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Special Report:
Policy Changes under Bush

Thompson brings mixed bag of blessings to new post

Policy shifts announced in several areas

Researchers, policy-makers, and patient advocates watching the first few weeks of the new Bush administration didn't have to wait long for indications that U.S. health policy will see some dramatic shifts in the next four years.

In addition to announcing plans to craft new patients' rights legislation, expand coverage of prescription drugs by Medicaid and Medicare, and improve access to health insurance for the working poor, newly appointed U.S. Secretary of Health and Human Services (HHS) **Tommy Thompson** used the first few days of his position to announce several controversial policy shifts.

Following his Senate confirmation hearing, Thompson indicated the department would launch a new safety review of the already approved early abortion pill mifepristone (Mifeprex), re-examine federal funding of research involving the use of embryonic stem cells, and begin a new initiative to increase the number of people willing to become organ donors.

The announcements sent tremors through the research community and reproductive freedom organizations as they moved to protect their interests and those of their constituents.

"One of our biggest concerns is the plan for a safety review of mifepristone," says **Monica Hobbs**, federal legislative counsel for the Center

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COMING IN FUTURE ISSUES

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Special Report: Policy Changes under Bush

for Reproductive Law and Policy (CRLP) in Washington, DC. "It is our position that there is no need to review the drug; it went through a lengthy approval process by the [U.S. Food and Drug Administration] already and has been proven safe and effective to use."

To re-review mifepristone at this point is simply inserting politics into a previously objective safety evaluation process, she claims.

Noting the former Wisconsin governor's support of a state ban on "partial-birth" abortions that called for a sentence of life in prison for physicians who performed the medical procedure, the CRLP had opposed Thompson's nomination as secretary, arguing his political stance against abortion would bias his decisions on health policy and medical research.

Now, they fear their concerns may be justified.

Coming on the heels of new legislation introduced by Sen. **Tim Hutchison** (R-AR) and Rep. **David Vitter** (R-LA) to require physicians who prescribe mifepristone to meet additional regulatory standards, the new review is just another effort to block women's access to safe, early abortions, she claims.[1]

Though as governor, Thompson was supportive of family planning funding, advocates are worried that President George W. Bush's opposition to abortion will put federal Title X funding at risk.

"Title X funds are the largest source of support for family planning clinics in this country," Hobbs says. "Under the previous administration, [HHS] Secretary Shalala repeatedly went to Congress to ask for increases in funding for family planning. We are concerned that this administration may want to allocate funds elsewhere previously designated for family planning. Or, they may institute the federal gag rule [prohibiting clinics receiving federal funds from giving out information about abortion]."

The CRLP and 29 other organizations recently sent a letter to President Bush asking for his support in increasing Title X funding, noting that Thompson expressed support for the program at his Senate confirmation hearing.

The CRLP also is concerned about continued support for the new medical information privacy regulations announced by the HHS late last year, and the FDA's plan to consider allowing over-the-counter distribution of emergency contraception,

the "morning-after pill," says Hobbs.

"We have a Top 10 list of items that we have concerns about with this administration, and those issues are on the list," she says.

Advocates for research involving pluripotent stem cells also are holding their breath as the new administration considers reversing a prior HHS policy allowing use of federal funds for stem cell research, provided it was conducted under strict guidelines.

Pluripotent stem cells, which have the potential to become any type of tissue in the human body, can be derived only from human embryos. Federal law prohibits the use of federal funds that involve the destruction of human embryos, but, last year, the HHS issued an opinion that stated federal funds could be used for embryonic stem cell research as long as federal funds were not used to derive the cells themselves (not used to fund projects that destroyed human embryos).

The department just issued guidelines on what kinds of stem cell research could be funded with federal money and outlined an approval process last spring, says **Tim Leshan**, director of public policy at the American Society for Cell Biology (ASCB) in Bethesda, MD. ASCB led a coalition of patient groups, medical researchers, universities, and medical societies in advocating for federal funding of stem cell research.

