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Decade of the Brain gives birth to new neuroethics

Conference focuses on ethics of treating brain disorders

A little more than 10 years ago, in 1990, the federal government launched the Decade of the Brain initiative, a focused effort to encourage research into the diseases of the brain and potential of the human mind.

The result has been stunning progress in the field of neuroscience, researchers and ethicists say. But now more effort must be made to understand the social and ethical implications these advances will have on our society.

"I think we are starting to be able to ask questions about individuals that we were not ever able to ask or probe before," says **Judith Illes**, PhD, senior research scholar in the department of radiology at Stanford University in Palo Alto, CA. "We need to look at how we do that responsibly and what are the ethical implications of doing that."

For example, Illes notes, new neuroimaging technology is allowing researchers to examine not only traditional concepts such as memory and language, but also allowing them to examine how changes in a person's brain activity may indicate other things — whether the person is angry or upset, aroused, or being untruthful, for example.

"That really brings to the foreground new issues: How do we use that data in a research environment? How do we communicate that data to the public? How might such information get used — in the courtroom, for instance — not just in the medical field," she says.

To begin looking at these issues, Stanford and the University of California at San Francisco held a conference May 13-14 in San Francisco to map this new field of study, which many are calling neuroethics.

COMING IN FUTURE ISSUES

- Children as research subjects and the duties of researchers
- Should we consider presumed consent for organ donation?
- Ethical issues in xenotransplantation
- Physician lawsuits against health plans

At the conference, neuroscience researchers, bioethicists, and public policy experts came together to determine what initial questions needed to be asked about the impact new knowledge about the brain will have on society, says conference chair **Zach Hall**, MD, former director of the National Institute for Neurologic Diseases and Stroke (NINDS), now president and CEO of EnVivo Pharmaceuticals Inc. in Redwood City, CA.

"It is more to map a new terrain than to come up with any answers right now," Hall says. "We are not going to solve the question of when is the use of stem cells appropriate or when should you use electrical stimulation of the brain in two days. But, [we wanted to] simply question and think and start the discourse — that was the goal of the conference." Attendees had plenty to discuss, he adds.

Use of stem cells on the horizon

One of the key topics discussed at the conference was the use of embryonic stem-cell transplants to treat neurologic diseases, notes **Barbara Koenig**, PhD, associate professor of medicine and the executive director of the Stanford University Center for Biomedical Ethics.

Although stem cells are thought to have the potential to treat numerous diseases of the body, neuroscientists already are discovering practical applications to treat problems of the brain and the impact that these treatments may have needs to be studied now, she says.

"We are probably likely to see more of an immediate impact," she explains. "It will be a long time before you can take a bunch of stem cells and grow a heart. But it might not be long before you can say, 'Here are two nerves that are no longer connected. Here are some growth factors that will get them to reconnect.' Those kinds of experiments are already going on."

It's important that the ethical implications of such technology are examined now, adds Illes. "One of the things we want to do is promote proactive bioethics. Very often, ethics comes into play once the research has been done and somebody says, 'Uh oh.' The results get reported in *Newsweek,* and the public is calling."

What if you can predict aberrant behavior?

As the field of neurology advances, scientists increasingly also are finding biological bases for

Available neuroethics resources

If you are interested in more information about neuroethics, conference organizers suggest the following resources and articles:

