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Can Laws Make Us Healthy?

The New O'Neill Institute for
National and Global Health Law
Certainly Hopes So.

BY ALAN DESSOFF

ast May, one man with a drug-resistant form of tuberculosis crisscrossed international borders on two transcontinental flights, endangering the health of hundreds and stoking a media frenzy. Last fall, contaminated spinach killed three people, sickened more than 200 and disrupted the lives of thousands before the outbreak was traced to *E. coli* at a California cattle ranch. Meanwhile, bird flu and other potential pandemics hover at the edge of our collective attention span. Health stories dominate the headlines and health issues loom large in

the public consciousness.

Often absent from the panic and news coverage, however, is a discussion of the legal issues underpinning these events: To what extent should individual freedoms be curtailed by deference to the public good? What regulations will stop contaminated produce from reaching the consumer? How can we counter a global pandemic?

The O'Neill Institute for National and Global Health Law, just inaugurated at Georgetown Law in April, hopes to tackle these issues as it becomes a world-class center for the scholarship and policy of health law.

“The Institute will find innovative solutions to the major health problems in the United States and across the globe,” says Associate Dean and Professor Larry Gostin, who was invested during the Institute’s inaugural program in April as the Linda and Timothy O’Neill Professor of Global Health Law and who serves as the Institute’s faculty director. “The effect of law on health care is not small or novel. It’s very substantial — and much neglected.”

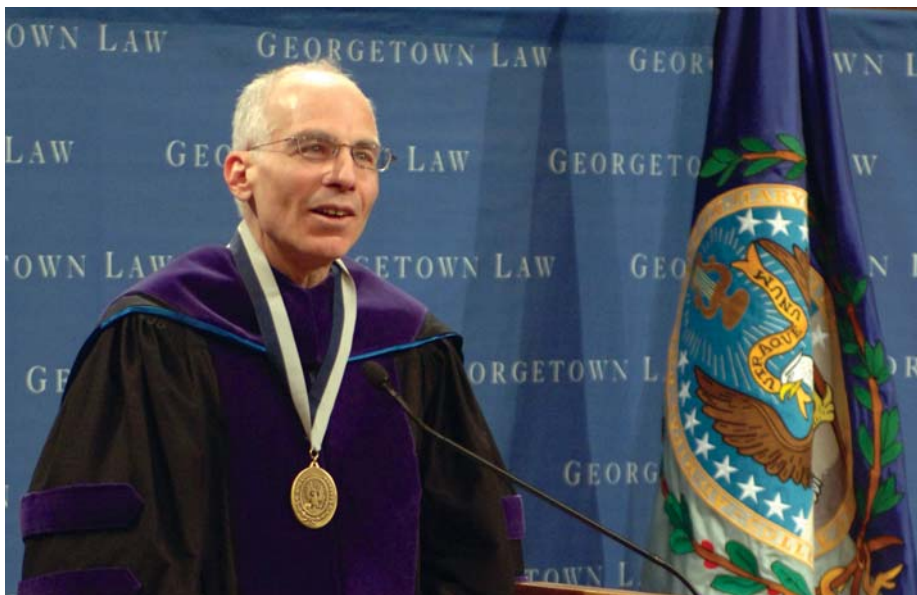
The O'Neill Institute is an ambitious undertaking. It presents an opportunity “to make a difference on these incredibly important questions of domestic and international public health,” says Dean Alex Aleinikoff. “Increasingly, law schools have looked to institutes and centers as a way to bring scholars together and have an impact on the world. We have every hope and intention of being the leading institution on national and global health law in the country.”

Historically, health law and health care have moved on separate and often divergent tracks. But through the Institute, the Law Center and Georgetown University’s School of Nursing & Health Studies are joining together to seek innovative solutions to the most pressing health concerns facing the country and the world — famine, obesity, infectious diseases, food safety and much more.

