

ARTICLES

THE EFFECTIVENESS OF PANDEMIC PREPARATIONS: LEGAL LESSONS FROM THE 2009 INFLUENZA EPIDEMIC

*Bradly J. Condon & Tapen Sinha**

I. INTRODUCTION	1
II. INTERNATIONAL HEALTH REGULATIONS AND DISEASE SURVEILLANCE.....	4
III. MEXICO'S PANDEMIC PREPARATIONS.....	6
IV. THE H1N1 (09) OUTBREAK TESTS PANDEMIC PREPARATIONS.....	10
V. WHO GUIDELINES FOR COMMUNICATING WITH THE PUBLIC DURING AN OUTBREAK.....	20
VI. TRADE RESTRICTIONS, THE IHR (2005) AND WTO LAW.....	23
VII. CONCLUSION.....	29

I. INTRODUCTION

The increasing frequency of global influenza pandemics, together with the SARS outbreak of 2003, have highlighted the need to improve

* This is a modified and fully edited version of Working Paper No. 1, International Federation of Red Cross and Red Crescent Societies Disaster Law Working Paper Series, <http://www.ifrc.org/what/disasters/idr/research/workingpapers.asp>. The authors would like to acknowledge financial assistance from the Instituto Tecnológico Autónomo de México and the Asociación Mexicana de Cultura A.C. for their generous support of this research. We thank Marcello Basili, Holger Hestermeyer, Anil Jain, Stephen Kay and Sajal Lahiri for their helpful comments on earlier drafts of this paper. We are solely responsible for the views expressed here.

international coordination, share information and minimize the economic impact when such outbreaks occur.¹ These concerns motivated the World Health Organization (WHO) to issue guidelines on communicating with the public during pandemics in 2004 and the member states of the World Health Assembly to adopt substantial revisions to the International Health Regulations (IHR (2005)) in 2005.² In theory, these instruments have balanced states' fears concerning the potential economic impacts of a transparent pandemic response with the public health needs for speedy action and sharing of information. The experience of the 2009 outbreak of the H1N1 pandemic (H1N1 (09)) – particularly in Mexico – has demonstrated some of the enduring problems with this balancing act, not all of which are the type that might have been supposed.

Article 2 of the IHR (2005) establishes the purpose and scope of the Regulations in the following terms: “to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”³ The objective of avoiding unnecessary interference with international traffic and trade reflects the concerns of countries regarding the negative economic impact of disproportionate responses to public health risks that lack scientific justification. There have been many such cases. Following an outbreak of cholera in Peru in 1991, even though the WHO and the U.S. Centers for Disease Control found that there was no basis for travel or trade restrictions, the European Community and other countries imposed import bans on fish and other perishable foods, inspection requirements and restrictions on travelers from Peru.⁴ In 1994, after India reported a suspected outbreak of plague, even though the WHO had advised that no travel or trade restrictions were appropriate, other countries canceled flights, closed borders to goods and people, and issued travel advisories.⁵ Such responses explain the past reluctance of countries to report public health threats.

In this sense, the IHR (2005) reinforce provisions in the “law of the World Trade Organization (WTO)” (WTO Law) discouraging excessive and unwarranted restraints to trade based on public health concerns. The mutually reinforcing features of the IHR (2005) and WTO law have been well analyzed.⁶ Together, IHR (2005) and WTO law should provide obligations, incentives and guarantees sufficient to prompt states to quickly report outbreaks of infectious disease. However, these incentives depend on rapid and effective WHO recommendations that, together with WTO law, would minimize the risk of economic harm caused by disproportionate trade restrictions. The 2009 influenza outbreak demonstrated that even if WHO recommendations are issued relatively rapidly, they are unlikely to be effective in preventing the use of disproportionate trade and travel restrictions. Moreover, WTO law is unlikely to prevent states from taking measures whose appropriateness would only become clear with hindsight.

Member States had until June 2009 to assess their ability to comply with the core surveillance requirements of the IHR (2005) and to implement a plan for ensuring compliance.⁷ Reducing the risk of disproportionate trade restrictions would enhance economic incentives to comply with surveillance requirements. While the IHR (2005) contain norms that discourage the use of disproportionate trade restrictions in response to disease outbreaks, health-related trade restrictions are regulated by the WTO. How to ensure that the incentives created by the international legal system function effectively in regulating responses to outbreaks of infectious diseases remains an open question.

This Article is organized as follows. We first consider the problems that the IHR (2005) were meant to resolve, such as the need for rapid reporting of outbreaks, the related need to minimize disproportionate travel and trade restrictions in response to outbreaks and the need for international leadership to coordinate the global response. We then analyze how the IHR (2005) are designed to achieve this end and how effective a tool the IHR (2005) proved to be during the 2009 influenza outbreak. We also consider the WHO guidelines for communicating with the public during a pandemic and assess the effectiveness of the

1. See Brady I. Condon & Tapen Sinha, *Chronicle of a Pandemic Foretold: Lessons from the 2009 Influenza Epidemic* (May 3, 2009), available at <http://ssrn.com/abstract=1398445>.

2. WHO Communicable Disease Surveillance and Response, *Outbreak Communication: Best Practices for Communicating with the Public During an Outbreak* WHO/CDS/2005.32 (Sept. 21–23 2004).

3. World Health Organization [WHO], *International Health Regulations*, art. 2, WHA 58.3, Fifty-Eighth World Health Assembly (2005), available at http://www.who.int/gb/ebwha/pdf_files/WHA58_3-en.pdf [hereinafter IHR].

4. Barbara von Tigerstrom, *The Revised International Health Regulations and Restraint of National Health Measures*, 13 HEALTH L.J. 35, 42–43 (2005).

5. *Id.*

6. See, e.g., John D. Blum, *Law as Development: Reshaping the Global Legal Structures of Public Health*, 12 MICH. ST. J. INT'L L. 207 (2004); David Byrne, *Is There a Lawyer in the House: The Law of Global Public Health*, 33 J.L. MED. & ETHICS 19 (2005); Emily Lee, *The World Health Organization's Global Strategy on Diet, Physical Activity, and Health: Turning Strategy Into Action*, 60 FOOD DRUG L.J. 569 (2005); Timothy J. Miano, *Understanding and Applying International Infectious Disease Law: U.N. Regulations During an H5N1 Avian Flu Epidemic*, 6 CHI.-KENT J. INT'L & COMP. L. 26 (2006); Jason Sapsin, *International Trade Agreements: Vehicle for Better Public Health?*, 33 J.L. MED. & ETHICS 111 (2005).

7. IHR, *supra* note 3, art. 5.

Mexican government's pandemic planning and communication strategy in addressing the H1N1 (09) epidemic. We then consider the role of WTO law in regulating the use of disproportionate trade restrictions in response to disease outbreaks.

II. INTERNATIONAL HEALTH REGULATIONS AND DISEASE SURVEILLANCE

An important objective of the WHO's regulatory powers is to harmonize national behavior through international standards based on scientific and public health principles.⁸ The 1969 International Health Regulations (IHR (1969)), which focused on relatively passive notification and control measures for cholera, plague, yellow fever and smallpox, were ineffective with respect to more recent global public health crises, including HIV/AIDS, SARS and the threat of an influenza pandemic. The IHR (1969) also limited the WHO's ability to respond to new outbreaks of disease by requiring the WHO to rely on official state notifications, rather than other sources. WHO member states often did not comply with the IHR (1969), failing to notify the WHO of cases of diseases and applying excessive health measures beyond those permitted by the IHR (1969).⁹ The risk of economic losses due to disproportionate trade and travel restrictions created a disincentive to report outbreaks of infectious diseases.

