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Symposium Articles

SYMPOSIUM

Law,
Science, and
Innovation:
The Embryonic
Stem Cell
Controversy

Guest Edited by
John A. Robertson

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Letter from
the Editor

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**Law, Science, and Innovation:
Introduction to the Symposium**

John A. Robertson

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**Embryo Stem Cell Research: Ten Years
of Controversy**

John A. Robertson

This overview of 10 years of stem cell controversy reviews the moral conflict that has made ESCs so controversial and how this conflict plays itself out in the legal realm, focusing on the constitutional status of efforts to ban ESC research or ESC-derived therapies. It provides a history of the federal funding debate from the Carter to the Obama administrations, and the importance of the Raab memo in authorizing federal funding for research with privately derived ESCs despite the Dickey-Wicker ban on federal funding of embryo research. It also reviews the role that scientists themselves have played in developing regulations for ESC research, the emergence of ESCROs as special review bodies for ESC research, and the thorough consent requirements for donation of IVF embryos to ESC research. With research now transitioning from the lab to the clinic, the article reviews the challenges of ensuring safety and consent in translational research. It concludes with a call for respecting those persons who have to using or working with ESC products and an account of how obtaining stem cells from a person's own cells will alleviate some but not all of the controversy surrounding ESC research.

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**Why Scientific Details Are Important
When Novel Technologies Encounter
Law, Politics, and Ethics**

Lawrence Goldstein

This paper focuses on the issue of what to do if a couple who generates embryos chooses to lawfully, and in their (and my) view, ethically discard those embryos. Specifically, is it appropriate to use the cells that come from "excess" embryos in medical research instead of discarding them when a couple has ceased trying to have any additional children?

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**Old and New Ethics in the Stem Cell
Debate**

Richard M. Doerflinger

The debate about embryonic stem cell research is a conflict not between "religion" and "science," but between two ethical approaches to the dignity of human beings. The newer, more pragmatic ethic is not necessarily more conducive to rapid medical progress as is often assumed.

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**Political Interventions in U.S.
Human Embryo Research: An Ethical
Assessment**

Ronald M. Green

For more than 30 years, beginning with the Reagan administration's refusal to support and provide oversight for embryo research, and continuing to the present in congressionally imposed limits on funding for such research, progress in infertility medicine and the development of stem cell therapies has been seriously delayed by a series of political interventions. In almost all cases, these interventions result from a view of the moral status of human embryo premised largely on religious assumptions. Although some believe that these interventions are valid expressions of religious values in the public sector, it is argued here that they, in fact, contradict Rawls's conception of public reasoning. Both the prohibition of research involving the human embryo as well as bans on federal funding for embryo-related research place the particular religious views of some citizens above the pressing health needs of almost all, and thus violate the ideal of civility implicit in the Rawlsian standard.

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**Creating Embryos for Use in Stem
Cell Research**

Dan W. Brock

In this paper I will address whether the restriction on the creation of human embryos solely for the purpose of research in which they will be used and destroyed in the creation of human stem cell lines is ethically justified. Of course, a cynical but perhaps accurate reading of the new Obama policy is that leaving this restriction in place was done for political, not ethical, reasons, in light of the apparent public opposition to creating embryos for use in this research. But the issue of whether the restriction is ethically justified remains important, even if only for another day in the policy arena.

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Chimeras, Moral Status, and Public Policy: Implications of the Abortion Debate for Public Policy on Human/Nonhuman Chimera Research

Robert Streiffer

Researchers are increasingly interested in creating chimeras by transplanting human embryonic stem cells (hESCs) into animals early in development. One concern is that such research could confer upon an animal the moral status of a normal human adult but then impermissibly fail to accord it the protections it merits in virtue of its enhanced moral status. Understanding the public policy implications of this ethical conclusion, though, is complicated by the fact that claims about moral status cannot play an unfettered role in public policy. Arguments like those employed in the abortion debate for the conclusion that abortion should be legally permissible even if abortion is not morally permissible also support, to a more limited degree, a liberal policy on hESC research involving the creation of chimeras.

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Reflections on Governance Models for the Clinical Translation of Stem Cells

Jeremy Sugarman

Governance models for the oversight of human embryonic stem cell research have been proposed which mirror in large part familiar oversight mechanisms for research with human subjects and non-human animals. While such models are in principle readily endorsable, there are a set of concerns related to their implementation — such as ensuring that an elaborated informed consent process and conducting long-term monitoring of research subjects are tenable — which suggest areas where gathering data may facilitate more appropriate oversight. In addition, it is unclear whether a new governance model based at individual institutions are sufficient to address the ethical issues inherent to this research. Regardless, some of the concerns that have arisen in considering the appropriate governance of stem cell research, particularly the important translational pathway of innovation in contrast to staged research, transparency and publication, and social justice, may be useful in science and translational research more broadly.

