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INSIDE

MARCH 2003

VOL. 19, NO. 3
(pages 25-36)

Consciousness vs. physiology: When is death really death?

Researchers reconsider the brain's role in preserving life

Even as this country struggles with a shortage of organs from donors, some ethicists are beginning to question the morality of harvesting organs from the group that serves as their primary source — patients who are brain dead but have functioning hearts, lungs, and circulatory systems.

Since 1981, the primary criterion for declaring a patient dead has been a clinical diagnosis of "whole-brain death" — this determination being based on the theory that the brain is the central integrator of the body's systems and, once the brain has irreversibly ceased to function, the organism as a whole will cease to function.[1]

However, recent neurological research is questioning whether the brain is indeed the central integrator of the body's functions and whether, when a person's brain is gone, they are as well.

"Whole brain-dead individuals have functioning circulatory systems which distribute oxygenated blood to the tissues and organs," argues **Michael Potts**, PhD, head of the philosophy and religion department at Methodist College in Fayetteville, NC. "Their respiratory systems also continue to function since the exchange of oxygen and carbon dioxide continues in the lungs and throughout the body, with the ventilator providing oxygenated air."

While it's true that without the use of a ventilator or other technology, those functions would cease, that also is true of many people who are clearly alive and conscious and depend on such technologies to continue to live, he argues.

"Many people who are clearly alive and conscious depend on technologies ranging from cardiac pacemakers to ventilators in order to continue to live," he notes.

In 2001, pediatric neurologist **Alan Shewmon**, MD, published a report describing the case of a brain-dead child who survived for 14 years after the diagnosis of brain death.[2]

Although this person no longer has a brain, the body — with the

assistance of mechanical ventilation and intravenous nutrition and hydration — has continued to grow, maintain metabolic functions, heal from infections and illnesses, etc.

Living without a brain

There have been numerous other reports of brain-dead pregnant women who have given birth to healthy babies, Potts adds.

Medical Ethics Advisor® (ISSN 0886-0653) is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Medical Ethics Advisor**®, P.O. Box 740059, Atlanta, GA 30374.

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Statement of financial disclosure: In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, board members have reported the following relationships with companies related to the field of study covered by this CME program. Dr. Cranford, Dr. Hofmann, and Ms. Rushton report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Dr. Banja reports receiving grant funding from the Agency for Healthcare Research and Quality. Dr. Derse, Mr. Guss, Mr. Miller and Dr. Murphy did not provide disclosure information.

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Subscription rates: U.S.A., one year (12 issues), $449. With CME: $499. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $359 per year; 10 to 20 additional copies, $269 per year. For more than 20, call customer service for special handling. **Back issues**, when available, are $75 each. (GST registration number R128870672.)

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"It is clear that whole brain-dead individuals are functioning at the level of an organism as a whole, which falsifies the main justification for the whole-brain criterion," he says.

Some ethicists feel, however, that to say a person is living because their body is functioning is a stretch.

"My view is that we are not human organisms — we are conscious beings whose existence is supported by the continued functioning of relevant areas of the brain," states **Jeff McMahan**, PhD, chair of the department of philosophy at the University of Illinois-Urbana, and the author of the book, *The Ethics of Killing: Problems at the Margins of Life* (Oxford University Press, 2002). "My view is that I am not one and the same thing as my body. What I am is a consciousness — my technical term for this is an 'embodied mind.'"

While it may be true that a person's body — the human organism — may continue to live after the brain ceases to function, it is difficult to say that the person also continues, he explains.

Brain-dead people are no longer capable of consciousness or awareness, and once the brain is completely destroyed, the damage is irreversible.

It is this determination that first led clinicians to embrace the concept of brain death over previous standards of determining death that relied primarily on cardiopulmonary functioning.

"In the late 1960s, we shifted from the older cardiopulmonary criteria of death," he explains. "The big moment came in 1968 when the Harvard Brain Death Committee presented arguments focusing on the irreversible loss of the capacity for consciousness. Basically, they argued that at the point the whole brain dies, we are sure the coma is irreversible."

