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2010

**The O'Neill Institute for National and Global Health Law:  
Discovering Innovative Solutions for the Most Pressing Health  
Problems Facing the Nation and the World**

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11 Minn. J.L. Sci. & Tech. 383-403 (2010)

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# GEORGETOWN LAW

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Georgetown Public Law and Legal Theory Research Paper No. 10-44  
July 2010

### The O'Neill Institute for National and Global Health Law: Discovering Innovative Solutions for the Most Pressing Health Problems Facing the Nation and the World

11 Minn. J.L. Sci. & Tech. 383-403 (2010)

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## RECENT DEVELOPMENTS

### **The O'Neill Institute for National and Global Health Law: Discovering Innovative Solutions for the Most Pressing Health Problems Facing the Nation and the World**

**Lawrence O. Gostin,\* Oscar A. Cabrera\*\* & Susan C. Kim\*\*\***

#### I. INTRODUCTION

Health is a vital condition of individual human wellbeing,

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The authors would like to acknowledge Lidia Niecko for her excellent research assistance and contributions to this article.

For more information on the O'Neill Institute for National and Global Health Law, please visit [www.oneillinstitute.org](http://www.oneillinstitute.org).

but it is an equally essential component of economic, political, and social structures, whether local, national, or international. Much of what we aspire to be as individuals or members of society relies on health. Despite health's vital importance to individuals and society, problems involving health are often both politically contentious and difficult to solve. The ongoing, emotionally charged debates in Washington over national health reform offer just one salient illustration. We can see such change beyond America's borders, as China is also reforming its health system.<sup>1</sup> We discover obstacles to reform in the complexity and enormity of our health care and public health systems, and the sharp ideological differences between stakeholders. The latter, however, poses an intransigent barrier to effective health policy reform, as diverse political perspectives and interest groups can impede reform based on science and evidence.

Although both sides of the health policy debate believe in their respective purposes, problems arise due to their distinctly different background preferences and disagreement over key policy questions.<sup>2</sup> This divergence of background preferences results in a lack of consensus between the parties, which, in turn, leads to a sustained lack of tangible progress in health policy reform.

In addition to the differences in background preferences, policymakers are easily influenced by distorted risk perceptions and other policy priorities. Instead of focusing on the risks that affect the largest number of people, or assisting populations suffering from disproportionate health burdens, the political system concentrates on the most visible issues at any given moment, especially those issues that instill fear in the public or receive prominent media attention. The most recent example of this lack of focus is the ongoing global response to the outbreak of a novel strain of Influenza A(H1N1) ("swine flu").<sup>3</sup> Anthrax, smallpox, and SARS are also memorable examples from the last decade.

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1. Christina S. Ho & Lawrence O. Gostin, *The Social Face of Economic Growth: China's Health System in Transition*, 301 JAMA 1809, 1809–10 (2009).

2. Lawrence O. Gostin, *Foreword: National and Global Health Law: A Scholarly Examination of the Most Pressing Health Hazards*, 96 GEO. L.J. 317, 317–18 (2008).

3. See generally Lawrence O. Gostin, *Influenza A(H1N1) and Pandemic Preparedness Under the Rule of International Law*, 301 JAMA 2376 (2009).

While the media, various politicians, and the public have focused on these high-profile health issues, much deeper systemic health problems have been neglected, such as the basic public health infrastructure, access to essential medicines, primary health care, and the global diseases associated with poverty. These bureaucratic, ideological, and political complexities in health policy and law create an important role for academia. Scholars can research, analyze, engage stakeholders, and problem-solve in ways that are not available in the political sphere.<sup>4</sup> Moreover, universities are the intellectual breeding grounds for future generations of policymakers, health professionals, business leaders, scholars, attorneys, physicians, nurses, scientists, diplomats, judges, and leaders in many other private, public, and nonprofit fields of endeavor.

The O'Neill Institute for National and Global Health Law at Georgetown University, established through the generous philanthropy of Linda and Timothy O'Neill, demonstrates how academia can play a vital role in addressing complex and diverse national and global health problems in a comprehensive, evidence-based, intellectually-rigorous, and nonpartisan manner.

## II. THE O'NEILL INSTITUTE FOR NATIONAL AND GLOBAL HEALTH LAW

### A. PURPOSE/MISSION

The O'Neill Institute for National and Global Health Law at Georgetown University was formally established in 2007 to respond to the need for innovative solutions to the most pressing national and international health concerns. Housed at the Georgetown University Law Center in Washington D.C., the O'Neill Institute reflects the importance of public and private law in health policy analysis. The O'Neill Institute is a joint project of the Law Center and School of Nursing and Health Studies and draws upon the University's considerable intellectual resources, including the School of Medicine, the Public Policy Institute, and the Kennedy Institute of Ethics.

