



## THAMMASAT UNIVERSITY

Globalizing Asia: Health Law, Governance, and Policy-Issues and Gaps!

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## Acronyms

ACRONYM	FULL NAME
ASEAN	Association of Southeastern Asian Nations
ACHPR	African Charter on Human and Peoples' Rights
ACHR	American Convention on Human Rights
APEC	Asia-Pacific Economic Cooperation
AQSIQ	General Administration of Quality Supervision,
	Inspection and Quarantine (China)
AusAID	Australian Agency of International Development
CARICOM	Caribbean Community
CEDAW	Convention on the Elimination of All Forms of
	Discrimination Against Women
CEWG	Consultative Expert Working Group
CIPIH	Commission on Intellectual Property Rights,
	Innovation and Public Health
CL	Competition Law
CRC	Convention on the Rights of the Child
CRPD	Convention on the Rights of Persons with
	Disabilities
ECOSOC	Economic and Social Council
ESCAP	Economic and Social Commission for Asia and the
	Pacific
GATT	General Agreement on Tariffs and Trade
GPO	Government Pharmaceutical Organization
2004	(Thailand)
GSPA	Global Strategy and Plan of Action on Public Health,
FCTC	Innovation and Intellectual Property
FCTC	Framework Convention on Tobacco Control
FTA	Free Trade Agreement
HITECH	Health Information Technology for Economic and Clinical Health Act
HIPAA	The Health Insurance Portability and Accountability
HIPAA	Act of 1996
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic Social and
recock	Cultural Rights
IDLO	International Development Law Organization
IHR (2005)	International Health Regulations 2005
ISO	International Organization for Standardization
IP	Intellectual Property
MA	Merger and Acquisition
MOU	Memorandum of Understanding
NCD	Noncommunicable Disease

ACRONYM FULL NAMI	
NGO Nongovern	mental Organization
<b>OCHCR</b> Office of th	e High Commissioner on Human Rights
<b>OECD</b> Organization	n of Economic Cooperation and
Developme	nt
PHI Protected H	Health Information
PPP Public, Priv	ate, and People
SAARC South Asian	n Association for Regional Cooperation
	oproach to International Chemical
Manageme	
	Asia Regional Office World Health
Organization	n
_	an of Action on Water Resources
Manageme	nt
_	on Trade Related Aspects of Intellectual
Property Ri	<u> </u>
	es Agency for International Development
UNCTAD United Nat	ions Conference on Trade and Development
UNESCO United Nat	ions Educational, Scientific, and Cultural
Organizatio	n
UNGA United Nat	ions General Assembly
<b>UNDP</b> United Nat	ions Development Programme
WFCTC WHO Fram	ework Convention on Tobacco Control
WGTCP WTO Work	ing Group on Interaction between Trade
and Compe	tition Policy
WHA World Heal	th Assembly
WHO World Heal	th Organization
WIPO World Intel	lectual Property Organization
WPRO WHO West	ern Pacific Region

#### **Executive Summary**

An introduction and warm welcome from Thammasat University President Prof. Dr. Somkit Lertpaithoon opened our Workshop on *Globalizing Asia: Health Law, Governance, and Policy – Issues, Approaches, and Gaps!* Dr. Sima Samar, Chairperson, Afghanistan Independent Human Rights Commission started her keynote address by asking about the "*Universality of Human Rights: Is there a Global standard?*" We heard powerful words and ideas informed by her experience as a human rights advocate and practitioner in war-ravaged Afghanistan. Her people are in great need and each advance there is hard won and fragile.

Dr. Samar drew upon her experiences to make recommendations about the observance of human rights obligations. She stressed the importance of universal access to rights that recognize the needs of the most vulnerable in the community. She spoke of the supporting role of law reform and the significance of the rule of law. She pointed out how the elimination of poverty and a variety of human rights obligations are inextricably linked to the right to health. She explained why accountability for compliance with international treaty obligations and human rights-based approaches are keys to promoting universal health. She concluded that "it is the moral responsibility of all of us to promote and protect human rights to save our own dignity and humanity."

Once under way, our Workshop addressed a wide range of topics from regional approaches to the implementation of the IHR (2005) to matters as diverse as health practitioner certification, nanotechnology risk management, and implementation of e-health and privacy strategies. Several presentations focused on the issue of health and trade laws and the vexed issue of WTO requirements for patent laws and their impact on access to medicines in developing countries. Presenters also asked our participants to consider the growing threat of NCDs while others reminded everyone that science remains unsettled on matters such as the role of migratory birds and their control in arresting the spread of avian influenza, leaving the region unable to fully assess the risk of communicable disease such as avian flu.

Presenters also reviewed the lessons they learned from earlier public health law experiences to address HIV regionally and beyond. Several presentations highlighted case studies for their applicability in Asia. These included the experiences of Thai universities with developing and teaching health law and public health law, the challenges in ASEAN dealing with communicable diseases and IHR (2005), the experiences of Singapore dealing with water and health, and the feasibility of a model public health law for the Asia-Pacific region.

The variety of presentations at our Workshop and the enthusiasm of our participants gave everyone the strong impression that our topics and discussions were important and timely. Presentations raised local, regional, and international legal, governance, and policy issues related to health and public health. Our Workshop experience reflected the reality of globalization in Asia and its web of expected and unexpected effects on health, law, governance, and policies of the region and beyond. Across the presentations as whole, some strong themes emerged from our Workshop.

#### Themes emerging from the Workshop

#### Risk management challenges arise when health risks and science are uncertain.

Many presenters asked how countries would manage their health risks in the face of scientific uncertainty. Concerns about risk management focused on several themes that included the emerging role of novel technologies in health care such as nanotechnology, the increasing presence of zoonotic diseases such as avian influenza and SARS, and the growing threats to personal privacy and security arising out of e-health adoption and use. Others saw unsettled questions about science, ethics, and law as challenging risk management paradigms in the modern world of health care that would require multidisciplinary teams to bridge the knowledge gaps. These teams must work collaboratively so they can inform governments and their policymakers on the science, law, ethics, and human rights questions so they may develop sound and informed risk management practices and policies.

#### Sustainable water management practices and policies support our right to health.

Sustainable water management and planning was an important theme raised in several presentations. Participants directed many questions and comments to our presenters on the need for a sustainable and clean water supply for health. Several presentations emphasized how important access to clean water is to realizing the right to health. The lessons learned from water management practices in Singapore attracted a great deal of interest and many questions, although some questioned whether the characteristics of Singapore, as an island nation, could be applied to countries within the region that are not islands. Even so, countries can learn lessons from other countries so long as they apply them appropriately.

#### Noncommunicable diseases and public health laws may limit the impact of globalization.

Many presenters worried about the rising number and frequency of NCDs sweeping across Asia. A number of them saw this theme as one where the law could potentially make a significant difference if we "don't wait too long." Public health laws regulating the promoters of the risk factors for NCDs – such as tobacco and alcohol regulations, or laws regulating food advertising and labeling – could reduce the health risks and costs associated with NCDs in Asia. Asian countries may wish to give greater emphasis to the legal frameworks, enforcement mechanisms, and interrelationships between national and subnational laws as a way of mitigating the impact of globalization on the spread of NCDs within the region.

#### Use of different strategies for WTO obligations and TRIPS flexibilities may protect national health.

Countries may choose different strategies to meet their WTO obligations while optimizing TRIPS flexibilities in order to protect national health. They may increase their access to medicines. Several presenters pointed out that TRIPS flexibilities were not well understood or well utilized by countries in the region. Further, there were concerns about how Ministries of Health and their personnel might improve their knowledge about TRIPS and gain the negotiation skills necessary to advocate for health considerations in country trade negotiations. One initial step might be to include Health Ministry personnel within the teams that carry out trade negotiations on behalf of each country. This practice might avoid the tendency to confine these processes to central agencies such as the Prime Minister's Department, Ministry of Finance, or Ministry of Foreign Affairs.

#### Realizing the right to health may require Ministries to distribute their budgets equitably.

Ministries of Health must balance their budgets in times of global financial uncertainty while also ensuring that quality health services are delivered to their populations in a nondiscriminatory way. Ministers of Health and their personnel must also be strong advocates for their national health budgets. They must make the case for the funding of their budgets and be prepared to defend them during negotiations with officials in other departments such as Treasury and Finance. Ministers of Health must also prevail at cabinet level amongst many competing priorities and political and economic agendas. Some presenters asked whether there is a potential tension between realizing the right to health and encouraging people away from more expensive health care in hospitals to less expensive primary care and community-based health care centers, clinics, and aid posts. Laws governing these issues could conflict with the right to health where the right to health demands wider access to services including expensive ones while laws and policies governing health financing and health administration may seek to reduce the scope and availability of some health services.

#### Sound domestic public health law may serve as a basis for meeting international obligations.

Several presenters emphasized the importance of sound domestic public health laws as a basis for addressing and managing the emerging demands, threats, and obligations of globalization on health. For example, participants saw the rule of law as a key foundational principle for the application of human rights. Other presenters pointed out that countries with weak public health laws could adversely affect the health of their citizens as well as those of their neighbors, especially when weak public health laws delay or preempt responses to health risks from across-the-border sources.

Several presenters also saw the constitutional entrenchment of the right to health as an important foundation for countries wishing to realize the right to health. Constitutional entrenchment together with supportive domestic legislation and policies are the necessary keys to implementing this right. Sound domestic public health law was also an essential building block for compliance with the IHR (2005). Some speakers also mentioned that regional approaches to the implementation of the IHR (2005), and other shared health challenges can be better advanced when good public health laws already exist.

