

American Bar Association
Moderator: Jonathan Todres
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{Transcript has been edited for clarity.}

OPERATOR: Good afternoon, ladies and gentlemen. My name is Ian, and I'll be your conference facilitator today.

At this time I would like to welcome everyone to the ABA section of International Law, What the Global Business Community Needs to Know About the New International Health Regulations.

At this time all lines have been placed on mute to prevent any background noise. After the speakers' remarks there'll be a question-and-answer period. If you would like to ask a question during this time, please press star, then the number one on your telephone keypad. If you would like to withdraw your question, please press the pound key.

Thank you.

It is now my pleasure to turn the floor over to your host, Mr. Jonathan Todres, Chairman of International Health Committee. Sir, you may begin your conference.

JONATHAN TODRES, CHAIRMAN, INTERNATIONAL HEALTH LAW COMMITTEE: Thank you and good afternoon.

My name is Jonathan Todres and I'm chair of the International Health Law Committee of the ABA section of International Law. I'd like to thank each of you for joining our teleconference today.

Together with our co-sponsor, the Public Health Law Association, we've organized this panel presentation with the hope of reaching out to the private sector, their counsel, as well as government entities that work regularly with the private sector to discuss some of the key issues that have emerged out of the new International Health Regulations and the growing concern over avian influenza and other infectious diseases, bioterrorism issues, as well as other threats to the public health.

We have an outstanding group of speakers today, so I'll only say a few brief comments by way of introduction, and then I'll briefly introduce each speaker in turn.

As some of you may already know, the new IHR, International Health Regulations, were adopted in May 2005. It was the first significant revision to the regulations in over 30 years. Though a revised draft had been in the works, many agree that the SARS outbreak of 2003, which infected individuals in more than 25 countries and cost the global economy billions of dollars, certainly added additional impetus for the revision.

The SARS experience clearly highlighted the need to strengthen the international community's public health preparedness. And the new IHR are a significant step in that direction.

As the regulations state themselves, their purpose is to 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.

This balancing is certainly one of the key challenges and also understandably one of the areas of particular relevance to the private sector. Accordingly, we've organized today's teleconference to explore some of the implications of public health development for the private sector and are delighted to have our distinguished speakers joining us today.

We've allocated time at the time end for questions. So, without any further delay, I'd like to introduce our first speaker, Dr. Marty Cetron.

Dr. Cetron is director of the Division of Global Migration and Quarantine at the U.S. Centers for Disease Control and Prevention. The division's mission is to prevent reproduction and spread of infectious diseases into the United States and prevent morbidity and mortality among immigrants, refugees, migrant workers and international travelers. Dr. Cetron has a wealth of experience. He holds faculty appointments at Emory University and at the School of Medicine and the Rawlins School of Public Health. He's worked at the CDC since 1992 and has played a leadership role in the CDC's responses to intentional and naturally acquired emerging infectious disease outbreaks, including anthrax, bioterrorism incidence, the SARS epidemic, and the U.S. monkey pox outbreak. He is also a part of the CDC Pandemic Influenza Planning and Preparedness team. We are delighted to have him here today. So, I'll turn the microphone over to Marty Cetron at this point.

MARTY CETRON, DIRECTOR OF DIVISION OF GLOBAL MIGRATION AND QUARANTINE, U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION: Thank you, Jonathan.

And let me start out by thanking you for the invitation and the opportunity to present to this group, but also let the group know that the slides are posted for participants who would like to go through these as well.

Let me just check and see if I'm coming across clearly. And I suppose there's a means by which the muted folks on the other end of the line can signal us if I'm not. I'm using a speakerphone here.

I'm going to start with a little bit of a context in terms of the IHRs and then about halfway through move into the topic I think that's on everybody's mind right now, is the pandemic influenza issues. But I'm going to try to tie these two things together, one giving a more concrete example of how the revision might apply.

So, what are the International Health Regulations? In fact, this revision has been going on for 10 years. Some of us have been part of it for most of that time. But most intensively post 2003 there's been really significant investments in time and energy, not just by the public health sector globally but in fact by all sectors of governments and member states that are participating, and the previous year involved an intensive intergovernmental process of negotiation through formal capital involvement.

The IHRs are a binding international agreement. And, in fact, these IHRs, indistinct with some in the past, were the language was specifically developed by member states of the World Health Organization through an intergovernmental process of negotiation. They were adopted by the World Health Assembly, as previous versions have been. And really this represents the first substantive change since 1969 or more than 30 years – 40 years since the previous IHRs were in process.

They were adopted in May of 2005. They're scheduled for implementation into force in two years in 2007. There is some indication from a recent meeting I attended in Geneva that that may be accelerated for voluntary adoption as it applies to pandemic influenza. This will be discussed at upcoming meetings at WHO.

These IHRs are really a wholesale substantive revision of the 1969 document. And I'll give you on the third slide that you have basically the areas where the proposed changes are dramatically significant. One of them is in the scope. This document talks about a scope that defines public health emergencies of international concern. And these are articulated in an algorithm in annex two that I will show you later.

But the scope of the '69 IHRs is really limited to infectious disease and, specifically, three infectious diseases of international concern – cholera, yellow fever and plague. This takes an all hazards approach, whether it's biologic, chemical, radiation, whether it's accidental, intentional or naturally caused. And that is that scope changes a significant difference from previous versions.

This also has an enhanced event management component. An epidemic alert and response component are key aspects of the new IHRs that are well articulated and, in fact, reflect a lot of the ways that WHO and member states behaved to the international SARS epidemic in 2003.

A third major point that really distinguishes it or enhances it from previous versions is the definition of core capacities, a set of expectations of member states who sign on to developing a minimum core set of surveillance and response capacities. And these are articulated most clearly in annex one of the document.

There's also a revised set of technical guidelines that expand the types of health measures that may be used both at ports of entry as well as on conveyances, be they sea ship or land conveyances that are crossing between international borders. And these technical guidelines are going to be issued as an accompaniment to the actual IHR itself. So, there'll be sanitation measures for aviation. And these are worked on through international trade associations like IATA and ICAO. And there will be international guides to ship sanitation as well as routine measures and guidance for the maintenance of sanitary facilities at ports of entry.

Finally, a significant area that's different in this IHR is the very specific articulation of technical assistance that's provided to member states. This is the carrot as opposed to the stick where IHRs in the past have been seen as a responsibility to report and to provide floor and ceiling limitations on the nature of response. But in fact some of these reporting were followed by consequences of actions – restrictive actions. And so, there wasn't really a carrot that went along with this. So, the carrot here is the promise of technical assistance to member states.