The IHR (2005) introduced a new surveillance system for all diseases and health events that may constitute a "public health emergency of international concern."¹⁰ The IHR (2005) expanded disease coverage, notification requirements, and the sources of information that the WHO can use regarding disease outbreaks. The IHR (2005) also set standards for public health responses to the international spread of disease, but leave States with considerable discretion regarding their implementation at the national level.¹¹

The central obligation of countries is to report outbreaks of disease, broadly defined, to the WHO. Article 6 of the IHR (2005) requires States to notify the WHO of all events, which may constitute a public health emergency of international concern within its territory, and any health measure that has been implemented in response to those events.¹² In making its recommendations, Article 9 allows the WHO to take into

account reports from sources other than notifications or consultations from the affected State.¹³

In addition to these obligations, the rise of modern communication technologies has given countries an incentive to report disease outbreaks to the WHO, in order to ensure the accuracy of WHO's report. These technologies (mobile telephones, email and internet) make it difficult for countries to suppress information regarding outbreaks of contagious diseases. Once the existence of an outbreak becomes known, the level of the public health risk and the effectiveness of the affected country's response influence the responses of other countries (trade and travel restrictions) and the economic consequences of those responses.

However, the H1N1 (09) outbreak demonstrates that the suppression of information is not the only issue that influences how rapidly disease outbreaks are reported. The outbreak must also be detected quickly. Mexico reported the disease outbreak quickly, once it became aware that it was not dealing with ordinary seasonal influenza.¹⁴ However, it later became apparent that the H1N1 (09) pandemic probably had begun much earlier.¹⁵ At the time, health officials mistook it for seasonal influenza, since it coincided with the normal influenza season and was relatively mild.¹⁶

The IHR (2005) establishes an Emergency Committee to give the Director General its views on the existence and termination of a public health emergency of international concern and on any proposed temporary recommendations. Once the Director General determines that a public health emergency of international concern exists, the Director General can issue temporary recommendations regarding measures to be taken by the affected State or other States to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.¹⁷ Article 17 requires that health measures recommended by the Director General be determined on the basis of a risk assessment appropriate to the circumstances, not be more restrictive of international traffic and trade and not more intrusive to persons than reasonably available alternatives that would achieve the "appropriate" level of health protection.¹⁸

13. *Id.* art. 9.

14. Brady J. Condon & Tapen Sinha, *Diario de la peste*, 31:378 *Nexos* 29, 30 (June 2009).

15. *Id.*

16. Condon & Sinha, *supra* note 1, app. A.

17. IHR, *supra* note 3, art. 48.

18. The language of Article 17 echoes some of the legal criteria applied in WTO law to trade-restrictive health measures in order to determine whether they can be justified under the general exceptions of General Agreement on Tariffs and Trade (GATT) Article XX (b) or permitted under the Agreement on Sanitary and Phytosanitary Measures or the Agreement on Technical Barriers to Trade. However, under GATT countries remain free to select their level of

8. David D Fidler, *The Future of the World Health Organization: What Role for International Law?*, 31 *VAND J. TRANSNAT'L LAW* 1079 (1998).

9. Von Tigerstrom, *supra* note 4, at 36.

10. IHR, *supra* note 3, art. 6.

11. *Id.* art. 13.

12. *Id.* art. 6.

Before the pandemic H1N1 (09) virus outbreak, some commentators believed that even if the WHO Director General were to declare a public health emergency of international concern and issue recommendations, affected countries would be unwilling to accept those recommendations and would seek to negotiate a compromise, as happened in Canada's case with SARS.¹⁹ However, these predictions failed to come true when Mexico faced the H1N1 (09) outbreak, underlining the unpredictable nature of epidemics and governmental responses.

III. MEXICO'S PANDEMIC PREPARATIONS

Mexico was prepared for an influenza pandemic well in advance.²⁰ Studies of earlier pandemics convinced the Mexican government that the benefits of pandemic planning exceeded the costs. It implemented its plan almost to the letter when the new virus was confirmed on April 23.²¹

Mexico is the only developing country member of the Global Health Security Action Group, a public health communications network whose other members are Canada, Japan, the United States, and several European countries.²² Criticism regarding the Mexican government's response ignores the complexity of recognizing and responding to an unexpected public health emergency.²³ The Mexican government knew that a flu pandemic could infect 25-35% of population. A model based on past pandemics predicted the following probable impact of a worst-

health protection and can select a zero tolerance approach. This wording seems to suggest that at the WHO level the recommendations of the Director General depart from a mere "appropriate" level of protection (whatever that may be). IHR, *supra* note 3, art. 17.

19. Jonathan F. Suk, *Sound Science and the New International Health Regulations*, 1 GLOBAL HEALTH GOVERNANCE (Fall 2007), available at <http://www.ghgi.org/suk.htm>.

20. Mexico passed legislation in July 2006 that mandated the creation of a National Plan for Preparation and Response to an Influenza Pandemic (Plan Nacional de Preparación y Respuesta ante una Pandemia de Influenza) and a National Committee on Health Security (Comité Nacional para la Seguridad en Salud) and made the plan mandatory for all levels of the national healthcare system. See Acuerdo del Consejo de Salubridad General por el que se Establecen las Actividades de Preparación y Respuesta ante una Pandemia de Influenza, DOF, 19 July 2006. The National Plan was published in August 2006. See Plan Nacional de Preparación y Respuesta ante una Pandemia de Influenza, available at http://www.fao.org/docs/cims/upload/221482/national_plan_si_mex_es.pdf (last visited Feb. 13, 2010) [hereinafter National Plan]. The plan sets out general guidelines for the preparation for and response to an influenza pandemic in order to mitigate the impact of an influenza pandemic in Mexico. The Mexican government also prepared a Guide for the Preparation of Institutions for an Influenza Pandemic (Guía para la Preparación de Instituciones ante una Pandemia de Influenza).

21. Condon & Sinha, *supra* note 14, at 31.

22. Global Health Security Initiative, available at <http://www.ghsi.ca/english/background.asp>.

23. Julio Frank, *Mexico's Fast Diagnosis*, N.Y. TIMES, Apr. 30 2009.

case-scenario pandemic in Mexico, assuming a duration of eight weeks peaking in the fifth week, 25% of population infected and 17% with a high risk of complications: 21,522-117,461 deaths; 80,727-352,513 hospitalizations; 11,798,789-20,710,591 medical consultations; 278% use of hospital capacity in the first week and 912% in the fifth week; 58% use of ventilator capacity in the first week and 269% in the fifth; 9,084.7 million MXN (672.9 million USD at 13.5) in direct costs and 148,853.8 million MXN (11,026.2 million USD) in indirect costs (1.6% of annual GDP).²⁴ The Mexican government took this public health risk very seriously.

Mexico's pandemic preparation plan envisaged three types of measures. First, medical interventions would focus on antiviral medication, vaccines, medical attention and personal protection equipment (e.g., gloves and masks).²⁵ In this category, Mexico stockpiled antiviral medications in advance, provided medical attention regardless of the healthcare coverage of the individual and distributed surgical masks when the outbreak occurred.²⁶ However, Mexico's stockpile antiviral medications in the first week of the outbreak was only 1.4 million courses of treatment, enough for only 1.3% of the population.²⁷ Vaccination was not an option initially, except for seasonal flu, since it would take several months to manufacture a vaccine for the H1N1 (09) virus.²⁸ Moreover, when the epidemic struck, Mexico was still in the process of expanding its vaccine manufacturing capacity, which was scheduled for completion in 2011.²⁹

Second, non-medical interventions would focus on personal hygiene (e.g., hand-washing), travel restrictions, quarantine, social distancing (e.g., school closures) and communication of risks.³⁰ In this regard, the Mexican government advised people on personal hygiene measures in

24. Pablo Kuri, Mexican Ministry of Health, "Preparación para la respuesta ante una Pandemia de Influenza," Presentation to ITAM Faculty Meeting, Nov. 29, 2007.

25. *Id.*

26. Condon & Sinha, *supra* note 1, app. A.

27. *Id.*

28. Keiji Fukuda of the WHO, on July 8, 2009, declared that the new virus would henceforth be called by this name. See World Health Organization, Transcript of Virtual Press Conference with Dr. Keiji Fukuda, Assistant Director-General ad Interim for Health Security and Environment, http://www.who.int/mediacentre/Pandemic_h1n1_presstranscript_2009_07_07.pdf. However, this name has not been universally accepted. As of August 2009, the CDC continued to call it the "Novel H1N1 virus."

29. Thelma Gomez, "OMS pide laboratorios a Mexico desde 1999," El Universal, Apr. 30, 2009, available at <http://el-universal.com.mx>. In 2008, the Mexican government announced the acquisition of a manufacturing plant that would have the capacity to manufacture 20 million vaccine doses annually and signed an agreement with Sanofi Aventis to produce vaccines in Mexico in conjunction with state-owned Laboratorios de Biológicos y Reactivos de México, SA de CV (Birmex).