#### Globalization means domestic laws and actions have regional or international consequences.

Globalization, by its nature, creates changes that extend far beyond national borders. There is an inextricable connection between domestic laws and actions of sovereign countries. The domestic laws and actions of one sovereign country may have regional or international consequences. Examples of the interplay of domestic laws and actions between sovereigns in the Workshop included countries:

- Taking stronger steps to manage their public health risks than are required by IHR (2005). These
  more stringent measures may harm trading opportunities and beneficial economic exchanges
  that negatively impact neighboring countries.
- Relying on weak human rights protections or providing limited access to health care
  opportunities for its citizens may enable their health problems spread across borders to reduce
  the health of other countries. Countries failing to acknowledge the right to health put the health
  of other countries at risk.

- Using global health laws as way to advance global health equity by enabling sovereigns to
  expand their health resources. Adoption of laws that support a freer exchange of health services
  between countries could promote health. Such laws could also exacerbate global health
  inequities when they lead to health workers fleeing from poor to rich markets creating
  inequities in supply and demand.
- Employing measures with unforeseen and detrimental environmental consequences to respond
  to health crises, such as an epidemic or a pandemic, can negatively impact countries. For
  example, China killed its sparrows as a way to reduce the transmission risks for avian flu.
  Unfortunately, this indiscriminate culling of sparrows resulted in an unanticipated
  overpopulation of worms which killed crops.
- Relying on weak communicable disease laws or failing to implement IHR (2005) may endanger
  the health of their neighbors. Conversely, adoption more stringent laws for managing the risks
  of an outbreak of communicable disease may reduce the risk of spread to neighboring country
  while reducing economic exchanges and wealth. There may be a tension between maintenance
  of sovereignty and international cooperation for health.

#### Globalization must be viewed in the cultural context of individual countries.

The cultural context of countries is crucial when considering the global application of ideas, policies, and laws. Individual presenters noted that countries:

- Failing to appreciate how cultural differences may influence their ideas, policies, and laws on basic concepts can lead to misperceptions. For example, experiences with personal privacy and health privacy in Asia reveal that these concepts may differ from western nations, especially those in Europe and the United States. Privacy must be considered within the context of the culture. Asians respect privacy, but there may be different levels privacy viewpoints. They may put access to high quality care above their needs for personal privacy when it comes to their promoting their health. Thus, cultural differences can lead to differences in ideas, laws, and policies in eastern and western countries.
- Implementing public health laws developed for western nations, such as Britain, during the early twentieth century have proved to be a poor fit when applied in Pacific countries in the twentyfirst century.
- Attempting to apply human rights to countries that possess social, cultural, and religious barriers to human rights can be especially difficult. Sexual reproductive health rights are one set of rights that may find application difficult in these countries.
- Providing aid must avoid simply transplanting an intervention which was successful in one country into another without careful consideration of the context.

#### Challenges to implementing a "human rights approach" in Asia may exist.

In a fast moving, confusing environment where countries are struggling to keep up scientifically, legally, ethically, economically, and socially, there can be complexities in the implementation of human rights obligations and in particular the right to health. Some presenters questioned whether countries:

Attempting to take a balanced approach may do so when they promote innovation in the public
interest in order to maintain public health while they also attempt to protect the rights of the
innovators to their intellectual property. For example, countries may take a holistic look at

- article 15 of the ICESCR, saying it binds States to design IP systems that strike a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of authors and inventors in such knowledge. This may help to make the case for using TRIPS flexibilities to maximize access to new medicine and protect health.
- Failing to appreciate the differences in cultural beliefs or concepts about certain personal matters, such as personal privacy, in Asia may contradict rights-based approaches to health, which create an obligation to protect the privacy of health information.
- Adopting the right to health may appear to conflict with the philosophy of encouraging people
  away from more expensive health care treatments and facilities in order to reduce costs while
  promoting health. Laws governing these issues could be contradictory.

#### Regionalized models or approaches proven successful may be useful.

A number of presentations presented models which had been successful in a regional context. These may have further or broader application in the region. Examples of regionalized models or approaches to addressing health issues included:

- Thailand's National Health Assembly.
- India's approach to the use of TRIPS flexibilities.
- Thailand's Government-Use Licenses.
- Civil Society's involvement in the International HIV/AIDS control efforts.
- Model Public Health Law for the Pacific.

For more information, please see the summaries of our presentations and links to their PowerPoint presentations or access all our Workshop materials by going to the *Globalizing Asia: Health Law, Governance, and Policy—Issues, Approaches, and Gaps* site contained within the Health Law section of the International Development Law Organization (IDLO) Website at <a href="http://www.idlo.int/english/WhatWeDo/Programs/Health/Pages/DetailsEvent.aspx?IDEVENT=227">http://www.idlo.int/english/WhatWeDo/Programs/Health/Pages/DetailsEvent.aspx?IDEVENT=227</a>.

# Summary of Issues Nominated by Delegates as the Most Important Areas for Action Following the Workshop

The final session of our Workshop brought participants together to distill the ideas that were flowing during the preceding three days into some agreed priorities for further work. These priorities reflect the emerging themes described above and we summarize them here. They include:

- Needing greater capacity building in a number of areas, including:
  - o Developing legislation within the Ministries of Health generally;
  - Using TRIPS flexibilities to improve the access to essential medicines;
  - o Developing or engaging multidisciplinary groups to address health related issues; and
  - Engaging other government portfolios in order to better protect health in the negotiation of bilateral and multi-lateral treaties.
- Increasing use of WTO and TRIPS flexibilities to protect health. This theme focused on capacity building, which received a great deal of attention throughout the Workshop, making it clear to us this issue deserves separate treatment in the future. WTO agreements require greater recognition of public health issues and better collaboration. Agreements should balance the profit interests of companies with long term public health development.
- Increasing emphasis on legal frameworks, enforcement, and the interrelationship between national and subnational laws, especially in the area of NCDs and tobacco control, to protect health.
- Establishing a place for a model for public health law that countries, especially developing countries, might access as a starting point when addressing legal gaps. Models of successful interventions, such as the Public Health Assembly of Thailand, may help countries address the challenges of globalization to their public health.
- Requiring water management and planning that makes water a sustainable resource for health.
- Creating sensible risk management plans for zoonotic diseases and nanotechnologies where the
  science and knowledge about risks may lag behind innovation and adoption. What do we do
  when we have a lack of knowledge and/or evidence? How do we cope with rising demands for
  treatment and/or vaccination and the push for an immediate response when the science, and
  knowledge about risk, is not yet clear?
- Recognizing that human rights and public health are related. Achieving equity and harmonizing
  international and national law may be difficult because of (1) capacity gaps drafting,
  implementing and enforcing laws and (2) problems in adopting or implementing human rights
  concepts, as a result of social, cultural and religious barriers, especially with sexual reproductive
  health rights.
- Seeing a great role for WHO in addressing the legal issues related to public health and public health law. The WHO must scale up engagement on these issues and its regional offices (WPRO, SEARO) should engage more substantively on legal priorities.

#### **Conclusion**

It was clear from the emerging themes and lively discussions and debates generated across our three day Workshop that our subject matter was timely and well-received. Countries in the region are identifying similar issues and attempting to address them. Moreover, countries are willing to share information about their experiences, to seek out successful models, and to ask regional groups to lead and to seek out lines of communication, tools and models of regionally successful measures from which all could learn.

#### **Opening Address and Welcome**

Globalizing Asia: Health Law, Governance, and Policy—Issues, Approaches, and Gaps.: President Prof. Dr. Somkit Lertpaithoon, Thammasat University, Thailand.

Dr. Somkit Lertpaithoon welcomed our participants and explained the purpose of our Workshop to bring together experts in public health, health and public health law, governance, and policy; to consider the issues, experiences, and gaps resulting from globalization; and to discuss their impact on health laws, governance frameworks, and health policies throughout the region and beyond. Recognizing the size and diversity of the Asia-Pacific Region, Dr. Lertpaithoon asked "are regional approaches feasible?"

Dr. Lertpaithoon saw the region as embracing the forces of globalization, which promise modernization and progressive change. However, replacing old technologies, processes, and thinking with new, more innovative processes can be destabilizing. The impact of globalization on health, health law, and governance can be a positive and transformative force, where the actions of people on opposite sides of our world can lead to mutually beneficial changes. These interactions may be viewed negatively by some who see them as a kind of "colonization." Globalization can affect the wealth and health of nations, but it also brings global recognition of important principles, such the right to health. Globalization may be creating new centers of political and economic power that lead to wealth and health of these rising powers. These efforts may also broaden the reach of the right to health, although they come at a time of extraordinary instability among nations caused by disparate elements such as climate change, unstable financial markets, and regional instability. The forces of globalization can challenge the very same laws, governance frameworks, and policies intended to promote the right to health.

Many countries, both inside and outside of our region, look to the process of globalization to improve their health systems and economies. Asian countries are active in innovation and research, and are entering emerging niche health markets such as medical tourism and nanopharmaceuticals. The ASEAN economic community is working to understand and respond to the regional economic effects of globalization on the health system and markets. The across-the-borders affects of globalization challenge the health and stability of Asia, which is home to over half the world's population.

Organizations such as the WHO and WTO are collaborating globally and regionally to educate countries throughout Asia and the world about the effects of globalization. These organizations are working with the International Development Law Organization (IDLO) to address the impact of globalization on public health law. IDLO has convened meetings in Rome and Cairo over the past three years, with delegates from 23 countries across the Americas, Europe and Asia, to discuss how the rule of law might be used to promote public health. IDLO plans to produce a Public Health Law Manual in collaboration with the WHO, the O'Neill Institute, and the University of Sydney) to assist policy-makers and law-makers in the process of public health law reform. These meetings are important to Asia since their outcomes may influence the development of public health laws in Asia. Asia needs to have a greater voice in, and influence on, any initiative affecting the rule of law in Asia.

Dr. Lertpaithoon expressed the hope that the workshop would enable all participants to identify gaps and areas countries should focus their efforts to respond to the effects of globalization for the benefit of the Asian region. *To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/Open.pdf*.

