of reason approach given the express language of Articles 2.2 and 5.6 and the prior Article XX(b) interpretations, but the Appellate Body's clear recognition of public health sovereignty in its interpretations of Articles 3 and 5 suggests that WTO panels will not repeat the approach taken to alternative measures in the Thai Cigarette Case. Just as the Appellate Body steered a middle course between deference and de novo review in setting the appropriate standard of review for scientific evidence, the Appellate Body appears to have pointed to, if not actually blazed, a via media between the deferential rule of reason approach and the very strict least trade-restrictive alternative approach under Article XX(b). Such a via media might be, in the Appellate Body's words, "essential for the maintenance of the delicate and carefully negotiated balance in the SPS Agreement between the shared, but sometimes competing, interests of promoting international trade and of protecting the life and health of human beings."247

V. Paradigm Lost? The Future of the Trade-Health Linkage

The global public health crises of emerging infectious diseases and the tobacco pandemic will keep the trade-health linkage front and center in international health law and international trade law. Given the central role of the science paradigm in both of these areas of international law, the future of the trade-health linkage depends greatly on how the paradigm operates. In this Part V, I explore the future of the science paradigm in international health law and international trade law.

1. International Health Law

a) Infectious Diseases

Since 1951, the IHR have served as the only set of international legal rules directly concerned with the prevention of the spread of infectious diseases.248 As elaborated earlier, the IHR embody the science paradigm; but the member States of WHO have rendered the IHR ineffective by (1) not keeping them relevant to the changing nature of the infectious disease threat, and (2) routinely violating them. The WHO is currently preparing a revision of the IHR to make them more relevant to the era of EIDs, but the proposed principles guiding the revision have left commentators

247 Id., para. 177 (describing requirements of Articles 5.1 and 2.2).

248 World Health Organization, Division of Emerging and Other Communicable Diseases Surveillance and Control, Emerging and Other Communicable Diseases Strategic Plan 1996 - 2000, 1996, WHO/EMC/96.1, 10 (the IHR constitute the "only international health agreement on communicable diseases that is binding on [WHO] Member States.").
unimpressed. A particular weakness of the IHR revision principles is no apparent desire to improve compliance with the Regulations. While the science paradigm will get an overhaul in the move from reporting just three diseases to reporting disease syndromes, WHO has not indicated publicly that it will attempt to improve compliance with reporting duties through monitoring and enforcement. Nor has it publicly confronted the problem of how to deal with excessive measures taken by WHO member States in violation of the IHR. All of which suggests the revised IHR may create an improved science paradigm that again is lost in the more irrational world of international politics.

The WHO might fruitfully explore how to utilize the WTO and the SPS Agreement to shore up the revised IHR. Historically, excessive measures taken by WHO member States seriously affected international trade. The maximum measures provided in the IHR are based on scientific principles, which suggests that excessive measures are suspect scientifically. These excessive measures could be challenged under the SPS Agreement as lacking a scientific justification. The IHR and WHO statements on the excessive measures in question could be powerful ammunition under the SPS Agreement in demonstrating that the measures lacked a scientific basis. The WHO does not necessarily need to build into the revised IHR an entire enforcement regime, but it could build the necessary bridges that would allow excessive measures to be challenged successfully under the SPS Agreement. In short, the revision of the IHR has an opportunity to link trade and health synergistically in pursuit of the objective of the maximum protection against the international spread of disease with minimum interference with world trade. The international health law and international trade law regimes would, thus, blend together in an overarching trade-health system. Such a coordinated approach could help health and trade experts secure a


250 The Revision of the International Health Regulations (note 114), 234 ("The current role and function of the IHR should be revised and expanded, particularly the practice of immediate reporting of only 3 specific diseases which should be replaced by immediate reporting to WHO of defined syndromes representing disease occurrence of international importance.").

251 Taylor (note 136), 1352 ("It is highly doubtful whether the revisions suggested by WHO's expert committee will adequately address the problems of noncompliance . . .").

252 Fidler (note 22), 858 (discussing weakness in WHO plans to educate member States better about excessive measures).

more appropriate balance in the trade-health linkage and avoid having the linkage degenerate into trade versus health.

b) Framework Convention on International Tobacco Control

A second important item on the horizon of international health law is the development of the proposed framework convention on international tobacco control. The substance of the actual framework convention and the specific issues that might be addressed in the protocols to it are not yet clear because the WHO initiative on the convention is still very young. The convention will, however, have to address the global tobacco trade. Derek Yach has argued that the "growing international support for an international convention on tobacco control . . . will in all likelihood require tobacco and tobacco products to be exempted from the terms of the World Trade Organization."254 Removing tobacco from the WTO regime will be a very controversial undertaking given the long-standing efforts by the United States and other tobacco-exporting countries to pry open new markets. Unless trade in tobacco is directly confronted, protocols on labeling, advertising, or educational campaigns will be vulnerable to the rapacity of multinational tobacco companies in the same way that similar domestic legislation in developing countries has been powerless to stop the growth of tobacco consumption. But no one should have any doubts about the difficulty of including trade regulations in the proposed tobacco framework/protocol strategy because of the historical behavior of the United States and multinational tobacco companies.255

