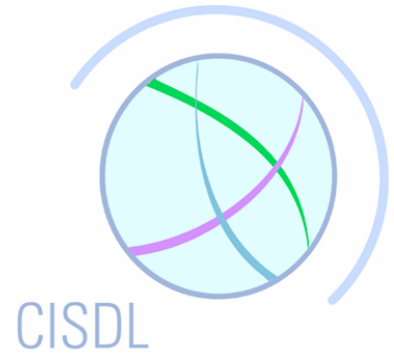


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Centre for International Sustainable Development Law

The CISDL should exist to promote sustainable societies and the protection of ecosystems by advancing the understanding, development and implementation of international sustainable development law.¹

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¹ In this context, sustainable development is defined as 'development which meets the needs of the present without compromising the ability of future generations to meet their own needs', as stated in 'Our Common Future: The Report of the World Commission on Environment and Development' (Oxford: Oxford University Press, 1987). Furthermore, sustainable development is seen as an open and participatory process of environmental, social, economic, cultural and political change. Sustainable development can be achieved through, *inter alia*, protecting and enhancing ecosystems, transforming the direction of investments and the orientation of technology, and re-designing institutions to ensure current and future potential to meet the needs and aspirations of communities.

International Sustainable Development Health Law

with Maya Prabhu²

While health has long been central to the sustainable development agenda, academics and scholars are only just beginning to analyze the relevance of international health law to sustainable development law. This work requires a great deal of future development, and this chapter simply presents a starting point, the identification of a future legal research agenda. Such an agenda seeks to encourage public health practitioners and international legal specialists to consider health law from a genuinely global perspective. It requires an understanding of international health law as a regime of international law inseparable from the interactions of other legal regimes with one another, and it seeks to combine a broad conspectus with selectively detailed excursions into particular health law areas.

The Historic Schism between International Health and International Law

There is a historic disconnect between international health concerns and international law. There are a number of reasons for this intellectual disengagement.

First, until recently, neither public health practitioners nor lawyers saw international health law as an “outcome-determining factor” for public health progress. Health problems, in general, have been seen as “technical” or “scientific” problems to be solved, rather than social and political ones to be debated and negotiated. Accordingly it has been medical, pharmaceutical, engineering and technological breakthroughs which have been given credit for the greatest advances in 20th century health.³ While this approach was appropriate in past decades when there seemed to be no limit to the scientific and antibiotic revolutions, for a number of the reasons laid out below, this approach is no longer viable; moreover, where “technical” has also come to mean static, nonpolitical and non-interdisciplinary, this is no longer sufficient.⁴

Secondly, any international health law which *has* developed is mainly the purview of public health experts, rather than legal experts. Much international public health policy emanates from health organizations, such as the World Health Organization (WHO), rather than from judicial decision-making bodies. And, despite the tremendous international legal powers given to the WHO,⁵ including the authority to adopt treaties addressing any matter in its domain, health law has tended to be derived from soft law processes. Policy implementation and enforcement have operated through recommendations and regulations rather than through legally binding rules. Even the interpretation and dispute settlement of those recommendations have tended to be governed by informal processes. In the words of one author, this “ethos” has been based on the assumption that public health progress can be better achieved through cooperation and consensus building rather than through a hard legal approach.⁶

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³ D. P. Fidler, “The Future of the World Health Organization: What Role for International Law”, (1998) 31 Vand. J. Transnat'l, L. 1079 [hereafter Fidler, *Future*]; A. L. Taylor, “Making the World Health Organization Work: A Legal Framework for Universal Access to the conditions for Health”, (1992) 18 Am. J. L. & Med. 301; M. Ghezuhly et al., “International Health Law”, (1998) 32 Int'l Law. 539; D. P. Fidler, *International Law and Infectious Diseases*, (Oxford: Clarendon Press, 1999) [hereafter Fidler, *International*].

⁴ *Ibid.*

⁵ WHO, Art. 19.

⁶ See generally Fidler, *International supra* note 106.

The International Health Regulations system (IHR) is a prime example of the present-day “soft law” approach to global health.⁷ The IHR was one of the earliest attempts by WHO to act collectively with regard to world health. Its purpose was to ensure the “maximum security against the international spread of disease with minimum interference with world traffic.”⁸ The IHR creates a comprehensive surveillance program for member states to monitor and respond to infectious disease in their respective countries - yellow fever, plague and cholera. However, neither the IHR nor the WHO Constitution permits action against states who fail to comply with a regulation. Moreover, the three diseases that are the focus of the IHR have been eclipsed by other infectious diseases in public attention and mortality. As such, the IHR have been increasingly criticized for being neither relevant to nor useful for addressing the public health problems of our time.

A final reason for the disjuncture between international law and medicine flows out of the IHR example. In addition to being without clear mechanisms to ensure compliance and enforcement, the WHO has sought to maintain a conscientiously “apolitical character.”⁹ Again, with the idea that global health is better addressed in a consensual manner, the WHO has eschewed the ‘strong-arming and sweet-talking’ that is the hallmark of negotiations of other international regimes. Consequently, international health law has not received extensive interest among lawyers, who have not seen their skills as necessary in its domain.