#### **Keynote Address**

Universality of Human Rights: Is There a Global Standard?: Dr. Sima Samar, Chairperson, Afghanistan Human Rights Commission, Former UN Special Rapporteur on Human Rights in Sudan, Former Minister of Women's Affairs, Government of Afghanistan.

Dr. Samar introduced the importance of the right to health by explaining its interrelationship with other human rights. She explained that violations of the right to health effect the achievement of other rights such as the right to education, and the right to food and nutrition. The right to health was first articulated in the preamble to the 1946 Constitution of the WHO as "a state of complete physical and mental and social wellbeing and not merely the absence of disease or infirmity."

The WHO Constitution further states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, and economic or social condition."

Dr. Samar also cited other conventions such as the International Convention on Economic, Social and Cultural Rights that recognize the right to health. As a Human Rights Commissioner and former Special Rapporteur on human rights in Sudan, Dr. Samar described the complexities in achieving the right to health.

Protecting and fulfilling the right to health involves certain obvious actions such as building hospitals and clinics and providing health care services. It also extends to addressing important determinants of health including access to food, water, shelter, adequate sanitation, health information, and benefits from scientific programs. The link between the right to health and clean water is obvious in developing countries. The mortality rate from lack of access to safe drinking water is huge.

The right to health includes freedoms, such as the right to be free from non consensual medical treatment. It contains entitlements, including the entitlement to preventive health services, reproductive health information and treatment, and equal and timely access to these things at national and community level. Dr. Samar emphasized the importance of being free from discrimination in the provision of health care and health information. States are responsible for ensuring that health care is accessible and of good quality. Facilities must respect medical ethics and be sensitive to gender differences. Quality requires that health professionals are scientifically trained.

States have an obligation to eliminate discrimination in all forms and to guarantee the right to public health and medical care. This includes freedom from racial discrimination for peoples such as Gypsies (Romani) in Europe. Even in hard times, vulnerable members of the community must be protected. The right to health is reflected in other relevant charters that include the African Charter on Human and Peoples' Rights (ACHPR); the American Convention on Human Rights (ACHR) – which added a protocol in

the area of Economic; the Social and Cultural Rights (Protocol of San Salvador 1988); the European Social Charter 1969; and the Convention for the Promotion of Human Rights and Fundamental Freedoms of 1950. Each of these charters and conventions contain provisions related to health. Dr. Samar noted that many Asian countries do not yet have any corresponding human rights instruments, although efforts are being made in the region to implement the right to health.

Protections are needed for vulnerable groups, who bear the burden of health disparities and suffer greater discrimination in the realization of their right to health. Dr. Samar identified several disadvantaged populations, including:

#### Women

In general, women, face more discrimination than other vulnerable populations, and this is particularly the case in Asia. Women need protection in relation to their biological functions since they bear children and ensure the survival of humankind. They must be protected from gender violence including domestic violence, which has a strong impact on health. Women are particularly vulnerable in patriarchal societies. Many modern societies are moving to protect women using treaties and conventions that recognize their right to health.

For example, both the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and the International Convention on Economic, Social and Cultural Rights (ICESCR) require the elimination of discrimination in health care as well as access to health care for all. Access to health services can be problematic for women, especially in rural areas. Highly trained female health workers are usually based in cities, and women's access may be restricted for cultural and religious reasons in areas where there are female health workers are unavailable.

#### Children

Children are a vulnerable population for a number of health risks in all countries including those in Asia. They are at risk for communicable diseases such as polio and malaria and malnutrition or a combination of these. As with women, countries may use conventions to invoke the right to health for children. For example, the Convention on the Rights of the Child (CRC) creates particular obligations to reduce these risks.

#### **Disabled Persons**

People with disabilities are a vulnerable population that may find themselves marginalized and treated as objects of charity and medical attention. Objectification can also depersonalize them. The Convention on the Rights of Persons with Disabilities (CRPD) promotes and protects basic rights for people with disabilities. To advance the right to health for disabled persons, states must provide health services designed to address and minimize disability. Principles supporting nondiscriminatory practices in health will help to ensure that the disabled have access to affordable health care.

#### **Migrants and Refugees**

Dr. Samar expressed concern over the rising number of conflicts around the world, including in her home country of Afghanistan. She saw armed conflict as a force that moves people and the conflict itself across borders to neighboring countries. The origin, nature, and types of conflicts may vary, but they can

violate the enjoyment of the right to health. Dr. Samar encouraged states to recognize the human rights of migrant and refugees, especially the right to health. States should treat entering migrants and refugees with dignity. Dr. Samar referred to her own experience as a refugee for seventeen years in Pakistan, telling the Workshop participants that it had not been positive.

Dr. Samar recognized that laws and policies to protect human rights need attention, particularly in the case of women and children. These obligations are legally binding in countries where human rights treaties have been ratified. Unfortunately, there are no prescriptions for countries on how to they should meet their obligations, but they are obliged to take all means, including legislation. At a minimum, states should afford vulnerable populations the right to access health services in a nondiscriminatory way. They should ensure their access to food, shelter, sanitation, and clean water. States must also ensure that these populations have access to safe medicines and drugs. National pharmaceutical policies should prevent the marketing of unsafe drugs. Countries should not adopt laws or policies limiting access to contraception or reproductive health services.

Above all, states should promote the right to health, not interfere with it. They should adopt legislation and administrative measures that ensure access to health care in nondiscriminatory way. They should create a national health policy and health plan covering their public and private sectors with full accountability. The United Nations, nongovernmental organizations, and private sector groups also have responsibilities. The UN is responsible for promoting its conventions and treaties. It should request that countries cooperate effectively on the implementation of human rights. Because the UN bears responsibility for its conventions and treaties, it should speed up its work on health and human rights. The private sector can have a negative effect by making accessibility and affordability more difficult. States should ensure that private businesses also respect right to health.

According to Dr. Samar, there is an appalling lack of respect for health and for the right to health in many developing countries. In a globalized world, where communicable and noncommunicable diseases do not stay in one country, and they spread across borders, all countries have a stake in the right to health.

Dr. Samar noted that our world, unfortunately, does not recognize one standard for the right to health. Differences arise because states and their leaders maintain different political opinions and behaviors toward this right. There remains a lack of social justice and respect for the equality of all human beings within Asia and beyond. She remarked that "living in Afghanistan, I personally feel the pain of discrimination." She closed by challenging everyone to unite and work hard to globalize human rights values and principles to save humanity.

#### Summary of Questions and Comments for Dr. Samar

1. What progress has Afghanistan made on the right to health? Afghanistan lacks a proper and practical strategy for the right to health. Partners come with their blueprint and implement what has been done in other countries. Unfortunately, this strategy has not proven successful. Physically, there are some health clinics, and most people have access to basic health services. It was recently announced that maternal mortality had been reduced from 1500 to 300 per 100,000 live births. There is real doubt that it has undergone such a dramatic reduction. In parts of the country people lack access to health services. According to a human rights commission report, 53% have access to health care and the quality is not good.

- 2. How could mortality rates be reduced so quickly? The first problem for my country is many people do not have the medicine or facilities they need for adequate care. A physical structure such as a building will not treat people. The second problem is my government does not provide public services to its people. Instead, it tends to contract out its public health services to NGOs. Different NGOs have their own ways of operating. There are also distribution problems: provinces may have a hospital in one of the centers, but no one looks at rural areas. My personal view is that government must be able to provide and support basic health services. Yes, states can contract out some parts of health care but not everything. People working within our health sector collaborate with the WHO or USAID rather than developing a plan based on the needs in our country. This approach has not been very successful. We still face challenges since polio persists, and in some places, we lack basic medical equipment such as x-ray machines.
- 3. How does your country ensure health care quality? A great many people, as patients, board flights everyday to get their health care in another country outside their own. Remember, some areas of my country do not have radiography machines. We do monitor our health care facilities, but monitoring takes a lot of staff. Our rule of law is weak. After all, Afghanistan is a country where guns rule rather than the rule of law at the moment. Again, reports are published every year, but I am not very happy with the quality of our reporting, especially on mother and child mortality. Access of women to contraception and family planning are limited by religion. Nevertheless, it is important that laws are developed which are sensitive to the context of the country.

# Rationale of Workshop, Agenda, and Anticipated Results.: Dr. William Aldis, Asst. Professor, Faculty of Public Health, Thammasat University, Thailand.

Forces are at work on a global level and the organizers of this Workshop have observed that neither law nor public health professionals have the skill sets to strengthen global frameworks acting alone. Countries in our region have so far not participated in some of the global shifts that are occurring, but they will be directly affected. So, our Workshop is designed to bring a variety of experts in public health, health and public health law, health governance, and policy together to discuss selected global health issues and problems, experiences, and gaps relating to globalization and its impact on health within the region and beyond. Many of them call for joint action by our law and public health colleagues in a multidisciplinary setting similar to the one we provide in our Workshop over the next three days.

We will begin by identifying the key issues and problems arising from globalization and its impact on the health laws, governance frameworks, and policies that influence health. Some current issues already identified by our participants include existing legal and regulatory challenges, insuring access to health information and protecting personal privacy rights, promoting human rights and the right to health, and emerging technologies which may have beneficial or deleterious effects. At the end of our Workshop, we may leave with more questions than answers, but we hope you, as participants, will leave with some ideas for actions we could take in future. We also hope we create new friendships and collaborations that you find instructive and useful.

# **1st Session: Globalization and Communicable Diseases in the ASEAN Region**

Public Health and Emerging Zoonotic Disease: Knowledge Gaps and Uncertainties in Asia – ASEAN's Role in Tackling Avian Flu.: Prof. Koh Kheng-Lian, Professor Emeritus, Faculty of Law, National University of Singapore, Singapore.