However, as knowledge of the brain's function has grown, it was discovered that patients who have brainstem, or "lower brain," function but have lost the functions of the cortex or "higher brain" are also not capable of consciousness or of regaining consciousness.

Then some advocated for new criteria — "higher-brain" or "neocortical" brain death to become the new standard — since consciousness was not possible for these patients as well.

"Those people say once the cerebral cortex or cerebral hemispheres are gone, the person is dead because there is no longer any possibility of consciousness," McMahan says. "The problem is that's the state that people in persistent vegetative states are in — they can be lying in a hospital bed without a respirator, spontaneously breathing,

heart beating without assistance. It is very difficult to argue that a biologically dead organism is lying on a hospital bed, breathing on its own."

At that point, the 1981 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behaviorial Research decided to keep the whole-brain standard based on the brain's role as the integrator of the main functions of the human organism.

Most states currently adhere to the Uniform Determination of Death Act, which holds that an individual can be declared dead either due to irretrievable loss of heartbeat and respiration or due to whole-brain death.

What defines death?

Now that that role has come into question, McMahan agrees that use of the whole-brain death standard is problematic.

Deciding who is dead and when is largely based on our beliefs as a society about the value of human life, what constitutes life vs. prolonged death and how we should deal with both.

"When I cease to exist is an individual choice," believes McMahan. "Since I think I am not the same thing as my organism is, I can believe that the higher brain criteria is the right criteria for my death, that when the cerebral hemispheres die, I have ceased to exist, but that is perfectly consistent with my body remaining alive."

Potts believes, however, that it is possible to have an objective, universal determination of death — but one that does not focus primarily on brain function.

In his view, a person continues to exist as long as their body continues to function as a whole.

"The organism is dead when it no longer functions as a whole," he explains. "This is true of plants, bugs, sharks, cats, and humans. However, the criteria that are sufficient to show that an organism is no longer a whole will depend on the type of organism. Obviously, the criteria for death of a tree with differ from the criteria for the death of a cat."

The proper criteria of death for humans should be understood in terms of the destruction of key bodily systems necessary for the integrated unified functioning of the organism, he adds. "The nervous system is one of these key systems, but so are the circulatory and respiratory systems. We know that bodily cells, tissues, and organs will not survive for long without the circulation of oxygenated blood. The proper criteria for the death of the human organism then should refer to these key systems: Death should only be declared after the destruction [not just the loss of function] of the circulatory, respiratory, and nervous systems. How long after the cessation of function such destruction occurs is a matter for medical science to determine."

But such a view can have pernicious effects in the real world, McMahan argues.

People who will never regain consciousness can continue to live in a motionless, twilight, unaware state though their organs may be able to help others live productive lives, and their families may be able to grieve and accept the loss of a person who will not return.

Many parents of anecephalic babies wish to donate their child's organs before allowing the child to die, but this is not allowed because these children have brainstem function.

"Anecephalic babies are born without a higher brain — so there is never any consciousness," McMahan notes. "They are empty, unoccupied organisms because there is no consciousness at all."

But because these organisms are considered alive, their organs cannot be harvested. The parents are allowed to take their children off life support to allow nature to take its course, but the organs will never be used.

Another option would be to admit that these organisms are alive in some way, but that they are not people capable of living in the way that we normally understand it, he argues.

But Potts contends that such thinking goes against the core values of respect for human life and the physician-patient relationship.

"I think the issues of withdrawing life support and/or organ donation need to be separate," he says. "Withdrawing life support from a dying patient is meant to allow nature to take its course — the patient does not receive extraordinary burdensome treatment. Just as it is not morally obligatory to give antibiotics to a terminally ill cancer patient, though it is morally permissible to do so, it is not morally required that a dying patient remain on a ventilator. The focus on withdrawing care is on the good of the individual patient, to allow that person to die as comfortably as possible."

The main problem with organ donation from beating-heart, brain-dead donors, Potts argues, is that if such donors are alive —there is good reason to believe they are — removing an unpaired vital organ (heart, liver) or both paired vital organs (both lungs or both kidneys) kills the patient.