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Gostin acknowledges that developing a system of global law to improve the health of the world’s citizens will be “a long process, maybe a lifetime’s work.” But “it has to start somewhere,” he says.

One place is food safety. The Center on Health Regulation and Governance is one of four centers that will comprise the Institute, and one of its first projects concerns the nation’s meat inspection laws. Georgetown Law Professor David Vladeck, director of the center, says the first step of his project will be a systematic review of the legal regulations that govern the production and sale of meat in the U.S. One illustration of “how antiquated the laws are,” Vladeck says, is that the Meat Inspection Act of 1906, the basic statute governing the U.S. meat industry, does not permit the principal regulatory agency, the Department of Agriculture, to require manufacturers and sellers to test for microbiological



PHOTOS BY BILL PETROS

agents. "That's not to say there isn't any testing going on, but the federal government cannot tell a meat seller that he has to test for E. coli," says Vladeck, an experienced public interest litigator with extensive expertise in food and drug law.

Vladeck hopes that the meat study will lead to an overhaul of U.S. food safety laws and a review of other countries' policies in this area. "I would like to see our work being a fulcrum for debate on food safety laws," he says. "These are issues that Congress doesn't often address comprehensively, and if we can prove that they have been thought through and that there is a broad consensus for reform, I think we can make some real progress."

At the same time, the project will have an international focus. "A lot of our work will go toward better understanding the international regulatory regime, because there are ongoing efforts to harmonize these laws. Our

principal concern is making sure they are fully protective of public health," says Vladeck.

The meat study is only one of countless ways the Institute will stimulate fresh nonpartisan proposals for health promotion, disease prevention and health care, nationally and globally. Through policy development, research, education, training, collaboration and dissemination, it will seek to influence policy at national, regional and international levels. Its audience will be diverse, including health professionals, lawyers, legislators, judges, academics, policymakers and others. More than anything, the O'Neill Institute hopes to provide a place where these big-picture issues can be studied and debated.

"On a national basis, health care is the most important economic issue going forward, particularly for the baby-boom generation, and the global dimensions of it are obvious, particu-

larly relating to pandemics. But the existing infrastructures in both public health and the law are incapable of dealing with it," says Tim O'Neill (L'77), a Managing Director at Goldman Sachs. O'Neill and his wife, Linda (NHS'77), who has been affiliated with the New York Presbyterian Hospital at Columbia University for many years and was a co-founder of the National Pediatric Cardiology Nurses Association, made the Institute possible with their \$10 million gift.

The infrastructure problems Tim O'Neill mentions were underscored by speakers at the Institute's inaugural, including Rep. Henry A. Waxman, D-Calif. Health law as a field is in many ways "an ad-hoc process," Waxman said. "We use the tax code for this, the police-power-of-the-state for that, and the Commerce Clause for yet another. Sometimes it's state law. Sometimes it's federal law. Sometimes it's international agreements." Still, although it



After he was inaugurated as the first Linda and Timothy O'Neill Professor in Global Health Law, Larry Gostin (opposite, left) thanked Timothy (L'77) and Linda (NHS'77) O'Neill (left) and vowed to "seek innovations to the world's most pressing health problems." In his speech at the event, Georgetown President John J. DeGioia (opposite, right) said: "This Institute will break down barriers between disciplines and serve as a convening ground for national and international discourse among the world's leaders. ..."

often is “confusing and confused,” health law is important — which is what makes the O’Neill Institute so vital, Waxman said, for its focus on “teaching students about health law and encouraging scholars to think about it.”