The recent proposed U.S. domestic tobacco litigation settlement256 has fortunately caused people to re-examine U.S. tobacco export efforts. In July 1997, legislation was introduced in both the U.S. House of Representatives and Senate proposing to make American tobacco exports and American tobacco advertising overseas subject to the

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255 An ironic story illustrates in a small way the uphill fight against global tobacco consumption. Yach reported that at the World Health Assembly meeting in 1995 at which delegates supported global tobacco control efforts "[t]here was an almost continuous presence of tobacco smoke at gathering points outside the main meeting halls of the World Health Assembly. Ashtrays sponsored by tobacco companies were prominently displayed and used even by Ministers of Health from a wide variety of countries. No attempt was made by WHO officials to try to implement a ban on smoking within meeting areas." Id.

restrictions on labeling and advertising in effect in the United States.\textsuperscript{257} The Senate version of the legislation also would prevent the United States Trade Representative "from undermining another country’s tobacco restrictions if those restrictions are applied to both foreign and domestic products in the same manner."\textsuperscript{258} The House of Representatives’ bill would prohibit federal funds from being used by the U.S. government to seek to remove or reduce foreign countries’ restrictions on tobacco products or to promote tobacco exports.\textsuperscript{259} In introducing the Senate bill, Senator Lautenberg starkly characterized past U.S. trade policy on tobacco:

Mr. President, the success tobacco companies have had in selling death overseas is not solely due to their own efforts. In the past, the U.S. Government assisted U.S. tobacco companies in hooking foreigners by using trade policy to dismantle foreign tobacco regulations, such as advertising bans, in several key markets. While most of this assistance occurred in the 1980s, its effects are felt today. Japan, South Korea, Thailand, and Taiwan were on the other side of this dispute with our Government over their antitobacco laws. They lost, their citizens lost, and the U.S. tobacco companies won. Smoking in these countries is higher as a result of past action by the U.S. Trade Representative.\textsuperscript{260}

The strength of such anti-tobacco sentiments in Congress was revealed in November 1997 when Congress passed and the President signed an appropriations statute that prohibits the use of any of the appropriated funds "to promote the sale or export of tobacco or tobacco products, or to seek the reduction or removal by any foreign country of restrictions on the marketing of tobacco or tobacco products, except for restrictions which are not applied to all tobacco or tobacco products of the same type."\textsuperscript{261} While this provision represents the first time "Congress has restricted employees of the government from contesting health regulations designed to reduce


\textsuperscript{258} Congressional Record, vol. 143, S7950-4, S7959 (statement of Senator Lautenberg). Senator Lautenberg’s emphasis on the non-discriminatory application of domestic tobacco regulations fits well with the rule of reason approach to the necessary requirement outlined earlier in the paper. Senator Lautenberg’s proposed legislation does not require that other countries adopt the least trade-restrictive tobacco regulations. Senator Lautenberg states that his proposed legislation conforms to the Thai cigarette ruling because the GATT panel “held that member nations can use various policies to protect health as long as they are applied evenly to domestic and foreign products”. Id. The GATT panel’s ruling in the Thai Cigarette Case did not, however, turn on a violation of a non-discrimination principle but on the ‘necessary’ requirement of Article XX(b).

\textsuperscript{259} U.S. House of Representatives bill H.R. 2135, § 5.

\textsuperscript{260} Congressional Record (note 258).

smoking in other countries,” the provision does not actually bar the United States from attacking foreign tobacco control laws resembling those attacked in Thailand because they do not treat domestic and foreign tobacco and tobacco products equally, as required by the statute. While, legally, challenges to foreign tobacco laws that violate the principle of national treatment are still possible, politically such challenges will be very difficult to mount with such laws on the books.

The anti-tobacco activity in the United States indicates that the framework/protocol strategy on international tobacco regulation will have to confront the global tobacco trade or the situation will continue to be one where trade prevails over public health as has already happened throughout the developing world. In many respects, the framework/protocol strategy on international tobacco regulation has to create a more powerful science paradigm for tobacco-related diseases in international health law and a deeper commitment to the paradigm for global public health progress to be made. The nagging fear is, however, that the creation of such a paradigm now the global tobacco pandemic is well under way may well be lost in the smoke increasingly inhaled and exhaled in the global village.