30. Kuri, *supra* note 24.

public announcements (including in President Calderon's press conferences), progressively implemented social distancing (moving from school closures to cancellation of public events to shutting down all non-essential services and advising people to avoid crowded, enclosed places) and followed the WHO guidelines for communicating with the public during an outbreak.³¹ The government did not impose travel restrictions or quarantine, due to the determination of both the United States Centers for Disease Control and Prevention (CDC) and WHO that containment was not feasible and that efforts should focus on mitigation.³²

Third, the maintenance of social and economic systems would prioritize security and legislation, water and food supplies, energy supplies, transportation, telecommunications and financial services.³³ When the government shut down non-essential services from May 1-5, these areas were not only left operating, but had their hours expanded.³⁴ These measures aimed to delay the peak in the epidemic, thereby reducing the number of cases and the burden on healthcare services that would otherwise occur (see Figure 1, below).³⁵

31. Condon & Sinha, *supra* note 1, app. A.

32. *Id.*

33. Kuri, *supra* note 24.

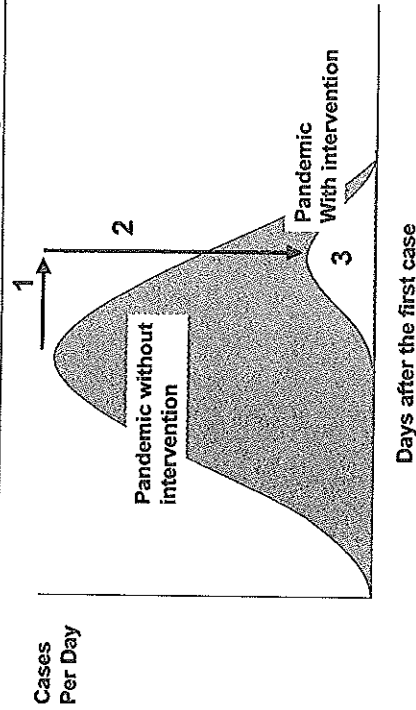
34. Condon & Sinha, *supra* note 1, app. A.

35. Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation, CDC (Feb 2007), available at <http://flu.gov/professional/community/index.html>.

Figure 1: The objective of an intervention is to postpone the onset and reduce the peak of a pandemic

Objective of Intervention

- 1 Delay outbreak peak
- 2 Reduce peak burden on hospitals and infrastructure
- 3 Reduce the number of cases and severity of outbreak



(Source: <http://www.pandemicflu.gov/plan/community/commitigation.html>)

Many members of the public, both in Mexico and abroad, were puzzled and alarmed by the dramatic measures implemented by Mexico in response to the epidemic.³⁶ Experts in pandemic response were not. Indeed, the Director General of the WHO repeatedly praised the Mexican government for its response to the epidemic.³⁷ This dramatic response had been planned for several years.³⁸ Mexico's pandemic preparations and its response to H1N1 were based on innovative intelligence and close cooperation with the world's most advanced economies, particularly Canada and the United States.³⁹

Nevertheless, there were gaps in Mexico's pandemic preparation. Insufficient supplies of masks, gloves and gowns meant that Mexico

36. Condon & Sinha, *supra* note 1, app. A.

37. *Id.*

38. See National Plan, *supra* note 20.

39. Kuri, *supra* note 24.

required donations from other countries, such as China and Japan.⁴⁰ Insufficient testing equipment forced Mexico to report suspected cases when the United States was reporting confirmed cases, which gave the initial impression that the situation was far worse in Mexico than it was.⁴¹ Mexico's stockpile of antiviral medicine, while sufficient for this outbreak, was far below what its needs could have been in a more serious situation.⁴² This may have been a factor in Mexico's decision to respond as aggressively as it did with mitigation measures. Had the government not delayed the peak as effectively as it did, Mexico could have had far more cases.⁴³ In that event, its supply of antiviral medicine probably would have been inadequate and further supplies could have been difficult to acquire.⁴⁴ While the expansion of this capacity to manufacture vaccine is insufficient.⁴⁵ While the expansion of this capacity was part of Mexico's pandemic preparation,⁴⁵ it appears that it will arrive too late for this epidemic.

There was a lack of coordination between different levels of government, most notably the Mexico City and federal governments, both of which gave daily news conferences regarding the latest influenza statistics in their respective jurisdictions.⁴⁶ Different political parties occupy the Mexico City government (PRD) and presidency (PAN) and this appeared to generate competition over public perceptions regarding who was doing the best job of addressing the crisis.⁴⁷ This lack of coordination was possibly linked to the upcoming elections for Congress in July 2009 and for president in 2012.⁴⁸ Party politics need to be set aside in an emergency and the government needs to speak with one voice. Pandemic planning should set these rules in advance. Finally, like the rest of the world, Mexico assumed that the epidemic would start in Asia.⁴⁹ This assumption turned out to be wrong. Pandemic planning should assume that a pandemic could start anywhere.

IV. THE H1N1 (09) OUTBREAK TESTS PANDEMIC PREPARATIONS

The H1N1 (09) outbreak provided the first test for the IHR and the

40. Condon & Sinha, *supra* note 1, app. A.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

45. Kuri, *supra* note 24.

46. Condon & Sinha, *supra* note 14.

47. Condon & Sinha, *supra* note 1, app. A.

48. *Id.*

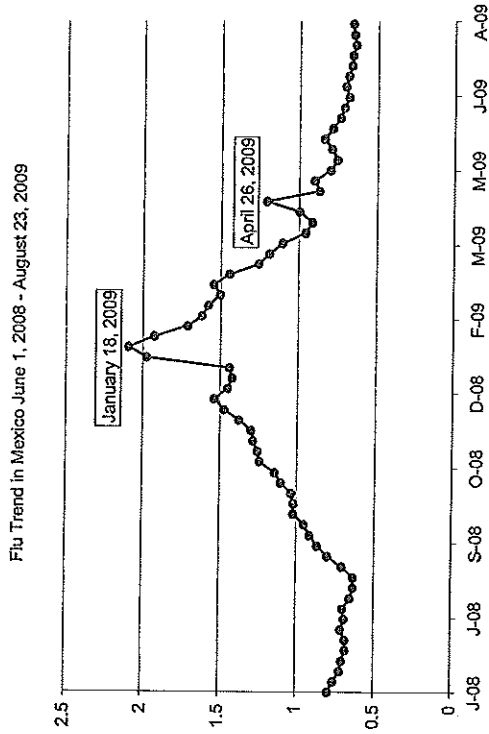
49. *Id.*

WHO. The WHO's response was better than some experts had predicted. Mexico's response was also better than many expected a developing country's response would be. However, the outbreak also revealed cracks in the new international framework for information sharing. We offer seven key observations.

First, Mexico complied with its obligation to report its outbreaks to the WHO.⁵⁰ This suggests an understanding of its obligations and the incentives to report outbreaks.

Second, Mexico's delays in reporting what later turned out to be cases of the H1N1 (09) virus appear to be due to insufficient technical expertise or equipment combined with the timing of the outbreak, rather than a desire to hide the outbreak.⁵¹ Figure 2 shows when the H1N1 (09) outbreak occurred in relation to the regular flu season in Mexico. The weekly trend did have an unusual peak in late April. However, this peak was nowhere near the peak that occurred in January 2009. Even with the peak, the level was lower than what took place in November 2008. Thus, there is no evidence that the Mexican Government delayed any reporting. On the contrary, it reported based on suspected cases even before they were confirmed.⁵²

Figure 2: An Unusual Uptick of Influenza Late in the Season



50. Condon & Sinha, *supra* note 14, at 30.

51. Condon & Sinha, *supra* note 1, app. A.

52. *Id.*

This might suggest that the obligation to report outbreaks may prove ineffective in the absence of adequate technical expertise and equipment. However, the United States also experienced delays, even though its earliest cases appear to have occurred around the same time as Mexico's earliest cases.⁵³ Thus, it is possible that some outbreaks may be difficult to detect or their seriousness may be difficult to confirm as quickly as we would like, regardless of the level of technical expertise and equipment. It may be that the timing of the outbreak and the nature of the virus were the primary cause of any delays.

