Symposium Articles

547 Preface: A Tribute to Bernard Dickens
Lawrence O. Gostin and Colleen M. Flood

549 Introduction
Alexander Morgan Capron

PART 1: PUBLIC HEALTH

551 How Litigation Can Promote Product Safety
Jon S. Vernick, Jason W. Sapsin, Stephen P. Teret, and Julie Samia Mair
Injuries are an important public health problem in the United States. Litigation against manufacturers or sellers of dangerous products can reduce the risk of future product-related injuries. A framework is presented to describe the mechanism for the successful use of litigation to reduce injury risks.

556 Using Litigation to Make Public Health Policy: Theoretical and Empirical Challenges in Assessing Product Liability, Tobacco, and Gun Litigation
Timothy D. Lytton
In the debate over the use of litigation to make public health policy, proponents and critics of the litigation disagree over the proper role of courts in policy making. This article examines these arguments and argues that (1) the two sides rely on competing ideals of the proper role of courts drawn from constitutional law, both of which are inapoposite to the traditional policy making role of courts in the context of civil litigation and (2) the central arguments of each side require further theoretical elaboration and empirical support.

565 Pandemic Influenza: Public Health Preparedness for the Next Global Health Emergency
Lawrence O. Gostin
Pandemic influenza viral infections pose a highly virulent and very real threat to the public’s health. Recent vaccine shortages have heightened the interest in, and need for, influenza preparedness on a global scale. This article identifies the primary interventions designed to prevent pandemic influenza, explores the inevitable legal and ethical questions associated with such interventions, and recommends the adoption of ethical values in public health decision-making.

568 Towards Progress in Resolving Dilemmas in International Research Ethics
Solomon R. Benatar
Unresolved controversies in international research ethics are addressed through a conceptual analysis that seeks the middle ground between polarized perspectives. A case is made for a more nuanced understanding of residual differences in the context of widespread agreements despite widely divergent world views. Seeking the middle ground through reasoned processes is seen as the solution to resolving seemingly intractable differences in international research ethics.

583 Research Involving Humans: A Time for Change?
Don Chalmers
The governance of human research ethics has been the subject of distinguished comment and analysis by Professor Dickens. This article examines the reasons underlying international moves towards greater regulation of human research activities and includes references to the Australian Report on Genetic Privacy.

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The Evolution of Research Ethics: The Current International Configuration
Sev S. Fluss
This essay reviews the principal stakeholders in the formulation of binding and non-binding instruments governing the ethical aspects of research involving human subjects. Particular reference is made to the contributions of the World Medical Association, WHO, UNESCO, UNAIDS, the Council of Europe, the European Union, the World Psychiatric Association, and the Council for International Organizations of Medical Sciences.

604
Regulating Research and Experimentation: A View from the UK
Sheila A.M. McLean
This article looks at the issue of research primarily from the UK perspective. Distinguishing initially between medical research and experimentation, it notes both the importance of medical research (and its relatively laissez faire governance) and the limited – and increasingly liberal – approach of UK law to experimentation. The article notes the inherent difficulties of obtaining a meaningful consent to research in particular, and that current international ethical codes – drafted by doctors for doctors – have moved considerably away from the Nuremberg Declaration’s emphasis on the voluntary participation of the individual. The article concludes by noting the more directive approach to medicinal product research initiated by the European Union, and asks whether this represents a move from ‘protectionism’ or paternalism in research towards recognition and vindication of a human rights based jurisprudence.

613
Institutional Conflicts of Interest: Protecting Human Subjects, Scientific Integrity, and Institutional Accountability
Gordon DuVal
In this paper, difficulties arising from the conflicting interests of universities and research institutions overseeing research are described. Some potential threats to human subjects and to research integrity are explored and some suggestions for strategies to address these conflicts are proposed.

626
Legal and Ethical Approaches to Stem Cell and Cloning Research: A Comparative Analysis of Policies in Latin America, Asia and Africa
Rosario M. Isasi, Bartha M. Knoppers, Peter A. Singer, and Abdallah S. Daar
This article surveys policies for human embryonic stem cell research and cloning in sixteen countries in Asia, Africa, and Latin America. It details policy development within each country and examines both the current policy framework as well and possible future directions.

641
Leopards in the Temple: Restoring Scientific Integrity to the Commercialized Research Scene
Trudo Lemmens
Recent controversies show how commercial interests may impact on the integrity of medical research and how this affects research subjects and health care consumers. While various regulatory mechanisms rely on the integrity of medical research, none of them currently provide sufficient safeguards. New regulatory measures are required to restore scientific integrity and to protect the public, including separating those who have financial interests in the research outcome from those who conduct clinical trials.

PART 3: BIOETHICS
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American Bioethics and Human Rights: The End of All Our Exploring
George J. Annas
American bioethics can be reborn as an effective force for promoting both health and human rights by recognizing its common historical roots with international human rights in World War II, especially the Nuremberg trials and the Universal Declaration of Human Rights. Bioethics, health law, and human rights are all members of a globalized human rights community that takes individual rights, the right to health, and the public’s health as core concerns.