- Beaulieu A. Images are not the (only) truth: Brain mapping, visual knowledge, and iconoclasm. *Science, Technology & Human Values*. 2002; 27(1):53-86.
- Blank R. *Brain Policy: How the New Neuroscience Will Change Our Lives And Our Politics*. Washington, DC: Georgetown University Press; 2001.
- Conlan R, ed. *States of Mind: New Discoveries about How Our Brains Make Us Who We Are*. New York City: John Wiley & Sons; 1999.
- Downey GL, Dumit J, Williams S. Cyborg anthropology. *Cultural Anthropology* 1995; 10:264-9.
- Dumit J. Objective brains, prejudicial images. *Science in Context* 1999; 12(1):173-201.
- Finger S. *Origins of Neuroscience: A History of Explorations into Brain Function*. New York City: Oxford University Press; 1994.
- Fukuyama F. *Our Posthuman Future: Consequences of the Biotechnology Revolution*. New York City: Farrar Straus & Giroux; 2002.
- Gross C. Brain, Vision and Memory: Tales in the History of Neuroscience. Cambridge, MA: MIT Press; 1998.
- Harrington A, ed. *So Human a Brain: Knowledge and Values in the Neurosciences*. Boston: Birkhauser Press; 1992.
- Harrington A. *Medicine, Mind, and The Double Brain: A Study in Nineteenth-Century Thought*. Princeton, NJ: Princeton University Press; 1987.
- Llinas R. *I of the Vortex: From Neurons to Self*. Cambridge, MA: MIT Press; 2001.
- Pietro C, ed. *The Enchanted Loom: Chapters in the History of Neuroscience*. New York City: Oxford University Press; 1991.
- Post S, Whitehouse P, Binstock R, et al. Abstract: The clinical introduction of genetic testing for Alzheimer disease. An ethical perspective. *JAMA* 1997; 277: 978-979.
- Preul M, Feindel W. A history of brain-imaging technology in neurosurgery. *Neurosurg Clin N Am* 2001; 12(1):127-143.
- Star L. *Regions of the Mind*. Palo Alto, CA: Stanford University Press; 1989.
- Whitehouse PJ, Juengst E, Mehlman M, et al. Enhancing cognition in the intellectually intact. *Hastings Center Report* 1997; 27:14-22. ■

or factors that affect human behavior. For example, advanced magnetic resonance imaging may be used in research to examine different sites of brain activation for people who abuse drugs, for children who have attention-deficit disorder, or people who are lying, says Hall.

This research has significant implications for people who experience substance addiction or exhibit antisocial or criminal behavior, explains Koenig. "We might have the potential for predicting different kinds of behavior. And if we can, should we do this? What effect will that have on different parts of our society?"

A new understanding of biological factors related to human behavior may drastically alter the criminal justice system, for example, she says. If there is some basis for criminal behavior in biology, how much responsibility should one bear?

"We are not just studying how many numbers people can remember anymore," says Illes. "We are now actually looking into their brain and seeing if some brain centers light up to fear-evoking stimuli or not, or sadness, for example."

Another area that needs more discussion is the use of enhancements to improve brain function, says Illes.

Researchers already are examining how electrical stimulation of certain centers of the brain can be used to treat degenerative neurologic disorders and chronic pain. But healthy people could also potentially use this technology.

"We need to look at patterns of the use of mental enhancers, from traditional things like use of amphetamines — which some people have used to stay up all night to study for exams — to new technology like transcranial magnetic stimulation, a single pulse to the brain, to boost your energy with your morning coffee."

Such questions have already come up with the increased use of mood-altering drugs such as Prozac and the increased use of Ritalin in children, say Hall and Koenig.

"How much should we allow? Should we allow it? Maybe we shouldn't [use] any kind of manipulation that could change people's personal characteristics," Hall says. "If we have a pill that makes you feel better, should everyone have access to it? Who will pay for that? What if we

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have a pill that will make you less shy at a party or better able to concentrate while working?"

Enhancements have the potential to alter our concept of a normal personality, says Koenig, and that will have implications for people who may be denied access to the enhancements.

"We have drugs that may improve cognitive function in patients with Alzheimer's," she says. "But if we do develop drugs to enhance memory, will there be justice issues about who gets them? Will there then be a new version of normal memory? There are a lot of issues surrounding that."

As research goes forward into degenerative illnesses of the brain, methods of protecting patients who suffer from these illnesses and who need to be included in clinical trials will also become an issue.

"Many neurological and psychological conditions involved reductions in cognitive ability, so our whole ability to conduct research and intervene is more complicated," says Koenig.

And, because the brain contains so much of what our society considers to be the self, a decision to deliberately alter a person's brain, even to heal a deadly disease, should be carefully examined, says Hall.

"The brain is responsible for many of the things that make us individuals," he notes. "If I do something to treat your liver, I am not going to change your personality. But if I do something to treat your brain, I may."

These questions should not just be answered by medical researchers and academic ethicists, but also must be addressed by society, he says.

"These are not questions that physicians or scientists should answer alone. They have to do with the core values of our society and we need to engage a broad spectrum of people," he says.

The San Francisco conference was limited to 50 participants carefully selected to balance representation from the fields of neuroscience, bioethics, and public policy, says Hall.

In addition, the sessions and breakout groups were scheduled to be two hours long, to allow an hour for discussion following each presentation.

Conference organizers plan to develop a consensus of what the attendees felt were the key neuroethics issues that require immediate attention.

