It would seem cutting first from those who have fewer claims on our resources may indeed mean cutting from the state’s most vulnerable residents. To be sure, some of those who would lose their access to kidney transplants under tough eligibility requirements are well-off enough to pay for treatments themselves. But since pediatricians need to use many or even most of these drugs in children, it is assumed those who contribute less by paying fewer taxes, etc. On these grounds alone, the policy is questionable, and therefore not only is the policy mean-spirited, it doesn’t even make sense.

But since pediatricians need to use many or even most of these drugs in children, it is assumed those who contribute less by paying fewer taxes, etc. On these grounds alone, the policy is questionable, and therefore not only is the policy mean-spirited, it doesn’t even make sense.

The Children’s Working Group, developed a report focusing on protection of child subjects. In summer 2000 the newly-chartered National Human Research Protections Advisory Committee was asked to give particular attention to this topic. A subcommittee, the Children’s Working Group, and then pursue related issues. Questions were immediately raised about its charter to emphasize research on embryos and fetuses, a particular interest of the Bush administration. In fact, Chair Ernest Prentice has stated that the “first priority is going to be additional protection of children.” Prentice anticipates that SACHRP will “endorse, clarify, amend or expand upon” the report of the Children’s Working Group, and then pursue related issues. In this regard, local IRBs need better guidance regarding portions of the federal regulations whose meaning has not been tested for use in research on children, local IRBs need better guidance regarding portions of the federal regulations whose meaning needs to be clarified. Children have frequently been used as “guinea pigs” in research, merits particular attention. The charge that research has led to calls for reform in our system for protecting human subjects. The protection of children, research has led to calls for reform in our system for protecting human subjects, research has led to calls for reform in our system for protecting human subjects.

A series of widely-publicized abuses in human subjects research has led to calls for reforms in our system for protecting human health. The protection of children, particularly the inadequate testing of drugs and biologics used to treat children, must be taken seriously.

On the other hand, children have frequently been described as “therapeutic orphans” because of the paucity of research on the health and development of children, particularly the inadequate testing of drugs and biologics used to treat children. This paucity of research on the health and development of children, particularly the inadequate testing of drugs and biologics used to treat children, has led to calls for reforms in our system for protecting human subjects. The protection of children, particularly the inadequate testing of drugs and biologics used to treat children, has led to calls for reforms in our system for protecting human subjects.

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"Children as Research Subjects: Guinea Pigs or Therapeutic Orphans?"
By Carol Tauer, PhD

From the Director...
In 1983, the FDA determined that pediatric testing of certain drugs was no longer required rather than voluntary.

When the FDA does not require pediatric testing, the manufacturer must state on the drug's label that it has not been adequately studied in children. This is a departure from the usual practice, where pediatric studies are conducted to ensure the safety and efficacy of the drug for use in children. The FDA's decision was based on the belief that the risks and benefits of the drug could be assessed adequately without subjecting children to the testing.

The FDA's action was intended to reduce the burden on children and their families, especially in cases where the drug is already approved for use in adults. However, some critics argue that the decision may lead to a decrease in the safety of medications for children, as the absence of pediatric data may result in the underestimation of potential adverse effects in this population.

The following examples of research involving children illustrate some of the controversies that surround this issue. The examples highlight the importance of balancing the need for scientific progress with the ethical considerations of protecting children.

**Human Growth Hormone for Short Children**

The development of synthetic human growth hormone (HGH) in the 1980s provided a potential supply of the hormone for the treatment of children with growth hormone deficiency. However, the treatment was not without controversy, as questions arose about whether the drug should be used for height enhancement purposes, particularly in healthy short children. This study raised conceptual issues about the concept of “minimal risk” research and the interpretation of federal regulations protecting children in research.

In the 1970s, a randomized controlled trial of HGH was initiated to assess its effects on growth in children with growth hormone deficiency. The trial aimed to enroll 80 children, give half of them HGH, and observe the effects on their height. The study was designed to demonstrate the safety and efficacy of HGH for use in children, but it failed to show a significant long-term effect on height gain.

The results of the trial were published in 1987, and the FDA subsequently issued a new policy that required pediatric studies for certain drugs. However, the controversy over the use of HGH for height enhancement purposes continued, leading to further debates and discussions within the scientific community.

The meaning of the concept of “minimal risk” research, which is regulated by the FDA, has been argued for decades. Proponents believe that allowing a “minimal increase in minimal risk” is beneficial to children who have a “disorder or condition” and can receive a variety of benefits. The FDA's decision to require pediatric testing for certain drugs was seen as an attempt to balance the ethical considerations of protecting children with the need for scientific progress.