664
What are the Limits of Bioethics in a Culturally Pluralistic Society?
Kerry Bowman
When patients and health-care workers come from different cultural backgrounds, they interact under the influence of unspoken assumptions about health care that are so far apart they may prevent effective communication. This paper explores the capacity of Western bioethics to adapt to the realities of increasingly culturally pluralistic societies such as those of North America.
PART 4: PRIVACY
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Challenging Themes in American Health Information Privacy and the Public’s Health: Historical and Modern Assessments
James G. Hodge, Jr. and Kieran G. Gostin
This article discusses the premise of balancing and the device of informed consent as featured in the HIPAA Privacy Rule, assessing the perceptual difficulties underlying these concepts for public health authorities. Like many health information privacy laws, the Privacy Rule draws upon the enumerated need to respect individual autonomous control of personal health information while attempting to balance communal goods in the collection and dissemination of health information. We suggest rebalancing individual and communal interests in identifiable health data to deemphasize notions of informed consent for disclosures for public health purposes.

680
The Changing Legal and Conceptual Shape of Health Care Privacy
Roger S. Magnusson
This paper reviews the changing conceptual nature of challenges to health information privacy. It argues that the debate about the legal protection of health privacy is best understood in terms of a series of shifts or transitions. The evolution of health privacy law demonstrates not only that the law's oversight of personal health information while attempting to balance communal goods in the collection and dissemination of health information. We suggest rebalancing individual and communal interests in identifiable health data to deemphasize notions of informed consent for disclosures for public health purposes.

PART 5: LAW AND MEDICINE
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The ELSI Genetics Regulatory Resource Kit: A Tool for Policymakers in Developing Countries
Zara Merali, Victor Boulyjenkov, Peter A. Singer, and Abdallah S. Daar
We discuss the University of Toronto/WHO ELSI Genetics Resource Kit. The Resource Kit functions as a tool to policy makers and, thereby, provides one solution to the problem of inadequate national ELSI genomics regulation, particularly in developing countries.

701
Disputes about the Withdrawal of Treatment: The Role of the Courts
Loane Skene
Can patients and their families use the court process to gain access to extratreatment that clinicians think is futile or unduly burdensome? Although courts have been reluctant to intervene in medical decisions, they have done so in some recent cases described in this paper.

708
An Appraisal of Abortion Laws in Southern Africa from a Reproductive Health Rights Perspective
Charles Ngwena
The article evaluates the abortion laws of Southern African countries from a reproductive health rights perspective. It is submitted that, despite the rhetoric of commitment to equality and the realization of reproductive rights for women, the majority of Southern African countries have been slow, if not averse, to liberalizing abortion laws.

718
Law and Clinical Research – From Rights to Regulation?
An English Perspective
J.V. McHale
Post Nuremberg and the Helsinki Declaration there has been a growth in the regulation of clinical research both nationally and internationally. Focusing on England and Wales this article explores the relationship between rights and regulation in relation to two case studies— the inclusion of persons without mental capacity in clinical research and the use of human material. Both are illustrations of areas where new/proposed new legislation will regulate the research process. The article critically examines the extent to which enhanced regulation necessarily safeguards the rights of the research participant.

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Commentary: Social-Ethical Values Issues in the Political Public Square: Principles vs. Packages
Margaret A. Somerville
The use of social-ethical values issues for political ends is now a major election strategy in countries such as Canada and the United States. Such issues include same-sex marriage, abortion, human embryo stem cell research, capital punishment, engaging in armed conflict, euthanasia, legalizing marihuana and access to health care. This article explores the role these issues, and their manipulation by politicians and the media, played in influencing Canadians’ voting decisions in the recent Federal election.

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Independent Articles

**741**
**Storing Newborn Blood Spots: Modern Controversies**
*Linda Kharaboyan, Bartha Knoppers, and Denise Avard*

In the first days following birth, blood is drawn from the newborn’s heel and saved on a Guthrie card to allow for screening and follow-up. The storage, subsequent use, as well as the information that may be revealed from dried blood spots raise a number of social, ethical and legal issues. The privacy and confidentiality of such genetic information deserve special protective measures. This paper provides an overview of some of the issues that need to be addressed when implementing policy on newborn sampling, storage, and, re-use in light of existing international, regional and national policies.

**749**
**What Conditions Justify Risky Nontherapeutic or “No Benefit” Pediatric Studies: A Sliding Scale Analysis**
*Loretta M. Kopelman*

To gain vital information about children’s conditions, many pediatric research regulations sometimes permit nontherapeutic or “no benefit” studies with higher hazards than would normally be allowed for healthy children. The United States, Council for International Organizations of Medical Science (CIOMS), and South Africa have similar rules for authorizing such studies. Yet, disputes exist about the moral justification for having higher risks for some children and about what constitutes a condition for this purpose. This analysis and the moral basis given for it may answer some objections to this policy. “No benefit, higher hazard” studies must be compatible with established duties to children, including the best interests standard.

**759**
**Shared Decision-Making and the Lower Literate Patient**
*David I. Shalowitz and Michael S. Wolf*

Although shared decision-making has become entrenched as an ideal model of the physician-patient relationship, physicians may have special difficulties realizing this model with lower literate patients. This article describes potential barriers to sharing decision-making with lower literate patients, and recommends approaches to addressing these barriers.

Columns

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*Joan Krause and Richard S. Saver*

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