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## National and Global Health Law: A Scholarly Examination of the Most Pressing Health Hazards

Lawrence O. Gostin


*Georgetown University Law Center*, [gostin@law.georgetown.edu](mailto:gostin@law.georgetown.edu)

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# FOREWORD

## **National and Global Health Law: A Scholarly Examination of the Most Pressing Health Hazards**

LAWRENCE O. GOSTIN\*

The health of individuals, families, and communities has deep, intuitive meaning. So much of what we aspire to be as individuals or as members of society relies on health. Our shared intuitions about the value of health manifest themselves in public and political concerns. The media widely reports threats to the public's health, such as a traveler with multi-drug resistant tuberculosis, E-coli from contaminated spinach, miners' deaths, unsafe children's toys, and dangerous pharmaceuticals. Election years predictably spur new, or refashioned, proposals for health care reform. And there remain enduring, intractable health hazards, such as tobacco, obesity, motor vehicle crashes, and endemic diseases such as HIV/AIDS. The public hears much less about the health of the world's poorest people, except perhaps during extreme events, such as a refugee crisis or a tsunami. But the world's poor suffer multiple, compounding disadvantages that well surpass the burdens experienced by those in richer countries—poverty, famine, tropical diseases, and often the atrocities of war and dislocation, to name a few.

Beyond the intuitive understanding of the importance of health lies a hard-headed recognition of its social, political, and economic dimensions. The fear of disease, disability, and death from epidemics, natural disasters, or bioterrorism can profoundly disrupt every facet of social life, with severe repercussions for business and trade—as the SARS outbreaks have most recently demonstrated. Even relatively minor terrorist events such as the anthrax attacks can be socially devastating. And when social and economic intercourse can be so adversely affected, politicians take notice.

It is obvious why health is such a vital issue locally, nationally, and globally. What may be less obvious is why problems involving health are so politically contentious and hard to solve. Certainly, part of the answer lies in the complexity and enormity of the health care and public health systems. But ideology also plays a large part in the apparent paralysis in health policy reform. Although both sides of the political divide engage in health policy debates with a seriousness of purpose, each approaches the problems with distinctively different background preferences.

Politicians sharply divide over key policy questions: Should public or private

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\* Lawrence O. Gostin, Associate Dean (Research and Academic Programs) and the Linda D. and Timothy J. O'Neill Professor of Global Health Law, is Faculty Director of the O'Neill Institute on National and Global Health Law at Georgetown University.

solutions be primary? What are the effects of regulation on markets and the economy? Should taxes be increased to pay for public benefits and services? What is the appropriate scope of governmental public health? Some policy makers would limit state action to cost-effective interventions narrowly designed to prevent discrete harms, such as the quarantine of highly infectious individuals. Others would allow paternalistic interventions to prevent or diminish harm to the person herself, such as mandatory seatbelts and motorcycle helmets or bans on trans fat in foods. Still others would broadly address the underlying socioeconomic conditions for poor health, which would entail redistribution of societal resources. The divergence of background preferences is understandable, but the resulting lack of consensus can effectively thwart political progress on health policy reform.

Even beyond the differences in background preferences, both ends of the political spectrum are prone to distorted risk perceptions and health policy priorities. Rather than focusing on the most significant risks that affect the largest number of people, or focusing on populations suffering disproportionate burdens, the political system often concentrates on the issues that happen to be most salient at any given moment, particularly if they produce fearful public responses and media discussions. Over the last decade, the government has lurched from one high-visibility event to the next, such as anthrax, smallpox, SARS, and pandemic influenza. While attention and resources have been lavished on these high-profile issues, much deeper systemic health problems often are neglected, such as the basic public health infrastructure, vaccines, primary health care, and global diseases of poverty (for example, infant diarrhea and malaria).

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

The complexity, enormity, and political divisiveness of health in the United States and globally creates an important role for academia. The academy can research, analyze, engage stakeholders, and problem-solve in ways that are not possible in the political sphere. Universities are also richly interdisciplinary by nature, incorporating every field of study relevant for cogent analysis—such as law, philosophy, economics, history, health sciences, and social/behavioral/political sciences. It is for these reasons that Linda and Timothy O'Neill recently made a \$10-million gift to establish the O'Neill Institute for National and Global Health Law at Georgetown University.