The essential vision for the O'Neill Institute rests upon the proposition that the law has been, and will remain, a

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4. Gostin, *supra* note 2, at 318.

fundamental tool for solving critical health problems in international, national, and local communities. By contributing to a more powerful, in-depth understanding of the multiple ways in which law can be used to improve health, the O'Neill Institute hopes to advance scholarship, research, and teaching that will encourage key decision-makers in the public, private, and civil sectors of society to employ the law as a positive tool for enabling more people to lead healthier lives.

## B. PROJECTS

The O'Neill Institute supports addressing urgent health problems through world-class research and scholarship by using a complex, comprehensive, interdisciplinary, and transnational approach that extends beyond a narrow vision of health law that focuses solely on health care as an industry or scientific endeavors. The O'Neill Institute's research programs are organized around three core areas:

- Global health law
- National health law
- Disease prevention and outcomes

Each of these programs combines elements of scholarship, reflective problem-solving, and teaching in ways that draw on the O'Neill Institute's intellectual strengths.

### 1. Global Health Law Program

The O'Neill Institute's global health law program merges the scholarly capacity of the Institute with the resources of its private and public partners, such as the U.S. Centers for Disease Control and Prevention, the Bloomberg Foundation, and the Bill and Melinda Gates Foundation. The O'Neill Institute also regularly collaborates with the World Health Organization (WHO). In the following section, we will provide concrete examples of on-going projects focusing on global health law.

#### i. Global Tobacco Control

Tobacco use is arguably the greatest public health threat facing the world today; if left unchecked, it could kill one billion

people this century.<sup>5</sup> The majority of these deaths will occur in developing countries targeted by the tobacco industry after stronger tobacco control laws and higher taxes reduced demand in developed markets.<sup>6</sup> The O'Neill Institute is a leader in the effort to reduce global tobacco use, and its approach is comprised of three primary components.

First, the O'Neill Institute, in collaboration with the Campaign for Tobacco Free Kids (CTFK), is researching the use of litigation as an approach for reducing tobacco use.<sup>7</sup> In countries that have ratified key U.N. human rights treaties or WHO's Framework Convention on Tobacco Control, or have otherwise adopted a positive right to health, litigation is an important tool in forcing the tobacco industry to comply with domestic and international law, as well as encouraging governments to adopt stronger domestic tobacco control regulations.

Second, in partnership with domestic and international organizations, the O'Neill Institute has drafted shadow reports to accompany States' Periodic Reports to U.N. human rights treaty monitoring bodies. These reports emphasize the close relationship between strong tobacco control laws and the protection of civil, political, social and economic rights. In Spring 2009, the Institute presented a shadow report to accompany Brazil's periodic report to the U.N. Committee on Economic, Cultural and Social Rights.<sup>8</sup> The Committee explicitly adopted two of the O'Neill Institute's proposed recommendations and invited Institute members to share our findings at a special session. Also, in January 2010, the Institute prepared and presented a shadow report to the U.N. Committee on the Elimination of All Forms of Discrimination Against Women focusing on human rights obligations in connection with women's health and tobacco control for the

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5. WORLD HEALTH ORG., REPORT ON THE GLOBAL TOBACCO EPIDEMIC, 2008: THE MPOWER PACKAGE 14 (2008), available at [http://whqlibdoc.who.int/publications/2008/9789241596282\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241596282_eng.pdf).

6. *Id.* at 21–22.

7. See generally Lawrence O. Gostin, *The "Tobacco Wars": Global Litigation Strategies*, 298 JAMA 2537, (2007); Lawrence O. Gostin, *Global Regulatory Strategies for Tobacco Control*, 298 JAMA 2057, (2007).

8. O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW ET AL. , PREVENTING AND REDUCING TOBACCO USE IN BRAZIL: PENDING TASKS (2009), available at <http://www.law.georgetown.edu/oneillinstitute/documents/O%27Neill%20Shadow%20Report%20-%20Brazil.pdf>.

Committee's periodic review of Egypt.<sup>9</sup>

Third, the O'Neill Institute works with advocates in low- and middle-income countries to develop rights-based arguments in support of tobacco control regulation. Also, we have collaborated with in-country partners to provide sound counter-arguments against tobacco industry challenges to tobacco control regulation.

The O'Neill Institute's tobacco control project has already generated influential scholarship, such as a comprehensive global litigation strategy report prepared for the project's funder, CTFK, which documents and analyzes tactics that have been or are being used around the world.<sup>10</sup> The litigation strategy report focuses on an individual's right to accurate consumer information, health, life, and safe workplaces. This report set the agenda for global litigation at the 2009 World Conference on Tobacco or Health in Mumbai, India, and also guided litigation strategies sessions for South American tobacco control advocates in Santiago, Chile in June 2009.

ii. "Planning for PrEP"