The diseases mentioned – again, it's an all hazards approach. There are automatic reporting for Category A diseases – smallpox, polio, human influenza of a new subtype, re-emerging SARS, re-emerging pandemic influenza and SARS. There also is a B list of diseases that are regionally defined, and they're listed on your slide – cholera, plague, yellow fever, viral hemorrhagic fevers, West Nile, as regionally appropriate.

But the real change in this all hazards approach is an algorithm that defines public health emergencies of international concern. And although you can't see the details of the schematic, it basically walks member states through a series of questions. Is the public health impact serious? Is it unusual or unexpected? Is there a significant risk of international spread? And is there a risk that international restrictions would follow as a containment measure to deal with this event?

In reality, if you answer yes to any of those four above questions you would end up as a country with a public health reporting responsibility for that event as a public health emergency of international concern.

The hot issue that came up during the intergovernmental negotiation process some of these can be expected. Universal applicability really applies to the ability to have the IHR enforce for non-WHO member states. In some cases this is for areas which have no significant government or are in significant turmoil. In some cases these are politically controversial territorial regions such as the relationship between Taiwan and mainland China. Many of you know that Taiwan is not an independent member state with access to WHO, but universal applicability is intended to provide a broader application to those beyond the member states of WHO.

The chemical, biological and radiologic issue and the next one, deliberate release, were very hotly debated topics in the language in the actual document, making less explicit than I've alluded to here, but that is what resulted from a consensus discussion. And it is meant to cover all of these emergencies.

Another very hot topic was whether the sovereign member states would have the ability to apply additional health measures beyond those specified in the document. And it was something that in the intergovernmental process was felt very strongly by member states that they needed to do this when WHO did not make a recommendation that sufficiently protected their sovereign interest, the ability to apply additional measures. That is, to go above the ceiling, as previously defined in the 69 IHRs, is in this document. However, justification and rationalization and scientific validity for going beyond

recommended measures needs to be defined through the process in order to do that. So, you can exceed the ceiling, but you have to have good reason to do it.

The process by which you could express reservation to individual articles was also hotly contested. Nobody wanted to see this public health document watered down as a sort of Chinese menu – we adhere to just those articles we like and ignore those we don't. And so, there was a higher bar set at defining the appropriate reservations.

Another difficult topic that was dealt with, which is very relevant to the United States, was one of federalism. Many state parties have federalist type systems of government in which it is not an automatic that commitments made by the federal government could be – these could express obligations that would be entered into by individual states, particularly states which have their own reporting responsibilities and so on. But it is intended to be the fact that member state governments have to bring on all their subjurisdictional entities to be obligated under this document.

And finally the issue of how this would apply to movement of armed forces, particularly in security environments, was discussed and addressed. And in the end it was decided that these will apply to all actors of state governments regardless of whether they're armed forces or civilian.

Let me shift gears a second from the broader precepts of the new IHRs, which I've just given you a short flavor of, to some of the contextual applications of this document in a 21st century world.

In the slide in front of you is, I think, a very poignant graphic that I use a lot, which looks at the evolution of the IHRs in the context of movement of the world's population, which has grown exponentially to over six billion and the speed in which we navigate around the globe from 365 days basically to 24 to 72 hours. This dramatic amount of globalization and mixing of populations really gives greater urgency to the need to have a document.

Now let's shift to the WHO stages of a pandemic influenza. The six stages of a pandemic flu are articulated on this line graph. I will say that right now we're probably sitting in pandemic alert phase three or four. There's some debate. WHO puts us at stage three. And that is we've got serious threatening subtype, novel subtype H5N1. But what most of the transmission for these 120 plus cases to date occur animal to human, that is, bird flue, exposures to humans, and very rare or limited instances of human to human transmission.

This effective and efficient human to human transmission sustained is necessary for a pandemic to spread globally. And it's felt by many international experts around the world that because of the mutability of this virus it may not take very much in order for us to see this adaptive change, especially with the co-infection of an H5N1 strain with a normal seasonal human influenza virus and the sharing of those gene types. We could see a mutation of H5N1 to cause sustained and efficient human to human transmission.

The way in which this epidemic will unfold will be determined by the epidemiologic parameters that are on your slide – incubation periods, the symptom profile, the degree of infectiousness, what age groups are affected, the reproductive rate, the number of secondary cases that will arrive from any individual case, and what the predominant modes of transmission will be.

Because of these variables the ranges of responses that one might take at international borders – and all of these responses are in fact enabled and permitted within the context of WHO's new IHR construction – could be very variable. What I show on the box on the left are the types of criteria, the decision-making inputs that would go into choosing the right output response in terms of border control. And they're well described there.

And then the three boxes on the right describe the graded levels of responses that one may take moving to increase in the restrictive compulsory and some would say draconian measures in which travel would either be restricted or halted entirely. I think it's fair to say that nobody will know for sure exactly how this may play out, other than the fact that the more draconian the measures are the more dramatic the impact is on

economic international trade and traffic. And the degree to which the actions have to be justified is much, much greater.

And so, we may see – I think it's more likely that we'll see activities in the first two boxes as more standard types of responses. But the ability to choose tools out of the toolbox from box three is certainly there.

The – I think the most important thing to understand is rather than an old fashioned concept of isolation and quarantine we will be moving into a mode should a pandemic hit either abroad or domestically, a means for increasing social distance. And they're articulated on this slide. I think perhaps the most important one that we're likely to see is targeted against population groups, which amplify viral transmission, particularly school-aged children. And I think it's very reasonable to expect that school closures will be an important part of the containment activities, especially given the inadequate global supply of antivirals as well as inadequate vaccine at the time.

What we hope to gain from these social distance measures at containment is to buy time for the production of antivirals and vaccines and other direct medical countermeasures.

JONATHAN TODRES: Marty, you have about a minute or two.

MARTY CETRON: Thank you. I think I should be wrapping up in one or two slides here.

The concept of moving to a snow day like approach in which the entire society scales back its interactions to a more limited amount of personal contact is very appealing because of its intuitive nature. It leverages instincts for preservation. It can be implemented rapidly and it's something that's understood in a less threatening vein. And I think we could really expect to see this going on both overseas and in the U.S. as a principle control measure.

I think that sort of wraps up the general material that I'd like – that I had wanted to present. And I hope I've given you a flavor of, one, the sort of enabling and permissive natures of the new IHR and the types of activities that we might see going into place were we to see the current epidemic of Avian Influenza escalate and form a pandemic potential with human-to-human spread.

So, why don't I just wrap up there?

JONATHAN TODRES: Thank you very much, Marty.

Next, I would like to introduce David Byrne. David is senior counsel with Wilmer, Cutler, Pickering, Hill & Dorr. He is also particularly well qualified to speak on the new IHR, as he served as the special envoy to the director general of the World Health Organization on the revision of the new regulations. He has also served as attorney general of Ireland and was – in 1999 was appointed the first European commissioner for health and consumer protection, where his responsibilities included a broad range of issues including policy development concerning food safety, public health and consumer protection, as well as Pan-European responses to food crises, health threats such as SARS, and the development of strategy on bioterrorism.

