Guest Editor:
Margaret O. Little, Ph.D.

In the 1990s, amidst reports that women were underrepresented in clinical research, a key issue in science policy was whether the health interests of women were being adequately addressed. In response, the federal government established the Women's Health Initiative to prioritize attention to women's health needs and commissioned the Institute of Medicine to study ethical and legal issues of including women in clinical studies. Much progress ensued: today, a majority of participants in clinical research are women.

But one group of women has been left behind — pregnant women. Although the 1994 IOM report recommended pregnant women be “presumed eligible for participation in clinical studies,” many researchers and IRBs still regard pregnancy as a near-automatic cause for exclusion. Such resistance, understandably connected to concern for fetal well-being, in fact comes at tremendous costs to women and fetuses alike.

As obstetricians well know, pregnant women often have serious medical needs. Indeed, chronic diseases requiring treatment during pregnancy are common: chronic hypertension and diabetes each complicate nearly 40,000 pregnancies annually in the U.S.; psychiatric illness complicates an estimated 500,000 pregnancies; cancer and autoimmune disease commonly occur with pregnancy, as do pregnancy-related complications, such as preeclampsia. In fact, two-thirds of women take four to five medications during pregnancy. Yet only a dozen medications are approved by the FDA for use during pregnancy, and all are for gestation- or birth-related issues like anesthesia or nausea. Any medicine taken to treat illness during pregnancy is used without data to guide effective and safe dosing. Pregnancy, it turns out, is an off-label condition.

Given that pregnancy often changes the activity of drugs in dramatic ways, this is deeply problematic. Recent studies reveal that pregnant women metabolize certain drugs such as amoxicillin so quickly that they do not achieve therapeutic levels at usual dosing levels. Other studies suggest that pregnancy alters drug metabolism in unpredictable ways. Further, with no data to reassure them, patients and their providers sometimes halt medications — a decision that can present far greater risks than the possible risk of continuing them. Untreated depression in pregnant women, for instance, is not only bad for the woman, it is bad for the fetus, with risks of prematurity, growth restriction, and postnatal complications. Women suboptimally treated for asthma have worse pregnancy outcomes than those who control it with medication. And when an untreated woman dies from cancer during or after her pregnancy, neonatal health concerns are one thing, the wrenching implications of life without a mother quite another.

Nor is the problem limited to wealthy nations. The treatment of malaria, for instance, which is responsible
for up to 10,000 maternal and 200,000 infant deaths annually, relies on post-marketing surveillance for the safety and efficacy of anti-malarials for drug resistant disease.

If we are to treat pregnant women’s illnesses effectively—something crucial to the health of both pregnant women and the children they may bear—we must study medications in pregnant women. Certainly, guidelines for research in pregnancy must include special safeguards and, as with any research involving those with a limited or absent capacity for consent, such as children, added protections for fetal interests. But mention of children is an important reminder: the pediatrics community has persuasively argued the need to conduct responsible research with children. Children are not just short adults—and pregnant women are not just women with big bellies.

Some needed steps are straightforward, such as increased funding for research. Others will be more complicated: addressing liability concerns and developing guidance for IRBs, including, most critically, a framework for managing and limiting risk-benefit trade-offs between woman and fetus. Taking these steps will be challenging, but doing any less compromises fetal safety and relegates pregnant women to second-class medical treatment.

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16th Annual Brennan Lecture

The KIE was pleased to host the Joseph B. Brennan Lecture on October 16, 2008, in the Riggs Library, with Robert Cook-Deegan, MD, director of the Center for Genome Ethics, Law & Policy, Institute for Genome Sciences & Policy, Duke University and Faculty Affiliate of the KIE as speaker. Dr. Cook-Deegan has extensive health policy experience, having worked at the National Academies from 1991 through July 2002. That work included helping write or supervise over a dozen policy reports while directing boards on cancer policy, mental health and neuroscience, and the Robert Wood Johnson Health Policy Fellowship Program. He joined the Office of Technology Assessment (OTA), US Congress, 1982-1988, where he directed four OTA reports on aging, dementia, biotechnology, and human genetics. He is author of The Gene Wars: Science, Politics and the Human Genome and a forthcoming book on U.S. health research policy.

