

THE HASTINGS CENTER

ACTIVITIES REPORT 2005-2006

UNDERSTANDING

*S*CIENCE



EXPLORING

*V*ALUES



IMPROVING

*L*IVES



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*** Retired as of June 1, 2007*



NEW LEADERS

I want to thank all of you who made financial contributions of whatever size to The Hastings Center these past two years. Your support is vital to every aspect of our work: research, education, publications, and opportunities for visiting scholars.

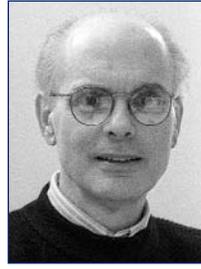
Your support secures for the Center independence and flexibility, as we bring our process to bear on the most challenging ethical issues in medicine and biology. Over the years, the Center’s work has influenced the way these issues are thought about and talked about in our society. This, in turn, directly impacts people’s lives, as they confront the often agonizingly difficult choices that come with medical and scientific miracles.

As I enter my second term as Chair, a process begun years ago at the Center is transforming its Board. In 1998, the Board instituted term limits, believing we had to increase the community of people who had both deep knowledge of the Center and commitment to its work. Old friends have left the Board, yet remain part of our close community. We have recruited new leaders. In the last two years alone, eight new Directors joined the Board, bringing expertise and relationships in medicine, biotechnology, finance, management, and the law.

To the Directors who completed their terms during 2005 and 2006, we extend our deepest thanks for guiding the Center to this important point. Some joined the Board long before we thought about limits. Eric Cassell shared his wisdom and insights into patient care as a Board member for 33 years. Richard Lamm, Christopher Getman, and the late Joseph Iseman also had long and rich experiences serving on the Board. We are indebted to each of them.

Sincerely yours,

Harold Edgar, *Chair*



NEW DIRECTIONS

In 2006, Harold Edgar appointed a Task Force on the Future of the Center, chaired by Dr. Robert Michels, to evaluate alternative visions of the Center’s mission, structure, and activities. We reaffirmed the Center’s commitment to creating knowledge through interdisciplinary research, and sharing that knowledge through education programs and publications. We also recommended new directions:

- Improve public understanding and inform public policy by strengthening the Center’s capacity to communicate with policy makers, journalists, and opinion leaders. A \$2.1 million grant from the Ford Foundation will help us accomplish this. The new initiative is described on page 5 of this report.
- Bolster our researchers’ ability to respond rapidly and decisively to important emerging issues.
- Forge new relationships with emerging bioethics programs in Asia and other parts of the world, where international cooperation in bioethics is sought.
- Create opportunities for leading thinkers to spend time at the Center and enhance our capacity to provide new insights and new approaches to perplexing problems.

Medicine and science change our lives. That was true in 1969 when The Hastings Center was founded, it is true today, and it will be true for our children and grandchildren. The Hastings Center helps us understand those changes and make wiser, better informed decisions. To all of you who supported the activities described in this report or who will support the Center in the coming year, thank you.

Sincerely yours,

Thomas H. Murray, *President*



U N D E R S T A N D I N G S C I E N C E

New project development is one of the most important uses of your donations to The Hastings Center. While not every project we develop is funded, many are awarded major grants by federal agencies or foundations. Projects can take months of staff time to design, submit, revise, and re-submit before they are ultimately funded. Once the grant is awarded, your donations provide vital indirect support and, at the conclusion of a project, often fully support writing and editing books and other final products.

A recent success story is a new project to examine the controversies around the dramatic increase in the use of psychotropic drugs to control behavioral and emotional disturbances in children. Our interest in these controversies grew out of several past projects directed by Erik Parens. That research examined surgical and pharmacological techniques used to enhance human bodies or to make them appear more “normal.” Other work by Parens and colleagues called for a more accurate public understanding of what life is like for people with disabilities.

Supported by your donations, Parens and Josephine Johnston devoted time over several years to design a major research project that would bring together thoughtful advocates of pharmacological treatment with thoughtful critics, 40 experts in total, to analyze the controversies about children and drugs. They submitted their proposal to the National Institute of Mental Health, and, in 2006, the agency approved a grant of \$438,000, about three quarters of the necessary funding. Future donations to the Center’s Fund for Children and Families will provide the rest.

A N A L Y Z I N G G E N E T I C T E C H N O L O G I E S

For decades, the Center has led public conversations about the ethical issues raised by genetic screening, research, and modification, and the past two years are no exception. A major grant from the National Institutes of Health has supported research that will guide state public health programs



The Hastings Center Process

A democracy inevitably brings together diverse sets of values to shape decisions, but these values must be based on fact, not fear—on balanced analysis, not bias. The Center provides an independent, nonpartisan forum where facts and values can be analyzed in an effort to find common ground. While this is a free flowing process, several noteworthy steps define the Center's unique approach:

- First, it is interdisciplinary. The Center has always understood that no single approach or profession can provide an acceptable solution to these problems. Rather, for each problem there is an appropriate mix of experts from a broad spectrum of disciplines.
- Second, it invites a diversity of voices. Most issues have a multiplicity of advocates offering a wide spectrum of opinion, and all but the most intractable are welcome.
- Third, presentations, dialogue, and discussion surface the relevant facts, outline the issues, and explore the points of agreement that exist between diverse opinions and values.

