

INTERNATIONAL BAR ASSOCIATION

Annual Meeting

ANTHRAX, SARS AND BIOWEAPONRY
Is Globalisation Bad for Your Health?

Wednesday, September 28, 2005

**HOW GLOBALISATION IS GOOD FOR YOUR HEALTH: THE
REVISION OF THE INTERNATIONAL HEALTH REGULATIONS**

An Address by David Byrne SC

International Bar Association 2005 Annual Conference, Prague

Wednesday, 28 September 2005

Introduction

Members of the IBA,

Esteemed guests and colleagues,

Mr. Chairman, Ladies and Gentlemen,

I would like to begin by expressing my pleasure at being here with you today in Prague, in the centre of a rapidly changing Europe, on the occasion of the 2005 annual conference of the International Bar Association. I wish to thank the IBA for hosting today's event and for recognising the role of the international lawyer in the area of public health. I would especially like to compliment the Medicine and Law Committee on compiling a programme of such immediate importance and topicality, which aims to bring attention to the public health risks associated with globalisation while highlighting the legal responses aimed to protect citizens and societies from emerging infectious diseases and bioterrorism. I feel extremely honoured to have the opportunity to share the podium with such a distinguished list of guest speakers, each of whom has dedicated their career to this subject.

Prague seems to me to present a particularly suitable location for today's discussion. The fact that we are meeting here close to the medieval square of *Hradcany Namesti*, with its central column designed by Ferdinand Brokoff in 1726 to commemorate Prague's struggle against the plague speaks to us all about the continuing relevance of today's topic.

This meeting offers an opportunity to examine visions and challenges for the future of international public health regulation. In many ways, the revised WHO International Health Regulations (IHR) can be seen as a revolutionary development. Having served as the special envoy of the DG of the WHO for the adoption of these regulations, I would now like to outline to you a few personal reflections and policy proposals arising from my own direct involvement in the drafting process.

The Health of Nations: Germs, Globalisation and Global Health Governance

This is an extremely exciting and challenging time for public health. There is a growing awareness that public health is no longer just a national issue, but an international one. Because a healthy population is an essential factor in economic development, the public health effects of globalization – positive and negative – have become increasingly important concerns. Therefore, globalization calls for a global approach to public health.

As a result of unprecedented population growth and an exponential increase in cross-border trade and travel, public health emergencies develop and spread more quickly in today's global village than ever before. Bacteria and viruses travel almost as fast as e-mail messages and money flows. On the other hand, advances in medicine and scientific progress also mean that information and solutions can also be communicated faster and further than before.

Recent crises in public health, particularly the outbreak of SARS in Asia and the epidemic of avian influenza, as well as the deliberate use of disease as an instrument of terror, have elevated the importance of international health co-operation. SARS showed how a deadly and poorly understood new disease can adversely affect trade, tourism and business markets. Meanwhile, the anthrax attacks in the U.S. in 2001 focused attention on the fact that after public security, perhaps the next most important thing is the protection of public health. Indeed, public health is now recognised as a global security concern.

Most recently, the public health emergency declared in the aftermath of Hurricane Katrina should serve as a salient reminder that tragedy can strike anytime and anywhere. Even a wealthy and resourceful nation like the U.S. is showing itself badly organised to deal with the immediate impacts. Not only is the hurricane in New Orleans a tragic human disaster, it is also an important economic story. And there may also be lasting political costs.

If citizens feel that political leadership is not addressing these issues properly, or is failing to protect them, disease can be very dangerous politically. After all, the health of our politics will be judged by the politics of health. My own judgment is that greater political and economic investment in public health saves time and money in the long run.

Is There a Lawyer in the House?