"No projects are currently under way — researchers have just started applying for funding — but, this is absolutely the worst time to withdraw the funds. It just puts everything at a standstill," says Leshan.

Scientists believe that pluripotent stem cells may hold the key to obtaining a cure for several genetically linked diseases, such as Parkinson's disease and Alzheimer's, as well as hundreds of other illnesses and injuries, says Leshan.

Ironically, University of Wisconsin researcher James Thomson was one of the leaders in discovering the potential of pluripotent stem cells, and then-governor Thompson praised his and others' efforts at the time.

However, President Bush has indicated his opposition to any research using cells from aborted fetuses. Most stem cell research uses cells from embryos left over from assisted reproduction procedures or aborted fetuses. Researchers have been unable to use embryonic cells from other

CME questions

1. According to Panos Zavos, professor of reproductive physiology at the University of Kentucky, human cloning is inevitable, but should:
   A. be pioneered in the open by qualified professionals.
   B. be regulated through government oversight.
   C. gain wider public acceptance first.
   D. all of the above

2. Which organization's ethics committee already has issued a policy statement on somatic cell nuclear transfer?
   A. American Medical Association
   B. American Society for Reproductive Medicine
   C. National Abortion Rights Action League
   D. American Hospital Association

3. Tommy Thompson, the new Secretary of the U.S. Department of Health and Human Services, announced policy changes or reviews on:
   A. the abortion medication mifepristone.
   B. federal funding involving embryonic stem cells.
   C. increasing organ donation.
   D. all of the above

4. As governor of Wisconsin, Thompson was instrumental in developing innovative approaches to:
   A. Medicaid prescription coverage.
   B. increasing organ donation.
   C. increasing enrollment in child health programs.
   D. all of the above

sources, such as embryos spontaneously aborted in a miscarriage, says Leshan.

Asked about his earlier support for stem cell research during a press conference his first day in office, Thompson indicated his position may have to change. "I've found out I am a cabinet member now," he told reporters.

In response to the decision, the ASCB drafted a letter to President Bush urging that he carefully consider all the implications before issuing an executive order withholding federal funds, says Leshan. The letter was signed by more than 100 professional societies, research institutions, and advocacy groups, including the:

- American Medical Association — Chicago;
- National Spinal Cord Injury Association — Bethesda, MD;
- National Alliance for the Mentally Ill — Arlington, VA;
- Johns Hopkins University in Baltimore;
- Alliance for Aging Research — Washington, DC;
- ALS Society in Woodland Hills, CA.

"We are encouraged that they are examining this issue and not immediately taking action," says Leshan. "We did not get a response to our letter. But, conversations we have had with administration officials indicate that they are seriously considering the issue."

Many people in the organ transplant community speculated Thompson also might decide to make changes in the new HHS organ allocation policy, which mandated organ sharing across wider geographic regions.

Wisconsin has a high rate of organ donation, and officials there filed suit against HHS, claiming the new policy would punish the state and unfairly benefit states with poor organ procurement programs.

However, since that time, the impact of the change in allocation has not been as drastic as many feared, says **Richard Cooper**, MD, professor and director of the Health Policy Institute at the Medical College of Wisconsin in Madison.

"My understanding is that the allocation approved by UNOS [the United Network for Organ Sharing] hasn't in fact created the problem that some of the people anticipated, and therefore, we had objected to earlier," he says.

Ann Pasche, spokeswoman for UNOS in Richmond, VA, the nonprofit agency that has the government contract to administer the nation's organ allocation lists, says they have had no indication from Thompson that he intends to seek a change in organ allocation policies.

"There has been an awful lot of speculation about this in the media, but we haven't heard anything. Right now, we are just going to wait and see," she says.

Thompson also announced plans to unveil a program to increase organ donations within the first 100 days of his term, she says. UNOS is encouraged about the news, but the organization has no details about the administration's plans, she adds.

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- **United Network for Organ Sharing**, National Transplantation Resource Center, 1100 Boulders Pkwy., Suite 500, P.O. Box 13770, Richmond, VA 23225-8770. Web: www.unos.org.