Despite major improvements in the prevention and treatment of HIV, the prevalence of individuals infected by HIV remains unacceptably high. As of 2007, approximately 33 million people were living with HIV, and 2.7 million people were newly infected.<sup>11</sup> Rates of HIV infection are highest in sub-Saharan Africa, which accounts for 67% of all people living with HIV.<sup>12</sup> Although that region has seen infection rates stabilize and begin to decline,<sup>13</sup> HIV infection rates continue to increase in Eastern Europe and Asia, disproportionately affecting injecting drug users, men who have sex with men

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9. O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW, WOMEN AND TOBACCO IN EGYPT: PREVENTING AND REDUCING THE EFFECTS OF TOBACCO CONSUMPTION THROUGH INFORMATION, IMPLEMENTATION, AND NON-DISCRIMINATION (2010), *available at* [http://www2.ohchr.org/english/bodies/cedaw/docs/ngos/ONeillInstitute\\_Egypt45.pdf](http://www2.ohchr.org/english/bodies/cedaw/docs/ngos/ONeillInstitute_Egypt45.pdf).

10. On file with authors.

11. JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS, 2008, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC 32 (2008), *available at* [http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008\\_Global\\_report.asp](http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp).

12. *Id.*

13. *Id.* at 31.



(MSM), and sex workers.<sup>14</sup>

Before a preventive vaccine becomes available,<sup>15</sup> one proposed HIV prevention strategy is the use of pre-exposure prophylaxis (PrEP). The idea underlying PrEP is straightforward—individuals would use existing HIV drug treatments as a prophylaxis against HIV infection.<sup>16</sup> However, in addition to understanding the efficacy of these drug therapies, it is also necessary to begin an examination of how PrEP trial results can be integrated into a comprehensive, global HIV prevention strategy. Although both researchers and HIV advocacy organizations optimistically await such results, they also caution that no matter the final outcome, PrEP is not in and of itself a “silver bullet” for HIV prevention.<sup>17</sup> Researchers have noted that public health decisionmakers need to start contingency planning now to prepare for the impending results of the PrEP trials.<sup>18</sup>

To that end, the O'Neill Institute sponsored the Bill & Melinda Gates Foundation-funded Planning for PrEP Conference in London, in June 2009. The conference serves as a launching point for organizing critical analysis of the impending results of the ongoing PrEP trials within the field of HIV/AIDS prevention and treatment programs. The conference brought together a group of experts in the field of HIV/AIDS research, key policymakers, and representatives from NGOs, to discuss the issues surrounding implementation of PrEP

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14. *Id.* at 30.

15. See AIDS VACCINE ADVOCACY COALITION, AVAC REPORT: THE SEARCH MUST CONTINUE (2008), available at [http://www.avac.org/pdf/reports/2008\\_Report/full.pdf](http://www.avac.org/pdf/reports/2008_Report/full.pdf) (discussing recent setbacks in the development of an AIDS vaccine, and making recommendations for future prevention-focused research).

16. See AIDS VACCINE ADVOCACY COALITION, WILL A PILL A DAY PREVENT HIV? 1 (2005), available at <http://www.avac.org/ht/a/GetDocumentAction/i/3116>.

17. See generally AIDS VACCINE ADVOCACY COALITION, ANTICIPATING THE RESULTS OF PREP TRIALS 3 (2008), available at <http://www.avac.org/prep08.pdf> [hereinafter AVAC]; see also Video: Pre-Exposure Prophylaxis: Could it Work? (Conference on Retroviruses and Opportunistic Infections 2009), available at <http://app2.capitalreach.com/esp1204/servlet/tc?c=10164&cn=retro&e=10656&m=1&s=20415&&espmt=2&mp3file=10656&m4bfile=10656&seektc=12.3&br=80&audio=false>.

18. AVAC, *supra* note 17, at 14–15 (citing Lynn A. Paxton et al., *Pre-exposure Prophylaxis for HIV Infection: What If It Works?*, 370 LANCET 89, 92 (2007)).

interventions. The O'Neill Institute is currently developing a summary publication of the conference findings. Furthermore, the O'Neill Institute, in collaboration with Imperial College London, has been awarded a follow-up, multi-year grant by the Gates Foundation to examine these issues in greater detail.

iii. Collaborations with the World Health Organization

The World Health Organization is the directing and coordinating authority for health within the United Nations system. WHO is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries, and monitoring and assessing health trends.<sup>19</sup> The O'Neill Institute has a number of ongoing collaborations with WHO to support its important role in global health.

a. WHO Health and Human Rights Database

In collaboration with WHO, the O'Neill Institute is developing two databases for compiling information about health and human rights. The first database (Law Database) will provide access to existing international instruments, constitutions, and case law on the "right to health" and other key health-related rights. This database will provide the starting point for analyzing the extent that these rights are enshrined in domestic and regional instruments, and how they are articulated and interpreted both domestically and internationally. The second database (Bibliography Database) will provide access through an annotated bibliography to existing published health and human rights literature.

b. WHO Course on Implementation of the International Health Regulations

In the globalized world, disease can spread far and wide via international travel and trade. A health crisis in one country can impact livelihoods and economies in many parts of the world. The revised International Health Regulations (IHR) is an international legal instrument that is binding on 194

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19. World Health Organization, About WHO, <http://www.who.int/about/en/> (last visited Dec. 2, 2009).

countries across the globe, including all WHO Member States.<sup>20</sup> The aim of the IHR is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. The IHR seeks to limit interference with international traffic and trade while ensuring the safety of the public's health.