Third, the WHO DG did declare a public health emergency of international concern, within forty-eight hours of laboratory confirmation that the Mexican virus was new and that it was the same as the U.S. virus.⁵⁴ While some might like to see a faster response, this contradicts prior speculation that the WHO DG would be unwilling to make such a declaration.

Fourth, two days after the declaration, the WHO raised the alert level to four and issued recommendations, before raising it to level five two days later.⁵⁵ Again, while some might like to see a faster response, this contradicts prior speculation that the WHO DG would be unwilling to issue recommendations. After the declaration of alert level five, there was speculation as to whether the WHO would raise the alert to the highest possible level of six. That declaration came much later – on June 11, 2009.⁵⁶

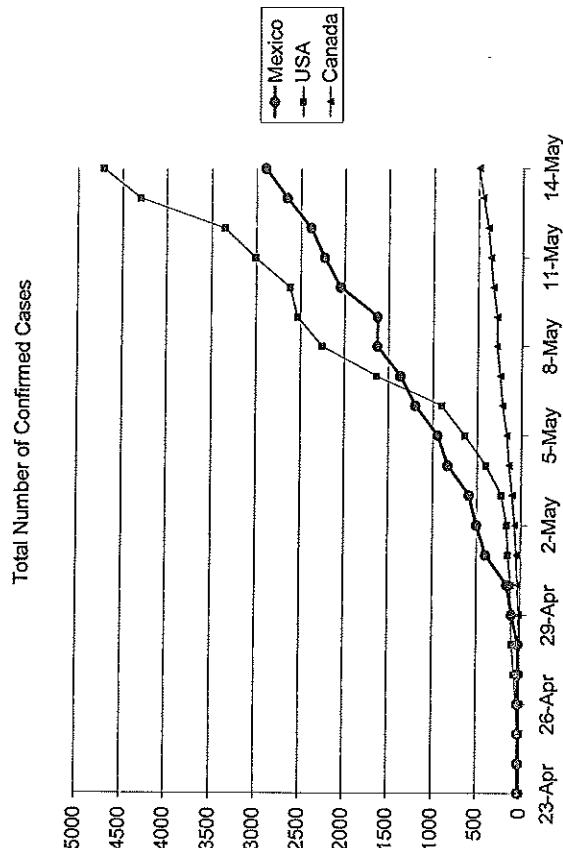
Fifth, a significant number of countries – from different parts of the world and with varying levels of economic development – chose to ignore the WHO DG's recommendations in introducing trade and travel restrictions.⁵⁷ In contrast to the reporting obligation, the WHO DG's recommendations are not binding.⁵⁸ This suggests that non-binding recommendations might not prove effective in minimizing the economic damage caused by disproportionate trade and travel restrictions. These trade and travel restrictions were more severe for Mexico than for other affected countries.⁵⁹ Despite the earliest confirmed cases surfacing in the United States and Mexico around the same time and the large number of cases in the United States, many assumed that Mexico was

53. *Id.*54. *Id.*55. *Id.*56. Press Statement of WHO Director-General Dr Margaret Chan, June 11, 2009, http://www.who.int/mediacentre/news/statements/2009/b1n1_pandemic_phase6_20090611/en/index.html.57. See *infra* Table 1.58. IHR, *supra* note 3.59. See *infra* Table 1.

the origin of the virus without any scientific evidence to confirm this conclusion.⁶⁰

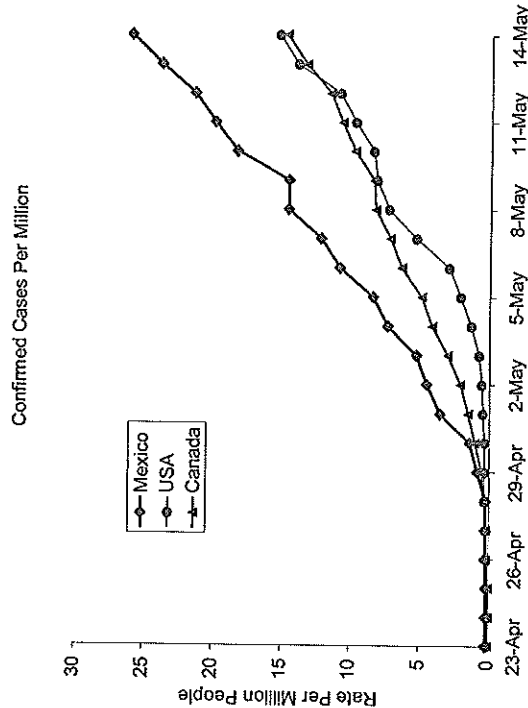
In Figure 3a (below), we display the number of confirmed cases in the three countries in North America: Canada, Mexico and the United States. While Mexico started with a larger number of confirmed cases, the U.S. figures exceeded that of the Mexican cases on May 7, 2009, two weeks after the pandemic broke out. The discriminatory treatment of Mexico is apparent. If one compares the confirmed cases per million people in Canada and Mexico, Mexico leads (see Figure 3b). However, the difference between the United States and Canada disappears altogether.

Figure 3a: Total Confirmed Cases in North America (April 23, 2009 – May 14, 2009)



(Sources: CIA Factbook (populations, est. July 2009), WHO, Public Health Canada, CDC, Secretaría de Salud (Mexico))

Figure 3b: Confirmed Cases per Million Persons in North America (April 23, 2009 – May 14, 2009)



(Sources: CIA Factbook (populations, est. July 2009), WHO, Public Health Canada, CDC, Secretaria de Salud (Mexico))

The perception that Mexico was the source of the problem appears to be due to three factors. First, Mexico initially reported *suspected* cases (a much larger number than confirmed cases) while the United States only reported *confirmed* cases.⁶¹ Second, Mexico applied serious mitigation measures earlier and more broadly than other countries.⁶² This not only helped Mexico avoid a greater number of cases in Mexico; it also represents a serious commitment to addressing a global health threat that benefited other countries as well.⁶³ Third, most of the early confirmed cases outside of Mexico were linked to travel to Mexico.⁶⁴ The earliest confirmed cases in the United States are an important exception to this pattern.⁶⁵ Thus, trade and travel measures that discriminated against Mexico were based more on the *perception* of risk than scientific proof of risk. One need only compare the number of confirmed cases in Mexico at the time that many of these restrictions

61. *Id.*
 62. *Id.*
 63. *Id.*
 64. *Id.*
 65. *Id.*

were implemented against Mexico with the number of confirmed cases elsewhere when restrictions were applied (or not) against other countries (see Table 1, below).

Table 1: Confirmed (Suspected) Cases Versus Travel and Trade Restrictions

Date	Confirmed (suspected)	Travel Measures	Trade Measures
April 23	Mexico 18	--	--
April 24	Mexico 18(1004); US 7(NA)	Brazil, Chile, Peru, Colombia, Ecuador, Guatemala, Nicaragua, El Salvador and Panama begin sanitary controls on arrivals from Mexico.	--
April 25	Mexico 18(1400); US 20(NA)	Japan starts screening arrivals from Mexico for fever. Argentina, Costa Rica, Dominican Republic and Honduras begin sanitary controls on arrivals from Mexico.	Nicaragua restricts pork imports from Mexico.
April 26	Mexico 26(1614); US 40(NA); Canada 6(NA)	US begins "passive surveillance" on arrivals from Mexico. China, Russia set up quarantines. Hong Kong advises residents not to travel to Mexico. Malaysia, South Korea and Japan check airport passengers for signs of illness.	--
April 27	Mexico 26(1995); US 64(NA); Canada 6(NA)	CDC recommends Americans forgo "nonessential travel" to Mexico. EU health minister urges Europeans to avoid nonessential travel to the US or Mexico, but later denies she issued any travel advisory.	China, Russia ban pork imports from Mexico and affected US states. Indonesia, Lebanon ban pork imports from Canada, Mexico and US.
April 28	Mexico 26(2498); US 91(NA); Canada 13(NA)	Britain, Canada, France, Germany, Switzerland advise against nonessential travel to Mexico. Australia recommends citizens who travel to Canada consult a doctor if symptoms develop. India and Malaysia warn citizens to restrict travel to Mexico, Canada	--