They are planning to publish a summary of the conference to inform the public and other interested parties, Hall reports.

"One of the things we hope to end up with is something that is accessible to the public," he says. "If someone asked, 'What is neuroethics?' they could sit down and read our document in a couple of hours and have a sense of what happened at the conference and what the main problems are." ■

What's more important: Physical or mental health?

Costs of mandated mental health coverage debated

With new support from the White House, the effort to pass mental health parity legislation gained momentum last month, eliciting hope from advocates for mental health care reform, but igniting the ire of the insurance industry and House Republicans who claim more mandates will push the cost of health insurance beyond the reach of even more Americans.

In a speech at the University of New Mexico on April 29, President **George W. Bush** expressed support for legislation requiring private health plans to give parity to mental health services — providing the same level of coverage as for services to treat physical ailments.

"Our country must make a commitment: Americans with mental illness deserve our understanding, and they deserve excellent care," Bush told reporters following a private meeting at the school with families of patients with mental illnesses. "They deserve a health care system that treats their illness with the same urgency as a physical illness."

Although Bush stopped short of endorsing the Mental Health Equitable Treatment Act, the bill proposed by Sens. **Pete Domenici** (R-NM) and **Paul Wellstone** (D-MN), and said he did not support a particular proposal, mental health advocates said his statement lent much-needed

Major provisions of the proposed Mental Health Equitable Treatment Act

1. Prohibit group health plans that provide mental health benefits from imposing treatment limitations or financial requirements on the coverage of mental health conditions unless comparable limits are imposed on medical and surgical benefits. This would prohibit discriminatory limits on the frequency of treatment, number of visits, days of coverage, or other limits on the duration or scope of treatment in private health insurance coverage for ALL mental disorders, and rule out higher copayments, deductibles, coinsurance, other cost-sharing, and limits on the total amount payable for mental health care. In closing these loopholes in the 1996 federal parity law, the bill draws no distinction among diagnoses;
2. eliminates the 1996 provision that exempts insurance companies and other firms from the requirements of the law if they have experienced an increase of more than 1% in their mental health costs;
3. shrinks the current small-business exemption (covering businesses with 50 or fewer employees) to an exemption of companies with 25 or fewer employees. It is estimated that this legislation would cover 100 million people.

Source: National Mental Health Association, Washington, DC.

support to parity efforts.

"I think what the president did was endorse the broad concept, and we are certainly delighted with that endorsement," says **Ralph Ibson**, vice president for government affairs at the National Mental Health Association (NHMA) in Washington, DC. "What it does is put a spotlight and energy behind this legislation that gives added impetus to members of his party in Congress to give new focus on and to work with him and others to craft legislation that could be adopted."

Advocates for improved coverage of mental health services have been trying for years to get legislation at the federal and state levels prohibiting disparities in reimbursements between physical and mental and emotional illness.

A previous parity law, the Mental Health Parity Act of 1996, also authored by Domenici and Wellstone, expired on Sept. 30. That law prohibited group health plans that offered mental health benefits and covered more than 50 employees from imposing different annual or lifetime limits on mental health care than the limits imposed on medical or surgical care.

However, a report last May from the General Accounting Office (GAO) found that the law had little effect on improving coverage of mental health services. Although 86% of employers surveyed reported compliance with the law, many of those employers instituted new and different restrictions on mental health benefits, the NMHA reports.

Employers are continuing to limit mental health benefits more severely than medical and surgical coverage — most often by restricting the number of covered outpatient visits and hospital stays and requiring higher copayments and deductibles for mental health services, Ibson says.

The current Domenici-Wellstone proposal would require private health plans covering more than 50 people to provide full parity of coverage for all categories of mental health conditions (other than substance abuse disorders) that are listed in the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*. **(See box, left, for summary of bill's provisions.)**

The bill is modeled on last year's establishment and implementation of mental health parity in the Federal Employee Health Benefits Program, which provides health coverage for 9 million federal employees, including members of Congress and their families.

But the proposal to cover all recognized mental health disorders is one of the key elements that make this proposal untenable, say representatives from the health insurance industry.

"We strongly believe that every new mandate, including expansion of mental health coverage, should face careful review, based on the latest and best scientific evidence, so that consumers can have confidence that their money is going to provide better health care," **Karen Ignagni**, president of the Washington, DC-based American Association of Health Plans (AAHP), said in a statement following Bush's New Mexico speech.