But what is the role of the law maker in all of this? Having spent 30 years in Irish and EU courts, I hope I can bring a legal perspective to the politics of global public health

The power of the law continues to amaze public health practitioners. Health issues have provided the substance for several definitive episodes of legal globalization: SARS, access to AIDS therapies, the global market in human organs, third world drug trials, international tobacco control. As a former EU Commissioner for Public Health, I saw how long scientists and practitioners had been campaigning against the use of tobacco products. Then the lawyers got involved and everything changed. In the U.S., the lawyers led the way by litigation. In Europe, the politicians took the lead, employing the law as their tool. We now have a comprehensive body of European legislation on the sale, marketing and advertising of tobacco products. And momentum is growing right across Europe for the introduction of smoking bans in work and public places.

Of course, the law cannot guarantee public health, but it can certainly operate as a creative catalyst. Law can also serve as an important and influential instrument to support the management of a public health emergency. The U.S. CDC Institute of Public Health Law, under the guidance of Gene Matthews, has done some excellent work in this area and I am happy to have been associated with their efforts. I believe that this is the way forward.

The more the world economic order globalizes, the more we require a global legal order. The increase in trade, particularly in food, and in travel requires a concerted legal and public health response. As you are aware, trade already enjoys an international legal

regime, governed by the WTO, and travel is beginning to develop its own set of legal rules, notably within the E.U. Now I would like to take this opportunity to set out how the WHO is attempting to establish a robust international legal regime in the area of public health through the revised International Health Regulations.

Regulating Risk: The Revision of the International Health Regulations

revised International Health Regulations (IHR) were adopted at the World Health Assembly in May 2005 and are expected to enter into force on 15 June 2007. . The purpose and scope of these regulations are 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 (Article 2). From a public health perspective, the new Regulations represent a considerable strengthening of national and international abilities to protect the health of populations.

The key elements of the IHR revision include better surveillance, increased transparency and a more rapid response – three fundamental requirements in handling any outbreak of communicable disease. Today's newly drafted regulations are also much more broad and flexible in scope, to meet the public health perils of a globalized world.

My task as the special envoy of the DG of the WHO was to concentrate on building a political consensus during the drafting process. As I mentioned earlier, I have been an EU Commissioner for Public Health - in the EU, we're used to the concept of pooling sovereignty to enable something to be done for the benefit of all. The world's health problems are shared problems and are therefore best tackled by sharing solutions. Of course, the revised IHR cannot hope to meet the expectations of everyone, but it certainly represents a better compromise than the status quo. While the negotiations surrounding the wording of the IHR may have been difficult, I believe the big issues that needed to be addressed were addressed.

The IHR date back in concept to the mid-nineteenth century, when cholera epidemics overran Europe. This paved the way for intensive disease diplomacy and multilateral cooperation. In 1969, the first modern version of the IHR was drafted by the Member States of the WHO to monitor and control a handful of serious infections. In subsequent decades, as new and re-emerging diseases were identified, it became clear that the regulations were dangerously limited in scope. In 1995, the World Health Assembly instructed the WHO Secretariat to begin the process of revising the IHR in the realization that the IHR no longer provided an adequate international legal framework to deal with the mounting microbial threats.

Making Sense of SARS

In 2003, the SARS epidemic quickly accelerated the IHR revision process. When the epidemic exploded out of China, only cholera, plague, and yellow fever were officially notifiable diseases. The revised IHR have been redesigned to broaden the disease coverage; to increase sensitivity for outbreak detection; and to provide guidance on more effective control measures.

It is often cited that the Chinese character for "crisis" is comprised of two symbols; one signifying "danger", the other "opportunity". Similarly, the SARS outbreak can be viewed as both a global health crisis and a blessing in disguise, sounding a short, sharp shock to the public health community. SARS showed that in today's mobile and interconnected world, infectious diseases can emerge and 'super spread' with deadly and debilitating effects. But it also showed that they can be successfully stopped.

The response to SARS demonstrated some of the positive features of a globalized society: the advantages of rapid information and communications technologies for emergency response, and the willingness of the international community to form a united front against a common threat. Of course, it's tragic that so many people had to die for us to learn this lesson – and the lesson is that if the revised IHR had been in effect at that

time, SARS would not have spread as far and as fast. The possibility, opened by SARS, that emerging diseases might be stopped has given the roles of national and international surveillance for epidemic-prone diseases even greater importance.