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1. Entous A. Republicans launch new attack on abortion pill. Reuters. Feb. 6, 2001. ■

Patient privacy rule still in limbo

The devil is in the details, experts say

Final rules released for complying with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 could have profound changes on the way hospitals provide care, experts warn.

Unfortunately, that means ethics committees will have to re-examine the policies and procedures in place for informed consent processes. **(See the goals of the consent process, p. 31.)**

Some providers have expressed concern that

the rule places an unreasonable burden on them to obtain consent from patients before disclosing medical information in almost any way. The requirement was strengthened from the original proposal so that now the patient must give written consent for just about any type of information release. Providers will have to retain the consent forms for a minimum of six years.

Under the new rule, patients may ask health care providers to restrict how medical information is used within the health care system for treatment, payment, or any other function. And after providing consent — restricted or not — for such purposes, the patient can revoke the consent.

The rule essentially gives the patient a great deal of control over how any medical information is used, and that will be a difficult change for providers, says **Geri Amori**, PhD, ARM, FASHRM, with Fletcher Allen Health Care in Burlington, VT. Even though providers have an ethical obligation to protect a patient's medical information from prying eyes, Amori says they also have been the arbiters of who gets to look and who doesn't. The HIPAA regulation takes that control from the provider and gives it to the patient.

"We can no longer be the beneficent paternalist," Amori says. "This rule will fly in the face of a lot of old-style medicine. It will change a lot of the routine ways things are done."

Amori says the rule creates a lot of new exposures for ethics committees to consider. The government can impose fines for not adhering to the privacy regulation, and Amori says it is inevitable that hospitals will be hit with those penalties. It is uncertain how those fines might be covered by insurance policies, but Amori says she doesn't expect they would be covered, since government fines usually are not.

As soon as the rule was released, health care organizations started protesting and promptly went to the new Bush administration for help. The Health Care Leadership Council, an association of 50 chief executives from large health care companies, immediately sent an appeal to the Bush administration, asking for "a more balanced approach to protecting privacy." The American Hospital Association also released a statement, saying it would ask the Bush administration for help in changing the rule.

The American Medical Association also expressed concern. The association agrees in principle with the Clinton administration's latest effort to safeguard the privacy of each American's medical records, according to **Donald Palmisano**, MD, of the American Medical Association's Board of Trustees. However, Palmisano cautions patients and physicians will not know the real benefits, burdens, and costs until the complex maze of new rules and regulations is closely analyzed.

"This is a big step, and the devil really is in the details this time," Palmisano says. "It's important to make sure that good intentions don't produce unintended consequences. We will be closely examining the new rules to make sure there are no dangerous loopholes or unexpected problems."

Palmisano, a surgeon and attorney from New Orleans who is a national expert on patient privacy and confidentiality issues, says there are three things he considers essential for patients' medical information to remain secure.

"Nothing should be disclosed without the patient's consent," he says. "Unfettered access to a patient's health information by government agencies and law enforcement is unacceptable. A patient's physician must not be unfairly held liable for any misuse of confidential patient information by some third party who might also be doing business with that physician."

Some changes good, others aren't

The HIPAA privacy rule was changed in some significant ways from its earlier proposal, and ethics committees are likely to find that some of the changes are good and others aren't. **Jack Rovner**, partner and co-chair of the Chicago health law practice group for Michael Best & Friedrich, says he is impressed with how much the rule was changed in response to the concerns of health care providers.

"They paid a lot of attention to industry comments and the need to accommodate some industry functions that the proposed rule would have made problematic," he says. "They kept in the forefront the government's idea that protections are necessary for the patient, so it's still a strong piece of rule-making."

Rovner says two of the most talked-about changes aren't likely to hit health care providers

hard. The final version of the rule requires patients to give written consent for virtually every release of medical information in the course of treatment, even going from one hospital department to another. That may be overkill in some providers' view, but it shouldn't create too much of a problem because providers already do that or something very close to it, Rovner says.