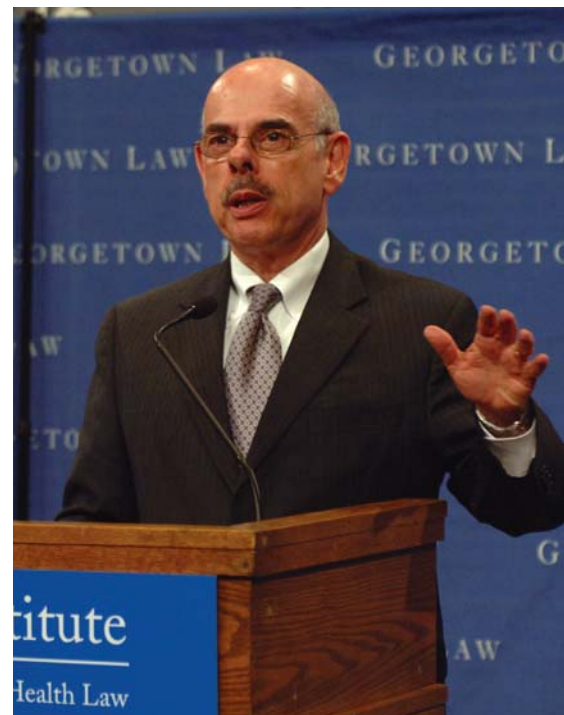
Gostin is one internationally recognized scholar who already has thought extensively about it. “To ensure effective and well-functioning health systems in poor countries, and to meet basic survival needs, the international community, in partnership with host countries, must invest in health system infrastructure,” said Gostin in his inaugural lecture (which will be published in the *Georgetown Law Journal* and will also appear in a two-part series in the *Journal of the American Medical Association*.) “It is not simply the amount of money spent that is important, but how those resources are invested and used. This requires a structured approach that sets priorities, ensures coordination, and monitors

The most important question ... is whether we can deliver the tools we have to the people who need them. That is one of the real challenges,” says NHS Dean Bette Keltner. “It’s not just designing a cure for a disease, but how we design the logistics and ensure that people who need care can actually get it.”

results. The innovative use of international law could provide just such a vehicle for change.”

But if law is to play a constructive role, new models will be required, says Gostin, who is heading up the Center for Global Health Law, another of the Institute’s four centers and the one designed to deal with profound questions of health and health inequalities around the world. The model Gostin proposes is a framework convention on global health. He cites the Kyoto Protocol to the United Nations Framework Convention on Climate Change and the Framework Convention on Tobacco Control as illustrations of how a global health framework convention might work. It would represent “an historical shift in global health, with a broadly imagined global governance regime,” Gostin says. “There is little doubt that the single most important way to ensure population health is to build enduring health systems in all countries.”

Gostin and other professors know there is no shortage of health issues to address, from the global HIV/AIDS



PHOTOS BY BILL PETROS

crisis to questions raised in the U.S. by such recent events as a student's murderous rampage at Virginia Tech. That incident, Gostin suggests, raised questions about whether student privacy laws prevented the removal of a mentally unstable student. "I've often said that law can be a tool for improving public health, and then sometimes it can be an obstacle to improved public health."

"How we balance the rights of individuals in a society with our capacity to protect society" is just one question that will underscore the Institute's work across a range of health law issues, agrees NHS Dean Bette Keltner. "Basically, we want to expand the toolbox of health care capacity, and the most important question if we do that is whether we can deliver the tools we have to the people who need them. That is one of the real challenges," says Keltner. "It's not just designing a cure for a disease, but how we design the logistics and ensure

that people who need care can actually get it."

Such challenges have long preoccupied Georgetown Law Professor M. Gregg Bloche, who is concerned about another major issue affecting the public's health: rapidly rising medical costs. "We have a problem that is out of control," he says, pointing to the influence of the pharmaceutical industry and the impact of the federal budget process on health care costs and potential legal restraints on health care reform initiatives.

"All these forces are operating to shape medical practice in ways that are profligate, often ineffective, sometimes harmful to patients, and certainly costly and inefficient," says Bloche, a preeminent scholar of U.S. and international health law and policy. Bloche's project on medical cost containment, co-sponsored by Georgetown Law and the Brookings Institution, is exploring alternative approaches to slowing the growth of medical spending and

getting more value from health care dollars.