Scope of the Revised IHR: From Specific Infectious Diseases to Public Health Risks

The revised IHR breaks radically with the traditional approach in a number of respects. Firstly, the revised IHR abandons a disease-specific approach for a more flexible strategy based on “public health risks”. These are defined as “a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger” (Article 1.2). The new approach is preferable because it is flexible, future-oriented, and covers all hazards (radio-nuclear, chemical, and biological).

We can all see that the current crisis in public health includes natural, accidental and intentional threats. Context and cause are less important than the common denominator of biological effect. While the sources may be different in each case, the effects on public are essentially the same and require similar rules and responses. Boosting capacity for disease surveillance is key to detecting all disease – whether created by nature, or by humans.

Biodefense, Biosecurity and Bioterrorism

While practitioners and policy makers view diseases like SARS as a threat to public health, bioterrorists may see them as weapons of opportunity. Many infectious diseases have become a ‘security’ issue, bringing a new set of partners to the public health table. While this arrangement is appropriate and necessary in many cases, it also includes the potential for abuse, by promoting anxiety and insecurity for political means and distorting public health priorities.

Concerns about a growing ‘militarization of medicine’ and a disproportionate funding of the prevention of bioterrorism have been building for some time. Most recently, the

dangers of diverting public health funding to national security can be seen in the response to Hurricane Katrina – from now on, the wisdom of bundling disaster relief with counter-terrorism efforts must be seriously questioned.

These observations are not intended to diminish the tragedies of terrorist actions, nor to negate the importance of developing effective ways of making sure such tragedies are not repeated. It is certainly justifiable for governments to appropriate substantial funds to prevent potential future threats to national security. But public funding for the prevention of other threats to public health should not be compromised. Predictable tragedies happen every day.

Perhaps the best solution to combating bioterrorism may be through existing public health channels, but with new action plans and strategies. This approach is consistent with the view that bioterrorism is on a continuum with traditional public health threats, and does not pose risks significantly in excess of natural disease outbreaks. Bioterrorism is therefore only a special case of a public health emergency.

But while there is a clear risk of being ‘blinded by bioterrorism’ and any over-concentration of resources, we must also be aware of the opportunities. Jumping on the ‘bioterrorism bandwagon’ can also offer a number of potential benefits for public health. Many experts perceive that the pathologies of fear induced by bioterrorism could bring greater institutional interest and investment to neglected national health systems.

However, creating the necessary synergies to address the different types of disease threats will require that the institutions responsible for public health, national security and disaster management develop a partnership of equals. Enhancing communication between the many agencies involved remains both a challenge and an opportunity for future efforts.

Capacity-Building, Surveillance and Notification

The revised IHR proposes a significant expansion in the scope of surveillance and notification duties. The purpose of these is to ensure maximum security against the international spread of disease with minimum interference to global traffic and trade.

Successful implementation of the IHR will depend on capacity-building in each country at all levels. Members of the WHO are now obliged to develop, strengthen and maintain the capacity to detect, assess, notify and report events potentially constituting public health emergencies of international concern (Art.s 5.1, 13 and Annex 1).

Member States must notify the WHO of all serious disease threats and potential international emergencies (Art.6 and 7). They must meet standards for national disease surveillance and response. And they must assign a representative to the epicentre of any fast-shifting emergency, to mediate communication between national and international authorities. No such intrusive duties appeared in the traditional international law on infectious disease control.

Although the IHR does not include a sanctions regime *per se* for States which fail to comply with its provisions, the potential consequences of non-compliance, especially in economic terms, will function as a powerful compliance tool.

An important and perhaps core provision of the convention is that the WHO can request a Member State to provide verification of a public health emergency where the WHO suspects that such exists (Art. 10). The WHO is required to offer collaboration to deal with the outbreak (Art. 10.3, Art. 13.3 and 13.4). In the event of a failure or refusal of collaboration, the WHO is empowered to make all relevant information available to Member States, particularly neighbouring states, and ultimately to the public (Art. 10.4).