Summary: Prof. Koh identified the dilemma in risk management presented by the uncertainties of science in the transmission of zoonotic diseases, such as avian flu. Zoonotic diseases represent a risk of transmission from animal to human, and if the disease mutates, then it may become human to human transmission, especially in Asia where humans and animals live in close proximity. The experience of Asia in recent outbreaks of avian flu illustrates how decision-making is hampered when the science of disease transmission remains uncertain. She noted China responded to its avian flu outbreak by resorting to mass culling of birds without a clear scientific basis resulting in unintended ecological consequences. Prof. Koh also saw recent experiences of Indonesia and ASEAN with outbreaks as lessons about how a country or region might better respond. ASEAN has acted with alacrity, providing technical assistance and dialogue. While Indonesia's experience illustrates the benefits of cooperation and government intervention to ensure that the public's health remains paramount in decision-making, Indonesia responded to patent harvesting by pharmaceutical companies by withholding material. Such actions could jeopardize efforts to control pandemics in the future. Further multidisciplinary thinking is needed to better calibrate policy and lawmaking to better manage the tension between special interests and global public interests. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/1-1.pdf.

# *IHR(2005) Regulations Update.*: Dr. Nyoman Kumara Rai, Senior Advisor to the Regional Director, SEARO, SEARO-WHO.

Summary: Globalization brings about a heightened need for worldwide public health cooperation. All international legal obligations arising from treaties have relevance to public health. International health law should be able to accommodate global public goods. A broad view would include most human rights treaties, or on a narrow view, only those related specifically to health, including the WHO Framework Convention on Tobacco Control (FCTC) and the IHR (2005). The success of international health law depends on existing domestic laws providing the foundations to support compliance with bilateral and multilateral agreements. These require certain building blocks in domestic laws. This manifests as horizontal challenges occurring between countries engaged in trade or from people traveling between countries. Vertical challenges may arise when countries have weak public health systems, including inadequate public health laws. Domestic public health laws provide essential building blocks for protecting national health and for implanting international obligations assumed under IHR (2005) and the FCTC. Without the necessary domestic laws, neither of them will be successfully implemented. Asian countries could benefit from support to develop their domestic laws. There is a role for the WHO and possibly for support materials tailored to fit regional needs and training as well as technical assistance. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/1-2.pdf.

China and the IHR (2005) Adoption: Lessons Learned.: Mr. Ma Bin, Office of Health Emergency (Centre for Public Emergency), Ministry of Health, Beijing, China.

Summary: The experience of China in implementing IHR (2005) illustrates some of the complexities of this process in a very populous country with many seaports, airports and land crossings. It shows the innovations and solutions used by China in its experience to date. It also illustrates the need to strike a balance in a globalized world between the sovereignty of states in managing their own public health risks and the importance of limiting the negative impacts of regional or global health risks on other countries as a result of domestic responses that are either too zealous or too weak. Although China is one of the largest developing countries in world, it continues to have a wide capacity gaps. This makes it impossible for China to be fully compliant with the IHR (2005) by 2014 or 2016, but it is making progress. China established three overlapping coordinating mechanisms that may be viewed as circles. The outer circle contained the regional coordinating mechanisms. The next circle contained the multiministry coordination mechanism. The inner circle contained the general coordinating mechanism comprising the Ministry of Health, the General Administration of Quality, Supervision, Inspection, and Quarantine (AQSIQ) and the Ministry of Foreign Affairs. In 2008, quarantine officials managed an outbreak of Chikungunya fever, and in 2009, an outbreak of H1N1. In 2010, the Chinese government detected an outbreak of polio in Xinjiang. The Chinese government collaborated with the WHO, which provided technical and intelligence reporting to its Ministry of Health using IHR (2005) with success. Even so, states have their own sovereignty and manage their public health risks in their own way. Globalization in the form of international travel and trade affects China and other countries as trading partners. Globalization may also impact how regional sovereigns manage their public health risks and implement the IHR (2005) reciprocally. There is a role for work that assists countries to see the need for regional and global perspectives in the exercise of domestic policy, and in the development of domestic laws to address public health risks. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/1-3.pdf.

*IHR (2005) IN CHINA HEATH QUARANTINE*.: Mr. Zhou Licheng, Department of Health Quarantine, Administration of Quality Supervision, Inspection and Quarantine, Beijing, China.

Summary: The General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and its agencies in mainland China are the competent authorities at each designated point of entry in its territory. After the issuance of IHR (2005), the Government of China (GOC) constructed its health quarantine legal system step by step. In 2007, AQSIQ took new quarantine measures on that simplified the entry and exit passenger health declaration formalities. In 2010, the GOC revised the partial clause of the specific rules of the Frontier Health and Quarantine Law which altered the infectious diseases that would prohibit visitors from entering. In recent years, the GOC strengthened health quarantine work under the IHR (2005). First, the core capacities of ports of entry (POEs) were strengthened. The number of quarantine officials and equipment has been strengthened. All kinds of quarantine standard operating procedures (SOPs) and emergency response mechanisms have been established and optimized. Second, various innovations on quarantine facilities were made including the infrared thermal imaging body temperature monitoring system, body temperature detection equipment for vehicle drivers, Self-Health Declaration System for Travelers, remote medical vector Identification System and other monitoring mechanisms. Third, fifteen International Sanitary Airports and Seaports were established. Fourth, good

coordination and communication with related countries and regions were kept. AQSIQ got several achievements by implementing IHR2005. In 2009, the influenza A (H1N1) was quarantined successfully with above 45% input cases of influenza A (H1N1) quarantined at POEs. In 2008, the first input case of Chikungunya Fever in China was found at POE. Several input clustered cases were treated successfully at POEs, including input Dengue fever clustered cases, malignant malaria clustered cases, and flu clustered cases. *To learn more, go to* <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/1-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/1-3.pdf</a> to view this presentation which begins at the end of *China and the IHR* (2005) *Adoption: Lessons Learned*.

#### **Summary of Questions and Comments for the 1st Session**

- 1. How effective is a WHO directive? If there is not an immediate response a state may not be able to wait and there is nothing to prevent a state from imposing more stringent measures. Whenever a country takes unnecessary stronger measures that go beyond the IHR (2005), WHO will not take corrective measures. There is concern that reciprocal measures may be taken by other member states. WHO is not in a position to police states. But WHO will respond when it is likely that reciprocal measures will be taken. Where HIV-related travel restrictions are placed on people, this is a restriction on individual freedoms. We need to improve preventive responses.
- 2. Are there issues of hard laws versus soft laws, especially in environmental law? Some sceptics say hard laws mean nothing, due to lack of capacity and lack of resources within a country. Some hard laws have soft law components; for example, a Memorandum of Understanding (MOU) on disaster management. Pandemics need to be managed under this MOU and this calls for worldwide cooperation. We need scientific evidence before we can react. Also, we cannot prescribe, in concrete terms, the response to pandemics we need an adaptive approach. This is where soft law comes in. Take the example of the gap between developed and developing countries. The priority in developing countries is infectious/communicable diseases.

# **2<sup>nd</sup> Session: Legal and Policy Challenges in Regulating Health Technology** in Asia

Legal and Regulatory Challenges to Innovation and Utilization in Asia.: Dr. Ton van der Velden, Pathfinder International Country Representative, Hanoi, Viet Nam.

Summary: Globalization poses challenges for countries interested in a global health workforce. This presentation addresses the problems arising when developing nations, such as Viet Nam, globalize their health care workforces. Questions remain whether countries can expand their capacity for health care by globalizing their work forces when not all foreign health workers receive equal training or credentialing. This presentation argued for the creation of a unified standard for licensure and credentialing of health care workers in developed countries. One way to achieve these goals would be to recognize the professional practice license issued by a county as an international practice license. For a professional practice license to be recognized as an international practice license, Dr. van der Velden believes it must (1) represent that applicants attained a good professional education meeting the requirements of the receiving country; (2) be subject to loss of license under a complaints process and standards of practice; (3) require continuing professional development; and (4) require the achievement

of an agreed standard of education and of core competencies. Nurses arriving from sending countries may have different roles, functions, responsibilities, and core competencies. Thus, the recipient countries must trust and acceptance these new arrivals. Currently, Viet Nam is revamping its practice statutes so it may develop uniform standards that enable it to expand its health care workforce while ensuring professional quality. Unfortunately, this process poses challenges that Viet Nam it trying to address. *To learn more, go to* <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/2-1.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/2-1.pdf</a>.

Nanosafety, Regulation, and Health: How Should Asia Proceed?: Dr. Lerson Tanasugarn, Dept. of Biochemistry, Faculty of Science, Chulalongkorn, Thailand.

Summary: This presentation addresses how risks presented by a new technology can be managed when science is unsettled on its hazards. Risk identification and assessment play a key role in risk management, but they need science to help inform them. Nanotechnology deals with the manipulation of materials on the scale of nanometers (1-100 nm) in at least one dimension. This ability to alter materials so they acquire new properties can lead to new applications that produce economic benefits and social changes. Nanomaterials are used in many industries including health care, where pharmaceutical and diagnostic imaging companies are creating new drugs and diagnostic applications. There may be unknown hazards with these new uses, because science and toxicology are lagging behind their entry into use. Potential human exposures to these unknown hazards are likely in nanomaterial manufacturing plant workers and consumers of cosmetics containing nanomaterials in their formation. Although other nanomaterials are manufactured for incorporation into nanocomposite materials, such as polymer resign tennis rackets, to restrict their release into the environment; they are unpredictable once they have reached their end-of-life period to become garbage in dump sites. Once there, they decompose releasing their nanoparticles into the environment. Some experts believe that any legal measure crafted to regulate nanomaterials must be strictly science-based. Others subscribe to employing the precautionary principle as a way to reduce the risk of possible harms when the risks are not fully known. Multiple organizations are looking at these issues to balance their advancement with their safety. These issues are important for Asian nations, such as Japan, Korea, China, and Thailand, since they are all quite active in this area. Asia has recently held forums on nanomaterials but their impact remain unclear. A variety of international organizations ranging from the Organization of Economic Cooperation and Development (OECD) and the International Organization for Standardization (ISO) to the WHO are also exploring the issues raised by nanomaterial uses and their risks. There will be a role for soft and hard laws in regulating the rights and obligations of practitioners, consumers, employers, and health facilities. The type of law will not be established until the science is better understood. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/2-2.pdf.