Beginning his talk with discussion on the Role of Bioethics in Research Ethics, Dr. Cook-Deegan offered perspective and background on the Nuremberg Code, Universal Declaration of Human Rights, the Belmont Report and the history and theory of informed consent. He approached this topic and the ensuing discussion of the Role of Bioethics in Genetics just as a professor might grade a student, assigning bioethics and its practitioners and policymakers a ‘grade’ for how they had performed in addressing the issues and resolving conflicts. He assigned an “A” for their role in influencing research ethics, but when he moved to the Role of Bioethics in Genetics, performance, to date, dropped to a “B-“. As he explained to this mostly lay audience, there were numerous reasons for this lower grade. He laid out what he saw as the role of bioethics in addressing issues in genetics research; to unbundle disparate concerns, specify problems, review arguments and perspectives, map policy jurisdictions and authorities, identify stakeholders, and, finally and most importantly, outstanding contributions and significant publications that have helped shape the direction of the fields of bioethics and humanities.

The award recognized his career involving teaching of over 10,000 students, authoring or editing some 42 books, and participating in over 30 legal cases including those of Karen Ann Quinlan and Baby K. Three other present or former faculty of the Kennedy Institute of Ethics, Tom L. Beauchamp, James C. Childress, and Edmund D. Pellegrino, are among the thirteen previous recipients of the ASBH award.

Senior Research Scholar and Rector of the Jesuit Community at GU, John M. Langan, S.J., Ph.D., participated in a panel on religion and human rights for the 60th anniversary of the Universal Declaration of Human Rights celebrated by the International Law Section of the American Bar Association in New York City. He also gave a keynote address for a similar anniversary celebration at Georgetown College, Georgetown, KY. He spoke on ethical questions about nuclear proliferation at the University of California, San Diego, and at the Methodist School of Theology in Ohio. He lectured on ethical approaches to war at Strake Jesuit High School in Houston, and on the moral issues raised by the five wars we are waging in Iraq.

Madison Powers, J.D., D.Phil., Director of the KIE, was profiled in a recent article in Georgetown’s Blue and Gray newspaper, and featured on the university website, in an article entitled “The Powers of Philosophical Debate,” written by Andy Pino. Excerpt: “As a philosopher, Powers engages in a theoretical debate about the role government should and should not play in pursuing the public interest, especially in the area of healthcare. A prolific scholar, Powers’ books and publications focus on issues including the moral foundations of health policy, gender and AIDS, justice and genetics, privacy issues and health care reform. And as a Georgetown professor for more than 20 years, he has built upon that work to help his students debate opposing ideas about the role and responsibilities of government. ‘Before taking Professor Powers’ class, I’d never really considered grounding my understanding of the limits of state power in a formal philosophical approach or a study of political morality,’ says Alisha Crovetto (C’10). ‘I’d read Aristotle, Mill and Locke in other classes, but never with a focus on the relationship between the individual and her government.’ Full text available at: http://explore.georgetown.edu/news/?ID=38571

John Keown, D.Phil., Ph.D. Rose F. Kennedy Professor of Christian Ethics, will be on sabbatical leave from Georgetown and working on completing a book on the inviolability of life and the law. He has been awarded the Herbert Smith Visitorship in the Cambridge Law Faculty for the spring semester 2009. He will address the Pontifical Academy for Life, Rome in February, and lecture on mental health and the law in Brazil in March.
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recommend process and general guidelines for policy.

One inherent issue in the emerging field is that “technologies are marching ahead at hyperspeed,” said Dr. Cook-Deegan, and there seems to be a “bioethics feeding frenzy” as a consequence.

Dr. Cook-Deegan identified what he believed would be the greatest challenges in the area of genetics and personal genomics as: managing conflict of interest amidst deep academic-government-industry mutualism; identifying what needs to be regulated and what does not — providing help with the “why?”; and the fact that human lineages will without any doubt be reconstructed in the foreseeable future (i.e., Icelandic genome project).

IBC 35
"Bioethics: Beyond the Soundbite"

IBC Director Maggie Little and staff have organized this summer’s 35th Annual Intensive Bioethics Course (June 1 - 5, 2009, with an optional library proseminar on Sunday, May 31).

