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IN THIS ISSUE

Congress shuts door on cloning, but don't lock it just yet, experts say

Dangerous human experimentation or vital research?

Even as a panel of experts at the National Academy of Sciences engaged in heated debate last month over plans by some scientists to begin cloning of humans, the U.S. House of Representatives attempted to settle the matter once and for all by voting overwhelmingly to ban cloning of human embryos for any purpose.

The bill, known as the Human Cloning Prohibition Act of 2001, was introduced by Rep. **Dave Weldon** (R-FL) and passed 265-162. An amendment proposed by Rep. **Jim Greenwood** (R-PA) to allow embryo cloning for "therapeutic" purposes was defeated on a vote of 178-249.

If passed by the Senate in its current form, the proposed law would impose a fine of up to $1 million and a 10-year prison term for any person who "performs, attempts to perform, or participates in human cloning" or who "knowingly ships or receives for any purpose an embryo produced through human cloning."

Supporters of the bill say it will halt dangerous human experimentation, while opponents argue that it will prohibit much-needed medical research. And that it will put the United States behind other countries, such as Great Britain, which allows the "therapeutic" cloning of embryos for research purposes — provided the embryos are not allowed to develop past a certain stage.

Stuart Newman, PhD, a professor of cell anatomy and biology at New York Medical College in Valhalla,

COMING IN FUTURE ISSUES

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testified before Congress in favor of the Weldon bill, and says it is high time lawmakers reigned in research in this area.

"Even those things that are not federally funded, I would like to see regulated," he states. "And certain things, like cloning of human embryos and manipulation of human embryos, I would like to see made against the law."

Newman is a founding member of the Council for Responsible Genetics, which opposes the buying and selling of human eggs and embryos, the manipulation of all human eggs or embryos by "transfer of cells, nuclei, cytoplasm, mitochondria, chromosomes, or isolated DNA or RNA molecules of human or nonhuman origin."[1]

The council is in favor of banning the production of human embryos for research purposes whether the source of funds is public or private, Newman says. Even if a cloned embryo is created for "therapeutic" purposes, there is too little standing in the way of these embryos then being used for reproductive purposes.

"At that point, gestation of cloned embryos would easily become defined as a matter of individual choice," he says.

As evidence of the "slippery slope" argument, he points out that many scientists have long been opposed to the creation of human embryos through fertilization to be used solely for research purposes. But, once a technological need was shown for embryos in research, many scientists have now tried to make a distinction between those embryos and cloned embryos.

Embryo cloning will inevitably lead to the production of "experimental" human beings, he says.

"We shouldn't be producing new kinds of embryos because of the possibility they will be used to create new kinds of humans," Newman says. "We have made these kinds of moral decisions before. We don't constantly revisit the slavery question, or the voting rights for women question. There are certain things that are done once we have made cultural progress. And I think deciding to not create and manipulate human embryos is that kind of thing."

Do our genes define us?

Attempting to clone humans at this point in time is unethical and irresponsible because it is unsafe, says **Gregory Pence**, PhD, a bioethicist and a professor of arts and humanities at the University of Alabama-Birmingham.

Current cloning experiments still see high rates

of unexplained mortality in the cloned animals, which is ethically unacceptable for human beings, he believes.

"Bringing a baby to birth is unsafe right now," he notes. "We need to try primate studies first. But I don't think we should throw the baby out with the bath water and ban embryonic cell cloning."

Same genes, different person

Pence questions the argument that cloning of embryos, even for reproductive purposes, violates the dignity of human life.

"There is sort of a philosophical crisis that is going on — that is, everybody has bought into the concept of genetic essentialism," he says. "I think one of the reasons people are so opposed to human cloning is that there is this huge message that, if you re-create the genes, you re-create the person."

Even if a person was created with the same genes as an existing person, the "clone" would have different experiences and be raised in a different environment than the original person, he argues.

"And, people are all assuming that the cures to diseases will be genetic, which is amazingly naive," he says. "Even when you have single-gene diseases, they are usually triggered by environmental factors, or are multifactorial both on the genetic side and environmental side. In the '60s, when I was in college, everything was environmental — you had DES [diethylstilbestrol] babies and thalidomide. And now nothing is seen as environmental; it's all genetic."