David, I will turn it over to you. We are delighted to have you today.

DAVID BYRNE, SENIOR COUNSEL, WILMER, CUTLER, PICKERING, HILL & DORR: Thank you. Thank you for those words of introduction. And thank you for the invitation to participate in this exercise.

I think it's probably valuable to say that the starting point on any discussion relating to the need for global legal order derives from the fact that the more that the world economic order globalizes the more we require a global legal order. And the increase in trade, particularly in food and travel, requires global public health responses. As we are aware, trade already enjoys an international legal regime governed by the WTO rules, and travel is developing its own set of rules, notably within the European Union and elsewhere.

Now the WHO is attempting through the Revised International Health Regulations to establish a robust international legal regime in the area of public health. And this is the second adventure by the WHO in lawmaking, the first being the framework convention on tobacco control, which came – which became law earlier this year. Even though the World Health Organization has in its constitution since 1948 the power to do this, these are the only two that they have done, but two important pieces of legislation nonetheless.

Now, perhaps it's worthwhile giving some brief history in the sense that the IHR dates 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 diseases.

In subsequent decades as new and reemerging diseases were identified, it became clear that the regulations were dangerously limited in scope. And in 1995 the WHO – the World Health Assembly of the WHO instructed the secretariat to begin the process of revising the IHR and the realization that the IHR no longer provided an adequate international legal framework to deal with these mounting threats.

So, in 2003 the SARS epidemic, which was quickly – quickly accelerated the IHR revision process when the epidemic exploded out of China, only cholera, plague and yellow fever were officially notifiable diseases. Now the IHR have been designed to broaden the disease coverage to increase sensitivity for outbreak detection and to provide guidance on more effective control measures.

The revised IHR were adopted at the World Health Assembly in May of this year, May 2005. And I refer you to slide nine here. The purpose of the regulations is prevention, protection, control and the provision of an effective public health response to the international spread of disease. They must be co-measured with and restricted to public health risks and must avoid unnecessary interference with international traffic and trade. This is set in article two.

The key elements of the IHR demand better surveillance, increased transparency, and a more rapid response mechanism, these I believe to be the three fundamental tools in handling any outbreak of communicable disease. As already indicated, my task as the WHO envoy was to build political consensus during the drafting process. Member states of the European Union are familiar with the concept of pooling of sovereignty or seeding of sovereignty to enable something to be done for the benefit of all, the concept being give a little get a lot.

The task faced at the WHO was to achieve this on a global basis. Mention has already been made of the sovereignty issues arising on this, and particularly the sensitivities that arose in relation to the relationship between China and Taiwan. That was one of the first issues that I was asked to address and did. And I think we've got a satisfactory – we do have a satisfactory outcome to that issue, whereby the one China policy is fully respected, but yet at the same time a mechanism has put in place so that there is absolutely no inhibition on contact between the people in the WHO in Geneva and the people in Taiwan in the event that there is an outbreak of a public health emergency of international concern in Taiwan.

The revised IHR breaks radically with the traditional approach in a number of respects. Firstly, it 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. This is definition set in article one, sub article two.

This new approach is preferable because it is flexible, future-oriented and covers all hazards such as chemical, biological or radio-nuclear. And, indeed, in the negotiations leading up to the final text there was some controversy about the inclusion of radio nuclear and, to some extent, chemical, but ultimately this was agreed, although the wording is probably a little bit opaque. But nonetheless, these concepts and these risks are included in the regulations.

We can all see that the current crisis in public health includes natural, accidental and intentional threats. However, 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 health 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. While practitioners and policymakers view diseases like SARS as a threat to public health, bioterrorists may see them as weapons of opportunity. Many communicable diseases have now become a security issue, bringing a new set of partners to the public health debate.

Concerns about distorting public health priorities and a disproportionate funding of the prevention of bioterrorism have been building for some time. More recently, the changes of diverging public health funding to national security can be seen in the response to Hurricane Katrina. From now on, the wisdom of bundling disease relief with counterterrorism efforts must be seriously questioned.

But I have seen in more recent weeks that there is a recognition of this issue. Substantial funds have been allocated in the United States and, indeed, elsewhere. And I refer to President Bush's speech in relation to this issue very recently where significant funds have been addressed to the public health issue.

The revised regulations proposes a significant expansion in the scope of surveillance and notification duties. Member states must notify the WHO of all serious threats and potential international emergencies, articles six and seven. They must meet standards for national disease surveillance and response, and they must assign a representative to the epicenter of any fast shifting emergency to mediate communication between national and international authorities. No such inclusive duties appeared in the traditional international – in the tradition of international law on communicable disease control previously. So, this is in fact quite new.

Although the IHR does not include a sanctions regime per se for states which fail to comply with its provisions, the potential consequences for noncompliance, especially in economic terms, will function as a powerful compliance tool. An important and perhaps the 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. I refer you to article 10.

The WHO is required to offer collaboration and to assist in dealing with such an outbreak, article 10 and 13 that deal with this.

In the event of a failure or refusal to collaborate by a member state the WHO is empowered to take all relevant information – to make all relevant information available to member states, particularly neighboring states and ultimately indeed to the public.

In such an eventuality the consequences are obvious to both travel and trade, especially in food, because, of course, individual member states can exercise their own sovereignty powers to protect their own interests. And obviously trade in food and travel are obvious consequences.

But, of course, by working together with the WHO to control either a public health event or the perception of a public health risk by other states, an affected state insures itself against the possibility of unilateral trade or travel restrictions being adopted against them. So, transparency pays in these circumstances. And the revised IHR will also allow the WHO to take into account report from sources other than notifications from states themselves or from WHO consultants. For instance, reports from NGOs can be taken into account. I refer you to article nine here.

This particular provision represents a radical break from the traditional approach under which surveillance efforts are restricted to information provided by governments only. And this is also significant in the sense that the WHO can turn up to a member state and ask for verification of a public health emergency where they get the information in that manner from an NGO and they are not required to disclose the sources. So, sources can be – can remain confidential.

These new rules were needed to bring clarity, transparency and certainty to the situation. In the future the 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 member state in recent years. Reference has been made to the power to take additional measures by individual member states. This can be done, but it must be justified.

And the concern here was that some member states felt that there may be temptation by some states in – where there's an identification of a risk to ban the importation of food from the area where the risk has been identified, even in circumstances where such a reaction is wholly unnecessary from a public health point of view to protect the population of the importing country. So, in other words, this can't be used as a trade measure – a trade protection measure.

JONATHAN TODRES: David, you have a couple minutes left.

DAVID BYRNE: OK.