"You sign an informed consent when you first go for care," Rovner says. "How much you have to change that procedure to comply with this rule depends on how extensive the consent already is."

Rovner notes, however, that the rule now provides penalties for not obtaining proper consent. Many providers will not have to change their procedure much for the initial consent, but the ramifications of failing to do so may be much greater than before.

Some providers have expressed concern about a change that extends the privacy protections to all medical records, both paper and electronic. The previous proposal covered only electronic records. While that change may seem like it increases the compliance burden, both Rovner and Amori say providers won't see much difference.

"The truth is that anything you have on paper these days, you probably have on computer, and vice versa," Amori says. "So that information would be covered in either case. The change could be more significant for some rural hospitals that don't use computers much, making the rule have more effect for them than it would have before."

'Minimum necessary' provision eased

The final version of the rule includes a major change that ethics committees will welcome. In the proposed version of the rule, providers could make available only the "minimum necessary" information about a patient even when the patient gave consent for the information transfer. That provision raised all sorts of questions about how physicians would communicate with each other, with some analysts suggesting the primary doctor would have to be cryptic when talking with a specialist for fear of revealing too much patient information. No one in the health care industry liked that scenario, and it apparently won't come to pass.

Now, the rule states that the "minimum necessary" provision does not apply to such physician-to-physician consultations. "That's a major change and a good one," Rovner says.

But the "minimum necessary" provision still applies to a great many situations.

"The 'minimum necessary' provision says employees should only see information they need to do their job. You can't just hand over the medical record and let them find what they need," he says. "That's going to require some major analysis of what everyone's job functions are and how you can control information so they get what they need to do their jobs but nothing else. Claims processing doesn't need to see the same information that the nursing staff does."

Other changes in the final rule allow integrated health care organizations to share information as if they were a single entity, even if they actually are several facilities. This changes recognizes the "real world of how health care is delivered," Rovner says. In a hybrid organization with both health care and nonhealth care members, the rule allows the information to be shared between the health care entities but not with others.

Also, protected health care information cannot be provided to any human resources department within the organization. The only exception is a situation, such as workers' compensation treatment, in which an outside employer has purchased the health care, and the patient has consented to such a release.

For ethics committees, the work starts now. Rovner and Amori suggest ethics committees start assessing how much current policies and procedures will have to be changed to comply with the rule. Amori suggests the greatest impact probably will be felt on the financial side of the health care operation. The rule makes it clear that billing employees, for instance, must not have access to protected patient information. It is not sufficient to ensure they do not disclose or otherwise misuse the information; systems may have to be revamped to ensure they do not even have access to that information.

Much of the ethics committee's work will involve assessing just what information is necessary for certain staffers to do their job. And risk management experts agree there are a lot of gray areas and unanswered questions that will not be settled until providers move forward and try to comply with the rule.

"We recently looked at some of the envelopes we use to mail information to OB/GYN patients, and that got us wondering," Amori says. "If the envelope says OB/GYN on the outside, does that reveal too much information about the patient? We don't know how far this is going to go. Questions are going to come up as we move along." ■

New privacy rules mean new requirements

The recently released privacy regulation, which will be fully implemented within two years, is being issued under the authority of the bipartisan Health Insurance Portability and Accountability Act (HIPAA) of 1996. These are the primary goals of the new rule:

• **Inform consumers how their health information is being used.** This new regulation requires health plans and providers to inform patients about how their information is being used and to whom it is disclosed. It also gives each individual patient a right to a "disclosure history," listing the entities that received information unrelated to treatment or payment that must be provided within 60 days.

• **Limit the release of private health information without consent.** This rule establishes a new federal requirement for doctors treating patients and hospitals to obtain patients' written consent to use their health information even for routine purposes, such as treatment and payment. Other nonroutine disclosures would require separate, specific patient authorization.