The IHR requires countries to report certain disease outbreaks and public health events to WHO. The IHR also defines the rights and obligations of countries to report public health events, and establishes a number of procedures that WHO must follow in its work to uphold global public health security.<sup>21</sup> Moreover, the IHR requires countries to strengthen their existing capacities for public health surveillance and response.

WHO is working closely with countries and partners to provide technical guidance and support to mobilize the resources needed to implement the new IHR rules in an effective and timely manner. In December 2008, WHO negotiated a partnership with the O'Neill Institute, the University of Pretoria, the University of Geneva, and the University of Lausanne to collaborate on a multi-year project to develop a new global health security-training course to facilitate national-level implementation of the revised IHR (IHR i-Course).<sup>22</sup> In particular, the O'Neill Institute will provide its expertise on the relevant legal issues.

The IHR i-Course's objective is to build human resources capacity by providing training in legal issues, surveillance, early warning and response systems, and health-systems management for national government representatives of WHO member countries. The first offering of this course will take place in Spring 2010.

### c. WHO Task Force on Ethics and Tuberculosis

To respond to the growing concern surrounding the re-

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20. World Health Organization, What are the International Health Regulations?, <http://www.who.int/features/qa/39/en/index.html> (last visited Dec. 2, 2009).

21. *Id.*

22. World Health Organization, Securing Global Health: IHR Implementation Course, <http://www.who.int/ihr/training/ihr/course/en/index.html> (last visited Feb. 2, 2010).

emergence of tuberculosis (TB) and drug-resistant strains of TB, WHO assembled an Ethics Task Force that will provide strategic advice to the WHO and Stop-TB Partnership.<sup>23</sup>

The WHO invited the O'Neill Institute to be part of this Task Force and co-author a paper on Human Rights and Ethics in Public Health Measures for TB, Multidrug Resistant TB (MDR-TB), and Extensively Resistant TB (XDR-TB) control. Ethics Task Force Meetings have been held in Toronto and Geneva. More recently, in Cancun, Mexico, the O'Neill Institute presented a summary of this paper at the World Conference of the International Union Against Tuberculosis and Lung Disease.

d. WHO Public Health Law Consultation

In collaboration with WHO and the International Development Law Organization (IDLO), the O'Neill Institute co-sponsored, "Public Health Law Consultation," a two day meeting in Rome in April 2009 to address current issues in public health law. Participants included representatives from WHO, Food and Agriculture Organization (FAO), the World Bank, the Joint United Nations Programme on HIV/AIDS (UNAIDS), IDLO, the O'Neill Institute, the United Nations Development Programme (UNDP), and civil society organizations and academic institutions from around the world.

The 22 legal experts present at the meeting endorsed an initiative to build governmental capacity to deal with infectious and non-communicable diseases threatening the health, safety and economic viability of people and their countries. As the next step, the public health law group agreed to focus on first drafting guidelines for developing public health legislation. The O'Neill Institute will lead this initiative. The sponsors of this first consultation are also preparing for a second meeting in Cairo in early 2010, for the purpose of launching a manual on national public health laws sponsored by WHO, World Bank, IDLO, and the O'Neill Institute.<sup>24</sup>

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23. The Stop-TB Partnership is comprised of a network of international organizations, countries, donors, and civil society organizations that have a collective interest in working towards the eradication of TB. For more information, see Stop-TB Partnership, <http://www.stoptb.org/> (last visited Feb. 2, 2010).

24. See generally International Development Law Organization, International Expert Consultation on

## iv. Collaborations with the World Bank

In addition to the O'Neill Institute's work with WHO, the O'Neill Institute has been actively engaged in projects with the World Bank. The O'Neill Institute has been collaborating with the World Bank to address issues related to public health laws in developing countries, including the development of global public goods for health.<sup>25</sup>

## a. Framework Convention on Human Services

Over the past decade, the Caribbean Community ("CARICOM") has made significant achievements in advancing economic and political integration, culminating in the CARICOM Single Market and Economy (CSME) in 2010. The CSME includes trade in goods, services, capital, skills, and free movement of labor.

To complement and support this historic single market economy, the World Bank and O'Neill Institute are drafting a Framework Convention on Human Services (FCHS). The World Bank has found that the medical and nursing capacity in the region compared unfavorably to those in OECD countries. The nursing shortage is expected to grow to more than 1 million nurses by 2020. This shortage is driven by aging populations and is largely independent of the current economic slowdown. The World Bank found that compelling external forces (through the global demand for nurses, especially in wealthy countries) impact the region.