By processing the often arcane arguments of basic research—submitting the theoretical world of science and technology to the rough-and-tumble world of public policy and clinical practice, the Center forges a democratic accommodation among diverse views. What emerges is a way of thinking about these moral problems that can be used by the ultimate decision makers—the public at large and their representatives—in shaping their lives and our society.

in making public policy decisions about genetic screening of newborns. New screening technologies, new knowledge about the origin and treatment of genetic conditions, and a rapidly changing health care environment are making decisions about what to test for and how to pay for screening more complex. Concerns about adequately informing parents and providing follow-up services are also growing.

Led by Mary Ann Baily and Thomas Murray, the newborn screening project analyzed four critical areas of newborn screening: fairness in the distribution of the costs and benefits of screening; information, consent, and privacy; consultation and decision making; and race, ethnicity, and socioeconomic status. The findings, which will be published in 2007, will guide the professionals, policymakers, and members of the public who make decisions about newborn screening. The Center is also working with the March of Dimes to reach expectant parents with basic information about genetic screening before their babies are born.

Advances in genetic technologies are also raising concerns in the realm of sport. Genetic screening, including the newborn screening just described, and genetic testing may be employed in the future to identify promising candidates for a particular sport. Because the effort to identify specific gene variants associated with specific traits has proven much more difficult than most people expected, as we confirmed during the Center's earlier project on behavioral genetics, one aim of our current project on genetics and sport will be to clearly distinguish between (1) new scientific developments that might lead to ethically troubling practices and (2) what some unscrupulous or misinformed people might try to sell to eager or desperate coaches and athletes.

Led by Thomas Murray, with funding from United States Anti-Doping Agency, the genetics and sport project will consider the implications of genetic science on Olympic sport, for both the integrity of competition and the health of athletes. For example, genetic screening and testing may

be used in the future by trainers to predict how an athlete will respond to pharmaceutical enhancement. Pre-implantation genetic diagnosis may be used by parents to select embryos most likely to succeed as athletes. The researchers will analyze and describe carefully the ethically relevant similarities and differences between genetic technologies aimed at sport versus other purposes.

The project will also examine the science and ethical implications of genetic manipulation of individual athletes, using a variety of gene transfer techniques. The cells targeted for manipulation may be somatic cells, such as skeletal muscle, which do not contribute genetic material to future generations or they may be germ line cells, which do contribute genetic material to offspring. The researchers will develop a realistic assessment of the likely time horizon and ways in which gene transfer may be used in sport. They will also explore possible strategies for preventing or detecting prohibited gene transfer and consider ethical issues these strategies may raise.

S H A P I N G P U B L I C P O L I C Y

Both genetic selection and genetic manipulation will intensify the debate over the concept of what is “natural” and how that concept fits in the ethics of sport. Some people will object to the use of genetic technologies for athletic enhancement simply because they feel these methods are “unnatural.” Gregory Kaebnick is participating in the genetics and sport project, while also conducting a comparative study of the very different ways ideas about “nature” are invoked in contemporary moral and policy debates about medical biotechnology, agricultural biotechnology, and the environment. With funding from the National Endowment for the Humanities, he is seeking answers to three kinds of questions: how nature is understood, whether and how moral claims about nature can be justified, and whether and how moral claims about nature may legitimately affect public policy.

I N F O R M I N G R E S E A R C H E R S

During 2005, Karen Maschke, Erik Parens, and other members of the Center’s staff continued an Education in Genetic Ethics (EDGE) program for investigators, institutional review board (IRB) members, and others who work at or have interests related to research in human genetics. In a collaborative project with the Institute for Bioethics, Health Policy, and Law at the University of Louisville and the Stanford University Center for Biomedical Ethics, two-day training sessions were conducted six times each year by staff members from the three institutions. A needs assessment was conducted before each training session to identify the topics that participants wanted covered, and respondents consistently mentioned informed consent, family and community harms, standards for IRB review of protocols, and the ethical and legal considerations involving privacy and confidentiality.

U N D E R S T A N D I N G

BIOETHICS AND THE PUBLIC INTEREST

In the spring of 2005, the national debate over the Theresa Schiavo case and a handful of other issues prompted journalists, policy makers, and opinion leaders to call The Hastings Center in greater numbers than usual. They sought our help in clarifying the clinical and scientific facts and the ethical dimensions of these issues. As we tracked these debates we observed, again and again, polarizing rhetoric that was undermining public understanding.

We held a retreat for Center staff that spring to discuss how to better serve the needs of the journalists, policy makers, and opinion leaders who were reaching out to us. We asked the Greenwall and Overbrook foundations to support a year of planning that would identify ways to increase the Center's ability to communicate effectively with these audiences and deepen our understanding of the issues of concern to them.

These planning grants allowed me to conduct a series of face-to-face interviews with key informants, including representatives of our target audiences and leaders of organizations with a track record of reaching these audiences in ways consistent with the Center's mission and nonpartisan approach. In addition, we began to test a variety of new products and activities aimed at one or more of these audiences, and to think about how best to utilize the Center's own research and our worldwide network of experts. The grants also supported a fundraising feasibility study to ensure that we could sustain these new products and activities over time.

