Symposium Articles

519 Preface
Lawrence O. Gostin and James G. Hodge, Jr.

I. THEORIES OF GLOBAL HEALTH LAW, POLICY, AND RIGHTS-BASED NORMS

526 The Duty of States to Assist Other States in Need: Ethics, Human Rights, and International Law
Lawrence O. Gostin and Robert Archer
In this article, Gostin and Archer explore the varied lenses through which governments are obligated to address humanitarian needs. States' responsibilities to help others derive from domestic law, political commitments, ethical values, national interests, and international law. What is needed, however, is clarity and detailed standards so that States can operationalize this responsibility, making it real for developing countries. Transnational cooperation needs to be more effective and consistent to provide assistance for the world's poorest and least healthy people.

534 The Proliferation of Human Rights in Global Health Governance
Lance Gable
Human rights play an integral role in the global governance of health. Recently, both structural and normative aspects of human rights have proliferated across multiple levels and within multiple contexts around the world. Human rights proliferation is likely to have a positive impact on the governance of health because it can expand the avenues through which a human rights framework or human rights norms may be used to address and improve health.

545 Advancing Health Rights in a Globalized World: Responding to Globalization through a Collective Human Right to Public Health
Benjamin Mason Meier
The right to health was codified in Article 12 of the International Covenant on Economic, Social and Cultural Rights as an individual right, focusing on individual health services at the expense of public health systems. This article assesses the ways in which the individual right to health has evolved to meet collective threats to the public's health. Despite its repeated expansions, the individual right to health remains normatively incapable of addressing the injurious societal ramifications of economic globalization, advancing individual rights to alleviate collective inequalities in underlying determinants of health. By examining modern changes to underlying determinants of health, this article concludes that responding to globalized health threats necessitates a collective right to public health.

II. THE PROTECTION OF THE PUBLIC'S HEALTH IN A GLOBAL ERA

556 Addressing the Global Tragedy of Needless Pain: Rethinking the United Nations Single Convention on Narcotic Drugs
Allyn L. Taylor
The lack of medical availability of effective pain medication is an enduring and expanding global health calamity. Despite important medical advances, pain remains severely under-treated worldwide, particularly in developing countries. This article contributes to the discussion of this global health crisis by considering international legal and institutional mechanisms to promote wider accessibility to critical narcotic drugs for pain relief.

571 Mapping the Scope and Opportunities for Public Health Law in Liberal Democracies
Roger S. Magnusson
The two questions, “What is public health law?” and “How can law improve the public’s health?” are perennial ones for public health law scholars. This paper proposes a framework for conceptualizing discussion and debate about the scope and opportunities for public health law within liberal democracies. Part 2 of the paper draws selectively on this framework in order to highlight some areas where law's potential role deserves greater acknowledgment and exploration.
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An Exploration of Conceptual and Temporal Fallacies in International Health Law and Promotion of Global Public Health Preparedness
Dhrubajyoti Bhattacharya
In February 2007, Indonesia withheld sharing H5N1 viral samples in order to compel the World Health Organization and Member States to guarantee future access to vaccines for States disproportionately burdened by infectious diseases. This article explores conceptual and temporal fallacies in the International Health Regulations (2005) and the Doha Declaration on the TRIPS Agreement and Public Health, as relates to global public health preparedness. Recommendations include adopting laws to facilitate non-pharmaceutical interventions; secur[...]

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Limited Liability and the Public’s Health
Lainie Rutkow and Stephen P. Teret
Corporations, through their products and behaviors, exert a strong effect on the well-being of populations. Industries including firearms, motor vehicles, tobacco, and alcohol produce and market products negatively impact public health. All of these industries are composed of corporations, which are legal fictions designed to provide limited exposure to liability, through a variety of mechanisms, for their investors and directors. This means that when actions are taken on behalf of a corporate entity, the individuals responsible generally will not face personal liability for the negative results of those actions. To illustrate this point, this article considers corporate products or practices that have caused harm in varied settings, and analyzes the role that limited liability played in these cases. In addition, the article identifies ways to modify or eliminate some of the principles and practices that accompany limited liability.

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Detention and the Evolving Threat of Tuberculosis: Evidence, Ethics, and Law
Richard Coker, Marianna Thomas, Karen Lock, and Robyn Martin
The issue of detention as a public health control measure has attracted attention recently. This is because the threat of strains of tuberculosis that are resistant to a wider range of drugs has been identified, and there is renewed concern that public health is threatened. This paper considers whether involuntary detention is justified where voluntary measures have failed or where a patient poses a danger, albeit uncertain, to the public. We discuss the need for strengthening evidence-based assessments of public health risk and suggest that we should reflect more profoundly on the philosophical foundations upon which our policies and practices are grounded.