• **Give patients access to their own health file and the right to request amendments or corrections.** The regulation gives patients the right to see and copy their own records as well as the right to request correction of potentially harmful errors in their health files. These access and amendment rights are a core part of efforts to protect individual privacy. Without them, a person with an improper diagnosis in his or her medical file could be denied health insurance and left no redress.

• **Restrict the amount of information used and disclosed to the "minimum necessary."** Currently, health care providers and plans often release a patient's entire health record even if an employer or other entity only needs specific information, such as the information necessary to process a worker's compensation claim. This new regulation restricts the information that is used and disclosed to the minimum amount necessary.

• **Require the establishment of privacy-conscious business practices.** The regulation requires the establishment of internal procedures to protect the privacy of health records. They include: training employees about privacy considerations in the workplace; receiving complaints from patients on privacy issues; designating a privacy officer to assist patients with complaints; and ensuring appropriate safeguards are in place for the protection of health information. Many responsible doctors, hospitals, and health plans already provide these common-sense services for their patients, and were instrumental in advocating for a national standard.

• **Create new criminal and civil penalties for improper use or disclosure of information.** In the past, there often has not been any legal basis to prosecute individuals who inappropriately disclose private medical information. This rule applies the standards included in HIPAA to create new criminal penalties for intentional disclosure up to $50,000 and up to a year in prison. Disclosure with intent to sell the data is punishable with a fine of up to $250,000 and up to 10 years in prison. The regulation also establishes new civil penalties of $100 per person for unintentional disclosures and other violations (up to $25,000 per person per year).

• **Require that information be disclosed only for public health priorities and other responsible research.** The regulation balances the need to protect the public health and support carefully monitored medical research against the need to protect personal medical records from misuse and abuse. The regulation recognizes that threats to public health, such as life-threatening and easily transmitted infectious diseases, will require appropriate monitoring by public health authorities. The regulation encourages health professionals to use deidentified records whenever possible.

• **Limit the disclosure of information without sacrificing public safety.** The rule strikes the proper balance between protecting privacy

and meeting the needs of law enforcement. Medical records often are important to the investigation and prosecution of serious criminal activities. At the same time, Americans must not be discouraged from seeking health care because of concerns about having their information inappropriately given to others.

In response to more than 50,000 comments submitted by the public, the final regulation was changed in these ways:

• **Extending coverage to personal medical records in all forms including paper records and oral communications.** The proposed regulation released last year was limited to electronic records and any paper records that previously existed in electronic form. The final regulation provides protection for paper and oral in addition to electronic information, creating a privacy system that covers all personal health information created or held by covered entities. Comments received on the proposed regulation affirmed the administration had the authority to extend coverage to paper records and overwhelmingly supported broadening the regulation to those records because it would be impractical to have two separate sets of privacy standards for different sets of records.

• **Requiring consent for routine use and disclosure of health records.** The proposed regulation released last year allowed routine disclosure of health information without advance consent for purposes of treatment, payment, and health care operations. The final regulation ensures written consent for disclosures by frontline providers, even routine ones, be obtained in advance. This new requirement was strongly supported by physician and patient advocacy groups.

• **Protecting against unauthorized use of medical records for employment purposes.** The proposed regulation did not clearly explain the regulation's limits on large self-insured employers' access to personal health information for employment or other purposes unrelated to health care without consent. The final regulation clarifies those employers cannot access medical information for purposes unrelated to health care.

• **Ensuring health care providers have all the information necessary to appropriately treat their patients.** For most disclosures of health information, such as health information submitted with bills, providers may send only the minimum information needed for the purpose of the disclosure. However, when treating patients, health care providers often need to be able to share more complete information with other providers. The final rule gives providers full discretion in determining which personal health information to include when sending patient records to other providers for treatment purposes. ■

Knock knock: Cloning's now a close neighbor

Scientists confront ethics of technology

If the intentions of a Kentucky fertility expert are realized, the world will see its first known cloned human being within the next two years.