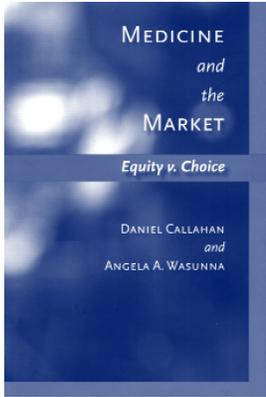
In July 2005, I began to talk with Susan Berresford, president of the Ford Foundation, about public understanding of bioethics issues and our plans to communicate more effectively with journalists, policy makers, and opinion leaders. We had a series of conversations as our plans began to take shape; in October 2006, I submitted a proposal for a capacity building initiative called Bioethics and the Public Interest.

In January, 2007, we received \$2.1 million from the Ford Foundation, the largest grant in the Center's history. We will create a communications department that will collaborate with our researchers, editors, and Fellows on strategic communications to our three target audiences. We will hire a researcher to track developments in public health law and policy. We will create new print and electronic publications, web-based services, and events in Washington, DC and elsewhere. Our Development Committee is planning a fundraising campaign that will cover the remaining costs of the three-year initiative and provide the support needed to sustain it for the long term.

Bioethics and the Public Interest is a natural extension of the Center's historical mission. Our long history of intellectual rigor, openness to a wide range of conflicting views, and our unparalleled reputation and network of expertise provided a platform from which to launch this initiative. To all who helped to build this platform over the past 38 years, thank you. I look forward to telling you much more about the initiative in future reports.

SHARING PERSPECTIVES

NEW BOOKS FROM THE HASTINGS CENTER 2005-2006



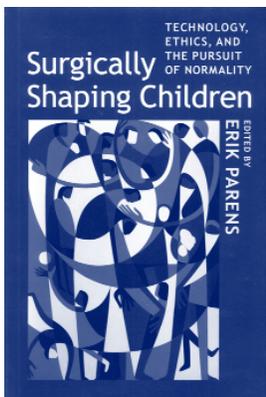
Medicine and the Market: Equity v. Choice

The Johns Hopkins University Press (2006)

This book seeks a clearer understanding of how countries around the world have used government and the market to make health care affordable and effective. The culmination of almost a decade of research by **Daniel Callahan**, the Center's founder, the book was supported by the Pettus Crowe Foundation, Ira W. DeCamp Foundation, The Rockefeller Foundation, and numerous individuals. To gain a clearer perspective of the market's impact in developing countries, Callahan collaborated with Angela Wasunna, an attorney from Kenya, during her six-year tenure at the Center. In addition to laying out the market-versus-government struggle, the authors assess the leading market practices, such as competition, physician incentives, and co-payments, for their economic and health efficacy to determine whether they work as advertised.

"A timely and necessary contribution. Whether or not one agrees with the authors' conclusions, the book is essential reading for anyone concerned with health care reform. It carries out the critical task of placing our national health care debates in the wider context of justice and health care reform around the world."

—Excerpt from a review by Nancy S. Jecker, PhD in the *Journal of the American Medical Association*



Surgically Shaping Children: Technology, Ethics, and the Pursuit of Normality

The Johns Hopkins University Press (2006)

Your donations enabled **Erik Parens** to edit this volume of essays on how, whether, and when surgery may be used to make children's bodies fit traditional social norms. The work issued from a research project, Surgically Shaping Children, that was funded by the National Endowment for the Humanities. Some of the contributors recount personal experiences making difficult decisions about surgery; while others reflect on the meaning of using technology to pursue normalcy. The book concludes with practical advice about how parents, children, and medical professionals can make better decisions about these surgeries.

"In his introduction, Parens describes the book as an exploration of the tension between the desire to have surgery performed to spare children the pain and suffering of being different and the desire to spare children the pain and suffering of being subjected to surgery. But the book does much more. It explains the philosophical, psychological, and medical reasons why this tension exists, and it challenges the assumptions that embroil us in that tension....[I]t should give readers both the courage to resist seductive influences and the inspiration to arrive at decisions less likely to lead to remorse, disruption of family ties, or disappointment with unmet expectations."

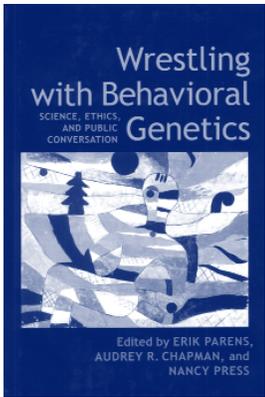
—Excerpt from a review by Sharon E. Sytsma, PhD, in *The New England Journal of Medicine*

After Harm: Medical Error and the Ethics of Forgiveness

The Johns Hopkins University Press (2005)

Medical error is a leading problem in health care that affects patients, families, and clinicians. What caregivers should do following the injury or death of a patient is still hotly debated, however. Drawing on sources in religion, ethics, and culture, **Nancy Berlinger** proposes an approach that emphasizes the importance of acknowledging fallibility, telling the truth, confronting feelings of guilt and shame, and

providing just compensation. The initial research that led her to write this book was supported by The Patrick and Catherine Weldon Donaghue Medical Research Foundation, as part of the Center's project on Promoting Patient Safety: An Ethical Basis for Policy Deliberation.