The number of theologians and religious figures opposed to cloning also has surprised him, he adds. "Even when you think someone would argue that the soul is immortal, and that it doesn't matter what genes you have, no one seems to be saying that. They are saying it is a real threat to personhood, to dignity."

Bill may ban more than cloning

Whether you are in favor of or against cloning human beings, another concern is that the language of any legislation banning "cloning" may prohibit more than the public realizes, says **Maxwell J. Mehlman**, JD, professor of law and bioethics at the Center for Biomedical Ethics at Case Western Reserve University in Cleveland.

"There has been concern that, depending on how the language reads, that laws could prohibit cloning of cell lines and reproduction of individual cells," Mehlman says.

Such a ban could affect many different types of research, he adds.

Pence agrees that the wording of the House bill could be construed to restrict more than embryo cloning, but Newman disagrees.

"I think the Weldon bill was prepared by

CME questions

9. The proposed Human Cloning Prohibition Act of 2001 would have banned:
   A. reproductive cloning only.
   B. reproductive and therapeutic cloning.
   C. replication of cell lines.
   D. none of the above

10. The company that may hold claim to the universal rights to research embryonic stem cells is:
   A. Geron Corp.
   B. Wicell Research Institute.
   C. Wisconsin Alumni Research Foundation.
   D. Celera.

11. In developing its guidelines for behavioral health services, Community Hospitals of Indianapolis decided that:
   A. treatment methods that were physically non-intrusive should be preferred over methods that are intrusive.
   B. treatment methods that affect the individual's sense of identity should not be used.
   C. treatment methods that support self-respect are encouraged.
   D. all of the above

12. In the *Wendland* case, the California Supreme Court ruled that:
   A. life support on an incompetent patient could not be terminated by a conservator without prior written instructions from the patient.
   B. Life support on an incompetent patient could not be terminated by a conservator unless the patient was brain-dead or in a persistent vegetative state.
   C. For patients neither brain dead nor in a persistent vegetative state, but who were minimally conscious, a conservator would need "clear and convincing evidence" that cessation of life support in that circumstance would be the wishes of the patient.
   D. none of the above

people who were cognizant of that [issue] and the language clearly just restricts using nuclear transfer to create embryos," he says.

Cloning: A reproductive right?

Pence also is concerned that the proposed law would make it a crime to "receive" a cloned embryo. "That might mean that a woman from the United States who went to England and underwent a procedure to receive a cloned embryo could be arrested upon returning home," he contends.

Some legal experts have indicated they will launch a constitutional challenge to the law, if it is passed, Pence adds. "The government cannot tell you whether or not you can use birth control. We have interpreted that people have the right to use assisted reproduction without interference, how can they ban this form of reproductive technology?"

Reference

1. Board of Directors of the Council for Responsible Genetics. *The Genetic Bill of Rights.* Accessed on the World Wide Web Aug. 17, 2001. http://www.gene-watch.org/bill_of_rights_text.html. ■

Experts divided over impact of Bush stem cell decision

Will stricter guidelines shut down research?

President Bush's recent decision to allow federal funding for embryonic stem cell research is drawing mixed reviews from scientists and bioethicists across the country.

Some approve of his permitting the research under more limited circumstances than the Clinton administration, while others predict the new guidelines will effectively end such research.

"This is basically just shutting it down," says **Gregory Pence**, PhD, a bioethicist and professor of arts and humanities at the University of Alabama-Birmingham. "It is only going to be approved in a very limited number of stem cell lines."

Federal law prohibits the use of federal funds to support research involving the destruction of human embryos, and harvesting embryonic stem cells necessitates the destruction of the embryo.

However, in 1999, the U.S. Department of Health and Human Services announced an interpretation of the law that allowed federal funds to be used to research stem cells as long as researchers worked only with stem cells themselves (not embryos) and could document that no federal funds were used to actually derive the cells. The National Institutes of Health developed guidelines for researchers interested in submitting proposals, but the process was put on hold with the change in administration.

Last month, the president announced he would permit the funding, but only to support research using any of the estimated 60 cell lines already in existence worldwide and, of those, only the lines that researchers could verify were developed from embryos leftover from infertility treatments and not those created specifically for research purposes could be used.