The most important incentive for compliance is that the IHR has been drafted by the member states for their own mutual benefit. And since communicable diseases potentially threaten every country, it's in every country's best interests to collaborate internationally. Experience in recent years, especially with SARS and Avian influenza, has taught member states that the WHO and the WHO a great deal about how to work together to prevent and contain outbreaks. And the revisions of the regulations reflect that particular experience.

The impact of SARS on the economy of Toronto also teaches us that there are significant problems not just with the public health but citizens in countries where there's an outbreak of such a disease, but also the impact on businesses can be very, very significant. And for that reason businesses should establish contingency plans based on the assumption that it may not just be a one off disaster that we're dealing with here, as we've been traditionally used to, but that the failure may be over – as a difficulty may arise over several months with staff illnesses, for instances, as an example. The insurance industry will be put under pressure.

And there are many ways in which serious adverse consequences can result for businesses in circumstances where they don't look forward and prepare and put contingency plans in place for the eventuality that we're discussing.

I leave it there for the moment. And I would be happy to answer questions later.

JONATHAN TODRES: Thank you very much, David.

I'd now like to turn to Linda Horton. Linda is a partner with Hogan & Hartson in the Brussels office. And she counsels clients on a broad range of issues, including pharmaceutical and medical device, animal health, food and cosmetic industry requirements set forth by EU regulatory authorities, and the FDA and other similar agencies in other countries. She is an expert on international food, drug, medical device and trade issues.

Linda joined Hogan & Hartson in 2002 after a long career with the U.S. FDA, working in a legislative, legal and international policy offices. She has served as deputy chief counsel for regulations and hearings at the Food & Drug Administration. And during her last eight years at the FDA she was director of international policy, leading activities on harmonization, agreements, trade, imports, exports, EU relations, and legislative models for national regulatory systems.

We're very pleased to have Linda Horton with us today to share her insights on the U.S. WHO relationship and other related issues.

Linda?

LINDA HORTON, PARTNER, HOGAN & HARTSON: Thanks very much.

When I was at the FDA and asked to take on an international assignment I returned to law school to try to figure out how the international norms like the International Health Regulations relate to U.S. administrative law. And this topic may be of interest to our audience as well.

One of the things to keep in mind is that each country needs to decide its relationship with international law. And in some countries the constitution might say that a treaty commitment automatically becomes part of the law. For example, a constitution of an European Union member state might have a provision that takes on board EU laws. In the U.S. we actually have a reference in the Constitution that does enable the importation of international law into U.S. law. The issue is somewhat controversial.

But there are other times when countries put distance between their national legal systems and the international legal system and then require themselves to go through some kind of overt act to take on board the commitments made at the international level. And the United States tends to be more in the latter category than others.

And so, with respect to our relationship with the World Health Organization, we've always been a major supporter of the World Health Organization. If I'm remembering correctly, the first director general of WHO was perhaps the U.S. surgeon general or some other senior official. The U.S. hosted the treaty signing conference, et cetera. And yet customarily we take the position that WHO's standards, even something like the IHR, needs to have national adoption in some way. And a quote in the slide the actual language in the 1948 law that states this bit of difference.

In the U.S. statement for the record on the International Health Regulations found on the State Department Web site we have the position that was taken in May at the World Health Assembly and also a prediction of how the U.S. intends to interpret the IHR and where the U.S. will actually file a reservation on one point.

Just to go through this for the audience, as Marty was just discussing, the IHR is to be interpreted broadly to cover a range of threats. Also, David covered this with respect to certain other threats. And the U.S. wanted a broad view, and that's what the negotiating history of the IHR support.

Also, the U.S. had a concern about the application of the IHR to countries' own armed forces and is taking the position that one can assume that of course the IHR is not meant to interfere with national security. That's under a broad international law principle.

The U.S. will submit a narrowly tailored reservation to clarify that the implementation in the U.S. will be in a manner consistent with our federal system of government. It is common for countries to delegate to state or provincial levels, or even local levels, many public health controls. That's one of the challenges in this area. And so, the reservation that the U.S. intends to submit will probably not place the U.S. in a position very different from that of many other countries.

The U.S. also had sought unsuccessfully a provision in the IHR that recognizes the principle impeding the IHR that a country will implement the resolution in a manner consistent with our constitution.

Then we have a series of executive orders because very commonly the way that the U.S. has taken on board certain requirements is issuance of executive orders. I do not know whether there'll be some kind of additional step for the IHR in the U.S. in terms of notice and comment rulemaking. During the Q&A period Marty might address this point. But customarily we've had a series of executive orders dealing both with international issues and also interpretations of the communicable disease provisions of the Public Health Service Act.

Turning to the slide on U.S. agencies, I recite the obvious, that the CDC is the lead agency, collaborates with many others including WHO at the international level, the FDA, the Department of Agriculture, and many other agencies at the national and global level. And then the states already are linked in a framework that coordinates with the CDC in a range of activities. And I'm sure there'll be a cascading down to the

states and the local governments of the new IHR information and how the local governments play a part in this.

Turning to the Public Health Service Act, this is old authority. In 1944 the Public Health Service Act codified a lot of preexisting authority. There was a key provision included authorizing the surgeon general (today the Secretary of Health & Human Services) to make and enforce such regulations as in its judgment are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the states or possessions or from one state or possession into any other state or possession.

And then there's a range of possible remedies that the Secretary could use, including a catchall clause, other measures as in his judgment may be necessary. And each time a public health crisis comes up that involves communicable diseases, lawyers at the Department of Health & Human Services need to get out this law, get out the regulations, and figure out what remedies are available in a particular case.

Now, in the second slide on quarantine authority I include a cite to a case that often elicits a few chuckles, but it's a serious topic. In the 1970s the FDA was concerned about baby turtles that were being sold as playthings for children and were a source of salmonella contamination. The FDA actually banned the interstate and the intrastate trade in small turtles. A court case brought by Louisiana resulted in the FDA action being upheld. And this very broad statement of the scope of the quarantine authority was enunciated in court and showed that even though the initial focus of the Congress in passing the law was movement between U.S. and other countries or among different states, the law was being interpreted very broadly in accordance with the modern view of the Interstate and Foreign Commerce Clause of the Constitution.

I also include in here key cites to authorities exercised by the CDC. Under the quarantine provision, the CDC is the principal agency. FDA has a delegation of authority that has allowed it to supplement its authority under the Federal Food, Drug & Cosmetic Act and that has been quite useful in that agency's response to communicable disease crises.

I have then a couple of slides about the bioterrorism legislation that was passed in 2002.

Just to wind up and allow plenty of time for Q&A, I'll just say that one of the big challenges here, again, is the role of states and the need for coordination. I wanted to include a reference to the draft Model Act by Professor Gostin and also to some other steps that have been taken to enable coordination and cooperation among the states.