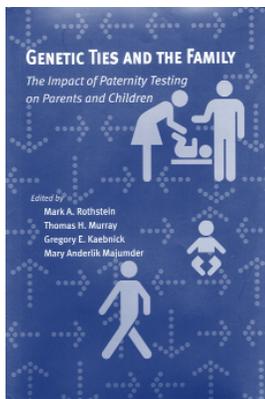
Wrestling with Behavioral Genetics: Science, Ethics, and Public Conversation

The Johns Hopkins University Press (2006)

This volume describes what behavioral geneticists have discovered about the role of genes in complex human traits like intelligence and mood. It also discusses the limits of that research and the influence of environments over gene expression. The essays examine what light such findings can be expected to shed on human variation, human equality, and the capacity to freely choose what one does and who one becomes. Co-edited by **Erik Parens**, the book is one product of a collaborative research project between the Center and the American Academy for the Advancement of Science.

“What sets this collection apart from others is the way that contributions from a diverse authorship are integrated to form a coherent whole, which is doubtless due to the process by which the book came about. Many issues are treated by several different authors, and each has their own perspective, which at times provides a lively debate; the ‘wrestling’ is clear to see! Doubtless this book will soon become a classic within behavioral genetics, and compulsory reading for the non-specialist seeking to understand the basic scientific, social, and ethical issues within the field.”

—Conclusion of a review by Jonathan P. Roiser in *The American Journal of Bioethics*



Genetic Ties and the Family: The Impact of Paternity Testing on Parents and Children

The Johns Hopkins University Press (2005)

If parent-child relationships encompass more than genetics, then questions about paternity cannot be settled definitively with a biological test. This volume of essays explores the cases in which parentage is challenged and sets out the issues relevant to deciding when to permit a challenge, how to conduct it, and how to decide it. Building on scholarship of the last quarter century—including the latest developments in law and social science research—this book discusses new legislation regulating genetic testing and the use of test results in establishing parental rights. Co-editors and contributors **Thomas Murray** and **Gregory Kaebnick** present papers that were part of a research project the Center conducted with the University of Louisville.

What Price Better Health: Hazards of the Research Imperative

The Milbank Memorial Fund and University of California Press (2005)

Author **Daniel Callahan** argues that the moral imperative to pursue medical research must be balanced with other social and economic needs. He looks beyond the promise of cures to reveal the difficulties that result when the research imperative is suffused with excessive zeal, adulterated by the profit motive, or used to justify cutting moral corners when humans are the subjects of research. He clarifies the fine line between doing good and doing harm in the name of medical progress. A grant from The Patrick and Catherine Weldon Donaghue Medical Research Foundation enabled Callahan to think about priority setting in research, and The Milbank Memorial Fund provided financial support for the book.

All of these books may be purchased through the Center's Web site www.thehastingscenter.org.



I M P R O V I N G L I V E S

Until the last decade, many Americans assumed their health care was the best anywhere, but recent evidence has shown that errors, waste, and other shortcomings are commonplace. In response, many providers and clinicians have acted to improve their performance. Unfortunately, uncertainty about the requirements for ethical conduct of quality improvement (QI) activities has discouraged some from using them.

The Hastings Center's research addressed this and other obstacles to improving health care in 2005 and 2006. A review of the systems for decision-making and care delivery near the end of life revealed profound misconceptions about patient rights and the role of the legal system. Another research project examined the belief that, in some contexts, patents may be impeding access to life-saving biomedical treatments or slowing research to develop new products. (Please see *Balancing Patent Rights* on page 11.) Access to care was also considered in the context of an emergency, such as a severe influenza pandemic.

A D V A N C I N G Q U A L I T Y I M P R O V E M E N T

Some of the best efforts to improve performance in health care have used a set of methods pioneered in manufacturing, called quality improvement or QI, that sequentially implement changes and monitor the effects of those changes to guide ongoing progress. QI raises ethical issues because attempts to improve quality may inadvertently cause harm, waste scarce resources, or affect some patients unfairly. Activities using QI methods may also be considered "research" that comes under ethical and regulatory requirements governing human subjects research. Uncertainty about these requirements can serve as a disincentive for improving quality.

The Center's project on QI brought together experts in the delivery, improvement, and oversight of health care and medical research, under the leadership of Mary Ann Baily. Funding from the Agency for Healthcare Research and Quality covered the majority of project costs, with several partner organizations



and individuals providing additional funding. The experts clarified the distinctions between QI and human subjects research. They recognized QI as an integral part of normal health care operations and one in which patients and providers have an obligation to participate.

The experts urged providers to develop internal management models that will ensure QI is conducted ethically. They recommended that QI practitioners and the research ethics community work together with the Office of Human Research Protection (OHRP) to identify those QI activities that require additional review as research. All of these findings were presented in a special supplement to the *Hastings Center Report* (July/August 2006) entitled *The Ethics of Using QI Methods to Improve Health Care Quality and Safety*. During 2007, project participants will continue to convey their recommendations through articles and presentations for the healthcare community. A volume of papers was also published in 2007.

MAKING DECISIONS AT LIFE'S END

Relieving the pain and suffering that may accompany death, and giving dying patients more control of their medical care, are central concerns of the Center and the field of bioethics as a whole. In 1987, the Center published *Guidelines on the Termination of Life-sustaining Treatment and Care of the Dying*, which is regularly used by doctors and nurses, medical scholars, ethics committees, and courts of law. The *Guidelines* formed the basis for an education program created by the Center and the Education Development Center, which is used by approximately 200 hospitals in 30 states.