SOURCES

- **Jeff McMahan**, PhD, Department of Philosophy, University of Illinois, 105 Gregory Hall, 810 S. Wright St., Urbana, IL 61801.
- **Michael Potts**, PhD, Philosophy and Religion Department, Methodist College, 5400 Ramsey St., Fayetteville, NC 28311-1420.

"Instead of unnecessary treatment being withdrawn, healthy organs are removed, not for the benefit of the donor, but for the benefit of another person," he says. "Actively killing the brain dead promotes treating people as only a means to an end and not as ends in themselves. It weakens the barrier against viewing other, less disabled, lives as not being worthy to live, either. This is a dangerous path to follow."

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New options needed to increase organ donations

As shortages continue, experts weigh alternatives

When a patient in Chicago nephrologist **Paul W. Crawford's** practice suddenly turned up with a new kidney after a trip to Mexico, the doctor didn't want to ask a lot of questions.

"I don't know how he got [the kidney]," he says. "He wasn't on their list long, if they have a list. I didn't ask him, because I was not involved in the decision. I had to follow him, because he is my patient and I won't abandon him. But I don't like the idea that he would do that."

Black-market alternative

As the shortage of available donor organs continues to worsen, physicians are beginning see patients take desperate measures in an attempt to save their own lives or those of their loved ones.

Crawford says he has had several patients turn up with transplanted organs after taking mysterious trips abroad. And although purchasing human organs is illegal in almost every country on the planet, it is well known that a vibrant black market in human organs exists. In several countries, particularly in the Middle East and in China, poor people sell their own organs or those of relatives, children, or condemned prisoners.

As a result, affluent U.S. residents can go abroad and purchase donor organs, while those not so fortunate must wait — and often die.

According to data collected by the United Network for Organ Sharing (UNOS), 17 people die each day in this country because a donor organ did not become available in time. Despite continued growth in the number of living organ donors, those organs are not nearly enough to meet the demand.

The situation has become so dire that many in the transplant community who have long opposed altering the nation's current altruistic donor system are arguing that major changes are needed.

"We definitely need a better system than what we have," notes Crawford, who also is the chairman of medical affairs for the Rockville, MD-based American Kidney Fund (AKF). "Most of my transplants are now living donors, related and unrelated. People have to turn to that because the cadaver list is so long, people just become distraught."

Even patients who don't go abroad will travel across the country in search of an area where the wait for an organ is not as long, he explains.

"If you are on a waiting list in Chicago, you have a five-year wait on average. But some people in Florida may wait only eight months or a year," he notes. "People who can afford to go all across the country getting on different waiting lists. People who can't are waiting five years."

More public education is needed to address the myths that many Americans still have about organ donation, Crawford believes. And more

recognition needs to be given to people who become organ donors and people who receive donated organs.

"We need people to be more vocal who have transplant organs and who are leading normal lives to speak out," he says.

Improving consent

A key problem, according to UNOS officials, is that, while studies show a majority of people are in favor of organ donation, fewer than half of families consent to have their loved one's organs donated when they are approached after that person's death.

Currently, there is no national registry of organ donors. Even if a person indicates his or her consent for donation on a driver's license or donor care, in most cases, permission must still be obtained from a person's next of kin.

A few states, including Texas, Nevada, Virginia, and Pennsylvania, have laws stating that a person's written consent to donate will be honored in spite of family member objections, but critics say such laws are often not enforced because of the fear that public disagreements with grieving families will discourage donation.

Last year, a similar law went into effect in Iowa, and organ procurement officials launched a massive public relations campaign to support it.

"What we now have is known as 'first-person' consent," says **Paul Sodders**, spokesman for the Iowa Donor Network, the organ and tissue procurement organization for that state. "The law now says that if you record your wishes — mark 'yes' on your driver's license or sign in with the Iowa Donor Registry, or even write it down on a sheet of paper — no one can override your wishes."