In such an eventuality, the consequences are obvious to both travel and trade, especially in food. But by working together with WHO to control either a public health event or the

perception of a public health risk by other States or their populations, an affected State insures itself against the possibility of unilateral trade or travel restrictions being adopted.

And the revised IHR will also allow the WHO to take into account reports from sources other than notifications from States and WHO consultations, e.g. reports from N.G.O.s (Article 9). This provision represents a radical break from the traditional approach under which surveillance efforts were restricted to information provided only by governments.

These new rules were needed – to bring clarity, transparency and certainty to the situation. In the future, the revised IHR should substantially reduce the risk of countries failing to disclose the existence of SARS or avian influenza as has been the case in more than one WHO Member State in recent years

Ensuring Confidence and Compliance

Of course, the most important incentive for compliance is that the IHR have been drafted by the Member States for their own mutual benefit. Since infectious diseases potentially threaten every country, it is in every country's best interest to collaborate internationally. Experience in recent years, especially with SARS and avian influenza, has taught Member States and the WHO a great deal about how to work together to prevent and contain outbreaks. The revisions in the Regulations reflect that experience.

Nevertheless, there are political realities involved in this. I know there are people who are more concerned about security and who are perhaps overly protective of their information. But in fact, they could often give more information relevant to public health without compromising on security considerations. Nobody wants the WHO – nor does the WHO itself want – to have access to information that may be of a sensitive or high-security nature unless it is relevant to the public health demands of the work it has to do.

Let me give you an example. We know that, for instance, in Canada, particularly Toronto, there was an outbreak of SARS that was very serious, many people died, and the economy was extremely badly affected. In Europe, that didn't happen. Anybody who

died in Europe – and there was only a very small number – contracted the disease outside of Europe. Europe got those extra couple of days warning as to how the disease was transmitted, and how the health community could protect itself. In Canada, by contrast, the health community didn't know what the disease was, didn't know it was transmitted by droplets, and didn't know that they would then transmit the infection on into the community. The lack of transparency that existed in some parts of Southeast Asia, with China delaying notification of the disease to the WHO, was an important factor. SARS provided a clear example of how ideology and politics can interfere with public health protection. Since SARS, serious questions have been raised regarding the handling of crisis communication.

The microbial world is mysterious and threatening and frightening to many people. Sometimes fear is worse than the disease, and fear drives fear. Addressing these perceptions is a necessary part of planning for infectious biological disasters. It was fear that encouraged the stigmatization of businesses, ethnic groups, and geographic locations where SARS appeared. The best remedy for fear is timely, accurate, and practical information provided in a coordinated fashion. We must fight fear with facts. In this case, Europe was lucky and Canada was unlucky. Information is what's important to improve your luck. And if information is inadequately transmitted then your luck may run out. That's what happened in 2003. Hopefully it will not happen again with the new IHR in place.

Of course there are also important sovereignty issues - I don't say that in any critical way – especially regarding countries that are in development and therefore feel they haven't yet found their feet. During one plenary session of the IHR, a senior official from one Member State stated that for him sovereignty was more important than health! Here the IHR confronts a fundamental paradox: while globalization threatens sovereignty with the spread of disease across borders, sovereignty threatens to frustrate efforts towards a strong public health protection. But in today's interconnected world, there is no choice. Sovereign frontiers are political, not natural, barriers that do not effectively prevent the international spread of infection.

And of course, Governments will want to look after their own populations first. I remember having discussions at EU level in relation to vaccines. There was a view expressed that countries are better placed to contribute to the shortfall in other countries when their own needs have first been dealt with. That might initially sound somewhat selfish, but given the political process, it would be extremely difficult for a government in any Member State not to have the resources and vaccines available to protect its own population – the population just would not understand that, would not forgive that. However, Governments should make resources available to enable the WHO to build up an increased emergency stockpile of vaccines to be deployed at short notice to deal with outbreaks of infectious disease.