Bush also announced the creation of a new Council on Bioethics, to be chaired by University of Chicago bioethicist **Leon Kass**, MD, PhD, which will evaluate stem cell research proposals.

Kass is a well-known opponent of abortion, cloning, in-vitro fertilization, and has criticized embryonic stem cell research in print, Pence notes.

Some feel restrictions are needed

Although the new restrictions may slow the process of embryonic stem cell research, that may not necessarily be a bad thing, says **Stuart Newman**, PhD, professor of cell biology and anatomy at New York Medical College in Valhalla and a founding member of the Cambridge, MA-based Council for Responsible Genetics. Newman is not opposed to research involving stem cells taken from embryos produced through infertility treatments, but does oppose the creation of embryos solely for research purposes.

"I don't believe we should go prematurely into human experimentation," he says. "It is striking to me that researchers have been working on stem cells in mice for 20 years and they haven't made that much progress. Maybe they just need to work on mice for awhile."

Where you stand on the ethics of stem cell research largely depends on whether you feel that human embryos are equal with human beings, or whether you feel they are just a group of cells, says **Maxwell J. Mehlman**, JD, professor of biomedical ethics and the law at the Center for Biomedical Ethics at Case Western Reserve University in Cleveland.

"My own opinion is not quite either — that they [embryos] are a form of potential human life,

even though they aren't human beings," he says. "Therefore, they should be accorded a certain amount of respect."

Ethically, one should also consider the potential benefits to existing people that medical advances from stem cell research could provide, he adds.

Where he has a problem with the current debate on stem cell research, he says, is the relative lack of attention to the number of embryos that end up being discarded through in-vitro fertilization (IVF) procedures.

"If we truly feel that destruction of human embryos is equal to the destruction of human beings, then maybe we should re-examine IVF, although I don't see that happening," he says.

Access to cell lines may be even more limited

Although Bush said his administration would permit research into 60 existing embryonic stem cell lines, many scientists questioned whether there were even that many available.

The administration claims it has documentation for 60 lines worldwide, though it does not know how many of these lines will meet the administration's criteria. In addition, there are concerns by researchers that some of the lines will not be of sufficient quality to study.

And, an article in the Aug. 13 *Wall Street Journal (WSJ)*[1] raises concerns that cell lines developed with private funding are covered by patent protections, which will further hinder some researchers in obtaining cells to work with.

According to the article, the Wisconsin Alumni Research Foundation (WARF), a for-profit affiliate of the University of Wisconsin, owns the fundamental patent governing all embryonic stem cells, regardless of which cell line they come from. Researchers at the University of Wisconsin originally discovered the potential of embryonic stem cells to eventually form any kind of human tissue.

"No matter how you derive a stem cell line, WARF has the right to block you from using it," **Arti Rai**, a University of Pennsylvania patent lawyer told the *WSJ*.

In fact, the foundation filed suit in August in U.S. District Court in Madison, WI, against Menlo Park, CA-based Geron Corp., claiming that Geron had tried to stop WARF from working with other researchers. Geron has a licensing agreement with WARF that gives it the commercial rights to certain cell types grown from the five stem cell lines developed by the university.

Both parties have since announced plans to settle the dispute out of court.

A key concern about restricting federal funding of genetic research is that, typically, research in the private sector occurs without accompanying federal oversight — the accompanying stricter rules governing research protocols and informed consent requirements, says Mehlman.

"And the goal of publicly funded research is to achieve benefits for the society at large," he adds.

If stem cell research is left largely up to the private sector, which develops innovated diagnostic and treatment options for disease, will those benefits be reserved only for the wealthy?

Private companies who invest significant time and money in stem cell research to develop medical tests and treatments will want to make their products available for whatever the market will bear, Mehlman says, which will probably be a considerable amount. "Part of the benefit of public research is to secure the benefits of the research for everyone," he says.

SOURCES

- **Gregory Pence**, University of Alabama-Birmingham, Humanities Building, HB 420, Birmingham, AL 31260.
- **Maxwell Mehlman**, CWRU School of Medicine, 10900 Euclid Ave., Cleveland, Ohio 44106-4976.
- **Stuart Newman**, Basic Science Building, New York Medical College, Valhalla, NY 10595.