The following examples of research involving children illustrate some of the controversies that surround this issue. The examples highlight the importance of balancing the need for scientific progress with the ethical considerations of protecting children.

**Ethical Dilemmas in Research Involving Children**

The ethical dilemmas in research involving children are complex and multifaceted. Issues such as consent, the ability to make informed decisions, and the potential for harm or benefit must be carefully considered. The FDA's decision to require pediatric testing for certain drugs was seen as an attempt to balance the ethical considerations of protecting children with the need for scientific progress.

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In requiring the testing of drugs for use in children, the Food and Drug Administration have encouraged the conduct of clinical trials with children. Opponents of this argument, stating that the FDA’s rule exceeded the agency’s authority to require pediatric testing. The FDA took care to note that clinical trials can and should be done without violating federal regulations or ethical norms.

Carol Tauer, PhD
University of Minnesota

In 1999 she was appointed to another NIH panel to recommend federal guidelines for research using stem cells derived from surplus IVF embryos. In 1994 Professor Tauer was appointed to the Human Embryo Research Panel that was charged to make recommendations to the National Institutes of Health (NIH) on ethical standards for federally-funded IVF and embryonic research. Although the recommendations of this panel were not adopted by the NIH, they have served as guidelines for other organizations and for privately-funded research.

Selected Publications

Basic Chapters


Bioethics Examiner

Involved greater than minimal risk. However, a majority approved the research on the basis that the subjects had a “disorder or condition” that were very short. Fast forward to 2003: Eli Lilly and Company asked the FDA to approve its HGH drug Humatrope for a new indication: unexplained short stature. Lilly based its application on the NIH study, for which Lilly had provided Humatrope, and on a randomized open-label European trial involving 399 children. The two trials showed that children on Humatrope gained an average of 1 to 3 inches of height.

On June 10, 2003 the FDA’s advisory committee on endocrinology drugs concluded that data from the studies demonstrated statistical effectiveness. Some wondered, however, whether the drug would improve short children’s lives overall. (In fact, there is considerable psychological research that shows that shortness per se is not correlated with psychological or life adjustment problems.) On July 2 the FDA gave final approval to labeling Humatrope for the treatment of non-growth hormone deficient but short children, the first approval of GH for healthy children who are simply at the low end of the normal curve (the shortest 1 to 2 percent). FDA approval unfortunately bypasses an unfinished debate to determine if the type of “disorder or condition” that justifies such burdensome research on healthy children?

S<small>IMPLA</small>N<small>S</small> IMMUNIZATION

Because of fears regarding use of smallpox as a bioterrorist weapon, doses of smallpox vaccine were resumed in late 2001. Since only limited amounts of vaccine were immediately available, diluted versions were tested in adults to determine whether they worked in children. Subsequently a study was proposed to compare response to the diluted and undiluted forms of the vaccine in children. Specifically children between 3 and 5 years of age.

The study was designed to enroll 41 children at two centers. The IRB for one center approved the study while the other did not, instead referring it for review by a federal panel. Panel members questioned whether this study was really necessary, whether children were expected to be the same as adults. Smallpox vaccine is known to carry a risk to pregnant women, and administration to adults in recent months has shown that adverse events do occur. Although this risk might be balanced by potential benefit to children in the study if they happen to be exposed to smallpox in the future, commentators agreed that the probability of such exposure was virtually zero. In January 2003 authorities at the NIH and the FDA determined that "there is no justification for the particular investment in children." In this case the purpose of federal public health research is to prevent an unnecessary and possibly harmful study involving very young children.

CLASSIFICATION OF AIDS FOR RESEARCH WITH CHILDREN

While we continue to conduct some types of research on children, local IRBs need better guidance regarding the protection of child subjects. In summer 2000 the newly-chartered National Human Research Protections Advisory Committee was asked to give particular attention to this topic. A subcommittee, the Children’s Working Group, developed a report focusing on portions of the federal regulations whose meaning was long divided investigators and application had not been renewed when it expired in summer 2002. Instead a new committee, the Secretary’s Advisory Committee on Human Research Protections (SACHRP) was established. Questions were immediately raised about its purpose, particularly in light of its establishment by the Bush administration. The new committee’s charter also mandates particular attention to research involving children. In fact, Chair Ernest Prentice has stated that “the first priority is going to be additional protection of children.” Prentice anticipates that SACHRP will “endorse, clarify, amend or expand upon” the report of the Children’s Working Group, and then pursue related issues such as compensation for children in research.