In an interview with the *Washington Post* last month, **Panos Zavos**, professor of reproductive physiology at the University of Kentucky in Lexington, announced he and a consortium led by Italian fertility physician **Severino Antinori** planned to produce a cloned baby in the next 12 to 24 months. Zavos also is co-founder of the Kentucky Center for Reproductive Medicine and In Vitro Fertilization, also in Lexington.

With recent advances in reproductive technology, human cloning is inevitable and should be pioneered in the open by qualified professionals, Zavos says.

Indeed, say fertility and biology experts, the know-how to clone a human already exists, and similar assisted reproductive technology procedures already are in widespread use. But serious safety problems and ethical issues remain that should be addressed.

At the same time, they say, assuming federal legislation barring the practice — which the United States has not passed — human cloning is just a matter of time.

The process by which humans would be cloned, somatic cell nuclear transfer (SCNT), is the same process by which scientists have cloned

sheep, mice, calves, and other animals.

Here's how it works: the nucleus from a cell of an adult animal is inserted into a denucleated oocyte cell. The resulting cell is given an electrical pulse to stimulate cell division and, ultimately, an offspring is created that shares the genome of the original animal.

The potential for SCNT to be used with human cells is so strong that the ethics committee of the Birmingham, AL-based American Society for Reproductive Medicine, of which Zanos is a member, issued a policy statement in November 2000 about the use of SCNT for human reproductive purposes.[1]

"Research into the science of reproductive somatic cell nuclear transfer is proceeding as investigators clone additional species by using the original and related methods," the committee reports. "Given the breadth and intensity of ethical concerns expressed globally about reproductive SCNT, it is important that caution be exercised before clinical use of this procedure is considered, even if safety concerns are adequately addressed."

Because several safety issues remain unresolved, current use of reproductive SCNT in humans is unethical, the committee concludes. But it emphasizes that research into possible appropriate uses for this technology should continue.

"As long as the safety of reproductive SCNT is uncertain, ethical issues have been insufficiently explored, and infertile couples have alternatives for conception, the use of reproductive SCNT by medical professionals does not meet standards of ethical acceptability," the statement concludes. "This situation does not, however, preclude research into therapeutic SCNT that does not involve transferring embryos to the uterus, provided that ethical procedures for conducting research are followed.[2] Nor does a moratorium on reproductive SCNT remove the need to study more carefully the ethical implications of cloning, especially for infertile couples."

Major safety issues exist

Most experts currently agree SCNT is too risky a process to use on human embryos expected to gestate in the womb.

"Right now, it takes a lot of tries to clone a mammal," says **Ray Moseley**, PhD, director of the program in medical ethics, law and the humanities at the University of Florida's college of medicine in Gainesville. Moseley, a former president of the Florida Bioethics Network, currently is a member of the ethics committee at Shands Hospital in Jacksonville. "It takes somewhere around 200 attempts to get a successful clone, [to be] able to successfully harvest an egg, and insert new genetic material into it. It takes a lot of tries to be successful. That is why it is only done on animals; you have lots of them, and it takes several tries to get a successful implantation."

It also normally takes several "tries" to achieve the birth of a live and viable animal produced by SCNT. Current animal cloning efforts have almost always had high rates of fetal or neonatal mortality in the offspring.

"All sorts of things go wrong," Colorado State University cloning researcher **George Seidel** told the *New York Times Magazine* in a February article about human cloning.[3] Cloned cattle and sheep often are born unnaturally large, some are lame or have limb deformities and organ deformities. "It can be a unique abnormality in each case. They can die within a few days after birth, or sometimes just can't make it after you cut the umbilical cord."

That level of risk for humans is almost universally considered unethical for research and is unlikely to occur. "We do need primates to be cloned first before we even attempt to do humans," says **Gregory Pence**, PhD, a professor of arts and humanities, and a bioethicist at the University of Alabama — Birmingham. Pence is a proponent of human cloning once the safety issues are resolved. "I think the announcement of what they intend to do is really premature."

On the other hand, Pence notes, the amount of embryos sacrificed for in vitro fertilization (IVF) frequently is ignored or underestimated.