Rationale for the Development of International Sustainable Development Health Law

However, a changing global context means that this division between the legalists and the medical experts is no longer practicable: international health concerns have been necessarily drawn closer to economic and social law. Conversely, those interested in economic and social development are less likely to under-appreciate the importance of investing in health.

There are a number of factors which capture the changing landscape. First, due to globalization, public health dangers now have a scale beyond the capacity of any single national health care system. Indeed, as the Centers for Disease Control (CDC) has suggested, any assertions about a distinction between national and international health are anachronistic.¹⁰ A population-based approach is needed now, one that is transnational in orientation.

While there is a tendency to treat globalization as a very recent phenomenon, it is undeniable that certain recent globalization processes have had particularly significant impacts on public health. These processes include increased travel, migration and cross-border trade; changes in individual behavior (especially sexual behavior); rapid urbanization; and hastened environmental degradation. The critical element in these processes is the way in which cross-border channels have increased in numbers and speed. Thus, populations have become vulnerable to disease-causing agents imported from elsewhere.¹¹

⁷ World Health Org., “International Health Regulations” *International Health Regulations*, 3d ann. ed., 91983, (July 25, 1969). See also: World Health Org., “Revision of the International Regulations: Progress Report” 74 *Weekly Epidemiology Rec.* (January, 1999) at 25; World Health Org., 78 *Weekly Epidemiology Rec.* (July, 1998) at 23 etc.

⁸ World Health Organization, Foreword to International Health Regulations online: <http://policy.who.int/cgi-bin/om_isapi.dll?infobase=Ihreg&softpage=Browse_frame_pg42> (date accessed: May 30, 2003).

⁹ H. Francis Shattuck, Jr. et al., “World Health Organization, Section Recommendation and Report of the American Bar Association” (1996) Ill. 30 Int’l Law. 688; Fidler, *Future*, *supra* note 106.

¹⁰ Noting that the “concept of domestic as distinct from international health is outdated” see U.S. Centers for Disease Control and Prevention, *Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States*, (1994) at 12; Observing that national health has become an international challenge see J.W. Le Deuc, “World Health Organization Strategy for Emerging Infectious Diseases” (1996) 275 JAMA 318.

¹¹ D. Fidler, “International Law and Global Public Health” 48 U. Kan. L. Rev. 1, 9 [hereafter Fidler, *Global*]; Institute of Medicine, *Emerging Infectious Diseases: Microbial Threats to Health in the United States*, (1992) at 77.

Globalization also has a negative “multiplier” effect on the impacts on health. For example, urbanization is associated with overcrowding and poor sanitation; environmental degradation is associated with changing weather patterns which affect habits and locales of disease-carrying insects and animals;¹² the liberalization of international trade has contributed to the dissemination of disease causing products such as tobacco; and cross-border travel has heightened the spread of Severe Acute Respiratory Disease (SARS) and HIV/AIDS. All of these circumstances confirm that the nature of public health is inherently global with causes related to the world’s growing interconnectedness and with consequences that must be addressed by international solutions.

As a second element of the changing context, the past decade has seen a growth in the power and reach of non-state actors. These actors have an increasing role in public health policy, law and practice.¹³

One positive example, from the perspective of patients or consumers, is the newfound effectiveness of nongovernmental organizations (NGOs). The best model is the campaign of NGOs against pharmaceutical companies over access to HIV/AIDS drugs in South Africa. *Medicins sans Frontiers* (Doctors without Borders) in particular was instrumental in affecting international governance by forcing the “intellectual property rights vs. public health debate” higher on the intergovernmental agenda; the campaign also supported South Africa’s exercise of public health sovereignty.

A less benign example, again from the consumer perspective, is the role of multinational corporations (MNCs) who have attempted to coerce international agencies’ and governments’ health policies; developing countries who are under pressure to present attractive investment and trade environments are particularly vulnerable. The examples around tobacco and pharmaceuticals have been well-documented.¹⁴ A more recent case is that of the sugar industry in the United States, which has threatened to challenge US funding for the WHO unless the WHO retracts its guidelines on healthy eating.¹⁵

The more the actors and the greater their variety, the more important formal legal channels become. The informal, consensual negotiations of the past become less successful when the system becomes more complex.

A final reason to draw the two disciplines together in view of changing circumstances is that many of the most pressing health concerns are deeply political issues. Climate change, destruction of biodiversity, trade in hazardous wastes – these are all highly contentious areas at the intersection of health and environment; they are also health *and* political issues. Relevant human rights questions include whether there is a right to a healthy environment, or where the right to health brings a corresponding right to medications (such as for HIV/AIDS). Political conflicts occur especially when health concerns interfere with trade. The furour over trade in tobacco, beef growth hormones, asbestos and genetically modified organisms (GMOs) are only examples. As these disputes continue to grow in number and volume, there will inevitably be

¹² Ibid. See also: D. Fidler, “Trade and Health: The Global Spread of Disease and International Trade” (1997) 40 *Germ. Y. B. Int’l L.* 30.

¹³ D. Fidler, “A Globalized Theory of Public Health Law”, 30 *J. L. Med. & Ethics* 150.