IBC 35 will provide participants with more choices, less programmed participation and will foster networking. It begins Monday with the Introduction to Bioethics lecture (Maggie Little), offers a new lecture by Bob Veatch on Autonomy in Law and Ethics, Carol Taylor on Care, Vulnerability and the End of Life, Madison Powers presenting Justice and Health Care, Tom Beauchamp on Research Ethics and Animals, Vanessa Northington Gamble discussing Race and Bioethics, Jim Childress on Ethics and Public Health, and will conclude on Friday with the esteemed Ed Pellegrino discussing Virtue in the Caretaking Professions. We’ll offer special topics on Ethics Committees, Feminist Bioethics, Human Stem Cells: A Global Perspective, and the always popular Bioethics movie matinee. IBC 35 has been approved to award 26.5 CME Category I credits for physicians attending all approved sessions. Individual tuitions have been increased to $1650 for the five-day course, with a discount of $50 for early registrants. We will award tuition scholarships to as many deserving applicants as possible, and they will fall into two categories — participants from overseas with significant travel costs, and other participants who may receive a discount in their tuition if they can demonstrate significant contribution to their communities as a result of their attendance.

Please see the website for all details of the course, with additional information to be posted, including this year’s full brochure, soon. If you have not attended in a few years, we’d be delighted to see you again, or we’d be pleased to have you recommend our course to your colleagues.

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The table represents a list of books available from the KIE bookstore, including their titles, authors, publishers, member prices, non-member prices, and quantities. The form includes sections for payment details, address information, and notes on the number of books ordered and the total amount enclosed.

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The Brennan Lecture, which focuses on bioethics, is highlighted, discussing the challenges in the field and the upcoming intensive bioethics course (IBC 35). This course covers various topics including justice and health care, research ethics, and public health, among others. It also offers special topics and film sessions.

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Save the Date!
Intensive Bioethics Course 35!
Bioethics: Beyond the Soundbite
June 1 - 5, 2009

Library News

Writers, Internet surfers, bloggers, indexers, and journalists alike may find the Bioethics Thesaurus Database useful. This latest tool contains more than 1,300 terms used in indexing materials for the GenETHX database. Terms can be used to assign keywords to articles or blogs you write, to search the Web, or just to learn more about relationships of bioethics terminology.

The online Bioethics Thesaurus Database allows one to: 1) download a full list of used terms and cross references, 2) search for more detailed information about each term or phrase, or 3) examine all entries beginning with a particular letter of the alphabet. The foundation of the database is the original Bioethics Thesaurus, used to index BIOETHICSLINE from 1975-2000. It has been extensively updated – particularly to include new genetics terms. See “Search Tips” for more information. We welcome your comments and suggestions.

A grant was awarded to Susan Cartier Poland, J.D., Research Associate, in October 2008 by the Bioethics Policy Research Center (BPRC), established at Ewha Womans University in Seoul. Ms. Poland wrote an analysis of the laws, regulations and policies in the United States relevant to embryonic research and genetic research, basing her discussion on cultural, political, and professional factors.

And a word about “news” that doesn’t grow stale . . . .

The library staff has just completed its busiest conference schedule ever, offering exhibits and training sessions since September in Richmond, Baltimore, Cleveland, Murfreesboro, Washington, and Philadelphia. If we missed you, please visit the “news” page on our website for overviews and updates of the topics discussed. The many links to conference themes and topics take you directly to searches of the ETHXWeb database. The secret behind the ongoing currency of these searches is that the database is refreshed every other week. Since the items are displayed with the most recently-published materials cited first, you can easily continue to track writings on all these topics. A similar approach is built into the new Quick Links pages, which rely on a variety of pre-formulated searches as well as links to other web sites. Quick Links cover: advance directives; Asian bioethics; Catholic bioethics; clinical research ethics; feminism; Jewish bioethics; nanoethics; and women, infants and children in health care and research. “Retrieve a Bibliography” at http://bioethics.georgetown.edu functions in a similar way.

Congratulations to Fazel Hanif, husband of Moheba Hanif (long-time staff member at the KIE) on his acceptance into The EHLS Scholarship Program at Georgetown. Fazel has just returned from a 5-year assignment in Afghanistan. The EHLS program seeks to enable naturalized citizens to develop their English skills for professional careers in the federal government, and is a partnership among the National Security Education Program (http://www.ndu.edu/nsep/), the Center for Applied Linguistics (http://www.cal.org/), and Georgetown.