The state law went into effect on July 1, and although it has not been on the books long enough to have a measurable effect in the donation rate, network officials believe its impact will be significant.

"We have had family members tell us that, without our presenting evidence that donation is what this person wanted, and with the existence of the law behind it, they would not have consented," says Sodders. "Within the first three weeks of the law's passage, we had a family that actually said to us, 'It makes sense now that you are showing us the driver's license and telling us the law, but we probably would have said no without that information.'"

In conjunction with the new law, the Iowa Donor Network has launched a statewide, computerized donor registry. People willing to have their organs and/or tissue donated after death can sign up on-line or send in their personal information to the network offices, Sodders says.

The network initiated a large publicity campaign about the new law and new donor registry and has brochures with information about registry at each driver's license registration office, he continues. "One of the things we found when we were doing publicity about the new law is that people were outraged that their family could overturn their decision. People assumed that if they marked 'yes' on their license or signed a donor card, it was an automatic thing."

An earlier Iowa effort would have gone even farther.

In 1993, students in a seminar at the University of Iowa School of Law wrote the Cadaveric Organ Donor Act (CODA), a proposed federal law that would have mandated a choice — people would have to either consent to be an organ donor, refuse consent, or opt for consent under limited circumstances when applying for a driver's license, Social Security card, or alien registration number.

Though the proposal garnered a lot of attention in the academic community, the effort didn't get off the ground in Iowa or elsewhere, Sodders says.

But such mandated choice laws are necessary if the public is ever going to consider organ donation a public and social responsibility, believes AKF's Crawford.

"I think organ donation needs to become more of a socially accepted and expected phenomenon," he says. "The law should be that if you don't want your organs donated, you sign something and then everyone else's organs will be donated but yours won't. We need laws that will get some of these organs that are going in the ground to go into people and save some lives."

Legalized organ selling?

Others argue that the only way to improve the public's willingness to consent is to allow donors or their families to receive some sort of financial compensation for their organs, and this sentiment appears to be growing.

Last summer, the American Medical Association's (AMA) House of Delegates voted to encourage organ procurement organizations to begin studying the use of financial incentives to improve donation rates.

Consent from families: Is there a better way to ask?

UNOS to determine best requesting practices

Given that fewer than half of families approached about organ donation give consent, it is essential that hospitals and procurement coordinators examine how they approach families at such a crucial time, say officials with the United Network for Organ Sharing (UNOS).

The organization will convene a conference on April 28-30 in Orlando, with more than 50 organ donation and transplantation professionals to discuss different donation request techniques and reach consensus on best practices.

Currently, a number of researchers are examining different approaches to the donation request process and the results of these efforts will be discussed at the conference, says UNOS executive director **Walter Graham**.

"One of our major goals as an organization is to help increase the number of organs available for transplantation in the United States," he explains. "By bringing together the nation's foremost experts on the organ and tissue donation request process with the organ procurement community, we will together decide on the best approach and how to implement it nationwide."

The conference will provide an interactive forum for researchers examining consent-related issues to present their findings then work with UNOS officials and representatives of the donation and transplant communities to develop a strategy for converting the new knowledge into practical, real-world practice, he states.

Research to be presented at the conference will identify the common facts, characteristics, temperaments and needs among professionals who are routinely successful when approaching families and potential donors.

Projects to be presented include:

- **Beyond Proficiency: Successful Organ Procurement Organization Donation Advocate Project,** A UNOS-sponsored behavioral study of the country's most successful donation advocates, funded by the F.M. Kirby Foundation.
- **Stage-Based Curriculum Training for Procurement Coordinators to Increase Family Consent for Organ and Tissue Donation,** a study of the Transtheoretical Model by the South-Eastern Organ Procurement Foundation, made possible by a grant from the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services.
- **Family Consent: Developing a Model Intervention to Increase Consent to Organ Donation,** a research collaboration of Laura Siminoff and Bob Arnold, made possible through grants from the Agency for Healthcare Research and Quality, Ohio Second Chance Trust Fund, and Wyeth-Ayerst Pharmaceuticals.
- **Study of Presumptive Approach to Consent for Organ Donation,** by Art Caplan and Sheldon Zink of the University of Pennsylvania, funded by a HRSA grant.
- **Interdisciplinary Experiential Training for End-of-life Care and Organ Donation,** a collaboration of Johns Hopkins University and the Transplant Resource Center of Maryland, funded by a HRSA grant.
- **Project to Increase Organ Recovery From Level I Trauma Centers** — Life Gift Organ Donation Center's program placing "in-house procurement coordinators" in trauma centers.