"The success rate for IVF is only about 20% per cycle, according to data on the CDC [Centers for Disease Control and Prevention] Web site," he says. "They put in about three embryos per attempt, and the average couple goes through three attempts before they give up. So, if you do the numbers — to get 50 babies, you may need 800 embryos. We seem to tolerate that loss of embryos all the time."

But even without the safety concerns, many bioethics professionals say there are serious unexamined ethical consequences to cloning humans.

In a sense cloning can be compared to engineering the human germ line, with all of the attendant ethical issues there, says **Sheldon Krimsky**, PhD, professor of urban and environmental policy at Tufts University in Medford, MA. Krimsky is author of a chapter on the psychosocial impact of genetic engineering of humans in the book

Engineering the Human Germline.[4]

"It is not really putting new genes in, but it is selecting the genes of one parent and foregoing the natural method of gene rearrangement of both parents into progeny," Krimsky explains. "There is a certain type of genetic manipulation going on here."

A child who is the product of cloning would be faced with tremendous psychological pressure, knowing he or she was a genetic copy of one parent, and possibly burdened with unrealistic expectations from his or her parents, he says.

"I think people would do this for primarily egotistical reasons — after all, if you were trying to create the perfect child, you wouldn't clone yourself," he says. "It puts tremendous psychic pressure on the child because we would have a kind of parental pathology with respect to wanting to transform a young child into a replica of one of the adults."

Inherent mysteries revealed

In addition, cloning would remove the normal inherent mystery of the person's development. He or she might, for instance, already know that he or she would develop certain illnesses or traits (moles, baldness, etc.). And it is likely that he or she would know, for the most part, what he or she would look like as an adult.

"It represents a kind of social pathology not to allow a child to develop in the best and most free a way as possible, given that you just cannot replicate the environment of any one individual," Krimsky believes.

In that context, cloning could be seen as a form of child abuse and, therefore, laws should be passed to prohibit it.

"I see the best potential in using the model of a convention, like the convention to prohibit the use of biological weapons or the human rights convention," he says. "We could sort of tag this onto human rights, you have the right not be a clone."

There also are issues of lessening biodiversity if cloning were to be practiced on a large scale, he adds. "The idea of trying to breed us as monogenetic organisms to keep perpetuating one genome," he muses. "Just imagine a seventh-generation clone. 'I want you to be just like your father because you are made in his image, and he was made in his father's image, you have to be made in mine.' That is not healthy for society. Once we start inbreeding of such enormous proportions, it will create all kinds of problems with susceptibility to disease."

However, there arguably are valid situations in which human cloning would be a beneficial reproductive technology, others argue.

"I think there has been this gigantic overreaction," says Pence. "This, right now, is a very inefficient procedure, and there are very few people who would probably want to try it. But it might make sense for some couples, particularly if there are autosomal-dominant hereditary diseases in their family."

Couples at high-risk of passing life-threatening hereditary diseases to their progeny might find cloning a preferable option to preimplantation diagnosis or therapeutic abortion of affected embryos, he says.

Also, couples who cannot produce gametes of their own could borrow an oocyte and conceive a child that at least one of them would have a genetic connection to, he adds.

Cloned children may not necessarily bear the brunt of extreme psychological distress that many fear, argues Moseley.

"I don't share a big concern on that issue," he says. "I see that someone you clone would still be a different person. Genetics is certainly important to your makeup, but it is your experiences that make you a person. If you were to clone me, you would have someone who is raised in an entirely different world that I was. I am 50; that person would not have the influences of Vietnam, of the disco era and bellbottoms and things that permanently warped me, but would, I hope, not warp the clone."

Additionally, use of the technology is not likely to be as pervasive as some people believe, he says.

"I do not fear that we are going to create these armies of cloned individuals or that we would be cloning people just to get their organs out of them," he says. "I have a fair amount of faith that humans are basically rational and will act in their long-term best interest. I do think we should be very careful, and we need to make sure there is public consensus on it. I think the scientists who think it should be done should be heard; and we should not automatically say, 'Forget it.' I do not feel strongly that it is a terrible thing to do, and I also do not feel strongly that we should do it."