		and the US. Japan requires Mexicans to obtain visas before arrival; sets up quarantine for suspected cases. Britain tells citizens in Mexico to consider leaving. Cuba and Argentina suspend flights to Mexico for 48 hours. Air Canada, Westjet and Transat suspend flights to Mexican beach resorts.	
April 29	Mexico 97(NA); US 109(NA); Canada 19(NA)	Ecuador, Peru suspends flights with Mexico. French health minister calls for suspension of flights from EU to Mexico. Five cruise lines stop all port calls in Mexico.	China ban imports of pigs and pork from Mexico and 3 US states.
April 30	Mexico 156(NA); US 109(NA); Canada 34(NA)	EU rejects French proposal to suspend flights with Mexico. Taiwan issues a red alert for citizens not to travel to Mexico, yellow alert for Canada and US.	—
May 1	Mexico 397(NA); US 141(NA); Canada 51(NA)	Hong Kong quarantines hotel. China suspends flights from Mexico to Shanghai. Nestlé bans all non-essential travel by its executives to US and Mexico.	—
May 2	Mexico 506(NA); US 160(NA); Canada 70(NA); EU 39	Chinese health authorities find and place under quarantine 164 of the 189 passengers and crew members aboard a flight from Mexico to Shanghai.	Ukraine, Philippines and Serbia ban pork products from US. Indonesia bans pork from Mexico, US, France, Canada, Israel, Spain and New Zealand.
May 3	Mexico 590(NA); US 226(NA); Canada 101(NA); EU 91	China is still holding Mexicans in quarantine.	China stops imports of Alberta pork.

May 4	Mexico 822(NA); US 403(NA); Canada 140(NA); EU 107	Argentina says it suspended flights with Mexico because of its seasonal influenza and dengue fever outbreaks. China quarantines 25 Canadian students, 2 US citizens, increases delay for US visas to 6 days.	20 countries have banned imports of pork and other meat from countries with reported infections. Russia extends its pork import ban to Canada and Spain, but lifts the ban for some US states.
May 5	Mexico 942(NA); US 642(NA); Canada 165(NA); EU 127	Mexico sends plane to get Mexicans quarantined by China. China sends a plane to get Chinese stranded to Mexico. China has quarantined Canadians and Mexicans based on nationality. Singapore orders a seven-day quarantine for all passengers arriving from Mexico, Canada and US.	—

Notes: The numbers of confirmed cases are based on WHO reports, backdated to take into account the one-day delay in reporting North American figures in Geneva. The travel and trade restrictions are based on media reports. Mexico began processing a backlog of suspected cases on April 28, at which point Mexico's confirmed cases began to increase rapidly.

Sixth, the WTO was remarkably slow to address the disproportionate trade restrictions, despite being the international organization with jurisdiction over such matters.⁶⁶ The WTO Director General's initial response, when prompted by a reporter's question, was merely that no WTO members had formally notified the WTO of any trade restrictions.⁶⁷ It took eight days from the start of the epidemic for the WTO to issue a joint statement, together with the Food and Agriculture Organization (FAO), World Organization for Animal Health (OIE) and WHO, that pork products handled in accordance with hygienic practices are not a source of infection for the H1N1 (09)

66. *Id.*67. *Id.*

virus.⁶⁸ The WTO is a member-driven organization, which may place limits on the Director General's capacity to respond quickly to the use of disproportionate or unjustifiable trade restrictions during disease outbreaks in the absence of formal notifications or complaints.⁶⁹ This suggests that WTO rules may need to be changed to allow the Director General to take actions in the absence of formal notification, as the IHR (2005) have done in allowing the WHO to gather information on disease outbreaks from non-governmental sources.

Seventh, lack of access to accurate testing equipment severely hampered Mexico's ability to quickly confirm the cause of death and illness.⁷⁰ This led to the perception that Mexico's epidemic was far worse than any other country's.⁷¹ While Mexico initially reported suspected cases on a daily basis, the United States limited its release of information to confirmed cases, which reinforced the perception that Mexico was much more seriously affected than the United States.⁷² This perception resulted in more severe trade and travel restrictions applied to Mexico than to the United States or any other country (see Table 1), as well as more severe domestic mitigation measures than elsewhere. Once Mexico had the capacity to test samples, it limited its release of information to confirmed cases, as the United States had done from the beginning.⁷³ These developments underline the importance of domestic testing capacity and an effective communication strategy for both domestic and international audiences. Figure 4 (below) compares probable and confirmed cases in Mexico. Figure 4 shows that there is a gap between the two. This arises directly from the lack of capacity and equipments available in poor states of Mexico where such epidemics are likely to arise. This stands in sharp contrast with the situation in the United States where a preliminary confirmation is available within 24 hours of a reported probable case.⁷⁴

68. *Id.*

69. BRADLY J. CONDON, *EL DERECHO DE LA ORGANIZACIÓN MUNDIAL DE COMERCIO: TRATADOS, JURISPRUDENCIA Y PRÁCTICA* 74 (2007).

70. Condon & Sinha, *supra* note 1, app. A.

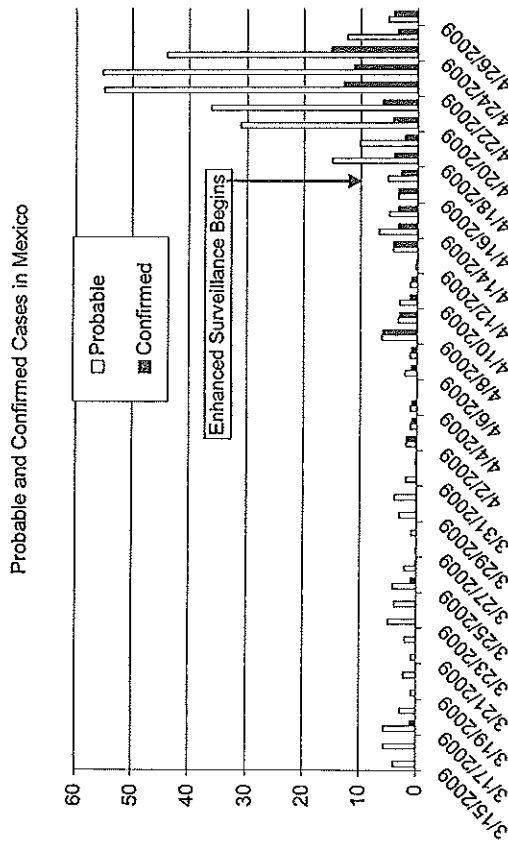
71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.*

Figure 4: Probable and confirmed cases of Pandemic H1N1 (09) virus in Mexico between 15 March 2009 and 26 April 2009



(Source: <http://www.cdc.gov/mmwr/>)

If Mexico's willingness to promptly report outbreaks was based on the notion that this would trigger WHO recommendations that would help to reduce the risk of disproportionate trade and travel restrictions, this incident may serve to undermine the IHR (2005) reporting requirements. However, it is not at all clear that this was Mexico's motivation for prompt compliance. A more likely explanation is that Mexico's political leadership recognized the need to respond quickly with mitigation measures in order to minimize the health risks to its own population. The inadequate government response to the 1985 Mexico City earthquake is considered to have been the beginning of the end for the PRI, the party that enjoyed a monopoly on power for seven decades, ending in 2000.⁷⁵ An inadequate response to the flu epidemic could have produced similarly undesirable political consequences for the Mexican President's party (PAN) or the Mexico City Mayor's party (PRD).⁷⁶ Effective and timely mitigation measures would also be likely to minimize the economic damage to Mexico's economy, regardless of the WHO recommendations or other countries' responses to those recommendations.⁷⁷

75. *Id.*

76. *Id.*

77. *Id.*

Another factor that created incentives for Mexico to report and to respond relatively quickly was the existence of confirmed cases in the United States, since this could allow Mexico to benefit from American bargaining power with other countries. However, this did not occur. Several countries imposed trade restrictions and issued travel advisories or restrictions that applied to Mexico without applying to the United States.⁷⁸ It is not clear whether this was due to differences between the two countries with respect to communication strategies (especially with respect to releasing data on suspected cases), surveillance and testing capacity (which would allow the United States to confirm or rule out cases more rapidly), international bargaining power (for example, pressuring the European Union (EU) health minister to retract her statement regarding travel to the United States)⁷⁹ or some combination thereof. Nevertheless, their different communication strategies do appear to have had a major impact on media reporting, which in turn influenced the perceptions and responses of other countries. It is unclear what impact this might have on incentives to report only confirmed cases, as opposed to both suspected and confirmed cases.