The Robert Wood Johnson Foundation, a leader in efforts to improve end of life care, funded the SUPPORT study in the mid-1990s to document the extent to which aggressive life-prolonging procedures were being used by hospitals in situations where they were either medically futile or unwanted by patients and families. At the foundation's request, the Center published an analysis of the results in the *Hastings Center Report* in 1995, under the title *Dying Well in the Hospital: The Lessons of SUPPORT*. In 2005, the foundation once again called on the Center to critique the most recent decade of improvements in end of life care and recommend future directions.

In response, Thomas Murray and Bruce Jennings convened a meeting of experts in medicine, law, and ethics, who identified conceptual and systematic flaws in recent efforts, particularly the lack of attention to the ongoing human relationships that surround a dying patient. They advised against new laws or regulations that direct certain outcomes (such as requiring feeding tubes in certain cases). Instead policy should focus on building and financing a system of more continuous, planned end-of-life care that would give families and health care providers the skills and tools they need to make better decisions and to provide better care for dying patients.

The lessons put forward by this group were published in a special supplement to the *Hastings Center Report* (November/December 2005) entitled *Improving End of Life Care: Why Has It Been So Difficult?* In November 2005, Murray and Jennings summarized these lessons at a Congressional briefing. Later that month, Murray and co-contributors Alan Meisel and Joanne Lynn briefed participants in the New England Forum for Women State Legislators, hosted by the Eagleton Institute's Center for American Women and Politics. The publication is available on the Center's Web site (www.thehastingscenter.org.)

GUIDING CAREGIVERS

The lessons in *Improving End of Life Care* will be incorporated into a revised, updated, and expanded version of the Center's *Guidelines on the Termination of Life-sustaining Treatment and Care of the Dying*, mentioned above. Funding from The Phyllis and Albert Sussman Charitable Trust and The Patrick and Catherine Weldon Donaghue Medical Research Foundation is allowing Nancy Berlinger and Bruce Jennings, with original author Susan Wolf, to lead an effort to update this 20-year-old resource. New sections on futility, palliative and hospice care, surrogacy, disability, diversity, and institutional politics will be included, as will special considerations for pediatric and adolescent patients.

Like its predecessor, *Guidelines on End of Life Care (Guidelines 2)* will be designed for professional caregivers, medical and nursing school faculty, ethicists and ethics educators, advocates for patient care, and lawmakers and policy makers. Significant attention will be given to understanding how each of these audiences prefers to receive and use new knowledge about caregiving. *Guidelines 2* will be disseminated in print and electronic form, beginning in late 2008.

ACCESS TO CARE

At a meeting in March 2005, sponsored by The Max and Bessie Bakal Foundation, experts convened by the Center explored how ethical interests and values might be used to achieve greater access and affordability in the health care system. The participants highlighted ways our health care system fails to live up to our public values and goals. They discussed how key concepts, such as choice, security, simplicity, predictability, and rationing, might serve as entry points for discussion or act as impediments to policy and institutional change.

An influenza pandemic will force difficult and tragic decisions about access to scarce health care resources. It will make rationing unavoidable—not only of vaccines and antiviral medications, but possibly also of hospital beds, ventilators, and other resources. In 2006, Trust for America's Health, a non-partisan organization dedicated to protecting communities, asked the Center for advice on how best to think about these decisions and other ethical issues in pandemic planning.

In September, 2006, Thomas Murray organized a briefing for members of the Senate Subcommittee on Bioterrorism and Public Health Preparedness featuring scholars who provided insights from American religious traditions on resource allocation. A backgrounder outlining how policy makers can act now to develop pandemic plans that are fair and that provide ethical guidance to physicians and other first responders is available on the Center's Web site (www.thehastingscenter.org). Pandemic planning was also the topic of a December, 2005 event, sponsored by the Pettus-Crowe Foundation, which is described on page 19.

At the local and regional levels, hospitals will have to collaborate among themselves, and with public health authorities, to develop ethically sound plans for allocating limited resources, delivering health care, and educating first responders in a pandemic emergency. Nancy Berlinger joined with John Tuohey of The Providence Center for Health Care Ethics of Providence Health & Services, a multi-state health care system with 29 hospitals and 47,000 employees, to convene a September 2006 meeting at The Hastings Center. With funding from the Providence Foundation, they brought together physicians, clinical ethicists, and public health experts, including clinicians who responded to recent public-health emergencies. These experts identified gaps in planning for a pandemic and are preparing resources to assist hospitals and medical schools in incorporating this planning into clinical ethics education.

BALANCING PATENT RIGHTS WITH ACCESS TO CARE

One third of the world's population lacks access to existing essential drugs, according to the World Health Organization. Cost of treatment, insufficient infrastructure, and lack of political commitment to health care all contribute to this situation. Further, treatments do not yet exist for many diseases in developing countries. Concerns about the dramatic increase in the numbers of biomedical patents being issued and their potential role in blocking access to treatment and stifling innovation convinced Josephine Johnston and former staff member Angela Wasunna of the need to clarify the uses and limits of the patent system.