The O'Neill Institute is housed at the Law Center in the nation's capital, reflecting the importance of public and private law in health policy analysis. The most critical social debates about health take place in legal forums—legislatures, courts, and administrative agencies—and in the law's language of rights, duties, and justice. Law grants government the power to act, sets limits, prescribes governance processes, specifies methods of accountability, and adjudicates disputes. It establishes the standards and procedures for activities and transactions of every actor that significantly affects health—including busi-

nesses, foundations, the media, and community-based organizations. The law affords individuals a broad set of rights in the health system, protecting interests in autonomy, bodily integrity, privacy, and liberty.<sup>1</sup>

The O'Neill Institute's mission is to find innovative solutions for the most pressing health concerns facing the nation and the world, through research, scholarship, and reflective engagement with partners in the public and private sectors. The Institute approaches the major problems of national and global health from multiple perspectives—breaking down barriers between disciplines and changing traditional ways of thinking. In keeping with Georgetown University's mission of social justice, the Institute seeks to improve health and reduce health disparities in the United States and globally.

The Institute's goal is to influence policy at the local, national, regional, and global levels. Its audience is diverse, including health professionals, lawyers, legislators, judges, academics, and multilateral organizations. And it will strive to improve understanding about how the law affects the prevention and treatment of injury and disease through policy development, research, education, training, collaboration, and dissemination.

By undertaking a diverse portfolio of research and scholarship, the O'Neill Institute will stimulate fresh, nonpartisan proposals for health promotion, disease prevention, and health care. The Institute's current projects include the development of a Framework Convention on Global Health (FCGH), in collaboration with the World Bank; international guidelines on the migration of nurses from developing to developed countries, in collaboration with Academy Health; implementation of the Framework Convention on Tobacco Control (FCTC), in collaboration with the Gates Foundation; global access to pain medication, in collaboration with the World Health Organization; food safety regulation, in collaboration with the Bauman Foundation; and American values in health care reform, in collaboration with the Brookings Institution.

Georgetown University launched the Institute at a two-day national conference in April 2007. Many of the speakers appear in this symposium issue of *The Georgetown Law Journal*, but additional distinguished guests included Dr. Julie Louise Gerberding, Director of the U.S. Centers for Disease Control and Prevention (CDC); Representative Henry Waxman, Chairman of the House Committee on Oversight and Government Reform; and Harvey V. Fineberg, President of the Institute of Medicine. Transcripts and webcasts of the inaugural symposium presentations are available at <http://www.law.georgetown.edu/oneillinstitute/program.html>.

Dedicated primarily to rigorous and impactful research, the O'Neill Institute has formed a Scholarship Workshop Series on National and Global Health Law. The Scholarship series contains academic papers from Georgetown faculty and Distinguished O'Neill Visiting Faculty, available at <http://lsr.nellco.org/>

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1. See generally LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* (2d ed. forthcoming 2008).

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The O'Neill Institute's projects are organized around four core themes, which are reflected in the organization of this issue of *The Georgetown Law Journal*: global health, health regulation and governance, health care financing and organization, and disease prevention and health outcomes.

#### GLOBAL HEALTH

A critically important, albeit often neglected, role of health law scholarship is to improve the functioning and longevity of populations around the world, focusing on such defining issues as the environmental and social determinants of health, diseases of poverty, the dual burdens of infectious and chronic diseases, and preparedness for public health emergencies. Global health governance is essential for setting priorities, coordinating activities, and ensuring cost effective interventions to prevent and ameliorate health threats in all regions. International law certainly is salient in global health, ranging from international health law (for example, the International Health Regulations and the Framework Convention on Tobacco Control) to the law of trade, arms control, and the environment. International human rights law both frames the discussion of governmental duties on the right to health and limits state action to safeguard the fundamental interests of individuals. Yet, despite the breadth of relevant international treaties, scholars and advocates see global health governance as largely dysfunctional.<sup>2</sup>