Right now, federal funds cannot be used to clone a human, and the National Bioethics Advisory Commission has recommended against the practice, says Krimsky. But, no federal laws exist banning the practice.

Some European countries have banned human

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cloning, and France has called for an international agreement on a ban.

"I am very worried about people criminalizing this without knowing what they are criminalizing," says Pence. "Florida tried to make a law that banned cloning and almost ended up banning cloned cell lines. People really do not know what they are banning."

Federal funding for cloning research simply would muddy the waters and slow the process down, Pence adds. "I would like to see all of the funding remain private. If federal funds are involved, you get too tied up in the abortion controversy."

Although some argue this would grant richer people access to technology that would be withheld from the poor, Pence argues this is not a problem solvable by bioethics.

"That issue doesn't bother me," he says. "Rich people can buy a Lexus and poor people can't. Rich people can send their kids to Stanford and poor people can't, and no one seems to be arguing to change that. This is not the main issue of equality if we are going to go for that."

Individual and hospital-based IVF clinics, where this process likely is to be performed, have their own ethical standards and procedures, and would unlikely be performing reproductive SCNT willy-nilly anyway, he says.

"A lot of people don't realize you have to use IVF to do this," he says. "Clinics set their own standards. It is not like you can just demand this of someone."

Far from being a case of technological advances outpacing government or bioethical oversight, cloning and genetic therapies are areas in which science has taken the unusual step of looking at the ethical implications of research ahead of time, notes Moseley.

"As academics always do, we are the ones grappling with the long-range implications of this and trying to determine what this technology will mean for us," he says. "Others may view it just one way or another, either positively or negatively. An academic is supposed to step aside and say, 'What are the implications for society? What are the ethical and legal implications?'"

With the Human Genome Project actually dedicating funds for the ongoing study of those issues, genetic technologies actually are out ahead of past major scientific advances, says Moseley.

"If you think about it, it is relatively unusual for us to be thinking about these issues before they occur," he says. "We haven't cloned humans yet, and there is a lot of discussion going on. It is not like somebody dropped the atomic bomb and

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then tried to figure out whether they should have done it or not."

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Hospitals urged to adopt new end-of-life approach

Physicians can involve additional people in the care of terminally ill patients to ensure their quality of life doesn't deteriorate in their final days, according to a study by Mayo Clinic researchers.

The study authors note physicians as a group may prolong end-of-life suffering with aggressive approaches to "cure" the patients' underlying disease rather than acknowledging the time has come to provide the patient with palliative care services.

However, strategies can be taken to reduce the suffering of a patient by orchestrating a multidimensional approach to helping ensure the quality of life at the end.

The special article, done for the Mayo Clinic Cancer Center Quality of Life Working Group, appears in *Mayo Clinic Proceedings*.

Physicians should alleviate suffering

Before the 1900s, most Americans died at home surrounded by their loved ones. Currently, as many as 60% will die in hospitals, and up to an additional 25% will die in health care-related facilities such as nursing homes. Physicians have had an ever-expanding role in the manner in which people die, with so many Americans dying in hospitals and other health care facilities.

"With modern medicine emphasizing genetic manipulations, high technology, and cure at all costs, we often neglect what was once the most sacred aspect of being a physician: alleviating suffering," the authors wrote. "Therefore, we contend that the approach to a person dying in the hospital must change from simply postponing death to focusing medical interventions on maintaining quality of life to the end."

The authors defined the term "quality of life" as the physical, psychological, social, and spiritual domains of health that are influenced by a person's experiences, beliefs, expectations, and perceptions.

The Mayo Clinic authors conclude their article: "We believe that the principles that have been so successful in improving the quality of life for hospice patients must be adopted in hospitals and related facilities such as nursing homes so that suffering can be relieved where the vast majority of Americans continue to die."

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