¹⁴ For tobacco see: Dr. G. H. Brundtland, “Response of the Director General to the Report of the Committee of Experts on Tobacco Industry Documents” WHO Doc. WHO/DG/SP (Oct. 6, 2000) at 1, online: <<http://tobacco.who.int/repository/stp58/inquiryDGres1.pdf>> (Last accessed: May 30, 2003); “Committee of Experts on Tobacco Industry Documents, Tobacco Industry Strategies to Undermine Tobacco Control Activities at the World Health Organization” (July, 2000) online at: <http://tobacco.who.int/repository/stp59/who_inquiry.pdf> (Last accessed: May 30, 2003); for pharmaceuticals see <<http://www.cptech.org>>.

¹⁵ S. Boseley, “Sugar industry threatens to scupper WHO” online: <<http://www.guardian.co.uk/international/story/0,3604,940287,00.html>> (Last accessed: May 30, 2003).

greater need for international lawyers to work them and for public health professionals to understand the law.

An Opening for a New International Sustainable Development Health Law

Fortunately, the last ten years have seen a burgeoning interest, meetings and activities related to national and international public health law.¹⁶ On the domestic front, states and health organizations have begun to use legal means to pursue public health concerns. For example, in Canada and the United States, state and provincial governments have pursued tobacco litigation to bolster public health measures. In South Africa and Thailand, governments have resisted pharmaceutical company pressure by asserting their legal rights under TRIPS to provide for generic drugs.

In December 1997, the WHO and the Indian Law Institute sponsored an International Conference on Global Health Law in New Delhi at which the delegates adopted the New Delhi Declaration on Global Health Law.¹⁷ For the first time, the WHO has exercised its treaty-making powers, in order to pursue the first international health treaty in the area of tobacco control;¹⁸ the WHO is also currently revising the International Health Regulations as a prelude to the development of a convention on infectious diseases.¹⁹

Finally, the WHO's "Health for All in the Twenty-First Century" policy emphasizes the importance of international law, stating that "WHO will develop international instruments that promote and promote health, will monitor their implementation, and will also encourage its member states to apply international laws related to health." The Health for All Policy demonstrates an appreciation of the importance of different international legal regimes to WHO's global work, including the three critical sustainable development regimes (human rights, international trade and environmental protection).²⁰

International legal regimes represent both the solutions and additional complications for the global public health agenda. On one hand, international human rights laws provide powerful arguments for improving access to life-saving AIDS cocktails that are protected by international patent laws. On the other hand, liberalizing trade regimes only hasten the transnational flow of goods and peoples who serve as vectors for microscopic health threats. International environmental and health specialists may find themselves as part of a united front taking a precautionary approach to GMOs but may find resistance from within WTO and GATT rules which take different approaches to legislating risk. The relationship between the international finance and debt regimes and their implications for health are only just beginning to be explored. From an ISDHL perspective, then, it is increasingly important to consider the linkages between "international health law" and the other legal regimes and to create methods to unravel the tensions between competing international agendas.

¹⁶ A. Taylor, "Globalization and Public Health: Regulation, Norms and Standards at the Global Level" (Background Paper for the Conference on World Health Cooperation, Mexico City, Mar. 29-Apr. 1, 1998. Unpublished manuscript on file with David Fidler) as quoted by Fidler, *Global, supra* note 115.

¹⁷ New Delhi Declaration, Dec. 7, 1997 [hereafter New Delhi Declaration].

¹⁸ See International Framework Convention for Tobacco Control, World Health As. Res. 49. 17., 49th Ass., 6th Plen. Mtg. WHO Doc. A49/VR/6 (May 26, 1996).

¹⁹ There are those who have articulated the need for a convention on infectious diseases, see D. Fidler, "Return of the Fourth Horseman: Emerging Infectious Diseases and International Law" (1997) 81 Minn. L. Rev. 771, 863-67. Others have seen this idea as unrealistic, see B. J. Plotkin, "Mission Possible: The future of the International Health Regulations" (1996) 10 Temp. Int'l Comp. L. J. 503, 515.

²⁰ "Health for All in the Twenty-First Century" WHO Doc. A51/5 (1998A) para. 2, 23, 25, 52. [Hereafter "Health For All"]. See also A. L'Hirondel & D. Yach, "Develop and Strengthen Public Health Law" (1998) 51 World Health Stat. Q. 79, 83.

Without diminishing the WHO's special role in creating international health law, a new legal research agenda in this area suggests that IHL ought to be on the agenda of all those organizations involved with SDL. Health is a multi-sectoral objective and must involve diverse legal regimes and organizations; IHL goes far beyond what the WHO may adopt under its international legal powers. There is a real need for a new and identifiable corpus of law that addresses the phenomena of global public health in a way that existing laws are unable to do.

Elements of an International Sustainable Development Law Approach

There are three elements of ISDL that have particular resonance for international health issues.

First, the precautionary principle, which has become intrinsic to international environmental policy, is important to international health law and policy. In a nutshell, the precautionary principle is innovative in that it changes the role of scientific data. It requires that once environmental damage is threatened, action should be taken to control or abate possible environmental interference even though there may still be scientific uncertainty as to the effects of the activities. As such it deviates from more traditional risk assessments based on a preponderance of available information; but it is not without foundation in medicine where the benefit of the diagnosis is often given to the patient ("Better Safe than Sorry."). As the precautionary principle solidifies its place in international law, it has the potential to be used as a mediating principle between equally laudable but conflicting goals in international law, especially in areas around health, trade and the environment.