My article for this symposium, based on the inaugural lecture for the Linda D. and Timothy J. O'Neill Professor of Global Health Law, explicitly searches for solutions to the most perplexing problems in global health.<sup>3</sup> The article's central claim is that the international community should join together to meet what I call "basic survival needs," such as sanitation and sewage, pest control, clean air and water, diet and nutrition, tobacco reduction, essential medicines and vaccines, and well-functioning health systems. By focusing on these major determinants of health, the international community could dramatically improve prospects for good health. If meeting basic survival needs can truly make a difference for the world's population, then how can international law play a constructive role? After explaining why national interests, ethical values, and extant international legal regimes cannot be fully effective, the article proposes an innovative mechanism for global health governance, namely a Framework Convention on Global Health (FCGH). The Framework Convention concept has already prominently emerged in high-level discussions at the World Bank, and will take shape through an international stakeholder meeting hosted by the

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2. See David P. Fidler, *Architecture Amidst Anarchy*, 1 GLOBAL HEALTH GOVERNANCE 1 (2007), available at [http://diplomacy.shu.edu/academics/global\\_health/journal/PDF/Fidler-article.pdf](http://diplomacy.shu.edu/academics/global_health/journal/PDF/Fidler-article.pdf); see also Scott Burris, *Governance, Microgovernance and Health*, 77 TEMPLE L. REV. 335, 336 (2004).

3. 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).

O'Neill Institute in collaboration with prominent international organizations and leaders of civil society.

Professor David P. Fidler, James Louis Calamaras Professor of Law, Indiana University School of Law at Bloomington, identifies an emerging global jurisprudence for public health: he discusses public health's increasing need for law and legal skills, the development of a distinct system or body of national and international law on public health, and the protection of population health as a strategic political and normative imperative in global affairs.<sup>4</sup> He explores the future facing this global health jurisprudence, particularly the challenges posed by "open-source anarchy," which reveal a global public health capacity crisis that threatens to damage the promise being glimpsed in the emergence of global health jurisprudence.

The foregoing articles enrich our understanding of normative and governance issues in global health, primarily involving public health strategies. But health care organization and finance are also critical tools in global health. Professor Timothy Stoltzfus Jost, Professor of Law, Washington & Lee University, has written widely on comparative health care systems. In this essay he asks whether global health care financing law is a useful concept.<sup>5</sup> Professor Jost argues that the domestic focus of health care financing systems—as well as the secondary role of law in the design, operation, and reform of health care finance—limits the role of global law. Nevertheless, he concludes that law does have a contribution to make in addressing the issues that face health care financing systems, particularly through the study of comparative health care law.

Jennifer Prah Ruger, Assistant Professor of Medicine at Yale University, presents a normative theory of global health law and examines the notion of global health equity in the foundation of global health law.<sup>6</sup> Professor Ruger, who has thoughtfully explored the normative dimensions of global health in her scholarship, further examines the various roles and limitations of global health law in health equity and global health policy, as well as the necessary conditions for global health law to be effective. She conducts a comparative analysis between domestic and global health law and policy. Based on that comparative analysis, Professor Ruger argues that achieving global health equity requires a reformation of domestic health law specifically to increase access to health care and improve the public health infrastructure.

#### HEALTH REGULATION AND GOVERNANCE

Although global health governance is a concept that is relatively new and thus requires considerable policy development, the same cannot be said about

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4. David P. Fidler, *Global Health Jurisprudence: A Time of Reckoning*, 96 GEO. L.J. 393 (2008).

5. Timothy Stoltzfus Jost, *Global Health Care Financing Law: A Useful Concept?*, 96 GEO. L.J. 413 (2008).

6. Jennifer Prah Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L.J. 423 (2008).

domestic regulation. National regulation is ubiquitous and politically charged. The federal government and the states regulate in virtually every health domain, such as food and drugs, consumer products, occupational health and safety, and the environment. But how do we know how to regulate most effectively, particularly when there exist such sharp differences in background preferences about the utility of regulation? Regulatory strategies often demand difficult tradeoffs between private interests and public goods, requiring a thorough analysis of regulatory regimes' justifications, personal burdens, effectiveness, costs, and fairness.<sup>7</sup> At the very least, scholars can help policy makers understand the problem of dysfunctional national and international regulatory regimes, whose internally conflicting roles and irrational structures put the public's health at risk. The best scholarship can identify regulatory gaps and suggest innovative governance strategies to achieve health and safety objectives, which include direct regulation but also explore incentives and private/public partnerships.