For more information about the conference, visit the UNOS web site at www.unos.org. ■

Existing educational campaigns and initiatives have failed to substantially increase the cadaveric donor pool, the delegates noted, and alternatives must be considered.

The AMA is not endorsing the use of financial incentives to increase organ donation. It is simply recommending that this concept be studied," **Frank Riddick**, MD chair of the AMA's Council on Ethical and Judicial Affairs, said at the time. "Sixteen Americans die needlessly each and every day because there aren't enough available organs to save their lives. As America's physicians, this is a problem we must address."

A 1984 federal law expressly prohibits any financial compensation or inducement to organ donors or families. However, if the law were modified to allow selling of organs or compensation to donors in limited circumstances, many

SOURCES

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- **Paul Sodders**, Iowa Donor Network, 8191 Birchwood Court, Suite J, Johnston, IA 50131.

more people would be motivated to participate, some experts feel.

"I really don't think people have much of a problem with the idea of organ donation, they just don't see anything in it for themselves," says **Gregory Crespi**, JD, professor in the Dedman School of Law at Southern Methodist University in Dallas.

Organ futures contracts?

Crespi has proposed the establishment of an organ futures market in which a person could, through an intermediary, agree to have his or her organs harvested after death, sold to an interested party, and then the money given to their estate.

The purchase price of the organs would be built in to the cost of the surgeries and covered by the insurance companies or public health plans paying for the remainder of the patient's care.

Crespi's proposal has been published, in depth, in at 1994 edition of the *Ohio State Law Journal*.[1]

"The way I imagine that it would work would be large intermediaries — probably insurance companies that would have several contracts — would present you something as part of a package deal when they sell you insurance," Crespi explains. "A company like Aetna might sign up with a million people for organ futures contracts, which means that, statistically over time, they can expect a pretty regular flow of people whose organs become harvestable."

Once a person with such a contract dies under circumstances permitting organ retrieval, the intermediary would post information about the available organs on an Internet site so that transplant centers could purchase them.

"When someone comes in and needs a transplant, they could go to the Internet connection and see what organs were available," he continues. "It would be electronic matching where people would access the system when they needed to buy or sell."

Arrangements could be made quickly so that the organs could be harvested and quickly sent to the center performing the surgery.

"I think the organ futures contract buyer as sort of an intermediary who would pay the estate and then charge whomever is buying the organs — that cost gets passed along to the cost of the surgery and whomever is financing the surgery," he says.

His calculations have placed the price of most organs at around $30,000, not a substantial amount to add to the approximate $200,000 cost of the entire surgery.

Of course, wealthy people would be better able to afford both the organs and the surgery, but that is already true now, he argues.

Patients able to pay out of pocket for expensive surgeries are able to get them before the less affluent. Currently, all people have to wait for organs. But under his plan, so many more organs would be available that the shortage would not be an issue, he says.

"Remember with more organs available, it might even drive the price down," he adds. "It may push a few more people onto Medicaid and public funding, but the people who are insured — basically, the insurance company is going to figure that all of these surgeries are going to cost a little more and pass it along in slightly higher health care premiums. Most of us would end up paying a few more dollars a year for a health insurance policy that now would pick up the cost of the organ as well as the surgery."

Benefit to heirs

Most people would be willing to sign up for an organ futures contract that would pay their estate approximately $150,000 for their organs if they are able to be harvested.

"It's like a free $150,000 life insurance policy if you happen to die in a certain way," he says.

The process should be entirely consensual and allow the person signing the contract to back out at any time, he notes.