With initial project development funding from individuals and family foundations, Johnston and Wasunna designed a research project proposal for the Sasakawa Peace Foundation. The grant allowed them to convene a diverse task force of research sponsors, patent and licensing specialists from universities, pharmaceutical industry representatives, health advocates, and legal scholars from Europe, Africa, Canada, and the United States. Through Center-hosted face-to-face meetings, the group debated the role of patents in biomedical research and treatment. The influence of patents in two case studies—on the progress of embryonic stem cell research in the United States and on access to HIV/AIDS treatment in the developing world—were examined and compared.

Documenting the role of patents proved to be complex. The task force concluded that the presence of patents may make treatments and vaccines too expensive for some populations. Simply removing patents will not guarantee access to essential medicine, however, if infrastructure or political will are insufficient. Regarding innovation, less evidence exists than was expected that patents are slowing down biomedical research, but the group felt this risk ought to be taken seriously until better evidence exists. It was equally difficult to measure the way patents encourage innovation. The influence of patents depends very much on the particular way the biomedical research is paid for and conducted.

Promoting access to treatments for life-threatening diseases should be a guiding goal for policy makers and others involved in developing biomedical patent systems and for those granting specific licenses for patented technologies, conclude Johnston and Wasunna in their final report, *Patents, Biomedical Research, and Treatments*. Spurring innovation by making new knowledge, techniques, and materials available to biomedical researchers should be a parallel goal. The limitations of the patent system to guarantee access and encourage innovation should be recognized, however.

The task force considered many positive ways to “tinker” with patent laws, policies, and licensing strategies to improve access to treatments and encourage innovation, which Johnson and Wasunna share in the report. They also describe practices and proposals outside the patent system that will help achieve these goals, particularly in developing nations. Ethical and practical justifications for balancing patent rights with the fundamental human right to health are offered. The report also examines moral arguments that some research products should be excluded from patent systems.

Free copies of *Patents, Biomedical Research, and Treatments*, may be downloaded from the Center's Web site www.thehastingscenter.org. Papers by task force members also appeared in a 2007 special issue of the *International Journal of Biotechnology*, entitled “Biomedicine, Patents, and Access,” with guest editors Johnston and Wasunna.

SHAPING BIOETHICS DEBATE

THE HASTINGS CENTER REPORT



Over the past two years, the *Hastings Center Report* has continued to shape bioethics debate by advancing evenhanded reflection from a wide range of political and professional perspectives. To deepen the *Report's* coverage of current events, we recently initiated a series of essay sets—periodic additions to the journal's usual 48 pages—made possible by a generous grant from the Cranaleith Foundation.

Each set features an overview essay on a major event or advancement in the field, followed by several shorter commentaries that take a closer look at facets of the topic. The first set, in the May-June 2005 issue, explored the moral, legal, and medical underpinnings in the case of Theresa Schiavo. The second set, in the January-February 2006 issue, focused on the new ethical questions arising as stem cell science edges toward the clinic.

And the most recent set, in the September-October 2006 issue, examined the bold legislative steps Massachusetts took last year toward universal health insurance coverage.

In 2005, the *Report* also launched a new column called "Policy & Politics." The column appears by arrangement with the American Society of Bioethics and the Humanities, the leading professional organization in bioethics. Early installments of the column, written by a rotating group of six authors, discussed how cultural conflicts have worked their way into scholarly bioethics, and how bioethicists should respond.

Readership. The Hastings Center has aggressively broadened the *Report's* reach through a number of Web-based strategies. Starting with the January-February 2005 issue, the *Report* became available online in "smart PDF"—a searchable format that preserves the appearance of the printed page. By the end of the first year, about 600 subscribers were receiving the *Report* electronically—many of them in addition to their print subscriptions.

Selected content from the *Report* is made available for free download on The Hastings Center's Web site through a redesigned page that features the current table of contents. Free content is also available from Medscape, a resource for physicians, nurses, and other health care workers run by WebMD. In 2005—the first year during which we supplied content to Medscape—*Report* articles were accessed about 45,000 times. That same year, content on the Center's Web site was accessed about 11,000 times.

Also beginning in 2005 was a partnership with Project Muse, a nonprofit service of Johns Hopkins University that makes journals available online to academic libraries. Through Project Muse, the *Report* has augmented its 4,500 direct subscribers with a further 1,300 indirect subscribers. In 2006, articles from the *Report* were viewed more than 11,000 times at libraries participating in Project Muse. The Center also signed a contract with JSTOR, a nonprofit service that makes older issues of journals available electronically to academic libraries. JSTOR will scan all 35 years of the *Report's* back issues.

In addition to these outlets, selected content from the *Report* continued to be available through a variety of databases including PubMed, the citation service of the National Library of Medicine. Articles are also offered as "e-docs" on amazon.com and through the information services ProQuest, Thomson Gale, and EBSCO. Through these services, we estimate that readers accessed the *Report* approximately 65,000 times in 2005. Overall, the *Report* is read by well over 100,000 people each year.

EXPLORING VALUES

BIOETHICS FORUM

Your donations enabled the *Report* staff to launch a new online publication in March 2006. *Bioethics Forum* (www.bioethicsforum.org) offers short, engaging commentaries on topical issues at the intersection of bioethics and public life. The *Forum* is updated weekly. Since its launch, over 125,000 readers have visited the site.

IRB: ETHICS & HUMAN RESEARCH

IRB publishes work that examines the challenging theoretical and practical issues raised by research with human participants. Its contributors include leading scholars, experts, researchers, and administrators in the field, and its scope has broadened over the past two years.