Now, as director of the O'Neill Institute's Center on Health Care Financing and Organization, Bloche hopes to stimulate more open discussion about "the failings of our medical care system" and what can be done to reverse them. "I can see part of my role as not just opining in a reflective way about things we already know but finding out about things that we don't know" and trying to reconcile apparent conflicts, says Bloche.

He points to research on Medicare and the federal budget done by Georgetown Law Visiting Professor Timothy Westmoreland, which shows that the current budget process treats extension of life for Medicare beneficiaries as a cost, since longer lives mean further financial demands on the system. "This doesn't take financial account of the benefits of a longer life," Bloche says.



The O'Neill Institute represents "an intersection of disciplines," principally law and health, "coming together to create an incubator for creative ideas," said Dr. Julie Louise Gerberding (this page, left), director of the U.S. Centers for Disease Control and Prevention, in a speech during the inaugural. Opposite page: NHS Dean Bette Keltner and Rep. Henry Waxman, D-Ca., also spoke at the event.

BILL PETROS

Similarly, while it might be relatively inexpensive to develop a new vaccine that will extend the lives of Medicare beneficiaries, that also “will show up as a huge cost because if the beneficiaries live longer, they will be using a whole lot more health care,” Bloche adds. “One thing that scholars have the opportunity to do, both as experts in the field and as public intellectuals, is to give voice to these concerns with good argument, good data, and hopefully, eloquence and passion.”

While Vladeck and Bloche tackle the legal underpinnings of major health care issues at home, NHS Professor Frank Wong is trying to come to grips with one element of the worldwide HIV/AIDS crisis in another country, China. A key problem there, Wong explains, is that the Chinese household system classifies people into two categories, urban or rural, and citizens need official permission to travel or relocate to a new city. “If you live in a rural village and want to move to Shanghai, technically speaking you have to register and get permission to

move. Otherwise, you get no benefits, nothing. The government doesn’t recognize you,” Wong says. As China becomes part of the global economy

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and more people move internally — mostly for economic reasons — the government has made some exceptions. Wong wants to study the policy implications of a waiver program that allows migrants to Shanghai who test positive for HIV to be treated for it there immediately (although eventu-

ally they’ll be required to register in their hometowns).

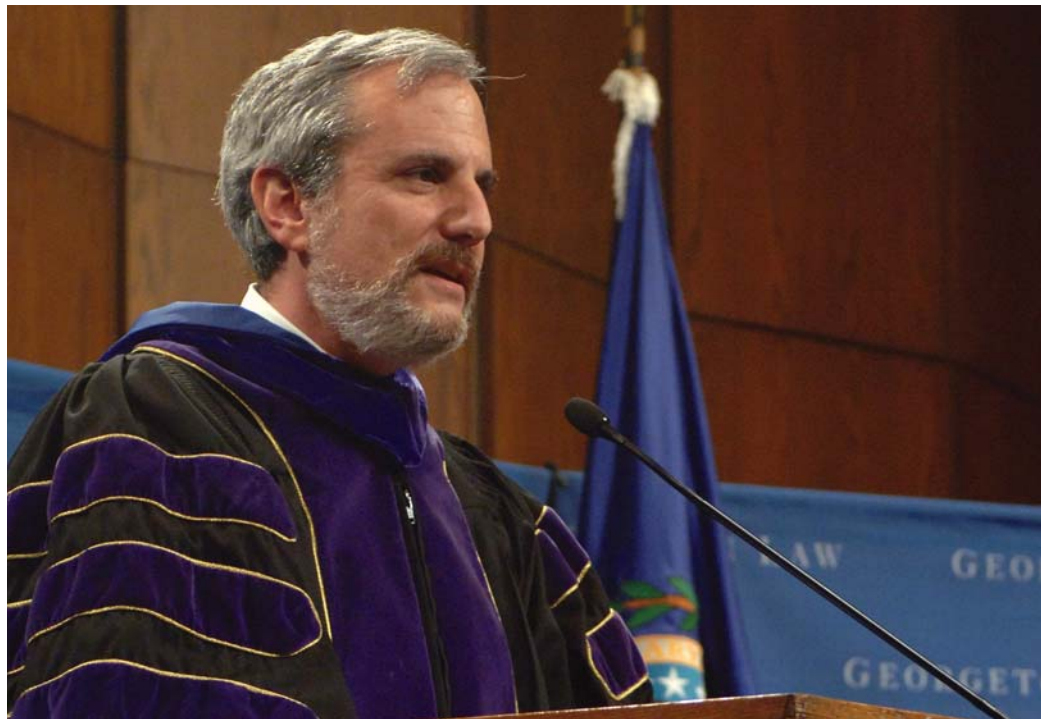
A related issue, Wong says, is how to encourage the Chinese to “come forward to get tested, get counseled and get treatment.” That is a Western concept that runs counter to conventional culture in China but is important when it comes to drafting health policy and regulation in the country, he says.