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Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law, and Ethics
David P. Fidler, Lawrence O. Gostin, and Howard Markel
The incident in May-June 2007 involving a U.S. citizen traveling internationally while infected with drug-resistant tuberculosis involved the U.S. federal government’s application of its quarantine and isolation powers. The incident and the isolation order raised numerous important issues for public health governance, law, and ethics. This article explores many of these issues by examining how the exercise of quarantine powers provides a powerful lens through which to understand how societies respond to and attempt to govern threats posed by dangerous, contagious pathogens. The article considers historical aspects of governmental power to quarantine and isolate individuals and groups; analyzes the current state of quarantine and isolation law in the United States in light of the recent incident with drug-resistant tuberculosis; and explores global aspects of public health governance and law highlighted by this incident.

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Nanotechnology in Global Medicine and Human Biosecurity: Private Interests, Policy Dilemmas, and the Calibration of Public Health Law
Thomas A. Faunce
This paper considers how best to approach dilemmas posed to global health and biosecurity policy by increasing advances in practical applications of nanotechnology. The type of nanotechnology policy dilemmas discussed include: (1) expenditure of public funds, (2) public-funded research priorities, (3) public confidence in government and science and, finally, (4) public safety. The article examines the value in this context of a legal obligation that the development of relevant public health law be calibrated against less corporate-influenced norms issuing from bioethics and international human rights.

III. ETHICAL VALUES IN GLOBAL HEALTH
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Ruth Lopert and Sara Rosenbaum
The importance of prescription drugs to modern medical practice, coupled with their increasing costs, has strengthened imperatives for national health policies that ensure safety and quality, facilitate affordable access, and promote rational use. Australia has made universal and affordable prescription drug coverage a priority for decades, within a policy framework that emphasizes equity and increasing transparency in coverage design and payment decisions. By contrast, the U.S. lacks such a national policy. Furthermore, federal Medicare reforms...
aimed at making appropriate drug coverage affordable and accessible employs two icons of the U.S. perception of fairness—the right to choose and the right to challenge coverage design limits—that mask the limited nature of the assistance. As the U.S. seeks to impose its values and priorities on other nations through the negotiation of bilateral and regional trade agreements, it becomes important to consider the two national experiences, in order to avoid trading illusory notions of fairness for true population equity.

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Looking Ahead: Addressing Ethical Challenges in Public Health Practice

Nancy M. Baum, Sarah E. Gollust, Susan D. Goold, and Peter D. Jacobson

Ethical challenges in public health can have a significant impact on the health of communities if they impede efficiencies and best practices. Competing needs for resources and a plurality of values can challenge public health policymakers and practitioners to make fair and effective decisions for their communities. In this paper, the authors offer an analytic framework designed to assist policymakers and practitioners in managing the ethical tensions they face in daily practice. Their framework is built upon the following set of six considerations: determining population-level utility of the proposed action; demonstrating evidence of need and effectiveness of actions; establishing fairness of goals and proposed implementation strategies; ensuring accountability; and, assessing expected efficiencies and costs associated with the proposed action. Together, these considerations create a structured guide to assist decision-makers in identifying potential ethical challenges and in assessing the moral considerations that underlie public health practice—and possibly even, if the conditions are met, reduce the creation of ethical tension. Although the authors’ empirical experiences provide the basis for the framework advanced here, their approach remains to be tested and evaluated by public health practitioners.

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The Ethics of Restrictive Licensing for Handguns: Comparing the United States and Canadian Approaches to Handgun Regulation

Jon S. Vernick, James G. Hodge, Jr., and Daniel W. Webster

The United States and Canada regulate firearms, particularly handguns, quite differently. With only a few state and local exceptions, the U.S. approach emphasizes the ability of most individuals to purchase, possess, and carry handguns. By comparison, Canada has a form of restrictive licensing for handguns that places a premium on community safety. The authors first review the potential individual and community level harms and benefits associated with these differing firearm policies. Using this information, they explore the ethical dimensions of the U.S. and Canadian approaches through three major themes of autonomy, prevention of harms, and social justice. The authors conclude that the Canadian approach is consistent with respect for the autonomy of persons, fosters the prevention of harms, and more appropriately furthers social justice.

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The Ancillary-Care Responsibilities of Researchers: Reasonable But Not Great Expectations

Roger Brownsword

This paper argues that, in a community of rights, the prima facie responsibilities of researchers to attend to the ancillary-care needs of their participants would be determined by a four-stage test (relating to placement, capacity, reasonable imposition, and fair demand). This test, it is suggested, sets a standard (and an example) for common law courts that are invited to recognize the ancillary-care responsibilities of researchers, whether as a matter of contract or tort law.