IRB increasingly offers articles based on empirical analyses of the ethical challenges raised when conducting research with humans. *IRB* also continues to cover the policies and decision-making practices of U.S. institutional review boards and federal regulatory agencies.



The March-April 2006 issue of *IRB* made news when a commentary in it questioned whether

the clinical trial of the drug PolyHeme was ethical.

The study of PolyHeme—a hemoglobin-based, oxygen-carrying resuscitative blood substitute—is being conducted under a 1996 Food and Drug Administration rule that permits IRBs to waive the requirement for informed consent in some emergency settings. The authors claimed this rule should not have been employed for the PolyHeme trial. Urgent ethical issues raised by this piece prompted us to issue a press release alerting the media to a prepublication posting of the article on the Center's Web site. Both the *Chicago-Tribune* and the *Wall Street Journal* covered the story.

Readership. In 2006, *IRB's* page on The Hastings Center's Web site was completely redesigned to offer the current table of contents and free download of the lead article in each issue. Selected free content is also offered from the Medscape service of WebMD, and further content is available from a variety of databases including EBSCO. *IRB* is also indexed with PubMed and included in the Center's contract with JSTOR, which will offer all 28 years of back issues electronically to academic libraries.

Because of the nature of *IRB's* readership, however, *IRB* content is distributed primarily in print form. While most *IRB* subscribers are individuals, groups with multiple-copy subscriptions use 85 percent of the copies circulated. Many of these are academic institutional review boards that distribute the journal to their members. *IRB* remains an essential tool for those overseeing human subjects research.

Building Ethics Capacity

The Hastings Center assists clinicians, ethics educators, and regulatory agencies in other parts of the world to improve health care delivery and to protect the health and rights of patients, research subjects, and health care providers. Difficult ethical issues have emerged in Haiti and other resource-constrained countries concerning HIV clinical trials and post-trial access to HIV treatments, particularly when adolescents are involved. IRBs and community advisory boards need educational resources and training to enhance their capacity to review research protocols and protect research participants. Researchers, clinicians, and policy makers need conceptual and problem-solving tools to address the ethical challenges of providing adolescents with access to HIV treatment and prevention services. The Center is working with Weill-Cornell Medical College and GHESKIO, an HIV voluntary counseling and testing center in Haiti that is also a site for several HIV vaccine trials, to provide the resources, training, and tools.

In July, 2006 Karen Maschke traveled to Port-au-Prince, Haiti to meet Dr. Jean Pape, Director of GHESKIO. While there, she also met with the Director of the GHESKIO IRB, the head of the community advisory board, the investigators and staff for the HIV vaccine trials, and the Dean of Quisqueya Medical School. She returned to Haiti in November to teach a two-week research ethics course to graduate students in the Master's in Public Health program at Quisqueya University. Maschke, who also serves as editor of the Center's *IRB: Ethics & Human Research*, will continue to work with physicians at Weill-Cornell and GHESKIO in developing research ethics programs for researchers, IRBs, and medical students in Haiti.

SPREADING THE WORD

- In December, 2005, Board members **Harold Edgar**, **Larry Palmer**, **Robert Murray**, and **Thomas Murray** joined former Board members **Irene W. Crowe** and **Andrew Klingenstein** in hosting a provocative discussion on ethical issues that arise in preparing for a flu pandemic, with a grant from the **Pettus-Crowe Foundation**. **Tom Murray** led **William Raub**, Science Advisor to the Secretary of Health and Human Services, **David Bowen**, then Minority Health Policy Director for the Senate HELP Committee, and **Jeffrey Levi**, then Senior Policy

Advisor for Trust for America's Health, in a "roundtable" discussion, before opening it up to the sixty guests in attendance at the Cosmos Club in Washington, DC. Among these were journalists, philanthropists, senior staff and fellows at the NIH, legal scholars, and health policy specialists.

- **Annette and Bill Ross**, members of the Center's President's Circle, introduced **Thomas Murray** to friends and neighbors at their home in New Canaan, CT, in March 2006. Murray spoke about the Center's deep interest in questions about biomedical technologies used to alter the human body. As many of the guests were parents of school-age children, the discussion focused on harmful messages parents may inadvertently send to children when recommending enhancements, such as growth hormone or cosmetic surgeries.

- To share the lessons of *Improving End of Life Care: Why Has It Been So Difficult?* with philanthropists, hospital administrators, and legal and medical scholars in Connecticut, Board members **Christopher Getman** and **Eve Hart Rice** hosted a dinner event in April, 2006 at Maury's, a landmark Yale institution. Guests heard from co-editors of the report, **Thomas Murray** and **Bruce Jennings**, contributor **Robert Burt**, a Hastings Center Fellow, and **Sherwin Nuland**, a Fellow and Board member. All participated in a discussion about our fears and concerns about death and ways that families and caregivers can better assist patients nearing death. The evening ended on a lighter note, with a serenade from Yale's Whiffenpoofs.

- Audiences in New York City learned more about the Center's work through a series of Hastings Center Seminars at the **Center for Religious Inquiry**, located at St. Bartholomew's Church in Manhattan. This collaborative pilot project was supported by a grant from The Greenwall Foundation to the Center for Religious Inquiry. During Fall 2005, **Daniel Callahan**, **Thomas Murray**, and **Bruce Jennings** each led a seminar on end of life issues, joined by distinguished colleagues from City-based institutions. A Spring 2006 three-part series focused on parents, children, and difficult decisions and featured **Karen Maschke**, **Josephine Johnston**, and **Erik Parens**, with other experts in communicating about these decisions.