The international focus is crucial to the O’Neill Institute. “Larry has laid out an ambitious but interesting prospect to really use legal instruments to make health a priority internationally. I think that will be part of the overall soul of the Institute,” says Bernhard Liese, interim director of its Center for Disease Prevention and Health Outcomes and chair of the Department of International Health at NHS.

NHS’s contribution, he says, will include trying to develop data that “you have to look at systematically in order to inform policy decisions” rather than letting “pressure groups” do it, Liese says. For example, he cites The Agreement on Trade-Related Aspects



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of Intellectual Property Rights (TRIPS), an international agreement administered by the World Trade Organization that sets down minimum standards for many forms of intellectual property regulation.

"There is quite a bit of evidence around that this is not very helpful to the countries" but "could be very beneficial to the pharmaceutical industry," Liese says. "But if you drill down and really look at the evidence each side has to provide, you find that there isn't all that much evidence. Do we know what the pharmaceutical industry really spends on research in developing a new drug? We don't know that. There are mounds of money traded around in industry circles, from hundreds of millions to a billion. But if you ask the industry to maybe open its books, they say no, it can't be done. It's trade-related."

"You can go through a whole list of issues for which we have partial data or no data. It would be nice to have considerable evidence on an issue, particularly in areas that are highly charged politically," Liese says.

No one expects the O'Neill Institute to produce immediate or dramatic results as it pursues its mission through research, scholarship and reflective engagement with partners in the public and private sectors.

Gostin sees more studies developing on a wide range of domestic and international issues. He says talks are underway with the Bill & Melinda Gates Foundation about a project on global tobacco control and "we're in conversations with people" about projects on obesity and chronic disease.

He also is looking for a way to jumpstart his framework convention proposal. "Any time you want to change world governance, it's extremely difficult," he says. "I think the best way of doing it is to build it up from a consensus among the stakeholders."

To begin, he wants to bring together key leaders and opinion makers in international health in the public and private sectors "to work out the broad principles" of a framework convention. There already is interest from the World Health Organization,

the Pan American Health Organization, and the U.S. Centers for Disease Control and Prevention, and "I think we have a lot of interest among industry and NGOs and philanthropies," Gostin says. He is thinking of hosting a first gathering of principal stakeholders in the United States. "But it certainly can't be just American; it will have to be international," he says.

A framework convention on global health "would not be easy to achieve politically or provide an ideal solution," Gostin says. But without some "innovative international mechanism" to improve the health of the world's population, he adds, "everyone would be worse off."



"The opportunity as I see it is to take a strategic look at how the law can improve the health of people in communities around the world and provide what we learn to policymakers in the public and private sectors," says John Monahan ('78, C'83), opposite left, who joins the Institute this fall as its executive director. Opposite right: Dean Alex Aleinikoff spoke at the Institute's inaugural last April while faculty, friends and supporters looked on.