Independent Articles

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Ethical Implications of Physician Involvement in Lawsuits on Behalf of the Tobacco Industry

Jess Alderman

The statements of physicians who serve as expert witnesses for the tobacco industry reveal subtle but significant problems. Some expert testimony obfuscates the important issues, and some initially reasonable statements later evolve into extreme positions during cross-examination. Such statements fall into a “gray area” of professional ethics, potentially misleading juries and adversely affecting professional integrity. Medical associations can and should strongly enforce professional standards that do not tolerate tobacco industry influence on physician expert witnesses.

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Jewish Perspectives on the Use of Preimplantation Genetic Diagnosis

Rabbi Mark Popovsky

This article presents an analysis of the ethical considerations raised by preimplantation genetic diagnosis (PGD) from a Jewish perspective. It weighs the Jewish imperatives to pursue good health against a number of harms that may follow from the expanded use of PGD technology, including increased medical risk to the mother, the destruction of embryos and possible emotional harm to the child born from this procedure. It pays special attention to the potential harms that may befall those in society who do not have access to PGD or who choose not to employ it.
Luck, Genes, and Equality
Dov Fox
This essay considers principles of distributive justice for access to reproductive biotechnologies which make it possible to enhance the traits of human offspring. The author provides prima facie reason to think that redistributive principles apply to genetic goods and proceed to evaluate the way in which four distributive patterns—egalitarianism, luck egalitarianism, prioritarianism, and sufficientarianism—would implement a just distribution of genetic goods. He argues that the currency of genetic redistribution consists in natural primary goods like health, vision, and rationality as these goods contribute to the biological component of basic capabilities, like being healthy, seeing properly, and being able to reason. The author develops a mixed sufficiency/priority approach to genetic enhancement, and defends this approach against objections.

Ethics at Phase 0: Clarifying the Issues
Jonathan Kimmelman
The Food and Drug Administration (FDA) and the European Agency for the Evaluation of Medicinal Products (EMEA) recently issued documents encouraging sponsors to consider microdose testing before launching Phase I trials, and many commentators predict that such methodologies will be applied more routinely in drug development. However, exploratory testing has provoked several ethical criticisms. Skeptics question the value and validity of microdose trials, and whether they present a reasonable balance of risks and benefits for subjects. Another major criticism is that such studies serve mainly commercial ends. The present article explores these and other ethical concerns for studies conducted in the oncology setting. It concludes that microdosing is not inconsistent with prevailing practices in Phase I research, and that in principle, such studies could strengthen the ethical basis for Phase I trials by providing them better evidentiary justification.
Dear Editor

In "Brain Death – Too Flawed to Endure, Too Ingrained to Abandon" (JLME 35:2), Dr. Truog mentioned that “[a]s noted above, most ICU deaths (as many as 90 percent in some centers), follow the withdrawal of mechanical ventilation. In these cases, in the act of removing the ventilator, the physician is the proximate cause of the patient’s death. This act is not regarded as a homicide, however, because it is done in a particular context, by an individual (the physician) in a role sanctioned by society, and with the consent of the patient or surrogate. Procurement of organs by physicians can be ethically justified by parallel reasoning.”

The ethical justification of societal sanction about procurement of organs before death by inferring its similarity to withdrawal of mechanical ventilation at the end of life is conceptually flawed. When mechanical ventilation is withdrawn, the intent is to allow the underlying fatal illness to proceed along its natural course. It is the progression of the patient’s underlying fatal illness after the withdrawal of mechanical ventilation that ultimately results in death. Thus, the underlying illness (and not the discontinuation of mechanical ventilation) is the proximate cause of death. In this situation, the physician removing the ventilator is not the proximate cause of the patient’s death. The Fourteenth Amendment of the U.S. Constitution grants that right to refuse medical treatment, including withholding or withdrawing lifesaving treatment (such as mechanical ventilation) and is not considered as either suicide or homicide. When organs are procured, the intent is utilitarian to remove organs surgically in a timely manner for transplantation before allowing the natural progression of the underlying illness and declaration of death. The physician’s act of removal of organs becomes the proximate cause of death and is (or can be) considered homicide even with voluntary patient/surrogate consent. The Fourteenth Amendment does not grant any individual (the physician) the right to actively end another human life. Nevertheless, certain countries and the state of Oregon have sanctioned physicians’ role as the proximate cause of death (homicide) by legalizing physician assisted death. If society is to permit physicians to procure organs for transplantation before the declaration of death, then the U.S. laws will need to be revised to avoid the charge with homicide.