The second principle is intergenerational equity and the eradication of poverty. This principle has particular implications for the health agenda related to both environmental pollution and infectious diseases. This principle asserts that the present generation has the obligation to refrain from depriving future generations of environmental, social and economic opportunities of well-being. Also, states should promote a fair utilisation of resources among members of the present generation and should focus in particular on the needs of the poor, who have the greatest priority.

With regard to this principle's application to the environment and health, this chapter notes that environmental pollution not only has health effects on present populations, but, by despoiling resources that contribute to health, it impairs the health of future generations. As we have learned more about the natural environment and its complexities, we have also learned more about the human body's sensitivity to apparently modest insults and about the problems associated with the migration of pollutants, their transformation and the potential for accumulation over time; not only is the harm passed down between populations, but, within families.²¹

The issue of infectious disease containment, in light of our current drug use practices and antimicrobial resistance, also calls for an analysis of harm to future generations. In the 1970s, experts believed that the fight against infectious diseases was won. But during the last two

²¹ There is a large body of evidence that shows many toxins are passed through breast milk. See *e.g.* E. Dewailly, A. Nantel, J.P. Weber & F. Meyer, "High levels of PCBs in breast milk of Inuit women from Arctic Québec" (1989) *Bull. Environ. Contam. Toxicol.* 43, 641-646; S. Patandin, P.C. Dagnelie, P. Mulder, E. Op de Coul, J.E. Van der Veen, N. Weisglas-Kuperus & P.J.J. Sauer (1999) "Dietary exposure to polychlorinated biphenyls and dioxins from infancy to adulthood: A comparison between breast-feeding, toddler, and long-term exposure." 107 *Environ. Health Perspect.* 45-51; J. Mörner, R. Bos & M. Fredrix, "Reducing and Eliminating the use of Persistent Organic Pesticides" online: <http://216.239.37.100/cobrand_univ?q=cache:ybj16GyAsf8J:www.who.int/water_sanitation_health/Documents/pesticides/Organicpestcont.pdf+%22persistent+organic+pollutants%22+and+breast+milk&hl=en&ie=UTF-8> (Last accessed: May 30, 2003).

decades, this opinion has been reversed. The spread of new diseases and the resurgence of diseases long considered under control has alarmed the medical community. Today, infectious diseases, particularly HIV/AIDS, have reversed hard-won gains in life expectancy in Africa and Asia. Moreover, the re/emergence of these epidemics has coincided with antimicrobial resistance. Until recently, science and medicine were able to stay ahead of the pathogens through the discovery of ever more potent classes of pharmaceuticals. This success has slowed markedly in no small part because of our own profligate use of antibiotics. How we choose to address this will have no small consequences for ourselves and our future generations, both at home and in developing countries.

Finally, the sustainable development law principle of integration and interrelationship, in particular in relation to human rights and social, economic and environmental objectives, has the potential to help elaborate the content of the right to health. The right to health had its first expression in the 1946 World Health Organization Constitution²² but attempts are still being made to endow the right to with meaning, to move it from beyond an indeterminate norm to one of tangible application. What makes this right difficult to formulate is that it is impossible to isolate: all economic, social and cultural rights are fundamental to ensuring the conditions in which people can be healthy. The right to health will insinuate itself in debates in every legal regime.

A Future Legal Research Agenda

International Health and Trade

Public health and the liberalization of trade as concretized in the World Trade Organization (WTO) can provide most the potent examples of laudable goals working at cross-purposes. The very goal of WTO law – to facilitate the increased cross-border movement of people and goods – only multiply the vectors by which disease is spread across borders. All the benefits of liberalized trade (increased access to improved and cheaper consumer products) apply in reverse to goods which have adverse health impacts (tobacco, processed foods such as soft drinks). And where environmental health concerns interfere with trade, the conflict can be intense. While public health has focused most significantly on the control of infectious diseases (and will continue to do so), trade conflicts are also likely to arise with issues such as the standards for the safety, purity and potency of biological and pharmaceutical products; the regulation of the trade of blood and human organs; and the trade of health information, services, and products over the internet.²³

The following areas are the likely areas for dispute in the future around trade and health:

First, states use public health rationales to restrict the imports of goods. States' rights to restrict trade on public health grounds remain a prominent feature of the international trading system for both developed and developing states. The contours of this protection have been articulated in Article XX(b) of GATT which extends protective measures to human, plant and animal life or health, in the SPS and TBT. It has also been extended by key WTO cases such as the dispute between the US and Canada and the EU about hormone-treated beef, Britain's challenge to EU's ban on beef because of concerns about bovine spongiform encephalopathy, and the Canada-France Asbestos disputes.²⁴ However, the international trade regime also attempts to constrain

²² "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, economic or social condition."

²³ Fidler, *Future*, *supra* note 106 at 1109-1110.