Modern scholarship on health regulation and governance has wrestled with questions of when to intervene and the degree of tolerable interference with private action. Those who resist regulation insist on hard evidence of existing harm and the proposed intervention's effectiveness before acting. Others who support government action to protect the public and the environment argue that waiting too long further increases the risk. Lisa Heinzerling, Professor of Law at Georgetown University, has cogently demonstrated the importance of early and strong regulation on the environment. In this symposium, Professor Heinzerling turns her attention to one of the most vital problems of our time, namely the effects of climate change on human health.<sup>8</sup> Her essay proposes a reframing of climate change in public discourse from an environmental threat to a public health threat. She moves beyond traditional debates on the "precautionary principle" and whether climate change in fact exists. Instead, Professor Heinzerling offers a "post-cautionary principle," acknowledging that climate change has occurred, in order to mitigate the serious adverse consequences climate change will have on human health.

No United States agency has received more critical scrutiny than the Food and Drug Administration (FDA), culminating in a major new statute, giving the agency additional powers and resources.<sup>9</sup> Dr. David A. Kessler, Dean and Vice Chancellor for Medical Affairs at the University of California San Francisco and former FDA Commissioner, and David C. Vladeck, Professor of Law at Georgetown University Law Center, explore the legality and wisdom of the

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7. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* (2d ed. forthcoming 2008).

8. Lisa Heinzerling, *Climate Change, Human Health, and the Post-Cautious Principle*, 96 *Geo. L.J.* 445 (2008).

9. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007).

FDA's effort to persuade courts to preempt most failure-to-warn claims.<sup>10</sup> Their essay first analyzes the FDA's justifications for reversing its long-held views to the contrary and explains why the FDA's position cannot be reconciled with its governing statute. The essay then examines why the FDA's position, if ultimately adopted by the courts, would undermine the incentives drug manufacturers have to change labeling in response to newly discovered risks. The background possibility of failure-to-warn litigation provides important incentives for drug companies to ensure that drug labels reflect accurate and up-to-date safety information. Dean Kessler and Professor Vladeck explain why the agency's view that it is capable of single-handedly regulating the safety of drugs is unrealistic. Even within the context of new FDA legislation, the agency does not have the resources to perform the Herculean task of monitoring the performance of every drug on the market.<sup>11</sup>

William Sage, Vice Provost for Health Affairs and James R. Dougherty Chair for Faculty Excellence at the University of Texas at Austin, has been an astute observer of American health care regulation. In response to a prominent editorial by Dr. Jeffrey M. Drazen,<sup>12</sup> Professor Sage explains how a relational approach has impeded health law's ability to effectively govern the American health care system, arguing that health law has traditionally focused on the physician-patient encounter rather than on achieving collective objectives (which he calls "regulatory duties").<sup>13</sup> Professor Sage traces health law's relational emphasis to private and public law, professional ethics and bioethics, budgetary and general politics, and health care consumerism. He concludes that four areas of health policy—conflicts of interest in biomedical research, managed care and pay-for-performance, health care transparency and education, and public health—require a more collective regulatory commitment.

Timothy Westmoreland, a core faculty member of the O'Neill Institute, is a leading thinker about the federal budget process. Because any proposal for universal health insurance will increase federal spending, how that spending is estimated and the ultimate size of expenditures will determine whether a health care plan is politically viable. Professor Westmoreland observes two problems: (1) the budget process favors policies that let sick people die rather than incurring future health costs, and (2) the budget process favors mandates rather

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10. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461 (2008).

11. Both the Institute of Medicine and the Government Accountability Office have explained the shortcomings of the FDA's recent performance, and expressed doubt about the agency's capacity to face an increasingly challenging future. See COMMITTEE ON THE ASSESSMENT OF THE US DRUG SAFETY SYSTEM, INSTITUTE OF MEDICINE, *THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC* (Alina Baclu et al. eds., 2007); U.S. GOV'T ACCOUNTABILITY OFFICE, *DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS* (2006).