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References
3. Id.

Robert Truog Responds

The comments of Verheijde and colleagues fail to comprehend my argument at several levels. At the level of causation, they claim that withdrawal of mechanical ventilation does not cause the patient’s death, but merely allows the patient’s underlying illness to proceed to death. Several years ago Dan Brock showed the fallacy of this line of reasoning by proposing consideration of two cases of ventilator withdrawal, identical but for the fact that in one case the ventilator is withdrawn by a physician, and in the other by a greedy nephew anxious to obtain an inheritance. The chain of causation is the same in both cases: the
ventilator is withdrawn from a patient with a terminal illness, leading to death. But in the former case we commonly say the patient was “allowed to die,” and in the latter case we say the patient was “killed.” Since in both cases ventilator withdrawal is the proximate cause of death (i.e., the patient would not have died at that time but for the action of either the physician or the greedy nephew), Brock argues, correctly I think, that both are cases of “killing.” It is the other circumstances surrounding the event (the role of the person removing the ventilator, the patient’s prognosis, the consent of the patient, etc.) that lead one to conclude that the former is a “justified killing” whereas the latter is unjustified.

The courts have had a difficult time accommodating this reasoning. On the one hand, they have consistently affirmed the rights of patients (or their surrogates) to refuse unwanted medical therapies. On the other hand, they have resisted accepting the implication that honoring this right requires, in some cases, that physicians must kill patients. This tension was explicit in the Quinlan case, where physicians argued to the court that they should not be forced to accede to the demands of the family to withdraw life support because it would violate their Hippocratic duty not to kill. This tension has been only partially relieved by our tolerance in accepting the “moral fiction” that withdrawal of mechanical ventilation at the end of life is an “allowing to die” rather than a “killing.” For example, today we frequently hear of the reluctance of some segments of society to “kill” patients by honoring their desire to have their feeding tubes removed, as dramatically illustrated by the Schiavo case.

If we are willing to face the facts of the matter, then we see that in both ventilator withdrawal and organ procurement, the actions of physicians are the proximate cause of the patient’s death, and both are acts of killing. As with ventilator withdrawal, whether organ procurement at the end of life is an ethical act depends upon the circumstances (again, the socially sanctioned role of the physicians, the certainty of the prognosis, and the patient’s consent). Whereas the euphemistic description of ventilator withdrawal as an “allowing to die” has been comforting in enabling patients, families, and clinicians to deny the extent of their moral responsibility in the act, this moral fiction has become an impediment to thinking clearly about the ethics of organ procurement.

I do partially agree with the authors of this letter on their final point, however. Since the current system of laws and regulations governing end-of-life care has been tolerant of the moral fiction that has been created around the distinction between “killing” and “allowing to die,” at the very least a reinterpretation of the these laws and regulations would be necessary before the approach I suggest could be implemented.

Robert D. Truog, M.D.

References

Dear Editor

In “Clinical Trial of Xenotransplantation: Waiver of the Right to Withdraw from a Clinical Trial Should Be Required” (JLME 35:2), Monique Spillman and Robert Sade propose to resolve the public health threat of xenotransplantation by forsaking the right to withdraw from a clinical trial. The authors argue that this formula is ethically justifiable, granted that disclosure of the waiver is explicitly included in the informed consent requirements for trial subjects.

The argument is based on an analogy with Ulysses contracts in the practice of psychiatry. Under such contracts, a patient with a relapsing psychiatric disease commits herself – during remission – to compliance with the psychiatrist’s future treatment requirements. According to Spillman and Sade, a similar contract could be useful to enforce compliance to xenotransplant surveillance, thereby “allowing the recipient to avoid akrasia, or weakness of the will, through a future error in reasoning.”

In terms of correcting one’s future “weakness of the will,” however, there seem to be some significant differences between the context of psychiatry and that of xenotransplantation. For one, it is conceivable that, when Ulysses contracts are drawn up for psychiatry patients, the enforced compliance is essentially for the patients’ own good. This motivation is lacking in consent to xenotransplant surveillance. Indeed, the contract primarily serves to protect the rights and freedoms of others. Some of the harsher constraints of...
the surveillance imply invading the patients’ right to non-interference in personal affairs and private life, the protection of confidential information, and – in the theoretical case of isolation – the right to liberty. It is important to note that those infringements may apply even if the xenograft is rejected and replaced by a human substitute. Such restrictions will plausibly involve a setback of significant psychological interests for the prospective recipient – and perhaps for the close contacts in her social environment as well. Ideally, clinical trials should intend to benefit the patient’s illness and enhance her quality of life, not impose an extra burden.