²⁴ See Case C-180/96, United Kingdom v. Commission, 1998 ECJ Celex Lexis 5270, at 3-4 (May 5, 1998); WTO Arbitrator's Report on European Communities-Measures Concerning Meat and Meat Products (Hormones, WTO Doc. WT/DS26/ARB (July 12, 1999); WTO Arbitrator's Report on EC Measures Concerning Meat and Meat Products Hormones, WTO Doc

States' ability to misuse their power to protect public health by making the use of science integral. Thus, an important question in the context of international trade liberalization, specifically in the context of the new round of WTO negotiations launched by the Doha Ministerial, is the extent to which government authorities are justified in taking a precautionary approach when they adopt unilateral HSE protection measures.²⁵

In this area, certain questions should be considered in future legal research. First, how can market liberalization be pursued without undermining genuine national concerns about the transmission of infectious disease? How does the precautionary principle affect what constitutes an adequate risk assessment for an SPS challenge? Since mounting or defending challenges to health and safety measures requires scientific capabilities and resources, how can developing countries achieve parity with major industrial nations? How can the public's concerns about "foreign disease" threats (via the transmission of goods and people) avoid violations of individuals' rights in the name of "safety"?

Tobacco and Trade

Tobacco use is an extraordinary threat both to human health and the environment; it is impossible to understate the seriousness. About one in every two long-term smokers dies from smoking. The WHO estimates that tobacco products currently kill 4.2 million people each year; by the year 2030, this annual toll will rise to nearly ten million deaths or one in six adults globally per year.²⁶ In addition to the absolute human cost, there are important regional variations. Country specific analyses of the tobacco industry by the World Bank in collaboration with the WHO found that tobacco addiction imposes high opportunity costs on many poor households, who spend significant proportions of their income on tobacco instead of on nutrition and other needs.²⁷ Most of the projected deaths will occur in low and middle income countries.²⁸ Moreover, as market share in industrialized countries decline, and tobacco companies target developing countries and world youth, the disease burden caused by tobacco usage will increase at an alarming rate.²⁹

Thus, there is no greater area of structural conflict between trade liberalization and public health than that of tobacco control. Empirical evidence confirms that trade openness leads to increased tobacco consumption.³⁰ Tobacco control measures such as tobacco tax increases, higher tariffs, smoking bans and health warnings on packaging all substantively reduce tobacco consumption.³¹

WT/DS26/15 & WT/DS48/13 (May 29, 1998), WT/DS48/AB//R (Jan. 16m 1998), WTO Doc. WT/DS26/R.USA (August 18, 1997).

²⁵ L. Ruessmann, "Putting the precautionary principle in its place: parameters for the proper application of a precautionary approach and the implications for developing countries in light of the Doha WTO ministerial" (2002) *American University International Law Review*.

²⁶ Summarizing World Bank, *Curbing the Epidemic* (1999), see WHO, "Economics of Tobacco Control" WHO Doc. A/FCTC/WG1/2 (Aug. 20, 1999) at 2 online: <<http://www.who.int/gb/fctc/wg1/PDFwg1/elt2.pdf>> [hereinafter *Economics of Tobacco Control*]; Intergovernmental Negotiating Body of the WHO Framework Convention on Tobacco Control, Activities Since the Previous Session, WHO Doc. A/FCTC/INB5/4 (Sept. 12, 2002) at 1 online: <<http://www.who.int/gb/fctc/PDF/inb5/einb54.pdf>>.

²⁷ Intergovernmental Negotiating Body of the WHO Framework Convention on Tobacco Control, Activities since the Previous Session WHO Doc. A/FCTC/INB5/4/ (Sept. 12, 2002) at 1 online: <<http://www.who.int/gb/fctc/PDF/inb5/einb54.pdf>>.

²⁸ *Economics of Tobacco Control*, supra note 130 at 2.

²⁹ WHO, "Opening Statement by the Director-General", WHO Doc. A/FCTC/INB1/DIV/3 (Oct. 16, 2000) at 1-2 online: <www.who.int/gb/fctc/inb1/PDFinb1/e1inb3.pdf>; "Burden of Disease" online: <www.tobacco.who.int/page/cf?sid=47>.

³⁰ A.L. Taylor & D.W. Bettcher, "WHO Framework Convention on Tobacco Control: A Global "Good" For Public Health" (2000) 78:7 *Bulletin World Health Organization*, 920-9 (Review).

³¹ J.P. Townsend, *Tax and Smoking in Europe*, (Copenhagen: World Health Organization, 1998); The World Bank; *Development in Practice Series: Curbing the Epidemic; Governments and the Economics of Tobacco Control*, (Washington DC: The World Bank, 1999); P. Jha & F.J. Chaloupka eds., *Tobacco Control in Developing Countries*, (New York: Oxford University Press, 2000).

Most countries have faced strong challenges to implementing comprehensive control measures. Some might even argue that an international ‘social license to exist’ must develop – and be denied to these companies. In this respect, an entirely new area of contention may be opened by the WHO’s Framework Convention on Tobacco which was adopted on May 21, 2003.³² The FCTC is a comprehensive multilateral treaty that will cover everything from tobacco smuggling to tobacco advertising, taxes, warning labels design and the extent of the liability of tobacco companies. In a hopeful example of non-health organizations supporting the work of the WHO, the World Bank specifically required that international agencies support the FCTC.³³ What makes the FCTC unique is that its structure is that of a framework convention or treaty with legally binding terms -- an important step forward from the WHO’s usual soft-law approach.

Tobacco control and trade promises to be an important area for the sustainable international health law agenda. Various questions need to be considered. First, what is the significance of TRIPS on trademark protection and the disclosure of confidential product information? What are the implications of GATS in relation to restrictions on cigarette advertising? What is the affect of the TBT in relation to packaging and labeling? Does the Agreement on Agriculture have implications for government supports to tobacco production?