12. Jeffrey M. Drazen, *Government in Medicine*, 356 NEW ENGL. J. MED. 2195 (2007).

13. William M. Sage, *Boston, We Have a Problem: Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy*, 96 GEO. L.J. 497 (2008).



than discretionary spending to keep expenses off of the federal books.<sup>14</sup> He concludes that sidestepping survivors' costs by excluding them in the PAYGO process<sup>15</sup> and comparing national expenditures on health care with total national expenditures would ameliorate these problems.

#### HEALTH CARE FINANCING AND ORGANIZATION

The key measures of any health care system are access, fairness, cost, quality, and choice. The United States health care system, by these measures, is not meeting the health needs of the population. The data are all too familiar, but the underlying indicators of success have been stubbornly resistant to change: nearly fifty million uninsured, including more than eight million children; the uninsured population rising by nearly six million from 2001 to 2005; and sixteen million adults underinsured.<sup>16</sup> The high rates of the uninsured and underinsured have profound implications for social justice, disproportionately affecting the poor and vulnerable. Low socioeconomic status (SES) Americans are much more likely to be ill and die young. And the poor, particularly ethnic and racial minorities, receive lower quality care, with poorer health outcomes.<sup>17</sup>

Consuming \$2 trillion, or \$6,700 per person, total health care spending represents 16% of the gross domestic product (GDP), and is projected to rise to \$4 trillion, or 20% of GDP, by 2015.<sup>18</sup> Part of these costs is attributable to discretionary private spending, but the economic burden still adversely affects the Treasury, with government bearing 44% of total costs through public programs. And 30% of health care dollars—more than \$1,000 per capita—is spent on administration. Total health care costs, as well as administrative costs, are considerably higher in the United States than in other industrialized countries.<sup>19</sup>

Despite the enormous amount spent in the United States on health care, there

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14. Tim Westmoreland, *Can We Get There from Here? Universal Health Insurance and the Congressional Budget Process*, 96 GEO. L.J. 523 (2008).

15. PAYGO (or "Pay-as-You-Go") requirements "restrict[] the Congress to passing only legislation that has a net estimated cost of zero (or less)." *Id.* at 527.

16. Cathy Schoen et al., *Insured but Not Protected: How Many Adults Are Underinsured?*, HEALTH AFF., June 14, 2005, at 5, available at <http://www.allhealth.org/BriefingMaterials/Insuredbutnotprotected-19.pdf> ("73 percent [of the underinsured] had annual incomes below 200 percent of the federal poverty level.")

17. Such health disparities are well documented and affect African Americans, Hispanics, Asian Americans, and Native Americans. See J. GOLDBERG ET AL., HEALTH POLICY INST. OF OHIO, UNDERSTANDING HEALTH DISPARITIES 3 (2004), available at <http://www.healthpolicyohio.org/pdf/healthdisparities.pdf>. Minority groups in the United States have a higher incidence of chronic disease, mortality, and poor health outcomes as compared with whites. Cancer incidence, for example, is 10% higher among African Americans than whites. See AM. PUB. HEALTH ASS'N, ELIMINATING HEALTH DISPARITIES: TOOLKIT 27 (2004).

18. NAT'L COALITION ON HEALTH CARE, HEALTH CARE COSTS, available at <http://www.nchc.org/facts/cost.shtml>.

19. Steffie Woolhandler et al., *Costs of Health Administration in the U.S. and Canada*, 349 NEW ENGL. J. MED. 768 (2003); see also WORLD HEALTH ORG. [WHO], WORLD HEALTH REPORT (2000), available at [http://www.who.int/whr/2000/en/annex01\\_en.pdf](http://www.who.int/whr/2000/en/annex01_en.pdf).