"If you sign up and change your mind, you can back out at any time, but your family could not override your wishes," he notes.

Under his proposal, a person must consent to offer his or her own organs — and a person's organs could not be sold after their death if they did not have such a measure in place, he notes.

"As with any system, there is the potential for abuse," he notes. "But I think these contracts can

be policed in a way that would take care of these concerns."

In addition, his plan would not cheapen the act of donating organs, but instead allow people to see the true value of the gift that people are giving, Crespi argues. "If you believe in organ donation as a social responsibility, you can still agree to donate your organs. Right now, if people donate their organs, they are only giving away something they cannot sell. Under my plan, if you agree to donate, it is a more meaningful gesture."

But any market system for selling organs will inevitably end up with the organs going to the highest bidder and leaving out people with limited means, argues Crawford.

"It would create a gambling or lottery system and that gets corrupted so easily," he notes. "If you have a system where people are paying, the poor people are going to go without while the rich people will all have them."

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Supreme Court to weigh Maine drug-discount plan

Manufacturers question price breaks

State health policy experts and pharmaceutical company officials are anxiously awaiting the U.S. Supreme Court's decision on a controversial Maine program designed to help residents unable to afford prescription drug coverage get lower-cost medications.

Known as Maine Rx, the state program requires pharmaceutical companies to provide the same discount to residents who do not have health insurance or drug coverage as they do to members of group health plans. Companies that do not agree to participate in the program will not have their products listed on the state's preferred drug list for Medicaid recipients.

Supporters of the program say it will help more than 300,000 people who currently don't have prescription drug coverage and, they argue, the state is simply doing what other countries have done for all of their citizens — using their large buying power to force drug companies to bargain.

Critics claim the program violates federal Medicaid regulations by altering the benefits Medicaid recipients receive to benefit people outside the program. The program also violates federal interstate commerce and antitrust laws, they argue.

If the Maine Rx prevails in court, others states are expected to unveil similar programs nationwide, experts say.

At heart of the debate, are the financial challenges faced by states struggling to control Medicaid spending and the rapidly escalating prescription drug costs, says **Michael Sparer**, PhD, assistant professor of health policy at the Mailman School of Public Health at Columbia University in New York City.

"Generally, all states are in a pickle right now," he explains. "Drug costs are escalating dramatically, and so is utilization. And Medicaid costs are rising at the same time many states are facing balanced-budget problems. They have two, sometimes conflicting, priorities: reduce Medicaid drug spending and provide prescription drug help to people ineligible for Medicaid but who can't afford private drug coverage."

States tinker with system

Maine's effort is just one of many strategies states are using to try to get pharmaceutical companies to bear some of the cost of treating the poor and frail with newer and increasingly expensive drugs, Sparer adds.

First in an effort to control escalating Medicaid drug costs, they have implemented "preferred drug lists," lists of medications that the state plan prefers that physicians use. Because it is illegal for Medicaid plans to restrict use of a drug or treatment based on cost considerations, they are not allowed to have drug formularies. However, the courts have ruled that preferred drug lists are permissible.

"States cannot deny coverage of a particular medication," he explains. "What they can say is that, 'These are the drugs we'd like for you to use. If you want another drug, call this 800 number and, if you convince us it's necessary, we'll pay for it.'"

Pharmaceutical companies have argued that such arrangements are the same as formularies, because physicians will not go through the extra hassle of calling the Medicaid administrator, but will just adhere to the preferred list.

"Studies in the states that have implemented such plans have shown that utilization of drugs not on the preferred list is significantly decreased," he notes. "But the courts have held that, as long as the state does not prohibit a person from receiving another drug, the preferred list is acceptable."

In order to have their drugs covered by Medicaid, federal regulations require the companies to discount the regular price by 15%, Sparer says. In addition, some states such as Michigan and Florida, have required the companies to cough up an additional 10% off the price to be on the preferred drug lists.