Reference

1. Regalado A, Carroll J, Johannes L. What access will researchers have to the 60 existing stem cell lines? *Wall Street Journal* Aug. 13, 2001. ■

Send us your thoughts

We'd like to know if President Bush's compromise on stem cell research will impact current medical research programs at your facility. Will restrictions on the use of existing stem cell lines mean changes or eliminations to planned research or programs already in place?

Let us know how your hospital is affected. Send your comments to Kevin New, managing editor, *Medical Ethics Advisor,* P.O. Box 740036, Atlanta, GA 30374. E-mail: kevin.new@ahcpub.com. ■

Network forms behavioral health ethics committee

Different issues requires different committee

Hospitals that offer behavioral health services (substance abuse counseling, residential mental health, and outpatient counseling) may want to consider forming a separate subcommittee of their regular bioethics committee to examine specific organizational and clinical treatment issues.

Community Hospitals of Indianapolis Inc., a central Indiana integrated health network of four tertiary care hospitals, six immediate care centers, three nursing homes, and other specialty care centers, did just that after providers decided they needed a better framework for addressing ethical challenges unique to behavioral health care.

"Behavioral care is a far different kind of care than medical-surgical types of care," says **Mel Schroeder**, director of pastoral care for Community Hospitals, and a member of both the network's organizational ethics committee and the new behavioral health ethics committee. "Behavioral care involves complicated relationships with payers, deciding who defines coverage, how the level of payment is determined, for example, what regulatory bodies are involved, and how government agencies get involved. It is a lot more complex, and there tends to be a lot more issues than simple ethical biomedical issues."

"Behavioral care is a far different kind of care than medical-surgical types of care. . . . It is a lot more complex, and there tends to be a lot more issues than simple ethical biomedical issues."

Complex issues involved

In behavioral health, you have issues of competence, of consent for treatment, and even treatment benefit, that are much more complex than what occurrence in medical-surgical sites of care, says **Paul Stewart**, MD, PhD, medical director of the network's behavioral care services.

"A patient's competence for making treatment decisions often is in question," he notes. "Sometimes you have family wishes that are opposed to patient wishes and maybe aren't serving the patient well, whether they are conscious of it or not, are really based on family inconvenience or family pressures."

After attending a conference on managed care and ethics, she decided to find out how ethical conflicts in behavior health were resolved in her service area, says **Sue Main**, quality resources coordinator for behavioral care services at Community Hospitals.

"I began to look at what we did when managing ethical questions that arose," she recalls. "I found some gaps. Typically, a staff person would just talk to another staff person about ethical questions; sometimes they'd go to their manager."

Year of preparation before opening

The providers of behavioral health at the hospitals wanted to establish a procedure that ensured that the treatment decisions made reflected the appropriate clinical and ethical values and that their decision-making process was examined and scrutinized, says **Jon Hendrix**, EdD, a private bioethics consultant who advises the hospital system and helped establish the committee.

The committee spent about a year in preparation before "opening its doors" for ethical consultation. During that period, they chose members of the committee, and went through a process of education and development of ethical guidelines and priorities that would govern their services.

"We looked at things such as what is coercive or what is voluntary in treatment," Hendrix adds. "Sometimes, we have to institutionalize people because they are mentally ill; that is often very coercive and not very voluntary."

The committee also reflected on a set of basic principles that should guide the delivery of their services, he says.

"They decided, for example, that methods that support self-respect should be encouraged; methods that are not destructive of individuals' ability to reflect rationally should be used whenever possible; and methods which rely upon deception or which affect the personal identity of individuals should not be used," he says. "Methods of influence which are physically nonintrusive are to be preferred over methods that are intrusive."

The process is not as simple as it may sound, given the number of different therapies and treatment modalities that have been open to providers of mental health services and disagreements

between some experts over what treatments are appropriate or inappropriate, Hendrix emphasizes.

"The history of behavioral treatments has really been wrought with some wild things," he continues. "[including] shock therapy, chemical therapy, and behavior modification treatments."

Diverse membership

Community Hospitals has three separate bioethics committees, one at each of the three tertiary care facilities and an overall organizational ethics committee at the network level. The behavioral care ethics committee exists as a subcommittee of the organizational ethics committee, says Stewart.