Including all diagnoses listed in the *DSM-IV* would require coverage of a "variety of situations," including academic problems, occupational problems, religious or spiritual problems, and even jet lag, Ignagni claims.

Such required-coverage mandates are one of the primary factors driving up the cost of health insurance, she adds.

A study commissioned by the AAHP and conducted by the accounting firm Pricewaterhouse-Coopers found that mandated benefits accounted

for 15% of the $67 billion increase in U.S. health care spending in 2001.

By comparison, general inflation accounted for 18% of the increase in spending; rising provider expenses accounted for 18%; drugs, medical devices, and medical advances accounted for 22% of the increase; increased consumer demand for 15%; litigation and risk management for 7%; and miscellaneous categories accounted for 5%.

"As a result of these added costs, many employers are now faced with the painful choices between reducing benefits, passing costs along to their employees, or phasing out health coverage altogether," she says.

In addition, the economic downturn exacerbated by the events of Sept. 11 coupled with rapidly rising insurance premiums may result in 6 million Americans losing their health coverage this year, a new policy study by the National Coalition on Health Care (NCHC) reports. (See the NCHC web site at www.nchc.org/survey.html.)

"While nearly 39 million people were uninsured for the entire year in 2000, we estimate that approximately 45 million people will have no health insurance coverage by the end of 2002 unless the government takes substantial actions to stem the incoming tidal wave of the uninsured," says **Joel Miller**, the NCHC's national policy director. "Further, during the three-year period [of] 2001-2003, we estimate that a total of 86 million Americans could suffer a gap in their health insurance coverage."

Substantially increasing the number of mandatory covered services without a study of the cost implications would substantially increase the burden on employers to provide coverage, Ignagni adds.

"Policy-makers should carefully consider the consequences of adding to the more than 1,500 mandates that already exist at the state and federal level," she says. "Proposals to mandate an expansion of mental health coverage at the federal level would add billions of dollars to health care costs at a time when 40 million Americans lack access to health insurance and many more are struggling to afford the coverage they do have."

However, cost data collected in states that have passed parity legislation indicate that the cost impact would be much less than the health plans are anticipating, says **Andrew Sperling**, deputy executive director for public policy at the National Alliance for the Mentally Ill.

"We have reliable information that the cost increases would be minimal," he indicates.

The report, "Parity in Financing Mental Health Services: Managed Care Effects on Cost, Access & Quality," the second in a series of reports to Congress issued by the National Advisory Mental Health Council, found that full parity costs less than 1% of annual health care costs. When implemented in conjunction with managed care, parity can *reduce* costs by 30%-50%, researchers found.

After the implementation of full parity at the state level, Maryland reported a 0.2% decrease in health care costs and premiums. Rhode Island reported a less-than-1% (0.33%) increase of total plan costs under state parity. Texas experienced a 47.9% decrease in costs for state employees enrolled in its managed care plan under parity.

Issues of civil rights

A total of 32 states now have some degree of mental health parity, and fairness bills are pending in several other state legislatures, says Sperling. However, several states, including Texas, have implemented narrower legislation than the proposed federal statute, limiting the parity requirement to specific, major mental illnesses such as depression, bipolar disorder, and schizophrenia.

Some lawmakers and policy experts have proposed similar limitations for the federal legislation as a way of limiting the initial cost impact. But, mental health advocates fear such limitations would gut the legislation's purpose.

Such limits, says NMHA's Ibson, fly in the face of the concept of parity — recognizing that mental disorders are illnesses in the same way that physical ailments are.

"In our view, medical and surgical coverage in most insurance draws no distinction by degrees of risk or severity," he says. "We would be very troubled by the idea, and we assume members of Congress would be horrified to be advised that insurance companies were drawing distinctions between cancer coverage — for example, viewing lung cancer as a serious illness but not covering skin cancer, or covering severe heart disease but not covering hypertension."

Establishing parity for mental health services is an issue of civil rights, Ibson says, a remedy for the discrimination that people with mental illness have suffered because their disorders have not been given equal attention.

"This legislation is analogous to civil rights legislation in terms of the arbitrary discrimination in the marketplace against a group of people who suffer from a particular array of

SOURCES

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disorders," he explains.

Opponents of the broader legislation have misrepresented the effect of relying on the *DSM-IV* as the standard for determining what is and is not a mental illness, he adds.