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Resolving Ethical Issues in Stem Cell Clinical Trials: The Example of Parkinson Disease

Bernard Lo and Lindsay Parham

Clinical trials of stem cell transplantation raise ethical issues that are intertwined with scientific and design issues, including choice of control group and intervention, background interventions, endpoints, and selection of subjects. We recommend that the review and IRB oversight of stem cell clinical trials should be strengthened. Scientific and ethics review should be integrated in order to better assess risks and potential benefits. Informed consent should be enhanced by assuring that participants comprehend key aspects of the trial. For the trial to yield generalizable knowledge, negative findings and serious adverse events must be reported.

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Translating Stem Cell Research: Challenges at the Research Frontier

David Magnus

This paper will address the translation of basic stem cell research into clinical research. While “stem cell” trials are sometimes used to describe established practices of bone marrow transplantation or transplantation of primary cells derived from bone marrow, for the purposes of this paper, I am primarily focusing on stem cell trials which are far less established, including use of hESC derived stem cells. The central ethical challenges in stem cell clinical trials arise in frontier research, not in standard, well-established areas of research.

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Allowing Innovative Stem Cell-Based Therapies Outside of Clinical Trials: Ethical and Policy Challenges

Insoo Hyun

This paper discusses exceptional circumstances under which patients outside of clinical trials are likely to receive innovative stem cell-based interventions. These circumstances involve: (1) stem cell interventions not initially amenable to a clinical trials approach; (2) expanded access to investigational stem cell products (“compassionate use”); and (3) off-label uses of FDA approved stem cell products. This paper proposes a new approach to regulating these exceptional cases.

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Overseeing Innovative Therapy without Mistaking It for Research: A Function-Based Model Based on Old Truths, New Capacities, and Lessons from Stem Cells

Patrick L. Taylor

Should innovative therapy occur only within a research paradigm and under institutional review board oversight? The health risks from current human embryonic stem cell clinical applications have raised again a fundamental question addressed first in papers submitted to inform the writing of the Belmont Report. Revisiting the thinking underlying the Belmont Report, together with examining changed circumstances since then, leads to a new model for overseeing innovative therapy based on its unique risks and context, important changes since the Belmont Report, and new opportunities for addressing risks through safety and quality systems in health care.

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Stem Cell Research and Economic Promises

Timothy Caulfield

In the context of stem cell research, the promise of economic growth has become a common policy argument for adoption of permissive policies and increased government funding. However, declarations of economic and commercial benefit, which can be found in policy reports, the scientific literature, public funding policies, and the popular press, have arguably created a great deal of expectation. Can stem cell research

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deliver on the economic promise? And what are the implications of this economic ethos for the researchers who must work under its shadow?

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WARF's Stem Cell Patents and Tensions between Public and Private Sector Approaches to Research

John M. Golden

While society debates whether and how to use public funds to support work on human embryonic stem cells (hESCs), many scientific groups and businesses debate a different question — the extent to which patents that cover such stem cells should be permitted to limit or to tax their research. The Wisconsin Alumni Research Foundation (WARF), a non-profit foundation that manages intellectual property generated by researchers at the University of Wisconsin at Madison, owns three patents that have been at the heart of the latter controversy. The story of WARF's patents and the controversy they have fostered highlights not only continuing tensions between proprietary and nonproprietary approaches to developing science and technology, but also an at least partly reassuring capacity of public and private sectors to deal with those tensions in a way that can render them substantially manageable, and frequently more manageable as a technology matures. More particularly, the cumulative story of WARF's patents features three leitmotifs that suggest how an attentive and engaged public sector might commonly succeed in working with public and private sector actors to achieve workable balances between proprietary rights and more general social interests: (1) right holders' decisions to pursue less than full rights assertion or enforcement; (2) the ability of government and other public sector actors to help bring about such decisions through co-option or pressure; and (3) the frequent availability or development of technological alternatives that limit research bottlenecks.

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Stem Cell Research as Innovation: Expanding the Ethical and Policy Conversation

Rebecca Dresser

Research using human embryonic stem cells raises an array of complex ethical issues, including, but by no means limited to, the moral status of developing human life. Unfortunately, much of the public discussion fails to take into account this complexity. Advocacy for liberal and conservative positions on human embryonic stem cell research can be simplistic and misleading. Ethical concepts such as truth-telling, scientific integrity, and social justice should be part of the debate over federal support for human embryonic stem cell research. Moreover, the debate should be conducted in accord with principles of deliberative democracy, including respect for people holding competing views.

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Will Embryonic Stem Cells Change Health Policy?