International Health, Access to Medicines and Intellectual Property Rights

Since the 1978 Alma-Ata conference, there has been recognition that access to essential drugs is vital for preventing and treating diseases affecting millions of people throughout the world. Indeed, most of modern medicine depends heavily on drugs and vaccines to treat illness.

However, the WHO estimates that currently one third of the world’s population lacks access to essential drugs, with this figure rising to over 50% in parts of Africa and Asia. Reasons for lack of access to various medicines are complicated and beyond the scope of this chapter. But in the SDL and Health debate, the appropriate focus is on the pricing of drugs especially as a result of international trade and patent laws.

A key question for a sustainable health law research agenda is to what extent the intellectual property laws have contributed to the difficulty of global access to essential drugs. TRIPS requires that all member countries provide exclusive marketing rights to holders of patents on pharmaceutical products for a period of at least 20 years. TRIPS is an exception to the general liberalization tenets of the trade regime. TRIPS attempts to harmonize protection of IP rights among members; it imposes a positive duty on countries, using norms developed in US-style intellectual property law be implemented globally. On the other hand, it provides some flexibility for states to address their public health needs by allowing several public interest exceptions to patent protection.³⁴

Many developing countries and human rights activists claim that these expensive drug prices are the result of strong patent protection.³⁵³⁶ What is unequivocal, however, is that the mere threat

³² For a complete discussion of the use of international law in connection with tobacco control see World Health Org., *World Health Report 1999: Making a Difference* (1999) 78; “World Health Assembly Adopts Historic Tobacco Control Pact” (Press Release, May 21, 2003) online: <<http://www.who.int/mediacentre/releases/2003/prwha1/en/>>.

³³ World Bank at 3-10.

³⁴ “Significant public and private investment, particularly in the United States, converted this killer into a manageable chronic disorder for many in the developed world.” J. Rein, “International Governance Through Trade Agreements: Patent Protection for Essential Medicines” (2001) 21 N.W. J. Int’l L. & Business, 379.

³⁵ See N. Ford & D. German, “AIDS and Essential Medicines and Compulsory Licensing” online: <<http://www.cptech.org/March99-c1/report1/html>>.

³⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments-Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

of legal action by pharmaceutical companies against countries shapes access as much as the actual patent laws. This inequality of resources and leverage is also a critical area for SDL. Critics have pointed out, for example, that during the anthrax scare following the September 11, 2001 terrorist attacks in the US, the U.S. government considered the compulsory licensing of Cipro, an anthrax antibiotic.³⁷ Although, ultimately, the United States did not issue compulsory licenses for Cipro, the U.S. government has been accused of using the threat of compulsory licensing as leverage to negotiate favorable terms from Bayer, Cipro's patent holder.³⁸ However, when faced with threats of compulsory licensing from countries which have sought to meet the pandemic needs of their own populations, the United States has zealously sought to protect the IP rights of its pharmaceutical companies.

Since the adoption of the Declaration on the TRIPS Agreement and Public Health at the WTO Ministerial Conference in Doha,³⁹ the fear of retaliatory action may have been somewhat minimized.⁴⁰ The Doha Declaration expressly recognizes that TRIPS "does not and should not prevent Members from taking measures to protect public health."⁴¹ Further, the declaration stresses that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to public health and, in particular, to promote access to medicines for all", and that member states have the right "to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."⁴² Although developing countries pushed for a legally binding interpretation of TRIPS, the Doha Declaration is a ministerial declaration and does not supercede TRIPS.⁴³ The status of the Doha Declaration is unclear, and interpretations of its import range from that of a "political statement" to that of "persuasive authority in the interpretation of TRIPS in the event of a dispute."⁴⁴ It is perhaps because of that reason that the United States in 2003 has moved to limit the application of the Doha Declaration.⁴⁵

The ways in which TRIPS impinges on access to medicine will continue to be a fertile area for ISDL for many years. Various questions need to be answered. How can the Doha Declaration inform other provisions of the WTO? Can international finance regimes help national strategies finance the supply and increase the affordability of essential drugs in both the public and private sectors? How might developing countries structure intellectual property legislation in a way that respects both producing and consumer country concerns? How do the contours of the "right to health" interact with intellectual property regimes?

*Health and GMOs*⁴⁶

³⁷ Describing U.S. pressure on South Africa and Thailand, on behalf of the drug industry, to prevent the implementation of laws to make HIV/AIDS drugs cheaper see S. K. Sell, "TRIPS and the Access to Medicines Campaign" (2002) 20 Wis. Int'l L.J. 481, 500-02.

³⁸ Ibid at 515-16.

³⁹ Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, WTO Res., 4th Sess., Ministerial Conference, WT/MIN(01)/DEC/2 [hereinafter Doha Declaration].

⁴⁰ Describing how countries who can barely meet the costs of purchasing drugs are not going to risk a legal challenge by an international pharmaceutical company see H. Walkowiaz, "AIDS in National and International Law" (Proceedings of the Ninety-Sixth Annual Meeting of the American Society of International Law, March 16, 2002) 96 Am. Soc'y Int'l L. Proc. 320 at 328.

⁴¹ Ibid at para 4.

⁴² J.M. Bergerat, "Tripping over patents: aids, access to treatment and the manufacturing of scarcity" (2002) 17 Conn. J. Int'l L. 157 at 164.