"I think people are misconstruing what the effect would be," Ibson says. "There is a lot of opposition that reflects people flipping through the manual and finding what they feel are sort of silly diagnoses. [They] then draw an illustration describing these sorts of extreme examples of the bad results that would emerge. You hear people say that employers would have to bear the cost of malingering or jet lag, etc."

However, there is a difference between having a disorder recognized in the *DSM-IV* and a health plan being required to pay for treatment, he adds.

"The bill is very carefully constructed to address a whole range of concerns that the business community raised when it was first considered by the Senate," he notes. "In fact, before anybody would be reimbursed or have insurance coverage for treatment — for jet lag, or whatever — there would have to be a finding that the treatment was medically necessary."

The criteria for defining medical necessity, as with physical ailments, rests with the health plan, not the beneficiary, he says. "It is the plan or the employer who pays for the plan that sets those criteria. In addition, it is very clear in this legislation that the full range of managed care techniques, which are brought to bear in making judgments about whether health care is to be provided, how long it will be provided, those are all the appropriate and permissible means of limiting costs, and they would still apply to all covered conditions. It is highly implausible that some of the horror scenarios would actually come to pass."

However, some advocates argue, even a limited parity law would be better than none. While it would be preferable to have legislation that recognized the necessity of treating all forms of mental disorders, a limited parity bill could be a good first step, says Sperling.

"In some states where limited legislation has passed, lawmakers have gone back later and expanded the legislation," he notes. "Although we would like to see a law that did not limit protection to severe diagnoses, we think even a narrower law would be beneficial." ■

DNR dispute involving preemie leads to lawsuit

Case spotlights parents' of disabled newborns rights

When babies are born extremely early and face devastating medical problems or severe handicaps, how much power should parents have to make decisions about their care? Should they be able to choose to withhold aggressive lifesaving measures? Should physicians be able to override the parents' decision if they disagree?

These are some of the questions the Texas Supreme Court will attempt to answer within the next few months.

In a case that is being closely watched by hospitals and neonatalogists across the country, parents of an 11-year-old severely disabled girl are suing the Houston hospital where she was born, claiming physicians there performed an aggressive resuscitation without their consent, resulting in severe injuries that cause extreme suffering and leave her requiring 24-hour medical care for the rest of her life.

Miller v. Columbia/HCA Inc.

According to briefs filed with the Supreme Court of Texas, Houston residents Mark and Karla Miller presented to the Woman's Hospital of Texas on Aug. 17, 1990, approximately four months before the scheduled due date, with Karla in premature labor.

After doctors were unable to stop the progression of labor, both the obstetrician and neonatalogist on call advised the Millers that at 23 weeks' gestation, their daughter would likely not survive delivery. If she were born alive, they advised, resuscitation would probably be necessary but would also cause significant complications,

including "cerebral palsy, brain hemorrhaging, blindness, lung disease, pulmonary infections, and mental retardation."[1]

Both physicians advised the Millers that they would need to consent to have the resuscitation performed on their daughter after her birth, and they did not recommend it, saying it would be an experimental procedure in so premature an infant. The Millers chose not to consent to the procedure, and asked that the child, when born, be given to her mother and that "nature be allowed to take its course."

Karla's medical records indicate that her obstetrician advised that a neonatalogist would not be required to attend the delivery.

However, hospital officials later informed the Millers that a departmental policy required a resuscitation be performed if the child weighed at least 500 grams, whether the parents gave consent or not.

Sidney Ainsley Miller, now 11, was born weighing 650 grams (just under 1.5 lbs.) and resuscitated. The invasive procedures required to resuscitate her and sustain her life, severely damaged her internal organs and circulatory system, her parents claim.

She now is severely retarded, legally blind, cannot walk, talk, or feed herself, and suffers from chronic pain, seizures, and spastic quadriparesis in all of her limbs. She will always require round-the-clock medical care.

Under state law, the Texas Family Code, they argue, decisions concerning Sidney's care were their sole responsibility unless the hospital obtained a court order finding that they were not acting in their child's best interests. No court order was obtained prior to the resuscitation.

However, hospital officials, in their response to the lawsuit, argue that they had a moral obligation to perform lifesaving procedures on Sidney, that federal emergency care regulations and the state's Advance Directives Act requires that they withhold resuscitative measures only if the child's condition were "certifiably terminable."

Sidney's injuries, they claim, were a consequence of her difficult and premature birth.

The Millers initially won $60.4 million judgment at trial, which was later reversed by an appellate court that found in favor of the hospital.