Thank you very much.

JONATHAN TODRES: Thank you, Linda.

Finally, I'd like to turn to Christopher Hagenbush. Chris Hagenbush is senior counsel for the Coca-Cola Company. He has global responsibility for providing advice and counsel to the Coca-Cola Company on a range of issues. During 2003 and 2004 Chris was group counsel for the Asia Pacific Strategic Business Unit of Coca-Cola and was based in Tokyo. He's active in a number of key trade and non-profit organizations. And also prior to joining Coca-Cola in 1990 he worked in a variety of in-house legal capacity with several other corporations working in the food, cosmetic, over-the-counter drug and packaged goods businesses.

Chris?

CHRISTOPHER HAGENBUSH, SENIOR COUNSEL, COCA-COLA COMPANY: Thanks, Jonathan.

Let me first make a couple of disclaimers. The first is that I am not an expert on international health law. The second, and this will become clearer as I speak, I'm vastly out of my depth when speaking about the International Health Regulations. And the last is this, my comments will be primarily practical and, I'm afraid, not very profound, but I think may focus the discussion more towards the commercial side of this issue.

I guess the question we are to focus on is how do we protect – how do we predict what impact all the new IHR will have on global companies.

As I look at the new IHR, I would like to break it down into simple and smaller parts. You've heard what I would characterize as the five key points. At least four of those have been addressed pretty extensively here, so we can talk more about those during the Q&A period. But I see this as an analysis of what does the expansion of reporting mean under IHR, what's the definition of a "public health emergency of international concern," what are the duties of member states and the duties of WHO, and then finally what is the likely impact from global companies.

It's that last point to which I'll direct my remarks because I think the other four have been managed pretty well already.

In terms of breaking down the issue as to the impact on global companies, what I really want to do is give my take on the relevance of the IHR rules to global companies like Coke. And in doing that I'd look at four things – variability about the nature of a particular business, aspects of people – and I'll tell you what I mean by that later – materials, and then finally reputation.

If we look at the nature of a given business and the potential impact of the IHR on specific industries, I think it's clear to see that the impact will vary depending on the nature of the particular public health emergency and the nature of the business. So, for example, if we consider what happened to Air Canada and Cathay Pacific during the SARS epidemic in 2003, it is clear that those two companies were severely affected. If your business is flying and nobody's coming into or out of the countries where you're based, it's pretty tough to run an airline business. And the economic impact on those two companies was devastating.

In the same way, tourism generally is adversely affected. I traveled extensively in Asia during 2003 and 2004. As late as the first quarter of 2004, the vacancy rates and the discounts in hotels and restaurants in Hong Kong were dramatic. And, of course, by that time it was pretty clear that at least the most destructive impact of the SARS epidemic was behind us. To the extent that the IHRs are going to increase the possibility for publicizing similar kinds of situations, I think their impact could be very significant.

There may be less obvious effects on other sectors of the economy. If you consider the consumer packaged goods industry, you might say, "Well, why is the IHR going to have an effect?" Well, I think it's going to have an effect in a couple of ways. One is that the reduction in tourism is going to have an impact on consumption of all kinds of products, and so the volume is going to go down. The negative effects of a practical "quarantine" cannot be forecasted in an annual business plan. At the end of the day, the best that can be done is to intelligently react to such challenges. Ultimately, good management really is not about predicting the future but managing events as they occur in the most effective and flexible way.

Alternatively, with the food and beverage industry, the first half of 2003, SARS was devastating to our China division. People couldn't travel; they weren't really even going to work or otherwise moving around more than absolutely necessary. If people aren't going to our restaurants and bars they're less likely to consume our product. And so, while home sales didn't experience a huge negative impact, sales in food service and hotels and similar outlets that rely on travel and entertainment to be successful were seriously affected.

I've also listed the pharma businesses. At first glance you might think, "Well, these kinds of major public health events may benefit pharma companies." And in some ways that may be true, but consider the shortages that we're seeing with respect to flu vaccine to understand that incredible demand in a very short period of time could also be very disruptive to a segment of the economy.

So, it seems clear that the IHR, or more specifically reportable events under the IHR, will effect different segments of the economy in different ways depending on the nature of the business.

As we consider the management of human resources – people - really the first issue for any company is ensuring and managing employee safety and the continuing health of any subset of a company’s in-house “public health community” that is associated with managing a business. Without an effective strategy for protecting the people who manage the business, there is no business.

Managing travel during a public health crisis is a very complex and important challenge for a business like ours. Many of us simply must travel to do our business effectively. When travel is simply not an option, contingency plans must be developed.

Personal concerns are also important. Long after the public health emergency is over there are people who look at risks in different ways. Some people were unwilling to travel to China or Hong Kong or Toronto even after the SARS epidemic had abated and travel restrictions were removed in the first and second quarter of 2004. Some employees just refused as a personal matter to visit those places for a substantial time after the crisis. Personal safety issues must be accommodated even as alternative ways to manage the business are identified.

It is important to respect privacy concerns in the workplace during a public health emergency. There’s a balance between the obligation that you have to the privacy of employees and public health needs for the business and for the place where in which you do business. And so, striking that balance can raise some very difficult and challenging issues as the needs of both the business and the employee are being met.

Let me turn to a discussion of production materials. I suspect that public health experts don’t often think about the potential affect of a public health emergency on supply chain considerations. Even for largely local businesses, a serious public health emergency can have a major impact on the ability to move materials. Someone who owns a poultry business in Thailand might probably find it difficult to convince customers that there is no supply problem. But even local customers probably are going to balk at buying and preparing poultry in the face of the threat of avian flu. The implications for smooth “just in time” materials supply in the context of a global business are geometrically complicated by a public health emergency on an international scale.

As David mentioned, contingencies and alternatives are essential to continued operation during a public health crisis. How effectively a particular company reacts when a key supply chain component is not available because of any disruptions including a public health emergency can be the crucial difference between success and failure in the marketplace. If you only have one source of supply from one country for an essential component, you will effectively be out of business if a public health emergency disrupts or effectively prevents the business from getting that component.

Exceptional challenges often require exceptional actions. During the BSE controversy several years ago, McDonald’s reacted by emphasizing other menu items because beef just wasn’t available or the price of beef made the business of selling value priced hamburgers unmanageable. McDonald’s is a big customer, so even though we thought about suggesting that they substitute Coca-Cola for cheeseburgers, we knew that was not a solution our valued business partners at McDonald’s could execute.

So, the last thing I want to talk about is the intangible “reputation.” I’ve broken the effect of a public health emergency down into three phases - reaction, action and outreach.