William M. Sage

Embryonic stem cells are actively debated in political and public policy arenas. However, the connections between

stem cell innovation and overall health care policy are seldom elucidated. As with many controversial aspects of medical care, the stem cell debate bridges to a variety of social conversations beyond abortion. Some issues, such as translational medicine, commercialization, patient and public safety, health care spending, physician practice, and access to insurance and health care services, are core health policy concerns. Other issues, such as economic development, technologic progress, fiscal politics, and tort reform, are only indirectly related to the health care system but are frequently seen through a health care lens. These connections will help determine whether the stem cell debate reaches a resolution, and what that resolution might be.

Independent Articles

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The Metamorphosis of Managed Care: Implications for Health Reform Internationally

Marc A. Rodwin

The conventional wisdom is that managed care's brief life is over and we are now in a post-managed care era. In fact, managed care has a long history and continues to thrive. Writers also often assume that managed care is a fixed thing. They overlook that managed care has evolved and neglect to examine the role that it plays in the health system. Furthermore, private actors and the state have used managed care tools to promote diverse goals. These include the following: increasing access to medical care; restricting physician entrepreneurialism; challenging professional control over the medical economy; curbing medical spending; managing medical practice and markets; furthering the growth of medical markets and private insurance; promoting for-profit medical facilities and insurers; earning bounties for reducing medical expenditures; and reducing governmental responsibility for, and oversight of, medical care. Struggles over these competing goals spurred the metamorphosis of managed care. This article explores how managed care transformed physicians' conflicts of interests and responses to them. It also examines how managed care altered the opportunities for patients/medical consumers to use exit and voice to spur change.

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Interpretation of the Subjects' Condition Requirement: A Legal Perspective

Seema Shah and David Wendler

The U.S. Federal regulations allow institutional review boards (IRBs) to approve non-beneficial pediatric research when the risks are a minor increase over minimal, provided that the research is likely to develop generalizable knowledge about the subjects' disorder or condition. This "subjects' condition" requirement is quite controversial; commentators have argued for a variety of interpretations. Despite this considerable disagreement in the literature, there have not been any attempts to apply principles of legal interpretation to determine how the subjects' condition requirement should be understood.

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Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of *JLME*.

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A Symposium Guest Edited by Lawrence O. Gostin and Emily Mok

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Diagnosing Consciousness: Neuroimaging, Law, and the Vegetative State

Carl E. Fisher and Paul S. Appelbaum

In this paper, we review recent neuroimaging investigations of disorders of consciousness and different disciplines' understanding of consciousness itself. We consider potential tests of consciousness, their legal significance, and how they map onto broader themes in U.S. statutory law pertaining to advance directives and surrogate decision-making. In the process, we outline a taxonomy of themes to illustrate and clarify the variance in state-law definitions of consciousness. Finally, we discuss broader scientific, ethical, and legal issues associated with the advent of neuroimaging for disorders of consciousness and conclude with policy recommendations that could help to mitigate confusion in this realm.

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Damage Control: Unintended Pregnancy in the United States Military

Kathryn L. Ponder and Melissa Nothnagle

Women's access to reproductive health care is an ongoing source of conflict in U.S. politics; however, women in the military are often overlooked in these debates. Reproductive health care, including family planning, is a fundamental component of health care for women. Unintended pregnancy carries substantial health risks and financial costs, particularly for servicewomen. Compared with their civilian counterparts, women in the military experience greater challenges in preventing unwanted pregnancy and have less access to contraceptive services and abortion. Current military policies, federal laws, and health care practices are not always consistent with evidence-based research and patient-centered care. A multidisciplinary effort on the part of military personnel, lawmakers, and health care providers is needed to eliminate these disparities. We discuss recommendations in the following categories: improving contraceptive education and adherence, expanding research, broadening access to the full range of contraceptive options including emergency contraception, and ensuring access to safe abortion.

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Beyond the Cold Hit: Measuring the Impact of the National DNA Data Bank on Public Safety at the City and County Level

Matthew Gabriel, Cherisse Boland, and Cydne Holt

Over the past decade, the Combined DNA Index System (CODIS) has increased solvability of violent crimes by linking evidence DNA profiles to known offenders. At present, an in-depth analysis of the United States National DNA Data Bank effort has not assessed the success of this national public safety endeavor. Critics of this effort often focus on laboratory and police investigators unable to provide timely investigative support as a root cause(s) of CODIS' failure to increase public safety. By studying a group of nearly 200 DNA cold hits

obtained in SFPD criminal investigations from 2001-2006, three key performance metrics (Significance of Cold Hits, Case Progression & Judicial Resolution, and Potential Reduction of Future Criminal Activity) provide a proper context in which to define the impact of CODIS at the City and County level. Further, the analysis of a recidivist group of cold hit offenders and their past interaction with law enforcement established five noteworthy criminal case resolution trends; these trends signify challenges to CODIS in achieving meaningful case resolutions. CODIS' effectiveness and critical activities to support case resolutions are the responsibility of all criminal justice partners in order to achieve long-lasting public safety within the United States.

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