#### Summary of Questions and Comments for the 2<sup>nd</sup> Session

- 1. How to ensure an adequate standard of care for health care workers with an international practice license? Regional licensing exams may be a practical option but this would need to be accepted by participating countries. There may be concerns in trusting a licensing exam, and such an exam might potentially further reduce an already constrained workforce.
- How do we manage nanotechnology when our risk management science is uncertain on these
  materials? One participant raised a report on workers in factory with respiratory symptoms.
   The factory contained poorly ventilated areas without proper safety standards and there were

so many contaminants that it could not be determined if nanomaterials were responsible for symptoms. Research/evidence is lacking. In this context, national accreditation standards would be useful.

3. What about risk assessment and what is an acceptable level of risk per product? There is no cumulative test. Dr. Lerson acknowledged that he uses nano materials in his clothes <u>and</u> these materials are in his skincare products <u>and</u> tools. Should we also be developing cumulative nano use guidelines? Workshop participants were not aware of any protocols on the cumulative use of nano materials. What about institution-specific protocols which are material focused? Should the aim be to reach the level where countries can assess the risk of products with multiple nano materials? There are many studies, variables, and many details. There is some utilization of nanoparticles in medicine. Future possibilities include the utilization of nanotech as a delivery device in combination products, and its use as a diagnostic and treatment device.

#### **3rd Session: Regulating e Health: Privacy and Other Challenges**

Global or Glocal e-Health Approaches in Asia: What Is New or Next?: Dr. Nawanan Theera-Ampornpunt, Health Informatics Division, Faculty of Medicine, Mahidol University, Bangkok, Thailand.

Summary: E-health is an important use of information technology which has the potential to increase access to and quality of health services and to reduce costs. There are divergent views on what constitutes e-health. Since 1991, significant developments in the adoption and use of information communication technologies have occurred worldwide, especially in the United States. The WHO published a "Systems Thinking for Health System Strengthening," where WHO lays out a framework for health systems that identifies building blocks on which a health system might be built. Information is the first building block, and one of the important building blocks, for a strong health system. The U.S. has adopted laws governing and promoting the use of health information technology, such as the Health Information Technology for Economic and Clinical Health (HITECH) Act and its "Meaningful Use" provisions, but many countries, including those in Asia, are slow to embrace e-health. Many developing countries have yet to enact similar laws. Thailand is in its infancy and lacks support of a national policy or governance. While its adoption rates are high, and possibly higher than in the U.S., it lacks important national standards and high quality education in e-health. Health information exchange remains limited to clinical settings. Recently, the National Health Commission of Thailand, established under its National Health Act, assumed the role of e-health governing authority. One goal is to develop a strategy for ehealth development. There may be a role for law and legal policy in helping countries within the region to develop parameters for the regulation of e-health that are suitable for the region. A great deal remains to be done. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/3-1.pdf.

### Health Information Privacy: Asia's viewpoint?: Dr. Nawanan Theera-Ampornpunt, Health Informatics Division, Faculty of Medicine, Mahidol University, Bangkok, Thailand.

Summary: Privacy concerns exist worldwide, but nations approach their health information privacy concerns differently. The globalization of health systems and of health information exchanges may magnify the risks related to the sharing of protected health information (PHI). Different views of privacy held by peoples and cultures of the world will challenge existing e-health information practices. Laws for managing information privacy concerns will need to function in both a domestic and a global context. For example, the U.S. relies on a legislative approach to protect PHI using both state and federal laws to address privacy, confidentiality, and security concerns. The primary U.S. federal law is the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which contains the privacy and security rules governing accesses, uses, and disclosures of PHI by covered entities. While it provides safeguards and compliance requirements, it is a permissive Act with multiple exceptions where patient authorization or consent may not be required for quality assurance and other administrative purposes. Provisions of HIPAA may be preempted by more stringent state laws which add complexity. Unlike the U.S., Asian countries and their peoples have different views about privacy. They want high quality access to care and are not so concerned about privacy. Thailand has issued a declaration of patients' rights which are not enshrined in law. There is an Official Information Act and a National Health Act which affect health privacy. There are questions about the enforceability of privacy laws in Thailand. During the recent floods, it was possible to access health information in breach of existing laws. Based on its experiences, Thailand may need to calibrate laws so they account for cultural attitudes to privacy. There also may be a role for regional thinking about how such privacy concerns might be managed in Asia. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/3-2.pdf.

#### Summary of Questions and Comments for the 3rd Session

- 1. What are other sources for rights to privacy or health privacy? The right to privacy may be found in a variety of different treaties, laws, and regulations. For example, the International Covenant of Economic, Social, and Cultural Rights (ICESCR) presentation couched it only in terms of moral obligations. A right to privacy can also be advanced as a civil rights matter or ethical matter where it might be valuable to link medical historical oaths and ethical standards. In the case of Thailand, The National Health Assembly of Thailand was created legislatively and has a mandate set out in its Act. It is a mechanism to empower the public. It allows the public and local communities to participate. There has been public praise for the National Health Assembly, but there have also been comments that it tends towards top down decision making. There is an understanding that there are requirements for local meetings in the Act.
- 2. How do Thai views on privacy affect health decision-making? Both top down and bottom up decision-making occurs. Doctors must see treatment within an ethical framework a more comprehensive vision that pushes doctors to see both the risks and benefits with sharing of health information. Health information and privacy are competing priorities, because health information necessary implies it will be shared openly to advance health while privacy is meant to protect the patient from harm by keeping health information secret, but it could harm the health of the patient.

#### 4th Session: Health and Trade Laws and Agreements

International Competition, Trade Laws, and Agreements: Regional Law and Governance, and Policy – The Thai Experience.: Ms. Inthira Yamabhai, Department of Heath Intervention and Technology Assessment Program, Department of Health, Ministry of Public Health, Nothaburi, Thailand.

Summary: The government of Thailand issues licenses for essential medicines under TRIPS in order to make certain medicines more affordable and available. She described the experience of the Thai government in issuing government use licenses in 2006-2008 in order to improve access and affordability for certain medicines still under patent. She asked "How might Thailand benefit from access to medicines and what retaliations might be expected for issuing licenses for medicines still subject to patent?" Under TRIPS, patents are protected for 20 years which protects the rights of inventors to reap the commercial benefits of their invention as a way recoup their research and development costs. Patent protection becomes an issue when it leads to high prices that exclude developing countries because they cannot pay them. Strategies for improving access include the use of compulsory licenses and parallel imports. The DOHA Declaration (2001) states that countries should implement the TRIPS agreement in a manner that is supportive of public health, by promoting both access to existing medicines and research and development into new medicines. Between 2006 and 2008, Thailand issued government use licenses to enable access to drugs to treat HIV, heart disease and cancer. The immediate effect was a reduction in the cost of medicines. The government's policy opened the window to the use of generics and the generic products were considerably cheaper. The policy also affected the price of the original (patented) product which was reduced by 40% when government issued licenses for generics. Government and NGO's supported the policy, but there were also negative responses and political pressures.

Thailand faced the threat of withdrawal of investments from the country. Subsequent to the issuance of government use licenses, duty free status was withdrawn by the United States for several high-value Thai exports. Despite this, Thailand's exports increased substantially, and foreign investment did not decline, although there was a significant decrease in the proportion of Thailand's exports which went to the US. For the three Thai products for which the USTR suspended duty-free entry, Thai exports to the US fell by US\$ 388 million in the following year, but this was more than compensated by an increase in exports to other trading partners of US\$ 521 million. Threats were made about possible litigation in international courts. While there are problems with this policy, the overall impact has been positive domestically, especially for increasing access to medicines. Based on the experience of the Thai experience, three factors must be considered in order to better understand and to maximize benefits from the use of licenses for medicines still under patent. These are (1) the number of patients in need, (2) the difference in price, and (3) the clinical advantage or additional clinical benefits of using the patented drug. The Thai experience illustrates that government use licenses are feasible, and the experience of Thailand may have broader application within the region. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/4-1.pdf or visit the published version of their study at http://www.globalizationandhealth.com/content/7/1/28.

Competition Law/Policy and the Consequences for Access and Innovation for Medicines/Health Care.: Mr. Ujjwal Kumar, Public Health Consultant and Former National Consultant (Trade and Health), Ministry of Health & Family Welfare (Government of India), New Delhi, India.

Summary: There are policy direction gaps that manifest into law and policy gaps and subsequent gaps in their implementation. Although competition law and policy may not be helpful in reducing the policy direction gaps, it is certainly a good tool to enhance access and innovation in health sector, particularly in a liberalized economy. CL and policy are different and they should not be used interchangeably. CL aims to: prevent practices that have an adverse effect on competition; promote and sustain competition in the market; and protect the interests of consumers. CL mainly deals with collusions and cartels, abuse of dominance, and merger and acquisitions (MAs) regulation. Competition policy deals with policyinduced distortions in market affecting competition based on competition principles. The interface of competition law and policy with the health sector occurs in all the subsectors, namely, pharmaceuticals, medical devices, health services, health insurance, and public health procurement. In the pharmaceutical sector, there could be collusion (cartels) between a variety of interests such as pharmaceutical companies, pharmaceutical companies and physicians, or other associations; abuse of dominance involving mainly intellectual property-related interests; and MAs having adverse effect on competition.