⁴³ Sell, *supra* note 141 at 517-18; "ministerial declarations within the WTO are not legally binding in the dispute resolution process, and in the event of a dispute the language of the treaties as approved by national governments would prevail over any contradictory declaration by the ministers" A.O. Sykes, "Trips, Pharmaceuticals, Developing Countries, and the Doha 'Solution'" (2002) 3 Chi. J. Int'l L. 47, at 54.

⁴⁴ See Sell, *supra* note 141 at 517-18 (citation omitted); Sykes, *supra* note 147 at 54.

⁴⁵ Online: <<http://www.cptech.org/ip/wto/p6/cptech03052003.html>>

⁴⁶ Online <<http://www.cid.harvard.edu/cidtrade/issues/biotechnology.html>>

Biotechnology and genetically modified organisms have ignited fierce debates over trade policy in the WTO, in TRIPS, and even amongst human rights thinkers. It touches every area of ISDL from trade to environment to health policy and as such will be a significant part of the ISDHL's work for many years especially as the Doha Round moves forward. The Doha Development Round will address biotechnology through negotiations on issues such as agriculture, intellectual property rights, sanitary and phytosanitary standards, and the environment. Specific discussions on biotechnology and trade and IP policy promise to be extremely contentious. There are a number of elements of the conflict but the crux of the matter for the Health Programme is the tension between developing countries' access to food and medical security and their right to determine what safety standards to set for themselves vs. the demands of the WTO rules.

This tension is exemplified by a dispute that has been brewing since the beginning of 2003, when the US announced that it would bring a case before the WTO dispute settlement committee to force the EU to lift a ban on genetically modified (GM) foods. The situation is compounded when EU trading partners are pulled into the fray: importing GM products into their adversely affects their ability to export to the EU. This poses a major dilemma for developing countries such as Zimbabwe and Zambia, which have refused emergency food aid from the US containing GM corn because they would no longer be able to export certain agricultural goods to the EU. Not only does this dispute capture concerns about the long-term health affects of GMOs, it raises new equity issues about what levels of safety ought to govern aid to developing countries.

The Biotechnology debate extends beyond the trade and human rights concerns to the implications of extending intellectual property to living organisms. These concerns are linked to fears that biotechnology will transfer resources from the public sphere to private ownership via the enforcement of intellectual property rights. Firms that have invested in the development of genetically modified varieties want to protect their proprietary knowledge, but many farmer groups have protested that enforcing intellectual property rights will disrupt their access to seed. These debates draw attention to the controversial TRIPS Article 27.3(b), which exempts advanced life forms from patentability but requires countries to establish some form of protection for plant varieties. This is also an area of concern for a new legal research agenda. It foresees the protection of indigenous plants and healing approaches as a flashpoint for developing vs. developed country tensions in the future.

GMOs and its implications for SDL will be a rich and varied debate. *Questions to be considered:* Will emerging understandings of the precautionary principle be used to justify the refusal of the transboundary movement of GMOs intended for direct use? How can developing country concerns about clearly defined liability be reconciled with developed countries' reluctance to assume liability for uncertain, foreseeable risk? How can long-term health concerns about the potential effects of GMOs be reconciled with the short-term food needs of developing populations?

International Environmental Law and Health

The environment is a major health determinant and worthy of a full chapter unto itself. Both "traditional" health hazards (such as lack of access to safe drinking water; inadequate basic sanitation; indoor air pollution from cooking and inadequate solid waste disposal) and "modern" hazards (such as water pollution from industry and intensive agriculture; air pollution from transportation or power stations, hazardous wastes, and other forms of transboundary pollution) contribute to about a quarter of human morbidity and mortality. Environmental changes too will increasingly affect human health. The fact that many people are not able to adapt to such circumstances, while others are forced to do so is the antithesis of sustainable development.

Fortunately, moving from environmental health to international environmental health law is not such a big jump. Much of international environmental law already does concern the protection of human health. A great deal of IEL is about shielding people from the health-damaging consequences of pollution and environmental degradation. IEL should be seen, therefore, as an important part of the international law that supports public health objectives.

Many questions need to be considered. How can public health practitioners and environmental experts work together to translate the inherent uncertainties around environmental hazards into concrete laws? What does the international human rights regime bring to the debate about the movement of hazardous wastes to low labour-cost environments, about the right to a healthy environment, about the tensions between the developed world's focus on the environment and the developing world's desire for development? How can the precautionary principle be reconciled with the desire for evidence-based policy in the area of health?

Health and Human Rights

There is a wealth of legal authority regarding the international human right to health. But this legal authority must be developed to deal effectively with the implications of the right to health, especially for developing countries, in the face of scarce resources that can be allocated to health. One approach that may yield concrete answers is the emerging application of budget analysis techniques to human rights issues.⁴⁷ In particular, domestic courts in countries such as South Africa,⁴⁸ Columbia⁴⁹ and India⁵⁰ has reviewed resource allocations made by governments in the health sector.

Given the plethora of debates within health and human rights, it would be foolish to canvas them all in this prospectus. However *further questions need to be considered*. How is the 'Right to Health' to be reconciled with TRIPS? How can access to basic health facilities be incorporated within international financial regimes, or, what new mechanisms need to be put into place to secure funding for basic health needs?