Potential synergy exists between the proposed tobacco framework/protocol strategy and international trade law. As the international consensus against tobacco consumption builds through the framework/protocol effort, WTO panels might give more weight to public health concerns in tobacco trade disputes (and possibly other SPS disputes) than the GATT panel in the *Thai Cigarette* Case. As with the IHR, the WHO should be building bridges with the WTO regarding tobacco in a comprehensive effort to link trade and health.

2. International Trade Law

The future of the trade-health linkage in international trade law depends upon the direction of a number of developments. The most fundamental area will be the interpretations of the SPS Agreement rendered by WTO panels because these decisions will form the ‘common law’ of the trade-health linkage. How bridges are built between international health law and international trade law, as suggested above, will determine whether WTO panel interpretations move away from the public health myopia witnessed in the *Thai Cigarette* Case. In addition, great questions remain about (1) how the science paradigm is affected by its politicization, (2) how WTO panels will deal with making scientific decisions under the politicized science paradigm, and (3) how WTO panels interpret the ‘necessary’ trade discipline in the SPS Agreement.

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The great danger in the international trade law area is that the science paradigm becomes, or becomes perceived to be, a facade for greedy trade interests rather than the traditional way of balancing trade and health objectives. If the development of international standards and the nature of national scientific research become, or become perceived to be, dominated by powerful trade interests, then the science paradigm will be seen as a sell-out to economics over health. If WTO panels continue to rely on the traditional interpretation of 'necessary', the 'common law' of the trade-health linkage may be rejected by many as anti-health; and the science paradigm will be perceived to be subordinate to the trade-related disciplines in the trade-health linkage.

Conclusion

The globalization of public health forces States to cooperate to deal with global health threats. The problem of emerging infectious diseases and the global tobacco pandemic pose serious public health problems all over the planet, but especially in the developing world. The processes of globalization, particularly international trade, act as stimulants for these global health threats. A key aspect of the need for international cooperation in facing the globalization of public health is finding ways to balance public health sovereignty and international trade interests. Striking the trade-health balance is an old challenge that dates back at least to the mid-nineteenth century, but its age does not dilute the relevance that it has as the new millennium approaches. Since the late nineteenth century, science has been at the center of the balancing efforts in international health law. In international trade law, science has more recently been given a similar role. In both areas of international law, the science paradigm dominates the trade-health balancing act. Science has become the standard against which national public health measures are evaluated. Science sets the standards that form the basis for international regulatory harmonization. Science becomes institutionalized in international organizations as they attempt to balance public health sovereignty and international trade.

The science paradigm does not, however, live up to science myths. The paradigm is subject to the machinations of States in international politics, which erodes our vision of the paradigm as an objective and universal source of wisdom perfectly balancing health and trade in international relations. The concerns about the science paradigm are serious and have to be faced forthrightly, but the concerns do not necessarily mean that the science paradigm is without merit in the continuing trade-health relationship. The fact that science has for over 100 years been at the center of the trade-health linkage suggests it has both deep appeal and practical value. The science paradigm promises to remain the center of gravity in the trade-health linkage.
Science is not, of course, the only feature of the trade-health linkage. As illustrated by the analysis of the trade-related disciplines of GATT and the SPS Agreement, non-discriminatory application of scientifically-based SPS measures remains mandatory in international trade law. The non-discrimination principles dovetail nicely with the science paradigm because discriminatory application of SPS measures often makes little public health sense when the risks posed in the two situations are the same. More problematic is the interpretation of ‘necessary’ because upon the interpretation of this term hinges the nature of the balance between trade and health in international trade law. The traditional GATT interpretation, found in the Thai Cigarette Case, subordinates public health to international trade, which produces not balance but disequilibrium. What has happened to tobacco consumption in Thailand and other developing countries proves that trade interests were allowed to run roughshod over public health objectives. Re-establishing equilibrium requires emphasis on the science paradigm and the maintenance of its purpose.

In the eras of the globalization of public health witnessed since the mid-nineteenth century, trade and health have been and currently are in tension. It is an unavoidable tension because of the structure of the international system and the nature of human diseases. As international trade continues to increase, and as global health crises develop, the tension will become acute. The political pressures on the science paradigm are becoming intense as the trade and health stakes are raised by the globalization of markets and of public health. In such an environment, matters can quickly deteriorate as trade and health factions square off for battle. The outcome of the battle is, however, known: at the end of the day trade and health will still be linked, but much damage may be done to the spirit and stamina needed in the delicate balancing of trade and health interests.

Diseases spread through trade by land and by sea have shaped the course of human history. Emerging infectious diseases and the global tobacco pandemic are merely the latest chapters in this ancient saga. The horrible human death and suffering on the horizon because of these two great global health crises should be sobering motivation to maintain perspective and to sharpen our determination to find sustainable and creative ways to coordinate trade and health in all areas of international law.