The main concern for developing countries in the medical devise arena is their lack of domestic manufacturing base as well as the presence of plethora of regulatory and nonregulatory entry barriers. Similarly, in health services there may be prevalence of collusions, tied selling, and certain malpractices that can lead to anti-competitive effects, including presence of regulatory and non-regulatory entry barrier. Competition law and policy may also be used to increase generic competition in pharmaceutical sector, including by advocating the use of TRIPS flexibilities. At international level, work related with competition law and policy is going on for some time. For instance, WTO Working Group on Interaction between Trade and Competition Policy (WGTCP) remains dormant, but it could be activated at anytime. UNCTAD has been working on this issue for a long time, and it has a rich repository on competition issues. There are pro competition clauses in WIPO Development Agenda inducing further work on such issues. Because of the importance of competition law and policy and its relationship to the health care sector, public health and law faculties in a university need to work together on such issues. *To learn more, go to* http://www.idlo.int/DOCCalendar/GHLPresentations/4-2.pdf.

Trade Negotiations: The International Health Policy Program Approach.: Ms. Chutima Akaleephan, M.Sc., International Health Policy Program (IHPP), Ministry of Public Health, Nonthaburi, Thailand.

Summary: This presentation began by asking whether the International Health Policy Program Approach to adapt the World Health Assembly process using its three elements of a triangle can improve intersectoral collaboration, public participation and creation of participatory healthy public policy. The Thai experience suggests that it can because the National Health Assembly is an innovative mechanism for public participation in public policy process including international trade. In the process of trade development, the Ministry of Commerce undertakes trade negotiations. It is responsible for prenegotiation, the process of negotiation itself, pre ratification and enforcement. The international trade governing body, the Committee on International Economic Policy, is chaired by the Prime Minister or

Deputy and the Vice Chair is the Minister of Commerce. The Minister of Health does not have a place on the committee or its subcommittees, but there is a health representative on the Working Group on Evaluation of Negative Impacts from FTAs. In Thailand, the National Health Assembly, which was established under the National Health Act B.E.2550 (2007), provides a model for formalizing community participation in the development of health policy, including international trade policy. It has been called the "triangle that moves the mountain strategy." It aims at improving intersectoral collaboration, public participation, and the creation of a participatory healthy public policy. By the fourth National Health Assembly in 2011, forty resolutions had been adopted of which seven resolutions related to international trade including universal access to medicines and the need for public participation of negotiations for Free Trade Agreements. They also included resolutions on the health and social impact of international trade in tobacco and alcohol. The National Health Assembly is an innovative mechanism for supporting public participation in the public policy process, including international trade negotiations and agreements. Health remains an important gap in the development of international trade policies in Thailand. More work is needed to better understand the health impacts of trade policies, and to generate evidence for the formulation of policy and negotiation positions in trade agreements. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/4-3.pdf or visit the following sites http://www.nationalhealth.or.th/ or http://www.samatcha.org for more information.

# Economic Implications of International Health Law.: Asst. Prof. Dr. Nitinant Wisaweisuan, Vice Rector for International Affairs, Thammasat University, Bangkok, Thailand.

Summary: Health is a medical service and a social service, but at the same time it has economic implications. Health care is very important capital for human resources. If lives are shortened as a result of a lack of health care or poor health care, then economic growth is impacted. How do we help people get access to quality health care? In Thailand, we have a government-backed insurance system the government and its taxpayers finance. There specific schemes for civil servants, middleclass, and poorer people to ensure their access and they involve the public budget. Consider how such expenses are accommodated. Middle class people get social security funds and access to health care while lower income people having access to the 30 baht scheme must pay 30 baht. People have access to health care, but it may lead to distortions and demands. In Thailand, there are many demands including health care, environmental issues, and compliance with the IHR (2005). Countries always have new diseases and new disasters. For example, Thailand had to cope with major flooding during the fall 2011. When asked about its performance, Ministry of Health responded that epidemics were avoided because people exercised caution and they had bottled water to drink. Ministry of Health, however, did not know about the waste management of empty bottles since they were not responsible. The lack of knowledge may play a role in how Thai villagers rely on traditional treatments and ways of living including health care. Villagers may not bring in advanced medicines and they may reject it. Knowledge about these practices may be lacking at higher levels of health planning. We need communication and understanding so we learn from each other at home and abroad. Health care services are an investment. Every country would agree public health is a necessity for all. They should not let expensive medical services prevent access where poor people are left behind. In economic terms, health care optimizes scarce resources to improve health outcomes. Laws can assist with public health reformation to improve health outcomes. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/4-4.pdf.

# 5<sup>th</sup> Session: Health, Pharmaceutical Patents and Access to Essential Medicines

Patent Harmonization: SE Asia Perspective.: Dr. Manisha Shridhar, International Trade and Health, WHO, Regional Office for South East Asia, New Delhi, India.

Summary: The World Health Assembly (WHA) set up a Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2003 to examine the challenges in the way of meeting the goal of ensuring access and innovation for medical products for developing country needs. This culminated in the Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property (GSPA) in 2008, which identified eight main elements and 25 sub-elements spread across 108 action points. The main elements cover important areas for action, such as prioritizing and promoting research and development, building and improving innovative capacity, transferring technology, and applying and managing intellectual property to contribute to innovation and promotion public health. Further to this, WHA established a group, Consultative Expert Working Group (CEWG), under element sever of GSPA to examine and recommend new, innovative, and sustainable sources of funding to make better use of existing resources for research and development for the specific health needs of developing countries. The key recommendation of the CEWG is a binding international instrument on research and development. The CEWG believes that agreement on this could have far-reaching effects on people suffering from all types of diseases in developing countries – now and in the future.

The CEWG has recommended that WHO play a central role in improving coordination of research and development in developing countries. There are different mechanisms for international engagement under the WHO Constitution. The origin and role of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) are important. As an international agreement administered by the World Trade Organization (WTO), TRIPS sets down minimum standards for many forms of intellectual property regulation and remains one of the most comprehensive multilateral agreements on IP requiring all countries to change over to a strong patent protection regime. While she noted that developed and developing nations have had their differences on its interpretation of "TRIPS flexibilities," the Doha Declaration confirmed the application of TRIPS flexibilities for public health needs of individual member states. The World Intellectual Property Organization (WIPO) also has a role where it has maded efforts to harmonize procedural and substantive patent law. The Patent Cooperation Treaty also simplifies provisions. Thus, the patent application and granting procedures in Thailand or any other country would be the same. Movements toward harmonization promoted by TRIPS and other agreements may be precluded by the domestic regulatory frameworks or judicial rulings in countries such as the U.S. The patent law landscape in these countries is also changing. Because patent laws and protections may impact public health in developing nations, SEARO is examining how to help countries in the Asian Region prepare to respond to WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA). It is encouraged that countries decide what is appropriate for them and to implement the provisions that best meet their requirements. The role of SEARO is to provide region-specific materials, training, and technical assistance to help countries in this complex area. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/5-1.pdf.

Panel Session: Access to Essential Medicines in Asia: Where Are We Now?: Moderator: Ms. Panida Panyangarm, Eisai (Thailand) Marketing Co. Ltd., Bangkok, Thailand.

Health, Pharmaceutical Patents, and Access to Essential Medicines.: Dr. Kitima Yuthavong, CEO, Pharmaceutical Research and Manufacturers Association.

Summary: This presentation reviewed the development of innovative drugs by the pharmaceutical industry. Bringing innovative drugs to market requires a tremendous amount of time and capital. Currently, less than 5% of medicines in the market are still under patent protection. Since most medicines are not patented, patients can access original and generic drugs. New drug development plays a key role in advancing medical treatments, reducing deaths from major diseases, improving treatments and outcomes for debilitating diseases such as Alzheimer's disease, and decreasing the overall costs for treatment. A patent term is 20 years from filing, but the effective patent life is reduced by the duration of research and development (R&D) and registration. Regulatory delays dramatically reduce the period of exclusivity. After patent expiration, generics can be developed, but the costs for developing an innovative drug is up to tens of thousands fold greater than a generic. Based on an OECD Study in 2010—Policy Complements to the Strengthening of IPRS in Developing Countries—there is a generally positive relationship of intellectual property rights reform to trade, foreign direct investment, technology transfer and innovation. Reforms concerning patent protection have tended to deliver the most substantial results. Overall, the policy complements determined to be the most constructive were related to inputs for innovative and productive processes and to the ability to conduct business. For lower income countries, formation of collaborative relationships or partnerships with industry and NGOs may improve their access to medicines. The key message for all countries is to provide policy support for the development of national private sectors and to create a policy environment which will attract global partners. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/5-2.pdf.

Mechanisms to Support Access to Medicines in Thailand.: Ms. Inthira Yamabhai, Department of Health Intervention and Technology Assessment Program, Dept. of Health Ministry of Public Health, Nonthaburi, Thailand.

Summary: Ms. Yamabhai shared her experience and that of the Health Intervention and Technology Assessment Program about mechanisms to support access to medicines in Thailand. The Thai government designed its health insurance system to achieve universal access to health care for its citizens. Its strategy for achieving its goals relied on key elements that included (1) mechanisms to increase access to medicines under patent, (2) rational selection of medicines, and (3) mechanisms to reduce prices (including wider use of nonpatented medicines, central procurement or bargaining with vendor managed inventory, GPO price moderation, and reference pricing listed on the website). The case study of the access to Efavirenz illustrates a well-known model of the "triangle that moves the mountain" strategy. This model refers to the combined operation of three elements or catalysts for change that are (1) knowledge and evidence (the power of wisdom), (2) advocacy by civil society organizations leading to public support (social power), and (3) high-level political leadership (political power). The Thai government granted a government use license for Efavirenz which increased its access. Thailand has applied this model to improve public health policies in number of different contexts with success. Ultimately, humans are the key success factor in bringing together each of the different roles and elements of this model. Supporting systems, including regulations, are also important to stimulate

and to manipulate the mechanisms for improving access to medicines. *To learn more, go to* <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or visit <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or visit <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or visit <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or or visit <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a> or http://www.idlo.int/DOCCalendar/GHLPresentations/5-3.pdf</a>

Health, Pharmaceutical Patents and Access to Essential Medicines in Asia.: Ms. Kajal Bhardwaj, Independent Lawyer (HIV, Health, and Human Rights), New Delhi, India.