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Public Health Law, *available at*  
[http://www.idlo.int/Documents/HIV/Consultation\\_Report\\_June\\_2009.pdf](http://www.idlo.int/Documents/HIV/Consultation_Report_June_2009.pdf);  
 International Development Law Organization, Public Health Law  
 Consultation, *available at*  
[http://www.idlo.int/Documents/HIV/Background\\_Paper\\_Consultation\\_April\\_2009.pdf](http://www.idlo.int/Documents/HIV/Background_Paper_Consultation_April_2009.pdf).

25. See Monica Das Gupta & Lawrence Gostin, *How Can Donors Help Build Global Public Goods in Health?* 2 (The World Bank Dev. Research Group, Human Dev. & Pub. Servs. Team, Policy Research Working Paper No. WPS 4907, 2009), *available at* [http://www.wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2009/04/20/000158349\\_20090420112159/Rendered/PDF/WPS4907.pdf](http://www.wds.worldbank.org/external/default/WDSContentServer/IW3P/IB/2009/04/20/000158349_20090420112159/Rendered/PDF/WPS4907.pdf) (comparing the type and availability of public health services between developed and developing countries); see also Monica Das Gupta & Lawrence O. Gostin, *Donors' Roles in Building Global Public Goods in Health: The Responsibilities of Donors and International Agencies*, 373 LANCET 1395, (2009) (suggesting that donors should focus on the provision of population-wide health services in developing countries).

The FCHS aims to promote an equitable balance of interests among health personnel, source countries and destination countries, with particular emphasis on the mitigation of adverse effects of free movement of nurses, particularly in poorer countries. The FCHS will take the World Trade Organization's obligations and WHO's draft code of practice into consideration.

## 2. National Health Law Program

National health law is an integral component of the social and political discourse in the United States. The O'Neill Institute has a number of projects in its national health law program that examine important issues in this area.

### i. Legal Solutions in Health Reform

The American public has increasingly identified health care as a key issue of concern. President Obama and federal lawmakers have called for major health reform to address multiple problems in the accessibility and affordability of health care. The current heated political and public debate shows that health reform will raise a predictable set of complex policy, management, economic, and legal issues. Therefore, it is critical that advocates of health care reform anticipate such issues in order to prevent legally resolvable questions from barring substantive health reform.<sup>26</sup>

With funding from the Robert Wood Johnson Foundation, the O'Neill Institute commissioned and published nine papers on specific legal issues raised in health reform debates. Each analytical paper offers a diverse set of legal options for addressing those issues. Together with a description of overarching legal themes, the papers were sent out to key constituents in academia, policy, practice, and to Congress.<sup>27</sup>

The O'Neill Institute continues its analyses and engagement in the ongoing health care reform debate by

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26. ELENORA E. CONNORS & TIMOTHY M. WESTMORELAND, O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW, LEGAL SOLUTIONS IN HEALTH REFORM: PROJECT OVERVIEW AND EMERGING THEMES 1 (2009), *available at* [http://www.law.georgetown.edu/oneillinstitute/projects/reform/Papers/Project\\_Overview.pdf](http://www.law.georgetown.edu/oneillinstitute/projects/reform/Papers/Project_Overview.pdf).

27. For access to these papers, see Legal Solutions in Health Reform, <http://www.law.georgetown.edu/oneillinstitute/projects/reform> (last visited Feb. 2, 2010).

addressing legal questions with additional scholarship, symposia, and a blog. For example, the ongoing debate over whether there is a constitutional problem with the enactment of an individual mandate to purchase insurance was addressed in one of the commissioned analytical papers released early in 2009. The debate also surfaced as a frequent issue in the media in Fall 2009 and again in early 2010. The Legal Solutions Project responded with legal analysis as to why the issue was a red herring.

ii. Food Safety Law

Concern over food safety in the U.S. has been growing in the past several years, due to the frequency of high profile foodborne disease outbreaks. While the existing regulatory system is designed to provide safeguards against the distribution of tainted food products, unacceptable quantities of unsafe produce and meat continue to reach consumers.<sup>28</sup> Foodborne illness stemming from infected food poses a substantial, but preventable, health burden on the U.S. population.<sup>29</sup>

Policymakers have long recognized the deficiencies of the patchwork food safety system, and there have been regular attempts to rationalize and modernize the regulatory regime. Bills which propose changes to the regulatory system, such as the H.R. 2749, the "Food Safety Enhancement Act 2009" that recently passed in the House of Representatives, are frequently introduced in Congress.<sup>30</sup>

Two O'Neill Institute projects have contributed to this ongoing examination of domestic food safety laws. First, the O'Neill Institute, supported by the Bauman Foundation, critically examined the outdated statutes governing meat safety. It developed key policy documents and established

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28. Kent Garber, *Just How Safe Is Our Meat?*, U.S. NEWS & WORLD REPORT, Feb. 22, 2008, <http://www.usnews.com/articles/news/national/2008/02/22/just-how-safe-is-our-meat.html?PageNr=2> (last visited Feb. 2, 2010).