"It's important to note that the bioethics committees at the hospitals are subcommittees of the medial staff at each of the hospitals," he says. "We are not just comprised of members of the medical staff, but have members who are from administration, quality resources, human resources, legal, the chaplain, as well as the clinical staff, psychiatrists, psychologists, and therapists who are on the front line."

The network provides a variety of behavioral health services, says Stewart. "We offer chemical dependency treatment as well as treatment for the emotionally ill. We have partial hospitalization programs, day and evening programs, and partial residential for both children and adults. We also own a traditional community mental health center. And, we have a special inpatient unit for the chronically mentally ill who need short-term stabilization."

It is important that the committee have representation from all of those levels of care as well as the representation from managers and administrative staff, he says, because the committee considers not only matters of clinical treatment, but other issues as well.

"One of the first issues that we took to the organizational ethics committee was the issue of confidentiality of mental health services for employees," adds Schroeder.

The committee uses a consequentialist model of bioethical decision making that takes into account not only how actions will reflect the organization's values and priorities, but also the potential consequences of each course of action.

Although the behavioral ethics committee members originally would have preferred that hospital employees seek mental health services elsewhere, after considering the financial difficulties this posed to the system, which is self-funded, they developed other recommendations.

"We ended up with some fairly substantial recommendations for the hospital to protect employees' confidentiality, but in a way that was also fiscally sound and didn't sink the hospital from the financial sense."

Futile care?

A current "hot-button" issue for the committee is the concept of futile care in behavioral care, says Schroeder. "This is a common bioethical issue in the medical-surgical arena. But, for mental health, that issue of futile care has not been addressed."

Their mental health providers are frequently asked to treat patients for whom they believe nothing more can be done to treat their illness, he adds.

"We have admitting physicians saying to our crisis folks, 'Please, please, please do not readmit so-and-so; treatment is of no value in this case,'" says Stewart. Federal legislation, however, requires hospitals to admit and stabilize patients who pose a credible threat to themselves or others.

How to deal ethically with that situation and with patients who have a history of violence to other patients or staff, also is a problem they face.

"How ethically do you deal with a patient who has a history of violence toward staff when he or she presents again for services?" asks Stewart.

In a recent situation, a severely mentally ill man with a history of violence, who had been a frequent patient in the mental health inpatient stabilization unit, was readmitted to the unit and threw a computer monitor at a staff person, barely missing her. After he was stabilized, the man was discharged and then taken to jail by police to finish serving a sentence for a crime that occurred prior to admission.

Several discussions by the behavioral ethics committee resulted primarily in recommendations to increase education of staff members and security personnel in how to deal with these potential problems.

"Surprisingly, our No. 1 choice was education: education of families, of patients, and staff; having enough well-trained staff, people who were sensitive to changes in patients who were prone to violence; and having security staff who were cross-trained to function as providers on the unit," says Stewart.

"We surprise ourselves. I think if you asked

SOURCES

- **Mel Schroeder**, **Paul Stewart**, and **Sue Main**, Community Hospitals of Indianapolis, Community Hospital North, 7250 Clearvista Parkway, Indianapolis, IN 46256.
- **Jon Hendrix**, 107 Glasgow Drive, Edinburgh, IN 46124.

any committee member, going into the discussion, what they thought their No. 1 recommendation would be, they probably would have said something like having more security personnel — not that we needed to improve education."

Take time in establishing committee

For other hospitals considering a behavioral care ethics committee, Stewart and the other committee members recommend taking time to establish guiding principles and learning about processes of ethical decision making.

"Don't do any quick-fix setup; make sure you take the time to train, read, and do some education," he says. "And, get the right people on the committee."

It would also be helpful for other committees specializing in behavioral health ethics to network and share information, says Main.

Most such committees are located at facilities that are primarily mental health providers. There are few tertiary care facilities that have taken this step, she believes. "It would be nice for us to have some contact with them and share ideas so we would not feel so isolated." ■

Federal study focuses on pediatric palliative care

Children don't receive same level of care as adults

Seriously ill children frequently don't get appropriate pain management and supportive services at the end of life because their conditions and treatments don't fit existing care models designed for adults.