"Florida has gone to the additional step of requiring companies to reduce their price by 10% or develop a disease management program with their drugs that will save an equivalent amount of money and provide more of a benefit to participants," Sparer adds. "I think some of the companies have been developing these disease management protocols there to avoid paying the rebate and accomplish some other case management goals."

Maine now wants to use similar leverage to get better prices for non-Medicaid recipients — a move pharmaceutical companies claim is wrong because, unlike the other strategies, it uses Medicaid patients as pawns in a scheme that is not designed to benefit them.

"The key question in the Maine case has been what do Medicaid beneficiaries get out of this?" he adds. "The pharmaceutical companies are arguing that it is zilch — their purchasing power is being used to leverage benefits for other people. So they could be harmed, in terms of impeded access to certain drugs, but they get no benefit."

Medicare gap part of problem

Essentially, states are caught between a rock and a hard place in terms of helping needy people who are not eligible for Medicaid but can't afford prescription drug coverage, he relates.

"Historically, states have felt this should be a federal responsibility and Medicare should cover it, but there are problems there, obviously," he says. "About a year ago, 28 states took state dollars and used that money to provide assistance to people without drugs to make drugs more affordable. These people didn't get Medicaid coverage but they got help with prescription drugs."

Now, cash-strapped states need someone — the pharmaceutical companies or the federal government — to share the burden.

Most of the costs of these types of programs are absorbed by people on or eligible for Medicare who do not have drug coverage, and most states will agree that these measures are just sorts of stopgap, temporary efforts in the hopes that Medicare will begin offering prescription drug coverage, Sparer says.

"The bottom line is, states are trying to figure out a way to provide drug coverage to those who lack coverage without footing the whole bill themselves," he relates. "If you are a state health policy director and your governor says, 'We are looking at a $1 million budget deficit, and you need to figure out how to save some money,' but he is also telling you that he has some elderly and low-income folks who don't have drug coverage but are needy and he wants to help them, what do you do?"

Plan may backfire

Before more states decide to jump on Maine's bandwagon, it may be worth examining some possible effects of this type of program, first, notes **James F. Blumstein**, PhD, professor of law and director of the Health Policy Center at Vanderbilt University's Institute for Public Policy Studies in Nashville, TN.

"It intuitively sounds good that government or other purchasers with power would bargain down sellers and that might make sense, but it depends on market conditions," he explains.

For example, if the state's percentage of the national pharmaceutical market were so significant that it dropped prices there significantly lower than market value, the companies might not be as quick to supply the state.

"You might not be just reducing the price, but also the availability of some pharmaceuticals," he notes. "Why would a company that is producing to capacity allocate its product to Maine rather than some other state if they could get higher prices elsewhere?"

Pharmaceutical companies might decide to not keep a warehouse in the state and ship all orders from outside. And they may decide to accept only orders from that state in sufficient enough quantities to make it cost-effective to ship in.

"Hospitals and pharmacies may end up having to order in quantities of 1,000 pills instead of 100," he explains.

However, Blumstein doubts that Maine carries such a significant amount of the market that its actions will significantly affect pricing.

SOURCES

- **James F. Blumstein**, PhD, Law School Building, Vanderbilt University, 2201 West End Ave., Nashville, TN 37235.
- **Michael Sparer**, PhD, 600 W. 168th St., Sixth Floor, New York, NY 10032.

"Ultimately, pharmaceutical manufacturers sell on a national scale, and I am not at all persuaded that Maine is really *the* market for the sale of pharmaceuticals."

If, however, other states were to enact similar programs, the situation could change.

"If more states wanted to do that and it became a higher percentage of the market, you could start to see problems," he adds.

The central problem for most states, say both Blumstein and Sparer is that they must try to use scarce resources to benefit the greatest number of people — while at the same time deciding on minimum levels of care everyone should have access to.

Medicaid beneficiaries may have a harder time gaining access to certain medications, but overall more people on limited incomes could afford needed medications.

It's the same dilemma the nation as a whole is facing over the rising costs of health care, Blumstein adds.