is little evidence of higher quality care compared to other developed countries, and even compared to some developing countries. The World Health Organization ranks the U.S. health care system thirty-seventh in the world, and Americans' overall health seventy-second among 191 member states.<sup>20</sup> Comparative data also show that the United States ranks low among OECD countries in critical areas such as life expectancy and infant mortality.<sup>21</sup> And the Institute of Medicine estimates that medical errors cause as many as 98,000 avoidable deaths annually.<sup>22</sup> Hospital capacity continues to decline—with nurse shortages impacting both the quality and economics of care—while demand continues to surge.<sup>23</sup> The CDC reports a 26% increase in ER visits from 1993 to 2003.<sup>24</sup> In those same ten years, the number of available ERs nationwide decreased by 12.3%.<sup>25</sup> A GAO study shows that 90% of hospitals boarded patients in their emergency departments for at least two hours during 2002, and that roughly 20% of hospitals reported an average emergency-department boarding time of eight hours or more.<sup>26</sup>

Apart from the effects on the health and vitality of individuals and the population, the health care system has spill-over effects throughout the economy: medical bills are overwhelmingly the most common reason for personal bankruptcy;<sup>27</sup> hospitals, particularly emergency departments, provide a safety net at considerable cost; and employer health care costs affect global competitiveness.

The popular view about the relative strengths of the United States' health care

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20. Press Release, WHO, World Health Organization Assesses the World's Health Systems, (June 21, 2000), available at <http://www.who.int/inf-pr-2000/en/pr2000-44.html>. The WHO study has been criticized by conservative commentators as biased because it marked down countries for having private or fee-paying health treatment and rated countries by comparison to their expected health care performance rather than objectively comparing quality of care. Furthermore, most Americans rate their own health as "excellent" or "very good." The National Health Interview Survey, released annually by the CDC's National Center for Health Statistics, reported that approximately 66% of survey respondents said they were in "excellent" or "very good" health in 2006. This percentage has been declining since 1998. See NAT'L CTR. FOR HEALTH STATISTICS, CENTERS FOR DISEASE CONTROL AND PREVENTION, EARLY RELEASE OF SELECTED ESTIMATES BASED ON DATA FROM THE 2006 NATIONAL HEALTH INTERVIEW SURVEY (2007), available at [http://www.cdc.gov/nchs/data/nhis/earlyrelease/200706\\_11.pdf](http://www.cdc.gov/nchs/data/nhis/earlyrelease/200706_11.pdf).

21. UNITED NATIONS STATISTICS DIVISION, POPULATION AND VITAL STATISTICS REPORT: SERIES A, available at <http://unstats.un.org/unsd/demographic/products/vitstats/serATab3.pdf>.

22. INST. OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM (2000).

23. AM. ASS'N OF COLLEGES OF NURSING, NURSING SHORTAGE FACT SHEET (2007), available at <http://www.aacn.nche.edu/media/pdf/nrsgshortageoct07.pdf>; see also LINDA F. MCCAIG & CATHARINE W. BURT, CTRS. FOR DISEASE CONTROL AND PREVENTION, NAT'L HOSPITAL AMBULATORY MEDICAL CARE SURVEY: 2003 EMERGENCY DEPARTMENT SUMMARY (2005), available at <http://www.cdc.gov/nchs/data/ad/ad358.pdf>.

24. *Id.*

25. *Id.*

26. U.S. GOV'T ACCOUNTING OFFICE, HOSPITAL EMERGENCY DEPARTMENTS: CROWDED CONDITIONS VARY AMONG HOSPITALS AND COMMUNITIES (2003), available at <http://www.gao.gov/new.items/d03460.pdf>; see also Mark A. Levine et al., *Improving Access to Health Care: A Consensus Ethical Framework to Guide Proposals for Reform*, 37 HASTINGS CTR. REP. 14 (2007); Steven A. Schroeder, *We Can Do Better: Improving the Health of the American People*, 357 NEW ENG. J. MED. 1221 (2007).

27. David U. Himmelstein et al., *Illness and Injury as Contributors to Bankruptcy*, HEALTH AFF., Feb. 2, 2005, available at <http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.63/DC1>.

system is that it offers individuals more choice, with the implication that greater choice equates with higher quality and lower cost due to competitive pressures. However, Americans may have less choice than is popularly believed: businesses often sharply limit the number of health plans offered to employees, and managed care systems often restrict availability of physicians. In any event, the evidence does not support the assumption that consumer choice significantly increases quality or reduces costs.<sup>28</sup>

These, and many other deficiencies, are well understood. However, the political community has not been able to agree on a solution, despite a proliferation of reform proposals during an election season. The ideological sticking point remains whether public or private solutions should be primary. None of the authors in this symposium purport to solve these complex problems, but they do help us understand important questions relating to medical decision-making, rationing, budgets, consumer-driven health care, and the general coherence of the system.