The laws in most states, in keeping with the doctrine of informed consent for medical treatment, recognize the parents as the surrogate decision makers for their children, and thus have the final say in what care the child should and should not receive, advises **Dawn Dudley Oosterhoff**, RN, LLB, SJD, a former neonatal nurse and a resident research fellow at the Canadian Catholic Bioethics Institute and graduate research fellow in the Department of Bioethics at the Hospital for Sick Children in Toronto.

However, this parental right must always be balanced by society's interest in protecting the welfare of children, she adds.

"Most people would agree that the parents should be the final arbiters," Dudley Oosterhoff says. "But don't forget that parents' decision-making responsibilities are circumscribed by child-welfare interests. If a parent makes a decision that we consider not to be in the child's best interests, the state has a duty to intervene and limit or override that authority."

Clinicians use community standards and accepted medical practice standards to judge whether they believe parents to be truly acting with the child's best interests at heart, and this is often a difficult thing to judge, she continues.

"The problem with neonates is there are so many uncertainties," Dudley Oosterhoff says. "There is still so much we don't know or can't explain or predict, especially with very premature babies. Every infant is different, and two infants with the same clinical diagnoses may fare very differently."

23 weeks is gray area

As medical technology increases and advances are made in neonatal care, more babies are surviving after being born at gestational ages once thought not to be viable, says **David Woodrum**, MD, a neonatologist and professor of pediatrics at the University of Washington in Seattle.

Very little clinical data are available to guide physicians caring for these very early babies and to a large extent the care they receive is experimental, he explains.

"With this case, you are talking about babies born at 22-25 weeks, and that is sort of our gray zone," Woodrum says. "I think most neonatalogists would agree that at 22 weeks or 23 weeks, and some would say 24 weeks, you would offer the parents as much information as possible and try to educate them about the issues involved, but still offer them the option of either aggressive care or comfort care."

Conversely, parents of babies born at 27 weeks probably would not be offered that option at Woodrum's hospital, he says.

"In that group of infants, where survival is

greater than 90%, and the prospects for the infant's long-term outcome, if not uniformly great are not uniformly terrible, the parent would not be offered that option," he says.

But in these very early situations, given the high potential for suffering by the child and the lack of good clinical data to predict how the child will do, it is perfectly legitimate for parents to choose palliative care and reject aggressive measures, Woodrum explains.

"Keep in mind that infants given comfort care are not abandoned," he adds. "If they are born alive, they get intensive care, but the type of care is noninvasive and not aggressive. It leans more toward comfort care and love, etc."

Invasive resuscitative measures, such as intubation and mechanical ventilation and intravenous lines, do cause injuries in babies who are this small and underdeveloped, adds Dudley Oosterhoff. This needs to be the focus of more long-term studies of infants who do receive aggressive care, she says.

"I think we, as clinicians, do have a responsibility to consider the long-term effects of these interventions too," she adds. "It is not just our responsibility to do everything we can to preserve life at that time. We should also take some responsibility for the injuries that we may cause in this process, as well."

Unlike infants who are born prematurely, but at a later gestation, physicians cannot reliably predict how an individual infant, born before 25 weeks, might fare with aggressive treatment, says Woodrum.

"There is just no way you can predict with that individual baby," he explains. "You can talk to the parents about the long-term studies that have been done, but they are all on children who were premature infants 15 or 20 years ago. You aren't really talking about the same thing, because they probably weren't as premature as these infants are and the technology wasn't the same."

Problems with uniform policy

Uniform hospital policies, like the one mentioned in the *Miller* case, that would require invasive procedures in all cases based on the infant's birth weight can present many ethical and legal problems, say Dudley Oosterhoff and Woodrum.

"In my hospital, there is no such policy and there is no such policy because we have consciously addressed this issue and decided not to do it," he explains. "It is too complicated a situation to have a bright, shining line at a certain weight or whatever."

It is difficult to believe that a set departmental or hospital policy would be unknown to obstetricians and neonatalogists practicing at that facility, he adds. "It doesn't ring true to me that it would have been a well-defined, well-known policy, and yet the neonatalogists went in and gave the parents a choice that would then be taken away."

The resulting conflict between the parents and hospital officials indicates a lack of transparency about the decision-making process that Dudley Oosterhoff finds troubling.