In summary, commentators agreed that the probability of such exposure was virtually zero. In January 2003 authorities at the NIH and the FDA determined that “there is no justification for the particular investment in children.” In this case the purpose of federal public health research is to prevent an unnecessary and possibly harmful study involving very young children.
to greater consensus on the ethical standards for evaluating such protocols. Committees like IACUC expect to produce guidelines that are more specific and helpful than the federal regulations.

Center News

Awards

John Song, MD, MPH, MAT, has been awarded a two-year National Institutes of Health (NIH) grant of $108,000 to explore the end of life (EOL) concerns and wishes of perhaps the most marginalized people in our society, those who live without the security of a home. Professor Song, along with Center colleagues Dianne Bartels, RN, MA, PhD, and Edward Kamin, MD, will conduct a qualitative investigation utilizing focus groups with several objectives including an exploration of the conceptions, concerns, and desires of homeless individuals regarding dying, EOL care and death, identification of the barriers that homeless individuals have to quality EOL care, and a description of the interpersonal relationships and communication challenges of homeless people related to these issues.

John Song, MD, MPH, MAT, is lead investigator of the University of Minnesota Medical School’s participation in the American Medical Association’s (AMA) Strategies for Teaching and Evaluating Professionalism (STEP) program. The University is one of ten partner schools chosen by the AMA to participate. The STEP Program was developed by the AMA in response to the need to prepare them to address difficult challenges such as appropriate end-of-life care, conflicts of interest, and the disclosure of medical errors. Through the STEP program, partner schools will develop and evaluative tools to help medical educators at the participating institutions as well as other medical schools.

John Song, MD, MPH, MAT, and Eric Moingin, MD, direct the new Phillips Neighborhood Clinic recently opened by the University of Minnesota during its "National Cover the Uninsured Week." The clinic is a partnership between the University of Minnesota Academic Health Center, the Community Health Care Center, the Center for Health Interdisciplinary Programs, and the Opiate Prevention Church. The clinic provides high-quality, affordable care, and, in many cases, free-health care to uninsured and underinsured people living in the Phillips Neighborhood of Minneapolis, with a focus on those who are homeless. No one is denied care for lack of ability to pay. Dr. Song opened the clinic three years ago. The clinic opened its doors in March 2003 with the help of enterprising and dedicated medical, physical therapy, pharmacy, nursing, and public health students from throughout the Academic Health Center.

Continued from Page 4

The January 2004 issue of the Bioethics Examiner is now available online and as a Reading Packet. A Guide to Research Ethics Reading Packet is available on the Center’s website at ce.cbm.umn.edu. The packet highlights key ethical considerations in scientific and health research and includes valuable on-line resources, case studies, and a glossary of terms. For further information on the graduate minor program visit the Center’s website at ce.cbm.umn.edu.

A Guide to Research Ethics:

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Continued from Page 4
This article previously appeared on the Op-Ed page of the Minneapolis Star Tribune.

In the face of the various rationing policies currently in place, those who seek care are dependent on the availability of resources, the acuteness of their presenting problem, and the extent of the problem itself.

The press release that accompanied the Minnesota Health Department’s release of the state’s trauma guidelines, “Whose Morality is It Anyway?”

The American Bar Association (ABA) meeting “Working in the United States” at the Hill, NC. For information, call 651-662-1330.

The Hippocratic Oath and the Ethics of Medicine.

Bioethics and Humanities Studies of Science Annual Conference, Minneapolis, MN. For information, call 612-870-1662.

The Ethics of Organ Transplantation of Africa: Images from South Sudan.}

The Ethics of Organ Transplantation of Africa: Images from South Sudan.

What have the experts who evaluate organ transplants in the state of Minnesota determined about who gets to wait? It seems they have not based their decision on whether the individuals who apply for organ transplants can pay for the transplant.

...or the voices of the patients who have waited the longest. The state of Minnesota has a long history of rising to this test, but we begin to fail when we cut services from those who have little if any voice. Frankfurt School famously taught us that the real test of a society is how it treats its least well off. Minnesota shouldn’t be the State of Minnesota in 2003.

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John Song, MD, MPH, MAT, will speak on end of life care Sept 30.

Stem Cell Research will be the keynote speaker Sept 17.

Jeffrey Kahn, PhD, MPH, will speak on “Ethics of Organ Allocation: What is Justice?” Sept 15.