- **Demos**, a non-partisan public policy research organization in New York City, invited **Daniel Callahan** and **Angela Wasunna** to speak about the findings in their book, *Medicine and the Market: Equity v. Choice*, at a May 2006 forum. Later that month, **Irene Crowe** and the **Pettus-Crowe Foundation** sponsored a reception at The Cosmos Club, at which Callahan and Wasunna spoke to representatives of the World Bank and other financial development institutions about the book.



Pilar Quintanilla

Residents of Garrison and the surrounding communities are invited to learn about bioethics at Friday evening seminars, held at The Hastings Center several times each year. Here, Mary Ann Baily introduces speakers from Hudson River HealthCare, who joined her in presenting an October, 2006 seminar on the ways community health centers work to ensure access to care for farmworkers.

Statement of Financial Position

As of December 31, 2006

	2006	2005
Assets		
Cash and Equivalents	346,414	157,531
Investments, at fair value	3,089,843	2,882,500
Receivables (grants and others)	254,934	552,175
Furniture and Equipment	8,948	10,706
Other Assets	7,034	3,728
Leasehold Improvements	1,281,196	1,325,460
Total Assets	<u>4,988,639</u>	<u>4,932,100</u>
Liabilities and Net Assets		
Payables and Accruals	108,572	150,838
Deferred Revenue	274,529	280,466
Total Liabilities	383,101	431,304
Net Assets	<u>4,605,268</u>	<u>4,500,796</u>
Total Liabilities and Net Assets	<u>4,988,369</u>	<u>4,932,100</u>

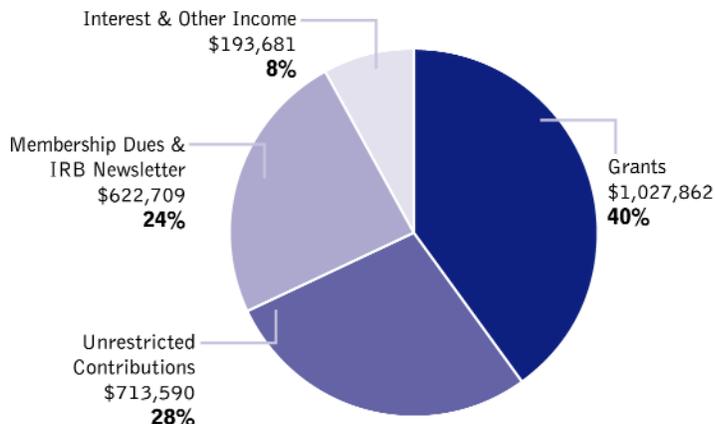
Statement of Activities and Changes In Net Assets

As of December 31, 2006

Operating Support and Revenue		
Grants, Gifts and Contributions	1,327,381	1,104,804
Government Grants	414,071	394,992
Membership Dues and IRB Newsletter	622,708	550,190
Interest and Other Income	193,681	191,560
Total Operating Support and Revenue	<u>2,557,841</u>	<u>2,241,546</u>
Operating Expenses		
Program Services	1,899,753	1,990,368
Management and General	431,361	619,924
Fund Raising	143,830	162,427
Total Operating Expenses	<u>2,474,944</u>	<u>2,772,719</u>
Changes in Net Assets from Operations	82,897	(531,173)
Changes in Non-Operating Income	155,984	(64,167)
Change in Net Assets	<u>238,881</u>	<u>(595,340)</u>
Net Assets, Beginning of Year	4,500,796	5,096,136
Restatement - Prior Year	(134,409)	
Net assets, Beginning of Year, as restated	<u>4,366,387</u>	
Net Assets, End of Year	<u>4,605,268</u>	<u>4,500,796</u>

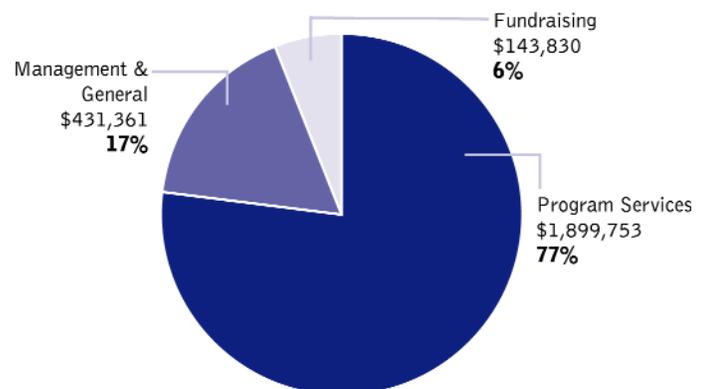
Support and Revenue

Year ended 31 December 2006—\$2,557,841



Expenses

Year ended 31 December 2006—\$2,474,944



G VALUES

STAFF*as of December 31, 2006*

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Deputy Director
Associate for Religious Studies

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Director, International Program

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2005-2006 ACTIVITIES REPORT

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To obtain a copy of The Hastings Center's complete financial statement for 2006, please write to the Development Department, The Hastings Center, 21 Malcolm Gordon Road, Garrison, NY 10524.