"It appears that the hospital's policy neglected to address individual considerations," she says. "It was an arbitrary policy and, so far as I am concerned, anathema to the purpose of clinical guidelines. Good decision-making guidelines do not guarantee or predict an outcome but facilitate a process that is fair and transparent."

Regardless of the outcome of the *Miller* case, neonatalogists need better models for interacting with parents of critically ill newborns and helping them make decisions, say both sources.

"The way the law is set up, with the informed consent doctrine, it sets up a system where the doctor provides information and the patient or surrogate decision maker makes the decision," says Dudley Oosterhoff. "But, the reality is this is almost never the way it works."

In the case of premature or very sick babies, you frequently have a mother who has undergone major medical procedures and, possibly, a father who is very upset and traumatized about the situation. It is very difficult for them to comprehend the decisions they are being asked to make, she says.

"I think it is important for the physicians to get involved in helping sort through what will this course of action mean in terms of what is important to your family and even go so far as to say, 'These would be my concerns if I were in your shoes,'" she explains.

In contrast to the situation with the *Miller* case, it is his experience that many parents are almost programmed to be optimistic about their child's prospects and want everything to be done, says Woodrum. "Most of the time, even when physicians advise or counsel no resuscitation, in that gray zone, parents say they want you to do it," he adds.

Most neonatalogists and neonatal nurses are not blindly out of control and ignoring parental wishes to stop care, as they have sometimes been portrayed to be, he continues. But it is very difficult for both the parents and providers to make a decision in the patient's interests when you cannot ask the patient.

SOURCES

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"I can't talk to my patients, so I have to negotiate this issue through a third party," Woodrum explains. "I don't think in terms of the patient's quality of life in the future since there is almost no way to ascertain that, but I do try to consider pain and suffering. My decisions have to do with whether I feel there would be misery and pain and suffering that would have to be endured early on and if there were all sorts of chronic problems to come later. If so, I don't have any problems making a decision to counsel parents against aggressive measures if it appears that there will be an inordinate amount of suffering, with a guarded chance of a successful outcome."

Reference

1. Petitioner's Brief on the Merits. *Sidney Ainsley Miller, By and Through her Next Friend, Karla Miller, and Karla H. Miller and J. Mark Miller, Individually v. HCA Inc. Hospital Corp. of America and Columbia/HCA Healthcare Corp.,* Supreme Court of Texas. Case: 01-0079 on Appeal from Court of Appeals for 14th District of Texas, Houston, Texas, Cause No. 14-98-00582-CV, Trial Court Cause No. 92-07830. ■

Transplant surgeons endorse compensation for donor families

Although unanimously opposed to outright exchange of money for human cadaver donor organs, the ethics committee of the American Society of Transplant Surgeons (ASTS) recently expressed support for a pilot program that would give limited reimbursement for funeral expenses or a charitable contribution to the families of organ donors as a way of thanking them for allowing their relative's organs to be used.

At its annual meeting held in April in Washington, DC, ASTS members discussed possible incentives to encourage donation of cadaveric organs without driving away people willing to agree to donate for free, according to a report in the April 30, 2002, edition of *The Washington Post.*

In recent years, living organ donation has increased significantly. Last year in the United States, kidneys transplanted from live donors outnumbered those using cadaver kidneys. But the number of people agreeing to donate organs after their death still is very low, and even if a person expresses a wish to donate, family members may later override that decision.

Because federal law currently prohibits the sale of human organs, legislation would be required for a pilot program to begin. Proponents at the conference said that a pilot program of offering limited compensation would allow health care policymakers to study its overall impact on donation levels as well as address ethical concerns, such as the possible compromising of informed consent and the potential for coercion of poor families.

Growing demand for donor organs has lengthened the average wait for an organ, with many patients expected to spend years on waiting lists. Desperation has pushed many patients to seek organs overseas where a black market for human organs flourishes in several countries despite legal bans on the sale of organs. More than 79,000 people in this country are waiting for donor organs. ▼

CA medical marijuana clubs lose court fight to remain open

A California judge has rejected claims by several medical marijuana clubs that distributing marijuana to patients who receive the drug under a doctor's care does not violate federal law.

"With or without medical authorization, the distribution of marijuana is illegal under federal law," wrote U.S. District Judge Charles Breyer in his decision in the *United States v. Cannabis Cultivators Club,* case no. 98-0085. Breyer, judge for the northern federal court district of California, issued his decision on May 3.