29. Dept. of Health & Human Servs., Ctrs. for Disease Control & Prevention, *Foodborne Illness: Frequently Asked Questions* (2005), available at [http://www.cdc.gov/ncidod/DBMD/diseaseinfo/files/foodborne\\_illness\\_FAQ.pdf](http://www.cdc.gov/ncidod/DBMD/diseaseinfo/files/foodborne_illness_FAQ.pdf).

30. H.R. 2749, 111th Cong. (1st Sess. 2009), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_bills&docid=f:h2749rfs.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h2749rfs.txt.pdf).

collaborative relationships with leading food safety experts and their affiliated institutions.

Second, the O'Neill Institute collaborated with the Produce Safety Project, an Initiative of the Pew Charitable Trusts at Georgetown University, to address issues surrounding produce safety regulation. The O'Neill Institute provided a detailed analysis of the Food and Drug Administration's (FDA) ability to regulate produce safety on farms,<sup>31</sup> as well as the U.S. Department of Agriculture's ability, under FDA guidance, to establish enforceable safety standards for domestic and imported fresh produce, from farm to fork.<sup>32</sup>

### iii. Systems Medicine

Understanding the interaction among genomics, the external environment, and individual behavior, is one of the fundamental tenets of health care. Modern medicine often neglects this comprehensive model, and treats disease in isolation without taking into account the dynamic, integrative systems in the human body. Proponents of a paradigm shift in "medical education and practice look toward 'systems medicine,' which incorporates the complex biochemical, physiological, and environmental interactions that sustain living organisms."<sup>33</sup> Although a holistic approach to medicine should benefit patients and society, consideration of the socio-legal, ethical, and economic implications is also essential.

The O'Neill Institute is collaborating with the Georgetown School of Medicine on a systems medicine project. This project is expected to produce scholarship and guidelines on systems medicine. "Evolving from Reductionism to Holism: Is There a Future for Systems Medicine?" was published in the *Journal of the American Medical Association* in 2009 as the first in a series of articles that will address this topic. The article introduced the key elements of systems medicine.<sup>34</sup>

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31. O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW, LEGAL AUTHORITY OF THE U.S. FOOD AND DRUG ADMINISTRATION OVER PRODUCE SAFETY (2008), available at <http://www.producesafetyproject.org/admin/assets/files/0021.pdf>.

32. O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW, USDA AUTHORITY REGARDING PRODUCE SAFETY (2009), available at <http://www.producesafetyproject.org/admin/reports/files/0005.pdf>.

33. Howard J. Federoff & Lawrence O. Gostin, *Evolving From Reductionism to Holism: Is There a Future for Systems Medicine?*, 302 JAMA 994, 994 (2009).

34. *Id.*



### 3. Center for Disease Prevention and Outcomes

The Center for Disease Prevention and Outcomes, based in Georgetown University's School of Nursing and Health Studies, also has a number of significant projects on global and national health issues.

#### i. Global Health Governance

Increased globalization, the emergence of a multitude of state and non-state donors, NGOs, and service providers, and an absence of a cohesive governance structure, have led to a noticeable lack of cooperation and coordination among global health actors.<sup>35</sup> This issue harms all populations, but has an especially devastating effect on the most vulnerable. The unprecedented influx of funding for global health programs, however, has led to heightened visibility and scrutiny amongst both the public and political leaders. The current outbreaks of novel Influenza A raises the profile of global health, but also places more pressure on WHO and donors to focus on pandemic preparedness. This detracts from our focus on the everyday health needs of the world's poor. These circumstances present a unique window of opportunity for the global health community to act boldly and innovatively.

There must be appropriate prioritization and increased efficiency, cooperation, and coordination within global health, to meet basic survival needs and improve the health of the most vulnerable populations. In light of the ongoing economic crisis, it is unclear how much longer the momentum advancing the global health agenda can be sustained. The global community must act quickly and collectively.

To that end, the O'Neill Institute assembled a small group of experts for a conference, "Global Health Governance" in April 2009. The purpose of the conference was to propose and analyze ethical, legal, and politically and socially feasible solutions to address the problem of disjointed global health governance. Proposals included an examination of WHO leadership (e.g., a "Committee C"), sweeping re-conceptualizations of the framework for international development assistance (e.g., Framework Convention on Global Health), and more targeted

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35. Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEO. L.J. 331, 383–86 (2008).

interventions, tailored to increasing access to medicines (e.g., Health Impact Fund). The group also analyzed global health equity, and the need to focus on social determinants of health.