Henry J. Aaron, Bruce and Virginia MacLaury Senior Fellow at the Brookings Institution, has long been interested in finding solutions to the most difficult problems in the health care system. Here, he looks at the growth of health care spending in America and the reasons for such growth.<sup>29</sup> He explains the paradox that spending generates benefits far in excess of total cost while current expenditures produce benefits far fewer than their cost. He explores the proposed methods to curtail spending and explains how health care could be rationed if information measuring the relative quality of providers is collected. Aaron's underlying message is that questions of cost and quality require public/private partnerships, and he sees a major role for government participation.

The essays by Professors Richard Epstein, Mark Hall, and Theodore Ruger in this symposium address a question that has perplexed scholars—namely, how to characterize and define the field of health care law. Clearly, this area of the law, though widely practiced, is different from many of the law's core disciplines. The tools used by health care scholars are eclectic, ranging from contracts and torts to constitutional law, with a heavy emphasis on empirical and interdisciplinary analysis.

Richard A. Epstein, James Parker Hall Distinguished Service Professor of Law at the University of Chicago, questions the usefulness of considering health care law as a separate legal field.<sup>30</sup> The resolution of complex problems demands an appreciation for doctrinal, empirical, and institutional frameworks. Consequently, Professor Epstein suggests that the O'Neill Institute can "beat back any criticism that treats its formation as wholly misguided." His underlying message is that government solutions and excessive regulation create the

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28. ROBERT F. RICH, *CONSUMER CHOICE: SOCIAL WELFARE & HEALTH POLICY* 78-79 (2005).

29. Henry J. Aaron, *Health Care Rationing: Inevitable, but Impossible?*, 96 *Geo. L.J.* 539 (2008).

30. Richard A. Epstein, *The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs*, 96 *Geo. L.J.* 559 (2008).

greatest difficulties in modern health care. In particular, he questions the sharp dichotomy in the modern approach to autonomy in health care, which gives individuals the absolute right to refuse treatment but heavily regulates their ability to obtain it. Warnings are preferable to bans, he argues, because they secure and maintain decision-making power with the individual.

Mark A. Hall, Fred D. and Elizabeth L. Turnage Professor of Law and Public Health at Wake Forest University, takes up the theme introduced by Professor Epstein about the coherence of health care law as a field.<sup>31</sup> Professor Hall attempts to resolve the “essentialism” versus the “law-of-the-horse” view of health care law by determining whether the legal system sees individuals who receive medical care more as patients or consumers. Because normal contractual rules do not apply between patients and providers, Professor Hall argues that law regards individuals more uniquely as patients, rather than as consumers. His essay is important in clarifying the differences between medical law and contract law and in contextualizing contemporary debates about consumer-driven health care.

Theodore W. Ruger, Professor of Law at the University of Pennsylvania, argues that it is time to deemphasize the quest for “a singular coherence” in health law.<sup>32</sup> Even if the field lacks a central core, he argues, it may still have an identifiable structure and special attributes worthy of study. Somewhat ironically, health law’s mixture of legal forms, its institutional multiplicity, and its interaction with external historical and political pressure—all features that separate it from the classical coherence model—are both generalizable and worthy of future examination. Professor Ruger is “generally skeptical that a single animating principle of internal logic, or a small set of such ideas, can be found to knit together the disparate strands of the field.”<sup>33</sup>

Michelle Mello, C. Boyden Gray, Associate Professor of Health Policy and Law at the Harvard School of Public Health and David M. Studdert, Professor and Federation Fellow at the University of Melbourne, apply both normative and empirical analyses to one particular area of intense health policy concern, namely medical malpractice.<sup>34</sup> Cueing off research findings suggesting the strong contributory role that hospital systems have in medical errors, they propose reframing medical malpractice discussions from an individual-centered framework to a “patient safety” framework. This framework emphasizes how “system failures” lead to injury, defining a “system” as interdependent elements operating to achieve a specific aim. In this model, medical errors should be viewed as malfunctions within the entire system. Medical injury causalities are multifactoral and web-like. It is difficult to clearly separate individuals from

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31. Mark A. Hall, *The Legal and Historical Foundations of Patients as Medical Consumers*, 96 GEO. L.J. 583 (2008).