Personal cultivation or use of marijuana for medical purposes still is prohibited under the state's Proposition 215 but under the ruling, marijuana clubs will no longer be able to distribute marijuana, even to patients under a doctor's care.

The clubs' legal arguments to stay open has been rejected previously by Breyer, but the Ninth U.S. Circuit Court of Appeals reversed the original decision, saying defendants could raise an issue of medical necessity. The U.S. Supreme Court reversed that decision when it held that medical necessity is not a valid exception to the Controlled Substances Act. ▼

NIH nominee supports federal funding of stem-cell research

Noted medical researcher **Elias Zerhouni**, MD, President George Bush's nominee to lead the National Institutes of Health (NIH), indicated strong support for federal funding of embryonic stem-cell research at his initial Senate confirmation hearing, the Associated Press reported on May 1.

Without federal funding, researchers would shy away from a field of study that promises to hold many major new advances in medicine, Zerhouni told reporters outside of the meeting.

In a hotly debated move last year, the Department of Health and Human Services (DHHS), which oversees the NIH, decided that only stem-cell lines already in existence could be used in federally funded research, and federal funds could not be used to fund efforts to derive stem cells from embryos or fund research involving cells obtained from embryos destroyed after the DHHS directive went into effect.

Many scientists believe that although the policy is sufficient to allow current research to continue, more stem-cell lines will be needed in the future.

Zerhouni seemed to echo this belief in remarks to the Senate committee, the report indicated, by saying the administration's decision was an "important advance" because it allowed some federal funding to go forward. However, he said that, if the current stem-cell lines proved inadequate later, he would "be the first one to assemble that information."

Zerhouni currently serves as the executive vice dean of the Baltimore-based Johns Hopkins University School of Medicine, chairman of the Russell H. Morgan Department of Radiology and Radiological Science at Johns Hopkins and professor of radiology and biomedical engineering. ▼

Medical students sue over residency system

A group of medical residents have filed a class-action lawsuit in Washington, DC, arguing that the National Resident Matching Program, the nationwide system that controls 80% first-residency positions, violates federal antitrust regulations.

The plaintiffs, who claim to represent a class of 200,000 residents, argue that the defendants

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Editorial Questions

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Call **Alison Allen** at (404) 262-5431.

— seven medical organizations and more than 1,000 private hospitals — use the program to keep residents' wages low and hours long. Almost all first-year residents work more than 100 hours per week and make less than $40,000 per year. Their salaries average out to less than $10 per hour.

The National Resident Matching Program uses ranked lists submitted by hospitals and the approximately 15,000 prospective residents. Both sides agree in advance to accept the match, and there is no room for negotiation about wages, hours, or other terms of employment.

Consequently, the suit claims, the hospitals, which share detailed salary information with each other, force residents to accept below-market wages for the length of their residency, typically three to eight years.

Proponents of the system have claimed that the residency program is not a purely commercial enterprise because it is an aspect of the education of physicians and ensures appropriate distribution of medical expertise across the country. Therefore, they contend, the system should not be subject to antitrust regulations.

If the suit is successful, the system would have to be redesigned. In addition, if the fair-market salaries were determined to be $100,000, the potential damages awarded to plaintiffs could exceed $12 billion and, in antitrust damages, the award would be tripled automatically. ■

CE/CME *Questions*

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21. Topics discussed at the San Francisco conference on neuroethics include:
A. Use of stem cells to treat neurologic problems.
B. Neurological enhancements, such as drugs and electrical brain stimulation.
C. Use of imaging techniques to discern and predict behavior.
D. All of the above

22. In the *Miller* lawsuit, a couple claimed that Texas Woman's Hospital in Houston:
A. Negligently refused to provide adequate medical care for their premature daughter.
B. Improperly disclosed information about their daughter's condition.
C. Performed an invasive procedure without their consent that resulted in harm to their daughter.
D. None of the above

23. Proponents of the Domenici-Wellstone mental health parity legislation:
A. Support mandated insurance coverage of major mental health disorders only.
B. Support mandated insurance coverage of all mental disorders listed in the *DSM-IV.*
C. Support a repeal of mandates included in the Mental Health Parity Act of 1996.
D. Support allowing beneficiaries to determine the medical necessity of health care claims.

24. Medical residents have filed a class-action suit against hospitals and professional organizations participating in the National Medical Resident Matching Program on what grounds?
A. Violation of the Occupational Safety and Health Act
B. Antitrust violations
C. Gender discrimination
D. None of the above