The April conference represented the beginning of a larger discussion. Future steps include a symposium issue of the *Journal of Law, Medicine & Ethics*, as well as the development of a more detailed strategy for global health governance.

ii. Food Safety Workgroup

In collaboration with Georgetown University's Office of the Provost, the O'Neill Institute has convened a Georgetown Food Safety Workgroup. The Workgroup includes members from the University, and examines how a multi-disciplinary approach can improve food safety at both the national and international levels.

The Workgroup is currently developing grant applications on a number of food safety related issues, including the creation of a food informatics portal focused on improving food safety. This portal gathers and integrates produce-related data from independent sources, thereby enabling users, that would include scientists and public health researchers and policymakers, to conduct sophisticated computational analysis about contamination, using reliable food production, environmental, and outbreak data.<sup>36</sup>

Furthermore, the Workgroup is preparing for a conference in Winter 2009 to discuss food safety in a globalized world. The conference will focus on imported food.

iii. Personalized Medicine and Indigenous Genomics

Indigenous nations and developing countries share a history of underdevelopment and colonial exploitation that has often left their members both politically and economically marginalized.<sup>37</sup> People in these indigenous communities suffer disproportionately from infectious diseases (such as HIV/AIDS,

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36. O'Neill Institute for National and Global Health Law, Food Informatics Portal, <http://www.law.georgetown.edu/oneillinstitute/nhs/food-informatics-portal/index.html> (last visited Feb. 2, 2010).

37. O'NEILL INST. FOR NAT'L & GLOBAL HEALTH LAW, DEVELOPING A FRAMEWORK TO GUIDE GENOMIC DATA SHARING AND RECIPROCAL BENEFITS TO DEVELOPING COUNTRIES AND INDIGENOUS PEOPLES 4-5 (2009), [http://www.law.georgetown.edu/projects/bridging/Developing\\_Framework.pdf](http://www.law.georgetown.edu/projects/bridging/Developing_Framework.pdf).

malaria, and diarrhea), and chronic illnesses (such as diabetes and heart disease).<sup>38</sup> Personalized medicine through health care tailored to individual patients' genotypes promises to dramatically improve treatment quality. Genomic science, however, has just begun to collect the data necessary to support personalized medicine.

In addition to understanding clinical issues, there will be important ethical and policy questions that must also be addressed. This will require international support and participation. Especially important will be the inclusion and participation of indigenous communities and developing nations themselves.

The O'Neill Institute began the process of analyzing relevant policy issues with a Colloquium in January 2009.<sup>39</sup> The Colloquium invited twelve influential participants with extensive experience in the conduct of biomedical research among indigenous peoples and developing countries to address a basic question: As genomic science develops across the world, how can the global community assure that indigenous nations and developing countries reciprocally benefit from their contributions to research?

Colloquium participants disagreed as to this dilemma's relative importance. Some participants argued that the history of poor scientific practice justifies refusing to join genomic research projects. Others argued that disease poses such a great threat to the well-being of people in indigenous communities and developing nations, that not participating in genomic research risks irrevocable harm. All agreed, however, that the dilemma potentially diminishes if the scientific community engages indigenous and developing communities in new ways—ways that employ genomic research as a tool for community development, as well as a source of scientific information. Adopting these new methods would also improve biomedical science by including continuous community engagement and progressive community empowerment as components of "rigorous scientific research."<sup>40</sup>

This project is expected to conduct many further activities, and produce influential scholarship on the topic of genomic research and indigenous peoples in the U.S. and other

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38. *Id.*

39. See generally O'Neill Institute for National and Global Health Law, Bridging the Gap between Genomic Science & Indigenous Peoples Global Group Tackles Indigenous Health, <http://www.law.georgetown.edu/oneillinstitute/projects/bridging/index.html> (last visited Nov. 15, 2009).

40. O'NEILL, *supra* note 25, at 4–5.

countries.

### C. SCHOLARSHIP

In addition to the scholarship generated in the course of the foregoing policy projects, the O'Neill Institute also supports the ongoing scholarship of affiliated faculty members, through the assignment of fellow time and other resources.

The Georgetown health law faculty, with O'Neill support, is currently preparing several major works that include:

- M. Gregg Bloche, *Do No Harm*<sup>41</sup>
- Lawrence O. Gostin, *Global Health Law: International Law, Global Institutions, and World Health*<sup>42</sup>
- Nan D. Hunter, *Access to Care and Coverage*<sup>43</sup>
- Kathryn Zeiler, *Medical Malpractice Liability Crisis or Patient Compensation Crisis?*<sup>44</sup>

Scholarship by O'Neill Institute faculty often has an impact in real-world policy. For example, O'Neill Institute's Faculty Director, Lawrence Gostin, proposed the idea of a Framework Convention on Global Health (FCGH).<sup>45</sup> Professor Gostin argues that the international community should address the world's most pressing health problems through a framework convention-protocol, specifically a FCGH.<sup>46</sup> The initial objectives of a FCGH would be to "[e]stablish fair terms of international cooperation, with agreed-upon mutually binding obligations to create enduring health system capacities, meet basic survival needs, and reduce global health disparities."<sup>47</sup> Drawing from Professor Gostin's scholarship, the Norwegian Directorate of Health plans to integrate components

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41. M. GREGG BLOCHE, *DO NO HARM* (Palgrave-McMillan forthcoming).