Summary: Ms. Bhardwaj began by contending that the dramatic drop in prices of HIV medicines from \$10,000 in 2001 to less than \$140 for the current preferred first line HIV medicines was a result of competition from Indian generic producers. Indian companies were able to supply generic medicines at low prices because India's 1970s patent regime did not allow product patents on medicines. Since the advent of the WTO's TRIPS Agreement, developing countries now have to grant 20 year patents on medicines. The tension between TRIPS and human rights was recognized within UN human rights bodies early on. In 2000, the subcommission on human rights of the UN Office of the High Commissioner on Human Rights (OCHCR) declared that there was an apparent conflict between TRIPS and international human rights law, as the TRIPS Agreement, "does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health..." In 2001, WTO members signed the Doha Declaration that reaffirmed their right to interpret and implement TRIPS to ensure access to medicines for all. Still countries struggle in using TRIPS flexibilities. While India used the full transition period (2005) to incorporate flexibilities in its national law, the Philippines incorporated safeguards much later in 2008 and a Supreme Court intervention was required in Sri Lanka to ensure the inclusion of TRIPS flexibilities in the national law. Asian countries have used these flexibilities including compulsory licences issued by Malaysia, Indonesia, and Thailand. Both India and the Philippines use strict patentability criteria to restrict patents on new forms and new uses of old medicines. TRIPS flexibilities are weakened when developed countries and multinational companies challenge or prevent their use through (1) engaging in litigation, (2) lobbying and training of patent offices, judges, and other officials, (3) creating confusion between generic medicines and fake medicines by misusing the term "counterfeit" which refers to IP infringement, and (4) pushing TRIPS-plus measures through WTO accession or free trade agreements. There is a place for hard and soft laws, regional assistance, and regional advocacy to help Asian countries to use TRIPS flexibilities more effectively (Powerpoints were unavailable).

## 6th Session: Future Directions in Health, Law and Governance

Don't Wait Too Long: Law and NonCommunicable Diseases in the Asia-Pacific Region.: Prof. Roger Magnusson, Faculty of Law, University of Sydney, New South Wales, Australia.

Summary: Noncommunicable diseases (NCDs), including heart disease and stroke, cancer, diabetes, and chronic obstructive pulmonary disease, and their risk factors (including tobacco use, obesity, poor diet and physical inactivity), are a major threat to health in the developing economies of the Asia-Pacific region. In 2005, 2.6 million people died from noncommunicable diseases in the ten ASEAN countries, but this is projected to reach 4.2 million per year by 2030. What is significant is that 30% of deaths

occurred in people aged 15-59. This is undermining the once-in-a-lifetime advantage that comes from the younger population structure and lower dependency rates of many countries in the region.

Public health law provides a powerful tool for countries to reduce the preventable component of NCDs, and to maximize the competitiveness of their economies. However, governments face three important obstacles. First, there is a tendency in many countries to look at risk factors for non-communicable diseases – such as smoking or poor diet – in terms of personal choices, rather than as problems that affect families, the economy, and the welfare of society generally. This can create strong resistance to laws and policies intended to influence choices and lifestyles. However, success in tobacco control did not come about – in countries that have reduced their smoking rates – simply because millions of individuals tried harder. It came about because of a partnership between public health law and health promotion campaigns. It took government commitment, laws, resources, and planning. It came about because of sharp increases in tobacco taxes and bans on tobacco advertising. The second obstacle governments face is overcoming political resistance to the need to regulate the businesses that are contributing to the problem, through the products they sell. The third obstacle is that many interventions will be required, not just one. Many of those interventions will be a political challenge, precisely because it means challenging the rights of profitable businesses to manufacture and sell products that are causing harm.

In closing, Prof. Magnusson emphasized that cost-effective policies and laws *are available* to reduce the disease burden caused by non-communicable diseases and their risk factors. The best buys for governments include: (1) protecting people from tobacco smoke and creating smoke-free places, (2) applying heavy-hitting tobacco warning labels, (3) enforcing bans on tobacco advertising, promotion and sponsorship, (4) raising tobacco taxes, (5) restricting access to retailed alcohol and enforcing bans on alcohol advertising, (6) raising taxes on alcohol, (7) reducing the salt content in food, (8) replacing trans fats with polyunsaturated fats, and (9) promoting public awareness about diet and physical activity through the media. *To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/6-1.pdf*.

Lessons for NCDs from Global and Regional Legal Responses to HIV.: Mr. David Patterson, Head, Social Development Programs Unit, International Development Law Organization (IDLO), Rome, Italy.

Summary: Mr. Patterson began by observing that we can distinguish legally binding commitments, such as WTO agreements, TRIPS and bilateral and regional trade and investment treaties, the Framework Convention on Tobacco Control and Human Rights Treaties from other normative nonlegally binding agreements. The latter include resolutions of intergovernmental bodies such as the United Nations General Assembly, UN Economic and Social Commission for Asia and the Pacific (ESCAP), ASEAN and Asia-Pacific Economic Cooperation (APEC). Which are more effective in influencing State behavior—treaties or resolutions? We can refer to the decade of experience in implementing the 2001 UN General Assembly Declaration of Commitment on HIV/AIDS when seeking, for example, to promote implementation of the 2011 UN General Assembly Political Declaration on NCDs. There are valuable lessons from the experience of building international momentum and agreements on HIV, and considering what might be possible for NCDs. In the case of HIV/AIDS, 20 years passed from 1981 when it was detected to the 2001 Declaration of Commitment on HIV/AIDS. The UN responses and initiatives addressing HIV/AIDS have been solidly anchored in international law and the human rights-based approach. Organizations such as UNAIDS, Inter-Parliamentary Union, UNDP, UNESCO, and IDLO have all published guidance on HIV and human rights. For NCDs, the WHO will develop global targets by May

2012 followed by a global monitoring framework. The UN General Assembly will also consider options for multisectoral action and partnership on NCDs in September 2012.So far however we are missing a link to a broad legal and policy framework to address social determinants of health. How should we monitor compliance with government commitments to respond to health challenges?

Civil society is an important part of the process, including the option to submit shadow reports. The involvement of civil society in the recent UNGA High Level Meeting on NCDs contrasted starkly with the involvement of civil society in the 2001 UNGA Special Session on HIV/AIDS. In 2001, 2,000 civil society representatives comprising 500 activist groups, service organizations, people living with HIV and the private sector participated. This included both Economic and Social Council (ECOSOC) NGOs and non-UN groups. To date, civil society engagement in the UN and other international action in HIV is broadranging. It includes women's, children's, faith-based, and human rights NGOs. There are global, regional and national networks of people living with HIV created, funded and engaged. There has been global success on the issue of access to medicines. By contrast, civil society involvement in the global response to NCDs has been mainly limited to health-focused NGOs, for example. NCD Alliance, with a focus on cancer, lung diseases, cardiovascular diseases, and diabetes. There is limited participation of affected communities. A broad range of CSOs must be engaged, such as affected communities, religious, women's, children's, and environmental groups. There are differences, however. For HIV, relevant legal interventions might be characterised as "low tech" with litigants often individuals. The kinds of relevant law include discrimination law, family law, labor law, property and inheritance law, and criminal law. For NCDs, relevant laws might include trade and investment law, labor law, and discrimination law. Legal issues related to IP and access-to-medicines are common to both fields. The kind of law utilized might be better characterized as "high tech" because the legal issues are complex, in part because the litigants are often multinational corporations. To address the challenges of NCDs multilateral organizations and forums such as WHO, UNESCAP, ASEAN, SAARC, and APEC must include multiple stakeholders, including civil society organizations. Law reform on social determinants of NCDs will be needed, together with monitoring and reporting of national legal and policy responses. There is also a need to engage and support broader civil society engagement through the language of development: human rights. To learn more, go to <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/6-2.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/6-2.pdf</a>.

Future Directions in Health Law and Governance, Human Rights, Right to Health and Improving Health: What Are the Links?: Ms. Helena Nygren-Krug J.D., LL.M., Health and Human Rights Advisor, World Health Organization, Geneva, Switzerland.

Summary: Ms. Nygren-Krug asked "what are human rights?" She noted there are multiple rights such as the right to water, food and nutrition, information, and among others. These rights have a strong linkage with public health. While recognition of the role of human rights in the domestic health governance arrangements of countries is crucial, governments negotiate rights, and thus, they may be limited. Human rights help establish relationships between governments, and they may provide a useful framework for health governance. The linkage of human rights to public health can be health promoting depending on how countries "do" human rights and public health. She pointed out that factors such as the price of essential medicines and health services may influence access and health outcomes. Likewise, human rights violations can lead to ill-health. Recognition of human beings as subjects of international law helps promote human rights, although health is seen as a domestic issue. Countries have legal responsibilities that follow a hierarchy that goes from International human rights law to National constitution then to National laws and policies and finally to State practice. Along with

following their legal responsibilities, countries should assess the coherence of their policies considering a range of documents relevant to health governance. According to Dr. Margaret Chan, Director-General of the WHO, "the world needs a global health guardian, a custodian of values, a protector and defender of health, including the right to health." A "right to health" has underlying determinants such as rights related to basic necessities such as clean water, food, and shelter among others and health care. They require availability, acceptability, acceptability, and quality. Getting to a right to health follows the principle of progress realization, where an obligation exists to use the maximum available resources toward achieving progressively the full realization of rights. Ultimately, Ministries of Health support the right to health when human rights are the first priority of government, an obligation of government as a whole, an obligation to protect human rights, a framework for broader analysis and action, enshrined in international and national laws, and monitoring mechanisms to enhance accountability. Progressive realization applies to everyone. Governments can help achieve progressive realization by committing resources, implementing "best buys" for legislation and policy, and upholding and enforcing public health laws. To learn more, go to <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/6-3.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/6-3.pdf</a>.