32. Theodore W. Ruger, *Health Law’s Coherence Anxiety*, 96 GEO. L.J. 583 (2008).

33. *Id.* at 628.

34. Michelle M. Mello & David M. Studdert, *Deconstructing Negligence: The Role of Individual and System Factors in Causing Medical Error*, 96 GEO. L.J. 599 (2008).

their environment, and the most promising opportunities for injury prevention exist at the organizational level. Reorganizing tort law to focus liability on the enterprise, rather than the individual, may alleviate some of these problems.

#### DISEASE PREVENTION AND HEALTH OUTCOMES

The fundamental purposes of any health system are the prevention of disease and improvement in health outcomes. Scholars who seek to find innovative solutions to the seemingly intractable health policy issues discussed thus far will need empirical data to evaluate what works, at what cost, and with what adverse consequences. This requires an interdisciplinary approach and scientific rigor. There is a growing recognition of the importance of research into health care quality, which can inform practitioners and policy makers about which treatments are most cost effective. The same could be said for understanding how medical care is organized and delivered. Although it is more complicated, public policy makers need data to evaluate governmental public health interventions. Government regulates in virtually every sphere of health. Do these regulations effectively prevent disease, disability, and death? Would different, or additional, regulation be more cost effective?

Michelle M. Mello and Kathryn Zeiler, Professor of Law at Georgetown University, have been leaders in empirical evaluation of health care and public health interventions. Their incisive article surveys the current state of empirical health law (EHL) research.<sup>35</sup> Although EHL research has the striking potential to alter policy, they argue that uneven research quality and poor dissemination to policymakers prevents EHL from having a more significant impact. Professors Mello and Zeiler urge universities to increase empirical methods training, research funding, interdisciplinary collaborations, and dissemination efforts to improve policy implementation.

Finally, Michael A. Stoto, Professor of Health Services Administration and Population Health at the Georgetown University School of Nursing & Health Studies, examines the importance of public health surveillance in disease prevention and health outcomes.<sup>36</sup> Historically, public health surveillance has relied on two different surveillance forms: case surveillance and statistical surveillance. Professor Stoto argues that policy makers combine and confuse these two distinct forms of surveillance. This, in turn, leads to faulty thinking in how to balance individuals' privacy rights with community welfare. Professor Stoto argues that new approaches are needed to resolve the tensions between individual rights and public goods. He offers four considerations to achieve an appropriate balance: (1) determine whether the public health intervention is likely to achieve its public health goals; (2) clearly determine the public health

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35. Michelle M. Mello & Kathryn Zeiler, *Empirical Health Law Scholarship: The State of the Field*, 96 GEO. L.J. 649 (2008).

36. Michael A. Stoto, *Public Health Surveillance in the Twenty-First Century: Achieving Population Health Goals While Protecting Individuals' Privacy and Confidentiality*, 96 GEO. L.J. 703 (2008).

need for individual rather than aggregate statistical data; (3) consider intermediate solutions; and (4) specify the circumstances in which public health goals can override individuals' privacy and confidentiality rights (for example, person-to-person transmissibility, bioterrorism).

The individual contributions of each of these authors to the field of health law has been significant, and yet the opportunity provided by this inaugural symposium demonstrates that the sum is even greater than the parts. The scholarship presented in this issue speaks to the high potential of the academy to identify the most critical problems in health systems, draw upon an interdisciplinary reserve of quality scholarship, and present the lessons of that expertise and analysis to a diverse audience of advocates, legislators, and other leaders in the field. I am proud of this, the O'Neill Institute's first step, toward its goals of supporting the promotion of national and global health through research and analysis, engagement, and problem-solving. I hope that in reading the material that follows, readers share my enthusiasm for what promises to be an enormously challenging and exciting endeavor for improving health in the nation and the world.