42. LAWRENCE O. GOSTIN & DAVID P. FIDLER, *GLOBAL HEALTH LAW: INTERNATIONAL LAW, GLOBAL INSTITUTIONS, AND WORLD HEALTH* (Harvard University Press forthcoming).

43. Book forthcoming, citation currently unavailable.

44. Kathryn Zeiler, *Medical Malpractice Liability Crisis or Patient Compensation Crisis?* DEPAUL L. REV. (forthcoming).

45. Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEO. L.J. 331 (2008).

46. *Id.* at 382–391.

47. *Id.* at 388.

of a FCGH into their proposal for a Global Health Convention later this year.<sup>48</sup>

#### D. TEACHING

The O'Neill Institute also responds to pressing health concerns by educating future researchers, policymakers, practitioners, and scholars. The O'Neill Institute teaches its students to rigorously analyze the theoretical, philosophical, political, cultural, economic, scientific, and ethical bases for understanding and responding to health problems. The O'Neill Institute helps to prepare our graduates to engage in multidisciplinary conversations about national and international health care law and policy with innovative multidisciplinary courses and degree programs.<sup>49</sup>

##### 1. Innovative Multi-Disciplinary Courses

###### i. O'Neill Institute Colloquium

The O'Neill Institute Colloquium, offered annually, is an interdisciplinary course that draws from the work of University scholars, policymakers, and the general health community. The Colloquium's goal is to engage leading thinkers and students in an enriching dialogue regarding critical health law issues. National and international scholars, practitioners and policymakers explore contemporary health issues with top students interested in health law and related issues from schools throughout the University. The Colloquium sessions are open to University faculty members and interested members of the public. The 2008 Colloquium focused on global health, while the 2009 Colloquium focused on U.S. health care reform.<sup>50</sup>

###### ii. Public Health Emergency Simulation

The Public Health Emergency Simulation is an annual

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48. Report to be released in 2010 (draft on file with authors).

49. O'Neill Institute for National and Global Health Law, LL.M. Programs, <http://www.law.georgetown.edu/oneillinstitute/academics/LLM.html> (last visited Feb. 2, 2010).

50. O'Neill Institute for National and Global Health Law, O'Neill Institute Colloquium, <http://www.law.georgetown.edu/oneillinstitute/resources/2008-colloquium.html> (last visited Feb. 2, 2010).

event that allows bio-defense masters students and global health law students to practice the knowledge that they have attained over the course of the semester. The students participate in a day long, simulated global public health emergency, and play the roles of the relevant health, government and other officials. Faculty members act as facilitators for the simulation. Previous simulation situations have addressed the global response to pandemic influenza, and food safety threats.

## 2. Graduate Degree Programs

### i. Global Health LL.M. Program<sup>51</sup>

Georgetown Law offers graduate students a unique opportunity to study global and domestic health law. The Global Health LL.M. Program offers U.S. and international lawyers the opportunity to advance their knowledge and skills through focused studies in core legal and policy courses on global health, individual and public health, human rights, trade law, bioethics, international economics, environmental law, biotechnology, and science. Many O'Neill Institute faculty and fellows develop and teach courses in this program.

### ii. Global Health Law and International Institutions LL.M. Program

In Fall 2009, Georgetown Law launched a new LL.M. program in Global Health Law and International Institutions, to be jointly offered with the Graduate Institute of International and Development Studies in Geneva, Switzerland. Students in this joint program spend the first semester at Georgetown Law, followed by a winter internship at an international institution in Geneva, and a spring semester at the Graduate Institute. The new program brings together two universities at the cutting edge of global health law and governance.

## III. CONCLUSION

In addition to the activities described above, the O'Neill Institute has many projects in development. In the global

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51. O'Neill Institute for National and Global Health Law, LL.M. Programs, *supra* note 49.

health law program, these include a close examination of China's health law with the prospect of a major grant on "democracy building." The O'Neill Institute is also starting a multi-year project on pre-exposure prophylaxis in partnership with Imperial College London, and has recently started to collaborate with the U.N. Secretary General's Special Envoy for Malaria in the task force for malaria high-impact countries

In the national health law program, developing projects include a follow-up to the Legal Solutions in Health Reform to address emerging issues on domestic health law reform. Finally, the Center for Disease Prevention and Outcomes is preparing additional projects on genomics and indigenous peoples, school closures and emergency preparedness, and public health and climate change.

The comprehensive, influential, and timely range of activities, research, scholarship, and teachings of the O'Neill Institute demonstrate the significant potential of academia to identify and respond to the most critical health concerns facing the world today.