V. WHO GUIDELINES FOR COMMUNICATING WITH THE PUBLIC DURING AN OUTBREAK

The "WHO Guidelines for Communicating with the Public during an Outbreak" (Guidelines) set out best practices for communicating with the public during an outbreak.⁸⁰ They focus on two questions: (1) how can communication hasten containment of an outbreak and (2) how can communication help mitigate the social and economic impact.⁸¹

The Guidelines first identify the unique circumstances, common to disease outbreaks, that create unique challenges for public communications: (1) outbreaks are urgent emergencies in which decisions and actions must be taken rapidly, often with support from an informed public; (2) the course of outbreaks is unpredictable, creating unanticipated setbacks and surprises; (3) outbreaks usually alarm the general public, causing great anxiety and extreme behaviors that cause social disruption and economic losses out of proportion to the true severity of the risk (including wearing masks, avoiding travel, fear of hospitals, stigmatization of patients and minority groups, riots, loss of

confidence in governments and significant drops in consumer consumption); (4) outbreaks have a high political profile, which can make them a high priority or impede control when information is downplayed or concealed to minimize economic consequences; (5) outbreaks generate media coverage that can help to inform the public or fuel public anxiety out of proportion to the actual threat; and (6) human behaviors usually contribute to the spread of the disease.⁸² These factors are influenced by the nature of the disease: airborne transmission, high mortality, international spread and the absence of a vaccine or cure will heighten anxiety, factors that the IHR (2005) take into account in determining whether an outbreak constitutes a public health emergency of international concern.⁸³ Disincentives to report outbreaks include economic impact, the absence of laboratory diagnostic capacity to confirm an unusual disease and the difficulty of spotting an unusual disease in countries where there is constant high morbidity and mortality from other infectious diseases.⁸⁴ Most, if not all, of these factors were at play in the H1N1 (09) epidemic.

Against this backdrop, the Guidelines identify five essential practices for effective outbreak communication, based on the experiences of several countries to disease outbreaks: (1) build trust, (2) early announcement, (3) transparency, (4) respect for public concerns, and (5) advance planning.⁸⁵ Trust comes from public perceptions (including those of the media) of the motives, honesty and competence of authorities and needs to be developed before a disease outbreak.⁸⁶ Scientific uncertainty compounds distrust of government and suspicions regarding its motives during an outbreak response, undermining compliance with recommended control measures and allowing counter-productive behaviors to flourish.⁸⁷ Distrust is created or increased by concealment, denial, understatement and bold reassurance unsubstantiated by the scientific evidence, both domestically and internationally.⁸⁸ Conversely, when government officials report on the outbreak frankly, openly, completely and constantly and engage outside experts, trust increases and control measures are more effective.⁸⁹ People who are alert to symptoms are more likely to seek early treatment and awareness of protective behaviors can help to prevent

82. *Id.* at 7-9.

83. *Id.* at 10. IHR (2005), Annex 2.

84. WHO Guidelines, *supra* note 80, at 10-11.

85. *Id.* at 3.

86. *Id.* at 23.

87. *Id.* at 23.

88. *Id.* at 24.

89. *Id.*

78. See *supra* Table 1.

79. Condon & Sinha, *supra* note 1, app. A.

80. World Health Organization (WHO), *Guidelines for Communicating with the Public During an Outbreak*, available at http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf [hereinafter WHO Guidelines], consulted Apr. 29, 2009.

81. *Id.*

further cases.⁹⁰ The first communication about an outbreak will influence public perceptions of subsequent communications; delaying announcements and concealing information can breed lasting distrust.⁹¹ While not all information must be revealed in real time, for example to protect patient confidentiality, limits on transparency must be carefully considered.⁹² Planning communication strategies in advance, while not essential to effective communication during an outbreak, helps to avoid mistakes.⁹³

With the exception of the lack of coordination among different levels of government, Mexico's communication strategy during the 2009 flu epidemic was largely consistent with WHO communication guidelines. Mexico was right to reveal suspected cases so promptly and frankly, even though this compared unfavorably with the U.S. strategy of focusing only on confirmed cases. Given the technical limitations Mexico faced in seeking to confirm cases quickly, a focus on confirmed cases could only have given the impression that Mexico was delaying and concealing information. Thus, given the circumstances, Mexico's international communication strategy was likely the right one.

Mexico's domestic communication strategy, while relatively well executed, appeared unable to overcome pre-existing mistrust of government in Mexico.⁹⁴ On April 30, a survey of 410 Mexico City adults revealed that 57% believed the government was underreporting the numbers, 10% believed the numbers exaggerated, 19% believed official figures and 14% were not sure what to think.⁹⁵ Only 49% were somewhat or very afraid of catching the flu, 50% felt little or no fear and 1% did not know.⁹⁶ Half believed facemasks somewhat or very effective in preventing infection and half believed they were mostly or completely ineffective.⁹⁷ From April 26 to May 8, we collected data on daily mask usage on the Mexico City subway system, sampling 400 passengers per day for a total of 13 days.⁹⁸ The percentage of subway passengers wearing face masks peaked on April 27 at around 60%. After that, it went down steadily to virtually zero when the alert level was reduced to Level 2 (yellow).⁹⁹

90. *Id.* at 12-18.

91. *Id.* at 24.

92. *Id.* at 24.

93. *Id.* at 25.

94. Bradley J. Condon & Tapen Sinha, *Who is that Masked Person: The Use of Face Masks on Mexico City Public Transportation During the Influenza A (H1N1) Outbreak*, at 6, available at SSRN: <http://ssrn.com/abstract=1429824>.

95. *Id.* at 3.

96. *Id.*

97. *Id.*

98. *Id.*

99. *Id.*

VI. TRADE RESTRICTIONS, THE IHR (2005) AND WTO LAW

The IHR (2005)¹⁰⁰ reflect the intention of its drafters to avoid conflicts with other international legal obligations, particularly WTO law. In particular, the drafters of the IHR (2005) have attempted to facilitate the compatibility between temporary or standing recommendations under the IHR (2005) and trade-related obligations by establishing criteria that are similar to those used in WTO law, especially the Agreement on Sanitary and Phytosanitary Measures.¹⁰¹

In Article 57.1 of the IHR (2005), "States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible."¹⁰² This provision reflects the presumption against conflict in international law.¹⁰³ Since the language of Article 17 reflects WTO law, it is unlikely that a conflict would arise between the two. However, Article 57.1 goes on to state that "[t]he provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements."¹⁰⁴ It seems highly unlikely that this provision would prevent a WTO panel from considering the scientific evidence that supports any recommendations issued by the WHO Director General, as a question of fact. A more reasonable interpretation is that a WTO panel would be free to disregard any legal determinations regarding whether a particular trade measure is "more restrictive of international . . . trade . . . than reasonably available alternatives that would achieve the appropriate level of health protection,"¹⁰⁵ as a question of law. This interpretation is consistent with WTO and General Agreement on Tariffs and Trade (GATT)¹⁰⁶ jurisprudence that has taken scientific evidence from the WHO into account in its analysis of trade-restrictive health measures under GATT Article XX(b).¹⁰⁷ It is also consistent with WTO jurisprudence that has found that WTO panels are not obligated to apply the rulings of non-WTO tribunals.¹⁰⁸

100. IHR, *supra* note 3.

101. *International Health Regulations Revision, Communication from the World Health Organization*, WTO Doc. G/SPS/GEN/522, 21, Oct. 2004, ¶ 6.

102. IHR, *supra* note 3, art. 57.

103. *Id.*

104. *Id.*

105. *Id.* arts. 17, 43.

106. *General Agreement on Tariffs and Trade*, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT], available at <http://www.worldtradelaw.net/turagreements/gatt.pdf>.