More importantly, the analogy is flawed in that Ulysses contracts are based on a diagnosis of some form of recurrent psychiatric disease or dysfunction. In other words, there are more or less objective grounds to justify the precautionary contract. In xenotransplantation, by contrast, there is no such evidence of disease; there is only a vague risk of infectious disease. The size and nature of this risk – whether it be a harmless influenza or a fatal pandemic, the range in between, or neither – and the probability that any of those scenarios will occur, are essentially uncertain and unquantifiable. Precisely because there is no demonstrable state of public health emergency, current public health law provisions cannot enforce long-term surveillance.4 In this respect, it is not clear that a trial subject’s future wish to discontinue participation to the research would necessarily be an “error in reasoning.” Rather, it may in effect be a very rational response to reclaim one’s rights and liberties if, after some years, one remains asymptomatic and no dangerous pathogens have been detected. However, the clinical trial investigators – fearing latent infection – may desire a much longer, perhaps indefinite test of time.

Furthermore, due to the level of uncertainty inherent in xenotransplantation, it is questionable whether fully informed consent is at all feasible, let alone whether consenting recipients can fully grasp the limitations to their future autonomy in the various ways that xenotransplantation involves.

Given that xenotransplant guidelines already imply a waiver of the right to withdraw from a clinical trial, the authors have rightly drawn attention to the fact that such a practice urgently requires further discussion and analysis. Nonetheless, it is highly dubious whether providing support by establishing this waiver in advance directives is the proper response.

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References
2. Id., at 270.

The Authors Respond
An Ravelingien makes astute observations and offers cogent arguments to counter our suggestion that Ulysses contracts might be useful in clinical trials of xenotransplantation. We agree with many of her points regarding Ulysses contracts: the clinical settings of psychiatry and of xenotransplantation are substantially different, and the medical compliance forced upon psychiatric patients is for their own good. Contrary to Ravelingien’s assertion, however, the Ulysses contract in xenotransplantation trials does not serve primarily to protect the rights of others, because it equally serves the patient’s good, albeit less directly than in psychiatry: the contractual waiver of the right to withdraw from postoperative surveillance may literally save the patient’s life. Before signing the contract, the patient-subject will have weighed the relative advantages and disadvantages of early xenotransplantation (high likelihood of survival) versus a substantially longer wait for a life-saving human donor organ (much lower likelihood of survival) versus opting for no transplantation at all (unlikely survival). She has determined that her good is best served by undergoing xenotransplantation, with the requirement for long-term surveillance.

We agree with Ravelingien that clinical trials should ideally benefit the patient and “not
impose an extra burden.” This aspirational ideal goal, however, is never achieved in reality. The problem for the patient-subject is not how burdens can be completely avoided; rather, it is how to balance the benefits and burdens associated with the clinical trial, a balancing act that she alone can carry out, based on her own value system.

Ravelingien is also correct in her observation that the Ulysses contracts used in psychiatry are based on a high likelihood of recurrent psychiatric disease or dysfunction, while in xenotransplantation, the risk of a xenogeneic infectious disease in the future is uncertain. The high degree of uncertainty at the time of entry into the study, however, becomes less so with the passage of time and the accumulation of information about actual risk of xenogeneic infectious disease. A patient-subject’s wish to regain his liberty rights after years have passed without symptoms or signs of infection and without evidence of xenogeneic pathogens might seem logical to him, but he would be in no position to weigh the danger of latent infection as accurately as the study’s investigators. If the investigators believe that a longer period of surveillance is necessary because of a still reasonable possibility of xenogeneic infection, then their rational analysis must outweigh the patient-subject’s emotionally based logic. His “error in reasoning” is to believe that he has sufficient expertise to make that determination. The decision to suspend or terminate surveillance can be made rationally only by the investigators, a condition to which the patient-subject agreed before entering the trial.

The risk of xenogeneic infectious disease arising from xenotransplantation is unknown, perhaps small. It is great enough, however, to lead the U.S. Public Health Service and the Food and Drug Administration to include in their respective guidelines a thinly veiled requirement for long-term, potentially lifelong infectious disease surveillance in transplant recipients. The right of self-determination inherent in clinical trial subjects must be respected; they must be informed of mandatory surveillance, and must signify their understanding by explicitly waiving the right to withdraw from surveillance until scientific observations justify release from the waiver. If waiver of the right to withdraw from the required surveillance is not permissible, as Ravelingien implies, then, out of respect for the autonomy of human subjects, xenotransplantation should not be allowed at all.

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Monique Spillman, M.D.