Jeffrey Kahn, PhD, MPH, will present “Bedside Ethics, Complex Choices for Complex Patients” at the Frontier of Law and Science: Applications for the Human Genome in Pre-Implantation Genetics Analysis of Embryos for Stem Cell Research” at the North Carolina Coalition Annual Reunion Conference, St. Paul, MN. For information, call 651-662-1330.

Jeffrey Kahn, PhD, MPH, will speak on “At the Tipping Point: The Ethics of Cloning” at the National Clinical Education (CME), University of Minnesota, Minneapolis, MN. For information, call 612-870-1662.

Jeffrey Kahn, PhD, MPH, will speak on “The Ethics of Organ Transplantation of Non-Human Primates” at the 3rd Annual Conference on “Perspectives on Nursing Theory and Practice,” New York, NY. For information, visit www.lsu.edu/ssss/.

Jeffrey Kahn, PhD, MPH, will speak on “Ethics in Policy Analysis” at the Comparative Policy Research Network, University of Minnesota, Minneapolis, MN. For information, email raichert@epi.umn.edu.

Steven Miles, MD, will speak on “Ethics and the Mentally Ill State for the Mentally Ill State” at the Society for the Social Studies of Science Annual Conference, St. Paul, MN. For information, visit www.sscs.org.

Steven Miles, MD, will speak on “Ethics and the Mentally Ill State” at the New England Directors for Mental Health Management, Blue Cross Blue Shield of Maine, Portland, ME. For information, call 207-526-6500.

Steven Miles, MD, will speak on “Ethics in Medicine” at the AAAMB Annual Meeting and Exhibition, San Francisco, CA. For information, visit www.aaamb.org.

Steven Miles, MD, will speak on “Health Care Reform” at the National Alliance for Health Information Privacy, St. Paul, MN. For information, call 651-254-7154.

Steven Miles, MD, will speak on “Evidence-Based Health Policy: Critical Analysis of Evidence for Song Cell Transplantation” at the American Society of Transplantation, Minneapolis, MN. For information, call 612-622-1927.

Steven Miles, MD, will speak on “Policy and Intervention: A New Perspective on Interventions for Public Health: a New Public Health” at the Association of Environmental Health Sciences Foundation, Homeland, NC. For information, visit www.aehsf.org.

Joan Liaschenko, RN, PhD, will speak on “=Public Health: a New Perspective on Interventions for Public Health: a New Public Health” at the Association of Environmental Health Sciences Foundation, Homeland, NC. For information, visit www.aehsf.org.

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On Dec 4, Steven Miles, MD, will speak on “The Hippocratic Oath of the Ethics of Medicine” at the Annual Meeting of the American Public Health Association (APHA), New Orleans, LA. For information, visit www.apha.org.

Garrison, MN. For information, visit www.garrisonmn.org.

Conference “Our Way” at the Minnesota Coalition Annual Reunion Conference, St. Paul, MN. For information, call 651-662-1330.

At the Wisconsin Medical Association/Medical Foundation of Chattanooga, Inc., Chattanooga, TN. For information, call 423-622-2872.

Northwestern Hospital, Minneapolis, MN. For information, email info@northwesternhospital.org.

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For more information, please contact Elizabeth Chambers at elizabethchambers@umn.edu or 612-624-9108.

Center Faculty & Staff

Assistant Director
LeeAnne Hoekstra

Director
Dianne Bartels, RN, MA, PhD

Debra DeBruin, PhD, and Edward Ratner, MD, will conduct a qualitative investigation utilizing focus groups with several objectives including an exploration of the conceptions, concerns, and desires of homeless individuals regarding dying, EOL care and death, society, those who live without the security of a home. It is possible that the research will provide evaluative tools to help medical educators at the medical schools.

The Center for Bioethics will have a number of ongoing projects that focus on the ethical and legal issues raised by the International HapMap Project (IHP), an effort to create a haplotype environment & the Life Sciences will work with Dr. Kahn on the project. Together with a working group of leading scholars from across the country they will present the danger that social categories of race and ethnicity will be mistaken for biological categories and thereby fuel race and ethnicity-based stigma and discrimination. This research will provide further information on the graduate minor program in Bioethics, with support from the Starr Foundation, has developed a new educational reading packet. The packet highlights key ethical considerations in scientific and health research and includes valuable evaluative tools. This reading packet is available on the Center’s website at www.bioethics.umn.edu.

Announcing New Center Reading Packet
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