Complex Humanitarian Emergencies and Sustainable Development

An emerging area for sustainable health law includes the intersection between complex humanitarian emergencies and sustainable development law. Humanitarian emergency situations have become more frequent, more widespread, more complex and long lasting, combining interstate and internal conflicts, large-scale displacements of people, mass famine, disruption of economic, political and social institutions, and, in some cases, natural disasters. As seen in

⁴⁷ See for an empirical application of the right to health to public health budgets: H. Hofbauer, G. Lara, *Health Care: A Question of Human Rights, Not Charity* (Mexico City: FUNDAR, Centro de Análisis e Investigación, 2002), <http://www.fundar.org.mx>.

⁴⁸ See *Treatment Action Campaign v. Minister of Health*, 2002 SA 8 (CC) in which the Court required the state to provide detailed treatments to reduce mother to child transmission of HIV. Conversely, the Court decided that the state's failure to provide free renal dialysis was justified after reviewing the resources available: *Soobramany v. Minister of Health, KwaZulu-Natal*, 1998 (1) SA 765 (CC). The court stated: "to be reasonable, measures cannot leave out of account the degree and extent of the denial of the right they endeavour to realise. Those whose needs are the most urgent and whose ability to enjoy all rights therefore is at most peril must not be ignored by the measures aimed at achieving realisation of the right."

⁴⁹ The Colombian Constitutional Court stated that since provision of health care is subordinate to the existence of economic resources, and is partial and progressive in nature, available resources should be used in a rational and equitable fashion in cases in which the restoration of health is actually possible. It therefore approved the removal from hospital of a girl who was in a stable but irreversible condition on the basis that hospital beds and room should not be occupied by persons whose state of health was not expected to improve, so as to deprive other persons of care. Constitutional Court, Judgement No. T-484 of 11 August 1992, *Revista Mensual, Jurisprudencia y Doctrina*, 1992, Vol. 21, PP. 1008-1109. Conversely, the state was required to provide treatment to an AIDS sufferer in a precarious economic state. Constitutional Court, Judgement No. T-505 of 28 August 1992, *Revista Mensual, Jurisprudencia y Doctrina*, 1992, Vol. 21, PP. 1101-1106.

⁵⁰The Indian Supreme Court held that the State is required to provide *at least the minimum conditions ensuring human dignity*, and ordered the government to provide suitable accommodation for a disabled woman living in a mental home. *Vikram Deo Singh Tomar v. State of Bihar*, (1988) Supp. SCC 734 at 736.

several locations recently (Kosovo, East Timor, Chechnya, Congo), these humanitarian crises can disrupt regional security and undermine efforts to promote sustainable development.

In virtually all post-emergency situations, resettlement of refugees, displaced persons and other disaster victims as well as the restoration of physical infrastructure are some of the major conditions for recovery. While peacekeeping, civilian, humanitarian, economic, social, and political activities are all part of the integrated process of post-crisis rebuilding, special attention should be given to the observance of the norms and principles of international law, including international sustainable development law. Failure to incorporate sustainable development can result in conflict over resources that lead to violent confrontation. Violent confrontations often wreck havoc on the vegetation, land, and water, undermining sustainable development still further. The period immediately post-conflict offers opportunities to make SDL an integral part of national strategies and programmes for sustainable development.

There are several important questions to be considered. How can ISDL principles be incorporated into the restoration of national legal and judicial systems in post-conflict situations? How would a comprehensive and coordinated response to rehabilitation and reconstruction by the United Nations system, Bretton Woods Institutions, humanitarian agencies and Governments involve the application of ISDL principles at all stages of development?

ISDHL Processes and Capacities

The New Delhi *Declaration on Global Health Law* states that “global health law” includes strengthening institutional and human capacity for law;” developing regulatory and legislative approaches to support “health for all” and ensuring monitoring and implementation of health law.⁵¹ These items do not represent principles of law but rather focus on processes and capabilities needed to improve the contribution of national and international law to global public health.

One area of critical importance to a new legal research agenda in this area is an investigation of the new global institutions that support public health. What transnational authorities and procedures are needed for national governments to promote and protect public health, both within and without the WHO? Should the WHO have its own adjudicatory organ consistent with the World Health Assembly to settle political questions of significant to health? What executive type enforcement power comparable to the WTO’s dispute settlement system’ threat of trade sanctions ought the WHO be endowed with?

Conclusions

While health has long been central to the sustainable development agenda, academics and scholars are only just beginning to analyze the relevance of international health law to sustainable development law. Health law and policy, as part of sustainable development law, is shaped by interconnections between social, environmental and economic law.

A legal research agenda in this area requires a great deal of future development, and this chapter simply presents a starting point, the identification of a future legal research agenda. Such research seeks to encourage public health practitioners and international legal specialists to consider health law from a genuinely global perspective. Globalisation has rendered many distinctions between national and international policy objectives almost meaningless. Legal frameworks and implementation efforts need to reflect this reality. The traditional schism must be bridged between health policy and international law relating to sustainable development. An ISDL

⁵¹ New Delhi Declaration, *supra* note 121.

perspective can help meet this challenge by addressing cutting edge areas of sustainable development law related to health, especially in key policy areas where international treaties and principles are fast becoming part of the operating environment for all actors.