How will WHO Member States benefit from the IHR?

To summarize, by adopting the IHR, Member States will benefit from:

- guidance in building the core capacities necessary to quickly report, assess and respond to public health risks and public health emergencies of international concern
- guidance during the outbreak verification process, including the management of sensitive information in emergency situations
- outbreak containment advice where necessary
- a framework for joint risk assessment and coordinated risk communication, as well as for containment and control actions during emergencies.

The revised IHR should serve as an up-to-date and innovative framework for global surveillance of, and response to the threat of infectious diseases, bioterrorism and other public health emergencies of international concern. They should enable a public health response which protects the health of all, and crosses borders as easily as SARS or a strain of avian influenza.

Conclusion: Global Health Governance - Globalisation is Good for your Health

All in all, the issues brought into focus by today's session are timely and hugely relevant. The picture is not entirely bleak. Epidemics grow when a disease outbreak is amplified - and controlling the amplifiers of disease is within our power; it's a matter of people, resources and political will.

There is one medicine that helps stem the tide of every disease, old or new, easily treated or drug-resistant. That medicine is international cooperation. Concern for health transcends governments, cultures, language and political divisions. We must look at public health as a global common good – that's the only way to keep globalization from becoming really unhealthy.

My key recommendations include the need for higher prioritization of public health at both national and international levels, greater funding, and a reinforcement of the powers of international institutions such as the WHO.

The revised IHR provide a new model of global health governance and an overarching set of international rules. However, as that great Czech statesman, Vaclav Havel, once said, "vision is not enough, it must be combined with venture." These new rules must be internalized in domestic policy implementation in order to be effective in realizing global public health objectives. The establishment of an effective international monitoring mechanism that ensures compliance with international health law in close liaison with a variety of actors (specialized agencies, NGOs and national health administrations) will strongly support this process.

However, I believe that the WHO is not funded sufficiently well. Health is too often seen as a cost rather than an investment. But the cost of not investing in effective public health is becoming increasingly obvious, as the case of SARS has conclusively demonstrated. And the returns on investment in public health can be potentially huge as effective disease prevention and health promotion greatly ease the pressure on providing medical

treatment. As the old familiar saying goes, “an ounce of prevention is worth a pound of cure.”

I am also of the opinion that the WHO doesn’t enjoy enough support. WHO is an organization that does its work quietly, efficiently, and at an extraordinarily high level of expertise. And sometimes in life those who are self-effacing don’t always receive the credit they deserve. For example, it was predicted that the Tsunami would create a public health disaster. This didn’t happen. The reason it didn’t happen was because experts in the field, particularly those led by the WHO, performed an excellent job. The core paradox in public health is that when public health is working well, the public does not have to worry and political pressure to commit resources is reduced. But success should not be self-defeating and it is for those of us who recognize the value of the work of organizations like the WHO to step up to the plate and ensure that they are fully supported and resourced.

And I believe that the Secretariat of the WHO should be given an enhanced status and authority. It should also enjoy a more defined role in the negotiation of international conventions. Currently, negotiation takes place between 192 Member States and things move along at a painstaking pace. Perhaps we can find inspiration in the present proposals to reform the United Nations’ structure, particularly the suggestion by the U.S. to cede executive control from the General Assembly to the Secretariat, but with tighter oversight and auditing.

There is an old proverb, “He who has health has hope, and he who has hope has everything”. But hope does not ensure delivery. It makes better sense to be prepared. While pandemics have caused peril and panic several times in the recent past, never before now have we had so many tools to respond to the threat of globalized diseases.

Never before have we possessed such a wealth of knowledge, never before have we benefited from such a level of expertise, and never before have we established such a comprehensive international legal framework to protect against future threats to global

public health. The challenge is immense, but so is our will and our ability. Let us never forget that our lives, and the lives of thousands of others, may depend on us getting it right, and doing it quickly.

Thank you for your kind attention.