But federally funded demonstration projects in five states are designing new ways of providing services to kids — ones that don't require parents and physicians to abandon treatments aimed at a cure in order to examine other options.

"The bottom line is, from the patient and family standpoint, we want to allow them to choose hospice-type care, which is really comprehensive compassionate care that is known as hospice, from the time of the diagnosis of a life-threatening condition, even when there is hope for a cure, through bereavement follow-up if a cure is not obtained," says **Anne Armstrong-Dailey**. Armstrong-Dailey is the director of the Alexandria, VA-based Children's Hospice International (CHI), the organization in charge of administering the projects and distributing the funds.

Last year, CHI received congressional funding for the first five demonstration projects of its Program for All-inclusive Care for Children (PACC). The PACC programs develop and coordinate comprehensive systems of care that allow seriously ill children and their families to have access to palliative pain management, supportive counseling and, in some cases, home health and hospice services even while curative treatment is pursued, says Daily.

This year, the program received an additional $885,000 from Congress, which will allow CHI to continue funding the existing five projects and start a sixth demonstration project in another state.

Studies have shown that more integrated models of providing palliative care and hospice support work best for children, as opposed to traditional "adult" models that have focused on providing palliative treatments to patients when there is little or no hope of recovery.[1,2,3]

Although advocates urge providers to see palliative care as part of the overall care plan for all patients, including adults, this inclusive approach is especially important for children, says **Cynda Rushton**, DNSc, RN, FAAN**,** clinical nurse specialist in ethics at Johns Hopkins Children's Center in Baltimore.

"Part of the problem with children is that sometimes their disease trajectories have been unpredictable," she explains. "Children who we think are not going to survive — they do. Then, you are sort of on this roller coaster of trying to figure out what the outcome will be."

In 1982, changes in the Medicare and Medicaid hospice eligibility standards required patients to have a physician's diagnosis that they were in their last six months of life. Additionally, all curative treatments must have stopped in order for hospice services to be reimbursed through Medicare and Medicaid. Many private health plans followed suit.

The result is that children are referred to

hospice very late in their course of illness, if at all, says Armstrong-Dailey.

"Seldom is a physician able to say — until it's at the very last moment — that the child is at death's door," she explains. "Most often, pediatric patients are in and out of the terminal stage for a number of years. And, how many parents do you know, or how many pediatricians do you know, who would be willing to stop curative treatments on a child, even if his or her chance for survival were one in 10 million?"

Lack of appropriate services a problem

Even if hospice referrals could be made in a timely manner, however, many communities don't have the resources to provide appropriate end-of-life care to children outside the acute-care setting, says Rushton.

"We don't have a lot of providers skilled enough to provide the care," she continues. "Some of it is lack of education and some of it is lack of specialized resources. Children, even in the end stages of their lives, still are usually receiving quite a bit of [medical] technology. We need people to be able to provide the emotional, psychosocial and spiritual support as well as some of that high-tech nursing care in the home."

Because seriously ill children typically need a high-level of medical interventions for a longer period of time, it is very difficult to get them plugged into existing services, she says.

'Terminal' should not be the focus

And, one of the main goals of PACC is to secure benefits of hospice services for chronically ill children who may not necessarily be near the end of life, says Armstrong-Dailey.

Families dealing with the serious, life-threatening illness of a child desperately need the supportive counseling and health care services that hospice provides for dying patients and that a comprehensive program should provide for all patients, she believes.

"I have personally talked with tens of thousands of parents over the past 20 years and, without exception, the parents will tell me that the time of crisis is the time of diagnosis, even when there is still hope for a cure," she says. "Most parents will tell you that the time of the child's death is anti-climactic, by comparison."

Parents of seriously ill children feel tremendous pain and guilt at the time of diagnosis, particularly if the disease is genetically linked, she notes. Families need help dealing with these issues early on in order to avoid preserve the strength of the family unit and appropriately make decisions about the care of the child.

"By dealing with these emotions, we can help families look at the situation in a realistic way, and to realistically examine what the options might be," says Armstrong-Daily. "It can help prevent the dysfunctional, destructive behavior that can shatter families. Without support, you often see an enormous increase in alcohol and drug abuse within families and destructive behavior by surviving siblings."