#### Summary of Questions and Discussion for the Sessions on Day Two

- 1. What level of law should be reformed? Consideration needs to be given to pitching law reform at national or sub-national level for best effect. In addition to national level consideration of NCDs sub-national level laws and customary laws potentially have a huge impact on health. Choosing the right level at which to regulate is a very important entry level decision. For example, implementing a national smoke-free law in China protects the health of millions of people. However, where political will is weak at national level, a progressive provincial government can still take things forward and it is important that national laws should not preclude this.
- 2. **Should smoking laws ban smoking?** Panellists made it clear that there was no suggestion that the mass production and sale of tobacco and tobacco products should be banned. Making tobacco an illicit drug would do little at this time to address the health problems caused by those addicted to tobacco products. Public health laws can reduce consumption by creating environments that better support healthy living; for example, by eliminating or drastically limiting tobacco billboards, and advertising in the media and at point of sale.
- 3. When ministries of health are weak, how may they be supported? Small legal units inside Ministries of Health lack skills, human rights knowledge, and support. However, regional approaches allow small countries to pool resources, and to take a common approach. The development model adopted by the Caribbean Community (CARICOM) provides an example.
- 4. **How can we convince governments to report?** Arguably there is less pressure on governments to address NCDs than to deal with HIV/AIDS. Aid conditionality is not a simple solution. Should donors penalise the population and withhold development assistance because governments are doing too little, or will this further harm public health?
- 5. What are investment treaties? India has approx 82 investment treaties in force (signed in 1990s). They provide incentives for investors, and are intended to reduce risk, by assuring investors of a friendly investment environment by giving investors the right to sue the government or to seek arbitration for interferences with their investment. Investment treaties

have implications for social and environmental policies and laws. The lack of information about the negotiation and contents of investment treaties is a matter of concern in some countries.

#### 7th Session: Health Infrastructure Issues for Asia

Water and Health: Challenges in ASEAN and Singapore's Experience.: Prof. Koh Kheng-Lian, Faculty of Law, National University of Singapore, Singapore.

Summary: Prof. Koh began by reminding the delegates that access to safe drinking water and sanitation are crucial for public health. Review of a number of countries in the ASEAN region revealed the main challenges in water governance and policy. These challenges include water pollution from industrial, agricultural, and domestic wastes. Also, the recent floods in Thailand, Philippines, Indonesia and Vietnam resulted in salt water intrusion into drinking water. Poor sanitation also contributes to water pollution. Different sources of water supply from urban, rural, and shared river basins bring different set of problems in terms of policy, law, governance, and management. The Singapore experience is a good example because it has won a number of international accolades for water management including Stockholm Industry Water Award in 2007. She reviewed the ASEAN Strategic Plan of Action on Water Resources Management (SPAWRM) and considered, inter alia, its Vision and Mission and their impact on some ASEAN member countries. How do these countries' systems measure up against the abovementioned Vision and Mission?" Using Singapore as an example, there is a need for legislation on clean water. Singapore created a set of laws, regulations, codes-of-practice and other means to ensure its access to a clean and affordable water supply. Unsafe drinking water puts people at risk of cholera, dysentery, typhoid, hepatitis, schistosomiasis and trachoma. Singapore is a small country with limited resources. So, it uses integrated water management where every drop of water counts. This is a key issue in human rights. Workshop participants should pay careful attention in their own countries to establishing an integrated approach to water management. Integration needs to be mainstreamed into budgets and other areas. Another illustration of integration is the "PPP" approach to management public, private, and people involvement. PPP encourages people to take ownership of 'water' and the 'implementation' of laws relating to water governance. While the experience of Singapore in integrated water management may provide a useful model for urban water supply, it may not be relevant for rural or shared water basins. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/7-1.pdf.

Globalizing International Universities: Lessons Learned and Future Directions.: Emeritus Prof. Vithoon Eungprabhanth, M.D., LL.B., Senior Advisor of the Health Law and Ethics Center, Faculty of Law, Thammasat University, Thailand.

Summary: Dr. V. Eungprabhanth reviewed the history of the development of the disciplines of health law and public health law as academic subjects and research in the Universities of Thailand. He described the development of centres, courses, and curricula in Thai Universities that grew alongside other legal and legislative developments and social movements. Examples included the promulgation of laws about health care and public health, better public understanding of the dangers of smoking, and the establishment of entities such as the Health Promotion Fund and the Thai National Health Assembly. Events such as the first successful case of a heart transplant in South East Asia in 1987 carried out at King Chulalongkorn Memorial Hospital made people ask "What is the legal definition of human death?"

Such questions caught the attention of physicians, ethicists, and lawmakers. They realized Thai law must catch up with technological advances. This led the Faculty of Medicine at Chulalongkorn University to hold legal and medical seminars on human death and brain death in Thai legislation. Two years later the Thai Medical Council announced criteria for brain death, with practical guidelines to assist physicians to determine the brain death of a donor before a transplant. Other events in Thailand such as campaigns against smoking by NGOs have generated discussions that result in the creation of laws and policies for tobacco control. Thailand in 2001 adopted a law creating a Health Promotion Fund that uses a 2% "sin tax" on alcohol and tobacco to fund a variety of major health programs in Thailand. In 2005 the Health Law and Ethics Centre was newly established in the Faculty of Law, Thammasat University under the distinguished leadership of Prof. Swaeng Boonchalermvipas as its Director. Prof. Swaeng is the first professor of law to devote vigorous attention to this field. The Health Law and Ethics Center of Thammasat University represents the first health law research institute to devote its work to protecting the individual from physical and mental suffering caused by diseases and violence and to saving the whole society for peace and passion. In 2007, passage of the National Health Act established the National Health Commission. This Commission organizes the National Health Assembly at least once a year. It also analyzes data and prepares reports for the performance of functions under the National Health Act. Thus, the disciplines of health, law, and public health in Thailand have evolved and are evolving with the help of its universities, and in closing Dr. Eungprabhanth expressed his hope that universities will maintain their focus on promoting peace, prosperity, and a global respect for human rights and social justice through their academic programs and outreach activities in health law. To learn more, go to http://www.idlo.int/DOCCalendar/GHLPresentations/7-2.pdf.

# 8<sup>th</sup> Session: What's next? Health Law in the Region: Prospects for Regional Approaches and Cooperation

Can Adoption of a Model Public Health Law within the Asia Pacific Region Improve Public Health Stewardship?: Ms. Genevieve Howse, Health Law Specialist Consultant, Principal of Howse Fleming Legal, and Adjunct Associate Professor, La Trobe University, Australia.

Summary: Ms. Howse began by explaining the responsibilities of ministries of health in terms of the concept of stewardship. They are stewards of their countries' health systems, and they are also responsible for providing the vision, planning, and policymaking for their health systems for its realization. This "responsibility of stewardship" means ministries must ensure their health sectors are properly governed at national and subnational levels. "Proper governance" is based on government policy and prevailing domestic and international values, where these have been accepted or ratified. This means that ministries must regularly reviews the legislation and regulations administered by the health portfolio. Ms. Howse noted that ministries may have different resources to help them in their reviews. Questions about the resources available, potential benefits of pooling regional resources, and benefits in a regional approach to public health lawmaking have been addressed by an AusAID funded research project on The Model Public Health Law for the Pacific Project. This project ran from 2008 to 2010 examining the feasibility and usefulness of a model public health law for the Pacific. The WHO Western Pacific Region provided funding for peer review of the Reviewer's Companion document. This work revealed that existing public health laws tend to be reactive rather than proactive. There is a general neglect of proactive approaches to population health. The Report found the public health acts of

the study countries had three significant deficiencies that include (1) having little resonance with traditional Pacific ways and customs, (2) failing to support the present policy approach to the protection and promotion of public health in their countries, and (3) being amended often over past decades so resulting laws no longer provide clarity about who has responsibility for performing public health functions, and under what circumstances. While Pacific Region countries have differences in politics, economics, geography, culture, current law, health planning and reform agenda, they share similarities in lack of resources, outdated health laws, challenges facing health systems, and a desire for reform. Although "one size does not fit all", in a region where countries have similar public health laws, some shared history, and some similarities in geography, health issues, culture, and social and economic issues, there is a role for a guide to the review of public health legislation which is region specific and which countries may use in whole or in part. Explanatory materials discussing the policy context and preconditions for the implementation of new legislation may assist law reformers and Ministry of Health officials and are worthy of consideration in the Asian Region. *To learn more, access her support materials at* <a href="http://www.wyro.who.int/topics/legislation/public health law legislators companion.pdf">http://www.wyro.who.int/topics/legislation/public health law legislators companion.pdf</a> or *qo to her presentation at* <a href="http://www.idlo.int/DOCCalendar/GHLPresentations/8-1.pdf">http://www.idlo.int/DOCCalendar/GHLPresentations/8-1.pdf</a>.

## **Appendix 1- Workshop Participants**

Speakers and Panelists:	Institutional Affiliation and Location:
Prof. Dr. Somkit Lertpaithoon	President, Thammasat University, Thailand.
Dr. Sima Samar	Chairperson, Afghanistan Independent Human Rights Commission, Kabul, Afghanistan.
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