107. Panel Report, *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes*, DS10/R - 37/S/200 (Oct. 5, 1990); Appellate Body Report, *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS15/AB/R (Feb. 16, 2001).

108. Panel Report, *Argentina - Definitive Anti-Dumping Duties on Poultry from Brazil*,

GATT Article XX(b) permits trade restrictive measures that are "necessary to protect human, animal or plant life or health."¹⁰⁹ The WTO Member that enacted the measure has the burden of proof to show that it meets the requirements of Article XX(b).¹¹⁰ First, the Member must make a *prima facie* case that the policy goal at issue falls within the range of policies designed to protect human, animal or plant life or health.¹¹¹ Once it is established that the policy goal fits the exception, the Member must demonstrate that the measure is "necessary" to achieve the policy goal.¹¹²

To demonstrate that the measure is necessary involves weighing and balancing a series of factors. First, the greater the importance of the interests or values that the challenged measure is intended to protect, the more likely it is that the measure is necessary. WTO jurisprudence has found that "few interests are more 'vital' and 'important' than protecting human beings from health risks."¹¹³ Second, the greater the extent to which the measure contributes to the end pursued, the more likely that the measure is necessary. While WTO law recognizes that "it may prove difficult to isolate the contribution to public health . . . of one specific measure from those attributable to the other measures that are part of the same comprehensive policy," the measure in question must be "apt to produce a material contribution to the achievement of its objective."¹¹⁴ Third, the less the trade impact of the challenged measure, the more likely that the measure is necessary. Thus, a complete ban on imports is less likely to qualify as necessary than less trade-restrictive measures, such as quarantine or inspection requirements.

The fourth issue is whether a WTO-consistent alternative measure the Member concerned could reasonably be expected to employ is available, or whether a less WTO-inconsistent measure is reasonably available. The weighing and balancing process of the first three factors also informs the determination of the fourth. The party that enacted the measure may point out why alternative measures would not achieve the same objectives as the challenged measure, but it is under no obligation to do so in order to establish, in the first instance, that its measure is "necessary." However, if the party challenging the measure raises a

WT/DS241/R (Apr. 22, 2003).

109. GATT, *supra* note 106, art. XX.

110. *Measures Affecting Asbestos and Asbestos-Containing Products*, *supra* note 107, at 57.

111. *Id.*

112. *Id.*

113. *Id.*; Panel Report, *Brazil - Measures Affecting Imports of Retreaded Tyres*, WT/DS332/R (June 12, 2007).

114. Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres*, WT/DS207/AB/RW (Dec. 3, 2007).

WTO-consistent alternative measure that should have been taken, the party defending the measure will be required to demonstrate why its challenged measure nevertheless remains "necessary" in the light of that alternative or why the proposed alternative is not, in fact, "reasonably available," in the light of the interests or values being pursued and the party's desired level of protection.¹¹⁵

In the context of GATT Article XX(b), WTO jurisprudence has confirmed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation and that they are not obliged to use an alternative measure that fails to achieve their desired level of health protection.¹¹⁶ Article 3.3 of the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) confirms the right of a WTO Member to establish its own level of sanitary protection.¹¹⁷ Similarly, the IHR (2005) provide that States be entitled to implement health measures in response to specific public health risks or public health emergencies of international concern, which achieve the same or greater level of health protection than WHO recommendations (Article 43.1(a)). When those health measures affect international trade, they will have to comply with WTO law. However, the right of a WTO Member to establish its own level of health or sanitary protection may not make this a difficult hurdle. In the case of import bans on pork in response to the H1N1 (09) outbreak, countries might argue that their measures aim to eliminate entirely any health risk. Since the WHO indicated that there was no risk as long as pork was properly cooked, countries might argue that the risk of improperly cooked pork required an import ban in order to eliminate any health risk.¹¹⁸

While the right of a WTO Member to determine an appropriate level of health protection is absolute, the measure it chooses to implement its policy, the manner in which it determines the appropriate level of protection and the manner in which it chooses to apply the measure can be challenged and set aside at the WTO.¹¹⁹ In order to justify a health

115. Appellate Body Report, *US - Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, WT/DS285/AB/R (Apr. 7, 2005).

116. Appellate Body Report, *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R (Feb. 16, 2001).

117. JOHN H. JACKSON, 2002 DOCUMENT SUPPLEMENT TO LEGAL PROBLEMS OF INTERNATIONAL ECONOMIC RELATIONS 123 (4th ed. 2002).

118. Condon & Sinha, *supra* note 1, app. A.

119. Gabrielle Marceau & Joel P. Trachtman, *The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade*, 36 J. WORLD TRADE 811 (2002).

measure under GATT Article XX(b), WTO Members may rely, "in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion."¹²⁰ While the scientific basis need not represent the majority view within the scientific community, it must have "the necessary scientific and methodological rigor to be considered reputable science" and be "a respected and qualified source."¹²¹ Under SPS Agreement Article 3.2, there is a rebuttable presumption that SPS measures that conform to international standards, guidelines or recommendations are consistent with the SPS Agreement and GATT. In the SPS Agreement, the standard setting bodies are clearly identified.¹²² Deviation from the relevant international standards, guidelines or recommendations must be supported by scientific justification (Article 3.3)¹²³ and take into account risk assessment techniques developed by the relevant international organizations (Article 5.1).¹²⁴ In the SPS Agreement, the requirement of a risk assessment (Article 5.1) and "sufficient scientific evidence" (Article 2.2) prevent the use of health measures for arbitrary or unjustifiable discrimination between Members or as a disguised

120. Appellate Body Report, *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R (Feb. 16, 2001); Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, WT/DS48/AB/R (Jan. 16, 1998).

121. Appellate Body Report, *Canada - Continued Suspension of Obligations in the EC - Hormones Dispute*, WT/DS321/AB/R (Oct. 16, 2008).

122. Annex A of the SPS Agreement provides the following definition of "international standards, guidelines and recommendations":

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
- (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

The WHO would qualify under paragraph (d) if so identified by the Committee. Jackson, *supra* note 117, at 129.

123. *Id.* at 123.

124. *Id.* at 123-24.

restriction on international trade.¹²⁵ An SPS measure must be sufficiently supported or warranted by a risk assessment, which may be conducted by the WTO Member in question, another WTO Member or an international organization.¹²⁶ The chosen level of protection must not affect the rigor or objective nature of the risk assessment, which must evaluate possible adverse effects using scientific methods.¹²⁷ Finally, under both GATT Article XX(b) and SPS Agreement Article 2.3, health measures must not be applied in a manner that results in discrimination or a disguised restriction on international trade.¹²⁸ While it is not clear whether the countries that imposed trade restrictions did so following a risk assessment that would meet the requirements of the SPS Agreement, the discrimination between pork imports from Mexico and other countries affected by H1N1(09) might be justifiable on the basis that the mortality and severity of the epidemic in Mexico is greater and the evidence indicated that the virus originated in Mexico.

Continued discrimination between Mexican products and products from other countries could fail the test of the Article XX chapeau once it became apparent that the risk in other countries was comparable to the situation in Mexico. In other words, as long as the same conditions prevail in the different countries with respect to the level of risk, the discrimination would be arbitrary and unjustifiable.

In most cases, health measures will be regulated by both the GATT and the SPS Agreement. The Agreement on Technical Barriers to Trade (TBT Agreement) does not apply to SPS measures.¹²⁹ However, extraterritorial health measures, which are aimed at protecting health outside the jurisdiction of the country that enacts the measure, could fall under the ambit of the TBT Agreement.¹³⁰ The Preamble of the TBT Agreement also allows each WTO Member to determine the level of protection it considers appropriate.¹³¹ Article 2.2 only requires a consideration of "available scientific and technical information."¹³² Since the TBT Agreement does not explicitly regulate risk assessment or require scientific bases for regulations, the implicit requirement for some scientific basis should be less rigorous than the explicit requirements of the SPS Agreement.¹³³ However, TBT Agreement Article 2.5 creates a rebuttable presumption of compliance with Article

125. *Id.* at 122.

126. Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, WT/DS48/AB/R (Jan. 16, 1998).

127. *Id.*

128. Jackson, *supra* note 117, at 122.

129. *Id.* at 150.