When a public health emergency or any unexpected event that has a global impact occurs the first reaction of a business must be almost instinctive. That’s particularly true if you’re a global company with a reputation to protect. So, it is essential to attempt first to manage public safety considerations. Necessarily public affairs management must follow quickly behind public safety. And then we must manage legal issues presented by a crisis. There must be a clear and well understood process in place to allow a quick and decisive reaction to the first wave of an event or incident.

I define “action” as the steps taken after the initial impact of the event or incident. This involves executing on contingency plans that are in place or need quickly to be established. This involves managing secondary effects and collateral issues.

Outreach is about longer term kinds of response. The example that I think of is the approach that we've taken to the impact of HIV-AIDS in Africa. The impact of the HIV-AIDS epidemic in Africa extends to all aspects of life, including commerce. Companies can be an important catalyst to help cobble together various kinds of resources to work towards addressing long term and vastly challenging solutions to the epidemic while keeping the business running, helping customers cope, and connecting with your consumers. The need to be a part of the solution to the HIV-AIDS pandemic in Africa is an essential part of any company's commitment to its business on the continent.

Finally, I guess I'd say that the real answer to how the new IHR is going to affect companies is yet to be determined. If I could predict the future I might be spending a lot more time at racetracks or on the beach than doing legal work, but at the end of the day it's impossible to know what the full impact of this new provision will be.

Successful companies will establish and work through institutions, relationships, procedures and resources to both try to anticipate as best they can but also to learn from what they've done in the past. Companies must attempt to plan for the unknown, conduct drills and role-play, and scenario plan. They must establish structures and processes to make sure there is a common understanding of roles and duties when an unexpected event or incident happens. Companies must learn from past incidents and from other companies that have reacted well in the past. Companies must conduct "post mortems" of past events, study best practices, and do benchmarking with other companies.

For example, to establish a plan for managing a product tampering event, it would make sense to study the reaction of McNeil Laboratories, the people who make Tylenol. Over the years, McNeil has a model for how to manage product tampering.

So, those are a few practical tips off the top comments that I hope you will find useful when considering the impact of the new IHR. I think at this point we ought to probably open it up for Q&A. Thanks.

JONATHAN TODRES: Thank you very much, Chris.

I think we will open it up to questions and answers now. That may take a moment to get organized, and I'll let the operator do that. In the interim I thought I might just ask a general question about the IHR that I'll open up to all the panelists.

Are there particular provisions that make it easier for businesses now to respond to public health emergencies? Or, alternatively, are there things that add additional burdens? If there are provisions of the IHR or processes in place to do either one, I'd be – I think panelists would – or participants would be interested in hearing about those.

DAVID BYRNE: David here. Perhaps I might just give my own reaction to that question.

The regulations are really designed to be responded to by the public health authorities in the member states of the WHO. And the obligations for compliance are placed there on the governmental authorities. The – I suppose the implications of that is that where there are businesses in member states engaged in businesses that impact on public health – mention was made a moment ago about the difficulties faced by, for instance, the poultry industry in Southeast Asia. So, obviously they have an interest in all of this.

And in the sense that there is an obligation on a member state to comply with principles of transparency and disclosure, I suppose they get their information from their own public health authorities, but also from companies like that. So, to that extent there is an implied subsidiary requirement or obligation, I suppose, although not a legal one because the regulation isn't addressed to companies. But, nonetheless, there is that requirement that they would make sure that their own public health authorities would be aware of issues that they know of that would adversely impact in public health and, therefore, to disclose that to the authorities to enable them to comply with their international obligations under the IHR.

MARTY CETRON: And this is Marty. I'd like to just add a couple of comments to David's well expressed thoughts.

One of the things – and this is the other side of that coin and the other side of that balance. There's no doubt that the – it's the public health emergency of international concern which has dramatic impact on business depending on what the issue is. So, the IHRs perhaps make more explicit some responsibilities through governments which will fall to industry, but it's the disease itself. It's the epidemic of sorts or the relief of an agent that's actually going to define what that major negative impact is.

On the positive side, I think the transparency and the forming of a consensus through which WHO can issue temporary recommendations that everybody would buy into and would be applied in some degree of uniformity across the world I think it's something that the business community can look to as a positive effect of having the IHR in place rather than every single state party issuing its own approach. There's a much more coordinated effort through world governance in WHO to have a common systematic approach to travel restrictions or entry requirements or banning of cargo or not or the protective measures that need to be put in place around safe movement of goods and services.

And to the extent that uniformity helps businesses that deal in a multinational context, I think this is a significant advantage of a tool like the IHR and the shift in power toward world governance over state sovereignty in this respect.

CHRISTOPHER HAGENBUSH: Yes. Let me just put what I would consider to be sort of the business spin on that.

I think that's right in terms of predictability. I mean, what is difficult in managing a business is the surprise. And so, when there's no way to know what impact a public health emergency is going to have, you're sort of left to your own devices. To the extent that there's a way to make a consistent or take a consistent approach to these kinds of issues, that will be helpful.

The flip side of that, though, I think, is the sort of short-term more parochial look at it, which says when you're faced with a greater number of these kinds of events that's a challenge to your business. And to the extent that this rule gets very strictly interpreted and results in a vastly larger number of public health emergencies of international concern that would have this kind of impact, then I think that's something that is going to increase the impact and going to cause us a fair amount of heartburn longer-term.

But I think in terms of the consistency that we get as a trade-off it's probably worth it at the end of the day.

JONATHAN TODRES: Thank you.

Is the operator on line to start us through the Q&A?

OPERATOR: Certainly. At this time I would like to remind everyone if you would like to ask a question please press star, then the number one on your telephone keypad. Once again, if you'd like to ask a question please press star, then one on your telephone at this time.

JONATHAN TODRES: We have received some e-mail questions. We are going to give priority to the telephonic questions. And all e-mail questions will be shared with the speakers either during or after the conference.

OPERATOR: Our first question comes from Michael Seng with John Marshall Group.

MICHAEL SENG, JOHN MARSHALL GROUP: Hello? Hello?

OPERATOR: Yes. Please pose your question.

JONATHAN TODRES: We can hear you.

MICHAEL SENG: It seems that from a clinical perspective doctors may need more than the on paper information provided for in revised Article 6.2 – “In order to prepare vaccines and run diagnostic tests we may need samples of biologic source material. Although this is provided for in Article 46, it should be noted that the provision is subject to international law.” Given that some countries have state secrets laws, to what extent will the revised IHRs be effective in combating outbreaks of emerging and reemerging diseases where a member state refuses to release biological source material?

MARTY CETRON: Well, you hit on – this is Marty Cetron. And you hit on a very hotly discussed topic in the intergovernmental sessions, and that is that between a complete transparency and openness in sharing of materials versus the national government’s rules about moving of these materials both in terms of national security but also in terms of the rules of engagement, if you will, about international trans shipment.