SOURCES

- **Anne Armstrong-Dailey**, Children's Hospice International, 901 N. Pitt St., Suite 230, Alexandria, VA 22314.
- **Cynda Rushton**, DNSc, RN, FAAN, Johns Hopkins School of Nursing, 525 N. Wolfe St., Baltimore, MD 21205.

Projects to provide important info for states

The demonstration projects will provide important information for states and communities that do not yet have systems in place to support pediatric palliative care.

Different states have different resources available and different levels of care already in place, she says. For example, in Florida, eight hospice programs that have been providing care for children are working in partnership with the children's hospitals in the state to coordinate services across the continuum of care. In Utah, there already is a network in place between two children's hospitals and the hospices and home health agencies statewide, while, in Kentucky, only two hospices — one in Lexington and one in Louisville — are in charge of designing a statewide effort.

"Each site is different from the others and we encourage that diversity," says Armstrong-Dailey. "What works in Tennessee is not necessarily going to work in Provo, UT."

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3. Masri C. Farrell CA, Lacroix J, et al. Decision-making and end-of-life care in critically ill children. *J Palliat Care* 2000; 16 Suppl:S45-S52. ■

Lung-volume reduction surgery too risky for some

Preliminary findings from the National Emphysema Treatment Trial, the multicenter trial evaluating the efficacy of a controversial lung-reduction procedure vs. conventional medical treatment, have found significantly higher mortality rates in some high-risk patients who received the surgery, according to an early report of an article to be published in the *New England Journal of Medicine*.[1]

The findings seem to support Medicare's decision in 1996 to restrict coverage of the procedure to subjects enrolled in a clinical trial, wrote **Jeffrey M. Drazen**, MD, in an editorial accompanying the article.

At the time, many emphysema patients and proponents of the surgery denounced the decision because it forced patients who wanted lung-volume reduction to either participate in research trials (where they risked assignment to the non-surgical control group) or pay for the procedure themselves. **(See "When should experimental surgery end?" *Medical Ethics Advisor,* September, 1998, p. 99.)**

Important findings

"These findings are important," Drazen states. "Some patients who were disappointed when they discovered they were in the control group can now be thankful that this assignment may have saved their lives. Indeed, in my opinion it does not make sense for anyone to undergo lung-volume reduction surgery outside a controlled trial."

Developed in the mid-1990s, lung-volume reduction surgery was a controversial procedure designed to improve the quality of life for patients with advanced stage emphysema. During the procedure, areas of emphysematous lung tissue were removed, reducing the overall size of the lung, theoretically improving lung function. Following the 1996 publication in the *Journal of Thoracic and Cardiovascular Surgery*[2] of one group's success with the procedure, many other centers began performing the surgery. Within months of publication of the original article, Medicare paid claims for 700 such procedures.

However, some patients did well after undergoing the procedure while other patients inexplicably did poorly. One of the goals of the national treatment trial is to determine which patients could be expected to do well with the procedure.

Preliminary results of the trial found that a subset of patients — those with a forced expiratory volume in the first second (FEV_1) that was 20% or less of their predicted value and either a carbon monoxide diffusing capacity that was 20% or less of their predicted value or evidence on computed tomography of a uniform pattern of emphysema throughout the lungs — had a 30-day mortality rate of 16% compared with a zero mortality rate when compared with medically treated patients with similar characteristics. And patients with these clinical criteria who survived after 30 days post-surgery did not appear to experience significant benefits from the procedure.

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2. Cooper JD, Patterson GA, Sundaresan RS, et al. Results of 150 consecutive bilateral lung-volume reduction procedures in patients with severe emphysema. *J Thorac Cardiovasc Surg* 1996; 112:1,319-1,329. ■

Life support must continue for noncomatose patient

In a case that was closely watched by the American Medical Association and several physician and patient advocate groups, the California Supreme Court unanimously ruled that life support cannot be withdrawn from patients who are not comatose or in a persistent vegetative state and have left no written instructions about their wishes.

The court upheld a lower court ruling in the

case that prevented a woman from removing the feeding tube from her severely disabled husband.

Robert Wendland, 49, suffered severe brain damage in a 1993 truck accident. His injuries left him in a "minimally conscious state," unable to walk, talk, eat, or go to the bathroom. In 1995, Rose Wendland, his wife and conservator, refused to consent to reinsertion of his feeding tube.