130. Marceau & Trachtman, *supra* note 119.

131. Jackson, *supra* note 117, at 149.

132. *Id.* at 150.

133. *Id.*

2.2 where a technical regulation aimed at health protection is in accordance with relevant international standards.¹³⁴ Moreover, under Article 2.2, the analysis of whether a technical regulation is more trade-restrictive than necessary to fulfill a legitimate objective will be very similar to the analysis under GATT Article XX(b).¹³⁵

It may be difficult for WTO Members to justify trade restrictions on products where there is insufficient scientific evidence that the product poses a risk to human health¹³⁶ or when the trade measures will not address the risk.¹³⁷ However, the IHR 2005 (like the IHR 1969) does not seriously deter countries from implementing trade restrictions that do not have a solid scientific basis. While the WTO provides the real disciplines in this context, the WTO process does not work quickly enough because countries can enact harsh temporary measures, keep them in place while the crisis lasts, and remove them before any serious WTO dispute settlement remedy can be secured.

Once an outbreak of an infectious disease has been reported, the affected country might have an incentive to comply with WHO recommendations regarding appropriate responses, in order to minimize the risk of disproportionate responses on the part of other countries. The WHO's assessment of the public health risk and the appropriate measures to take will carry more weight than the affected country's assessment of the situation. Failure to comply with WHO recommendations, or under compliance, could have a negative impact not only on the protection of its citizens but also on the affected country's effort to persuade other countries to avoid imposing trade and travel restrictions. Given the economic and political incentives, there is probably no need to make compliance with WHO recommendations mandatory as far as they apply to the affected country. The key obligation is to report the outbreak, at which point the risk of negative economic consequences becomes real.

It would be redundant for the IHR (2005) to provide enforceable legal obligations to regulate the use of disproportionate trade restrictions in response to a reported outbreak, since those obligations are addressed in WTO law. The key role of the WHO in this regard is to provide an objective risk assessment and to make recommendations regarding appropriate responses based on scientific evidence, both of which are provided for in the IHR (2005). The WHO's determinations on these issues may be relevant to determine whether trade-restrictive health

134. *Id.* at 123-24.

135. *Id.* at 45.

136. Appellate Body Report, *European Communities - Measures Concerning Meat and Meat Products (Hormones)*, WT/DS48/AB/R (Jan. 16, 1998).

137. GATT Panel Report, *Thailand - Restrictions on Importation of and Internal Taxes on Cigarettes*, DS10/R-37S/200 (Nov. 7, 1990).

measures can be justified under the general exceptions of GATT Article XX (b) or permitted under the SPS Agreement or the TBT Agreement.

When countries impose unjustified trade restrictions it may take a few years to resolve the matter through the dispute settlement system of the WTO, by which point the economic damage has already occurred. In the age of internet, email and mobile telephones, it has become difficult for countries to suppress information about outbreaks of disease. The use of disproportionate trade measures in response to outbreaks of infectious diseases undermine international health protection by discouraging reporting of such outbreaks and undermining incentives to comply with WHO recommendations under the IHR (2005). Global Health Law and World Trade Law can and should be mutually supportive. However, the formal dispute settlement system of the WTO is unlikely to be effective in addressing this issue. Rather, disproportionate trade restrictions will have to be addressed in negotiations in which countries are persuaded that it is in the best interests of all countries to comply with the existing legal framework in order to ensure that both the multilateral trade system and multilateral cooperation on world health issues function adequately.

Transparency needs to be encouraged (and discriminatory and excessive trade and travel restrictions discouraged) in the interests of public health. For example, information regarding the behavior of (H1N1) in the Southern Hemisphere winter is important to determining whether a vaccine is necessary, according to the WHO. In an effort to determine how this virus might behave in the next Northern Hemisphere winter, the CDC negotiated with the Pan American Health Organization and health ministries in Latin America and other Southern Hemisphere countries to monitor the virus during their winter flu season. If countries perceive that they will suffer from more severe trade and travel restrictions the more transparent they are, this will discourage the sharing of vital information.

VII. CONCLUSION

Accelerating globalization has changed the context in which the WHO works, and has hastened the spread of infectious diseases. Moreover, the multiplicity of players involved in tackling global health issues has increased the need for global leadership to convene and coordinate activities related to international health. In the wake of the SARS epidemic, the IHR (2005) provided for binding obligations (reporting outbreaks) and non-binding recommendations from the WHO. In addition, the WHO studied best practices regarding communication strategies during an outbreak. Many countries used past

experiences with pandemics to prepare pandemic plans, including Mexico and the United States. All of these developments were put to the test in the H1N1 (09) epidemic. As a result, the experience with that epidemic is a source of valuable information on how to continue improving national and global responses to public health threats of international concern.

The lack of financial assistance to help many developing countries build their required core surveillance and response capabilities under the IHR (2005) is an important gap in pandemic preparedness. The A/H1N1 outbreak highlighted the difficulties that can arise in rapidly detecting public health threats, even in a middle-income country like Mexico or a wealthy country like the United States, both of which had engaged in intense international cooperation and preparation for such an event. In addition, this outbreak revealed an asymmetrical application of travel and trade restrictions between Mexico and the United States.

In our view, Mexico was singled out for more numerous and more severe treatment for all the wrong reasons. Mexico reported the outbreaks and determined the seriousness of the threat as quickly as the United States. Mexico applied mitigation measures more quickly and more broadly than any other country. Mexico communicated its actions and all of the latest developments honestly and transparently. Mexico's exemplary treatment of this outbreak limited the spread of the virus both within Mexico and internationally. The disproportionate response of several countries to Mexico's response may well discourage other countries from acting so quickly, effectively and transparently in future disease outbreaks, to the detriment of all countries.

The lack of any effective recourse under either the IHR (2005) or the WTO compounds the problem of disproportionate and asymmetrical travel and trade restrictions and creates disincentives to report outbreaks and deal with them in a transparent and decisive manner. This is of particular concern in view of the importance of rapid and transparent responses to disease outbreaks and suggests a need for increased attention to the issue of such travel and trade restrictions on the part of both the WHO and the WTO. Finding ways to avoid such inappropriate responses should also form part of the pandemic preparation process at the national level.

TOO BIG TO FAIL – TOO SMALL TO COMPETE: SYSTEMIC RISK SHOULD BE ADDRESSED THROUGH ANTITRUST LAW BUT SUCH A SOLUTION WILL ONLY WORK IF IT IS APPLIED ON AN INTERNATIONAL BASIS

Sharon E. Foster*

I.	INTRODUCTION	32
II.	THE FINANCIAL SERVICES REGULATORY CYCLE: FROM REGULATION TO DE FACTO DEREGULATION TO DE JURE DEREGULATION AND BACK AGAIN.....	36
A.	<i>The Definitional Problem</i>	36
B.	<i>The Regulatory Cycle Begins</i>	37
C.	<i>The Beginning of the Deregulation Cycle</i>	39
D.	<i>The De Facto Deregulatory Cycle</i>	41
E.	<i>More Foreign Deregulation – The European Union's Second Banking Directive</i>	43
F.	<i>De Facto Deregulation Accelerates in the United States</i>	45
G.	<i>De Jure Deregulation</i>	47
H.	<i>The Financial Crisis Starting in 2007 Leads to Re-Regulation</i>	48
III.	THE ANTIDOTE TO TOO BIG TO FAIL IS ANTITRUST	50
A.	<i>Financial Service Firms are not Exempt from Antitrust Laws</i>	50
B.	<i>The Origins of Too Big to Fail</i>	51
C.	<i>Systemic Risk Analysis</i>	52
D.	<i>Will Systemic Risk Analysis Work in an Antitrust Context?</i>	53
E.	<i>Systemic Risk Analysis and Sherman § 2</i>	53
F.	<i>Too Big to Fail and Monopoly Power</i>	54
G.	<i>Systemic Risk Analysis Allows for Price Control</i>	55
H.	<i>A Too Big to Fail Firm May Eliminate its Competitors</i>	56
I.	<i>Mergers Under Clayton § 7 and Too Big to Fail</i>	57
J.	<i>Systemic Risk Analysis</i>	59

* Associate Professor, University of Arkansas School of Law. The Author would like to thank the University of Arkansas School of Law for its grant support.