It’s clear that the IHRs intend for this type of sharing to occur and for WHO to be brokering this kind of exchange of materials for timely identification, creation of counter measures and collaborative confirmation, and all the reasons you say.

And one can only say that the IHR’s intended to explicitly imply that this type of cooperation is needed and would be sought out and is the norm. But it cannot actually compel it. And without the – we would not have gotten through the intergovernmental process without the precautionary language that was inserted in there that you read out.

So, the hesitancy you see reflected pushback from selected member states, and that’s where the consensus ended up. I don’t think we would have gotten a consensus if some of those compromises weren’t made from the original language, which was more explicit about the role of governance.

David, I don’t know if you had any other comments about that.

DAVID BYRNE: No, that’s my view also.

OPERATOR: Once again, if there are any remaining questions please press star, then one on your telephone keypad.

Our next question comes from Demetris Vryonides, Self Practice.

DEMETRIS VRYONIDES, SELF PRACTICE: Yes, good morning. First of all, I would like to congratulate the American Bar Association International Health Law Committee and the Public Health Law Association for taking the initiative to organize this teleconference at a time during which the world seems to be facing increasing public health threats.

We have the privilege during the annual conference of the International Bar Association in Prague this last September to host both Mr. David Byrne and Mr. Gene Matthews as keynote speakers. And I wanted to refer back to that discussion, which was not identical but similar to the present session, where Mr. Byrne had indicated how the international health regulations were in essence a product of consensus building.

He had also pointed out that the regulations contained a degree of pooled sovereignty. A similar point was made in the present teleconference.

However, David also asserted that capacity building for implementation of the International Health Regulations is really down to the member states of the World Health Organization and that it seems that this is more of a problem for less developed member states.

So, given those realities and those utterances, I was wondering whether there was any thoughts been given by either the secretariat of WHO or the broader business community for the need to address the financial

and technical assistance that needs to be brought forward to developing countries in a number of sectors and situations for proper implementation of the International Health Regulations.

Lastly, how would the business community react to such an initiative, for example setting up a trust fund under the auspices of WHO?

Thank you.

DAVID BYRNE: Maybe if I responded briefly – David here – in relation to that.

This is certainly an issue of some concern during the negotiations. And some of the lesser developed countries thought that something should be included in the IHR relating to the provision of resources for capacity building. But the view ultimately was reached that to seek to do that would create a degree of controversy surrounding the regulations that might ultimately undermine an agreement on the core issues related to public health. And, therefore, they were left aside to be dealt with in other areas, the belief being that there are other systems in place internationally to provide funding for issues such as this. And I have to say I think that was probably the correct decision. But the fact still remains, and Demetris's question is a good one.

I know from the reading that I've seen recently that there's a measure being looked at in the World Bank as to whether something along these lines should be done. I think not necessarily focused on the IHR, but rather the need to provide funding to combat diseases of the type that we see now like Avian influenza.

So, there is a move in that direction. We've seen what President Bush said recently in relation to the provision of funding. There's talk about the establishment of stockpile of medicines and vaccines under the auspices of the WHO and otherwise.

So, there's certainly a move in that direction by public authorities and international institutions. Whether there's a role for business in that is another issue. Maybe those international business organizations that we all know about can provide some leadership in that area, so as to ensure that the funding that is available to international organizations and the more developed countries in the world that they should be encouraged to provide funding in that direction.

JONATHAN TODRES: Operator, are there other telephonic questions, or shall I move on to e-mail questions?

OPERATOR: Once again, as a reminder, if you'd like to ask your question please press star one on your telephone at this time.

We have a question from Marian Adly with Fulbright and the University of Toronto.

MARIAN ADLY, FULBRIGHT AND THE UNIVERSITY OF TORONTO: Good afternoon. Thank you.

I have a follow-up question from just the previous question. And that is a concern regarding the building capacity for especially developing countries that don't have existing ability to respond and contain a threat. And in the other presentations – in the prior presentations there was a lot of reference to providing technical assistance to member states, getting additional assistance, and it was all referenced by the World Health Organization providing that.

And I think that David was questioning that there is perhaps other measure to be able to provide that instead of through the World Health Organization. And he mentioned examples of the World Bank. But I think there should also be a distinction between preventive long-term frameworks of responses developing systems with the World Bank and a preventable approach to combating diseases as opposed to a more reactive response if something happens. And I think in that aspect that the urgency of providing technical assistance and resources to those developing countries will be a key and critical and that a clear

identification of how that will be taken care of is crucial now as there's a lot of talk about pandemic planning.

My greatest concern is the building up a false sense of security that in a time of crisis a developing country turns to the World Health Organization after something has come and that the trust essentially shall be broken because the resources just are not there.

Secondly, I have a question about has there been talk about creating something such as a health security council for the World Health Organization, something that can be clearly delineated for the other responsibilities to global health that the World Health Organization has to make clear that the councils and the World Health Organization can be very specific to responding to those threats.

MARTY CETRON: This is Marty Cetron. Let me take a first swipe at some of these.

The issue you bring up about mechanisms of providing technical assistance, be they preventative investments with a longer forecast or response assistance, is a good one. And I think because the focus of this call is on the IHR and the role of WHO and the IHR in giving back to member states, that aspect of it has been emphasized. But it shouldn't be by any means perceived that that is the only mechanism by which this technical assistance goes. There are numerous both bilateral as well as multilateral regional and otherwise structures by which this assistance can be funneled.

And equally discussed and perhaps even more so discussed recently in Geneva on the pandemic flu issues were all of the existing frameworks by which both the World Bank and other groups, separate partnerships are in place to provide both short-term, intermediate and long-term assistance. And there are probably too many to even elucidate here. But the U.S. is involved in numerous of these bilaterally and multilaterally.

In terms of the second issue about global health security and a health security council, it's probably interesting to note that the subsets of member states have actually formed a variety of organizations. Some that are even identified specifically around this topic is global health security, an action group, and so on. So, these entities do exist. They often don't exist necessarily within the framework of WHO, but they certainly exist at other multilateral and bilateral arrangements through which actions are brought to bear.

And I think point for their need is well taken, but we shouldn't – simply because we're focusing on IHR we're looking at WHO's role in global governance, but it's not the only means by which these types of health investments get made.

MARIAN ADLY: Thank you.

OPERATOR: Our next question comes from Anthony Moulton with the Centers for Disease Control and Prevention.

ANTHONY MOULTON, CENTERS FOR DISEASE CONTROL AND PREVENTION: Hi. This is Tony Moulton in the Public Health Law Program at CDC. Just a very quick question.

But, first, I'd like to just say greetings to David Byrne. It's great to hear your voice again.

DAVID BYRNE: Hi, Tony.