Although he left no written evidence of his wishes, Rose Wendland said her husband had indicated in several conversations prior to his accident that he would want to be allowed to die under such circumstances. However, Robert Wendland's mother, Florence, and sister disagreed and sued to have food and hydration maintained.

Robert Wendland died of pneumonia on July 17 of this year, but the court decided to rule anyway in order to clarify the law.

In stating the court's opinion, Justice **Kathryn Mickle Werdegar** wrote that Rose Wendland's account of the conversations she had with her husband did not "establish clear and convincing evidence that the conservatee would desire to have his life-sustaining treatment terminated under the circumstances in which he now finds himself."

However, the court noted that its ruling was confined only to a narrow group of people: people who are conscious and who have not left formal, written directions for health care.

California state law permits conservators to have the "exclusive authority" to give consent for medical treatment to be performed on the conservatee provided decisions are made in good faith and considering medical advice. Last year, the state legislature amended the law to specifically include health care decisions involving the withholding or withdrawal of artificial hydration and nutrition, though that provision was not in affect when the appeals court made its ruling.

The California Medical Association and the Los Angeles County Medical Association filed amicus curiae briefs with the court in support of Rose Wendland, contending that courts should not interfere in decisions that previously had been left up to doctors and families. ▼

ACP, AMA to oppose physician-assisted suicide

The American College of Physicians has joined the American Medical Association (AMA), American Nurses Association, and The American Geriatrics Society in officially opposing physician-assisted suicide.

A paper published in the Aug. 7 issue of the *Annals of Internal Medicine* says the 90,000-member American College of Physicians (ACP) believes physicians should always look for ways to improve care for the dying.

"Legalization [of physician-assisted suicide] would undermine the patient-physician relationship and the trust necessary to sustain it; alter the medical profession's role in society; and endanger the value our society places on life, especially on the lives of disabled, incompetent, and vulnerable individuals," the authors wrote. "The ACP-ASIM remains thoroughly committed to improving care

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for patients at the end of life."

Providing more and better care for pain and suffering, treating depression more aggressively and increasing access to hospice care are essential to help terminally ill patients die more comfortably, the paper stated.

Assisted suicide would damage the patient-physician relationship, jeopardize the medical profession's role of healing, and lessen the value placed on life, according to the paper.

The paper emphasized the group's strong support for a patient's right to refuse or halt treatment. ▼

Medical journals to adopt anti-censorship policies

In an attempt to crack down on "censorship" of clinical research by large pharmaceutical companies, four of the world's most prominent medical journals — *The New England Journal of Medicine*, the *Lancet*, *Annals of Internal Medicine*, and the *Journal of the American Medical Association* — have reportedly decided to jointly adopt a new editorial policy stating they will refuse to publish research funded by drug companies unless they receive written assurances that the authors had complete scientific independence, claims a report in the Aug. 5, 2001 issue of *The Washington Post*.

A joint editorial, reportedly to be published in September issues of each of the journals, will outline the new requirements.

The new policy is designed to address concerns that pharmaceutical companies attempt to block publication of studies that reach conclusions not beneficial to the companies' products or alter research findings to omit damaging information, the *Post* reported. ▼

Patients, states to benefit from new rules

U.S. Secretary of Health and Human Services (HHS) Tommy G. Thompson has proposed new regulations to give Medicaid beneficiaries patient protections similar to those contained in proposed congressional "patient's bill of rights" legislation.

The new regulations will guarantee Medicaid beneficiaries access to emergency department care, a second opinion when requested, direct access to women's health services, and the right to appeal adverse coverage decisions.

In addition, the regulations would prohibit Medicaid managed care plans from instituting restrictions, such as gag rules, on provider-patient communications; and, the regulations would require states to approve of marketing materials used by the plans.

The proposed rule would replace regulations put in place by the Clinton adminstration and would allow states to have more "flexibility" in deciding how best to provide patient protections and use managed care within Medicaid plans, according to a press released issued by HHS.

The proposed new rule was published in the *Federal Register* on Aug. 20. The mandatory 60-day comment period will end Oct. 19, and final regulations are expected to be issued around the first of next year. ■