ANTHONY MOULTON: And my question, and it may be something we would discuss later on, is for Mr. Hagenbush, who's right here with me in Atlanta, I believe, today. And that's just whether there are any practical things that you think the Public Health Law Association members or our little program at CDC or public health legal councils around the country could do over the next year or so, let's say, that would be beneficial to legal counsel to corporations large and small around the country.

DAVID BYRNE: My first reaction to that question is that I think the Public Health Law Association is a wonderful innovation. I think it's an organization that's in existence now for maybe four years. It's quite a young organization. As you know, I visited there some months ago.

And the fact that many international lawyers are now looking at the importance of the rule of law in relation to global threats and global problems, probably that are brought about by globalization, whether it's terrorism, fraud and corruption in business, or the pandemics issue and health issues that we're talking about. International lawyers are now looking at these issues.

And that's why I believe the Public Health Law Association is well placed to give leadership in that area and is currently doing that. And the more that your work becomes known among lawyers I think the better. How practically you go about that I haven't given any deep thought to, but the engagement that we're now involved in is one obvious way forward. And the connection between the Public Health Law Association and the American Bar Association seems to be very much a move in the right direction. And the more that you engage in these kinds of activities the better you're known.

I think your good work isn't known as well in Europe, I believe, as it ought to be because essentially you're a U.S.-based organization. But I think because your focus is global I think your activities should be more global as well. And I would certainly moves in that direction and to make your work known more to policymakers certainly in the United States, in Europe and the developed countries, and indeed ultimately the developing countries, so much the better because you've got to achieve a greater awareness of the need to approach these kinds of issues from a rules-based point of view and also then the willingness to achieve some kind of implementation of that.

One of the strong impetuses for the establishment of the revision of the International Health Regulations was the fact that the WHO acted in the way it did during the time of the SARS epidemic in 2003 when the WHO issued the travel advisories. That had very significant impact on the economies of the countries that were involved in that. And I know that some people did make the point that it was questionable whether the WHO was acting with a sound legal base or not. The fact that they did what they did, of course, meant that they curbed the and reduced the spread of the disease.

So, it was a very positive engagement by the WHO, but a lot of people felt that, look, we need to put something in place to ensure that it's properly legally supported. Other institutions other than the WHO took the view, well, look, we want to put some kind of parameters on the exercise of this kind of authority and, therefore, the establishment of the IHR was a good thing.

So, the globalization itself, the problems arising from global disease and other problems that I mentioned a moment ago are putting into peoples' minds the need for a global approach to this and, therefore, international lawyers must ban together in putting forward arguments and coming up with solutions like the IHR to achieve the best results from a global public health point of view.

ANTHONY MOULTON: Thank you, David. That's a wonderful call to action.

CHRISTOPHER HAGENBUSH: Yes.

I think also that – we've talked before about building bridges between the business community and the public health community. And I think what we mean by that is establishing the relationships that are value added to what businesses do. And there's nothing more wrenching than to have no answer for the question what do we do next when your client asks you about a particular public health emergency.

So, that – building those kinds of relationships and establishing that value, I think, is critical and I think a lot of the things you talk about, David, are examples of that. But, I mean, I there are other models for this kind of communication already.

I mean, if you look, for example, at antitrust enforcement authorities, they speak a lot to each other. There's a lot of communication back and forth about global companies and the impact they may have on

competition. The same thing could be done with respect to the public health community and establishing those kinds of interactions both between countries but also between companies and the authorities in various countries. Where we do business, I think, is probably the best thing we can do to prevent and prepare for unforeseen emergencies like this happening in the future.

Linda's had a lot of experience in this area. I'd be interested in her take on this.

OPERATOR: Once again, if there are any remaining questions, please press ...

JONATHAN TODRES: I think we're ...

DAVID BYRNE: Could I give a short – a further response to that – David here – to that point that was just last made?

I think that there may need to be an interaction between those involved in World Trade and those involved in public – global public health. And I was interested to see that on the agenda for the next executive council meeting of the WHO in January there's an issue on the agenda of health and trade. And this is a very, very big issue. In fact, it may lead to the possibility of some controversy in the sense that sometimes the constraints that may need to be put in place for the protection of public health may have the risk of an adverse impact on trade.

And I know the International Health Regulations are drafted in such a way that it's designed to be with minimum adverse impact on trade, but there may inevitably have to be something leading in that direction. And, therefore, if that difficulty may arise it should be addressed as an early stage. And that's why I think what the WHO are doing in January is a good thing.

I might add to that that I understand that in the WTO there is a committee on the environment. I don't think there is an equivalent committee on health. Maybe that needs to be looked at because of the increasing nexus between these two issues, where there's a potential for conflict, as I said, but yet at the same time where there are huge benefits involved in handling the health aspect of it properly for the protection of good trade so that you don't have a situation like occurred a couple of years ago arising from the lack of transparency in Southeast Asia on Avian influenza where in Europe I and my staff we had to ban the importation of all poultry from Thailand because of a failure to disclose the existence of Avian influenza and the failure to be transparent about the issue.

And yet in the international rules relating to food safety there is a provision contained in most of the rules, which is described as regionalization. By that I mean that you are required to reduce the impact of, for instance, a ban on the importation of some foods to the region that's most affected, and thereby reduce the impact at a very minimum.

Now, that's more easily done if the public authorities in that region or in that country have been transparent in the disclosure of the disease, are in a position to do something about it, and therefore other countries can trust that country with the public health consequences that are arising, thereby leading to the possibility for regionalization to the smallest affected area.

So, there are lots of positive outcomes that can be achieved for trade if the public health aspect of it is properly addressed.

CHRISTOPHER HAGENBUSH: David, I think that's right. And I would submit that public health already has an impact on trade. And I think to the extent that WHO and the IHR regulations can make that predictable standardize it, give us a clear guidance as to how to go forward and speak with one voice as to what these kinds of impacts are going to be. It'll be much better for commerce than to have a patchwork of different responses from various countries depending on things other than public health sometimes.

DAVID BYRNE: Yes.

JONATHAN TODRES: Thank you very much.

Unfortunately, we are running out of time. I think in many respects we view this as the beginning of a dialogue on these issues. So, we encourage those of you who participated on the call to reach out to your colleagues and your clients. We also encourage you to reach out to those of us at the Public Health Law Association and the International Health Law Committee of the ABA.

I just want to conclude by expressing my great appreciation to each of our speakers for their valuable insights today. I also want to take a moment to thank those behind the scenes, both at the ABA and the PHLA, for their work in putting this together.

Finally, I thank each of you for your participation in the teleconference.

DAVID BYRNE: Thank you.

MARTY CETRON: Thank you.

DAVID BYRNE: Thanks, all.

OPERATOR: Thank you. This concludes today's ABA section of international law conference call. You may now disconnect your lines, and have a great day.

DAVID BYRNE: Thank you. Bye-bye.

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