"There is a moral principle to say that everyone should have the same thing that I would provide for my wife or my husband or my parents or kids," he notes. "But regrettably, not everyone is Bill Gates and we cannot afford as a society to treat everyone like they are." ■

NEWS BRIEFS

UT Supreme Court upholds 'wrongful-life' statute

The Utah Supreme Court has upheld the constitutionality of the state's Wrongful Life Act, which prohibits parents of children born with genetic problems from suing the clinicians who interpreted the results of prenatal genetic tests.

The original case was brought by Utah residents Marie Wood and Terry Borman, who sued the University of Utah Medical Center in Salt Lake City after their daughter was born with Down's syndrome.

According to the suit, the parents sought genetic counseling because they knew their child was at a higher risk due to the mother's age. Tests performed at the medical center showed their was an 85% chance that their child would be born with the condition, but physicians told the parents that the test carried high false-positive rates and there was only a small chance the baby would be affected.

After the child was born in August of 1998 with Down's syndrome, the parents sued, saying that physicians were negligent in performing and interpreting the tests that would have allowed them to make an informed decision about whether to go ahead with the pregnancy. They also claimed the Wrongful Life Act that prohibited their lawsuit from going forward was unconstitutional.

In a 3-2 decision, the court decided the law was constitutional because:

- Utah residents were never guaranteed the right to sue for wrongful life before the state passed a law against it in 1983.
- The statute does not interfere with a woman's right to have an abortion.

In their suit, Wood and Borman argued that physicians could "unduly burden" women because doctors — knowing they are immune from a lawsuit — could withhold information that would otherwise lead women to terminate their pregnancies.

But the court said "this possible scenario is too tenuous to hold that the statute has the effect of placing a substantial obstacle in the path of a woman who seeks an abortion."

In a dissenting opinion, Chief Justice **Christine M. Durham** argued that the Wrongful Life Act does unconstitutionally deny Wood's and Borman's access to a court, that the physician's negligence interfered with the couple's right to make an informed medical decision, and that the Wrongful Life Act stopped the couple from going to the court to be compensated.

"Here, plaintiffs were injured in person and property," she wrote. "The right to be compensated for a personal injury is a property right that requires access to the courts for enforcement."

Attorneys for the parents are petitioning the court for a rehearing. ▼

Consumer group claims doctors' strike unlawful

The doctors' strike orchestrated by the Medical Society of New Jersey violates federal and state antitrust laws and should be investigated, the national consumer rights' group Public Citizen said in letters sent Feb. 4 to the Federal Trade Commission (FTC) and New Jersey Attorney General David Samson.

"Antitrust laws do not countenance individuals or organizations from collectively refusing to serve their clients [here, their patients] in order to gain leverage with the legislature," the letter states. "The [Medical Society of New Jersey] has plainly engaged in collective activities the express purpose of which is to cause doctors throughout New Jersey to deny medical services to their patients as a means of pressuring the New Jersey legislature to enact laws that will increase the economic well-being of doctors. It is the unlawful nature of the means, not the legislative ends, that gives rise to the violation of law."

Section 5 of the FTC Act outlaws unfair methods of competition, and the New Jersey doctors' walkout is almost identical to a similar action taken more than a decade ago by lawyers who refused to serve indigent clients, the group claims. In that case, the U.S. Supreme Court determined that the lawyers had violated antitrust law.

The letters ask the commission and the attorney general to investigate the conduct of the society and make a public announcement that the walkout violates the law. If the society is found to have broken the law, a court could order it to cease its activity.

To verify the society's involvement, the letters cite documents posted on the society's web site in which the society pledges its full support to carry out the strike. The letters were signed by Alan Morrison, director of the Public Citizen Litigation Group, Sidney Wolfe, MD, director of Public Citizen's Health Research Group, and Frank Clemente, director of Public Citizen's Congress Watch. The letters can be viewed at: www.citizen.org/congress/civjus/medmal/articles.cfm?ID=8974. ▼

NEJM retracts study after authors point to forgery

The *New England Journal of Medicine* announced Feb. 10 that it is issuing a retraction of a study published in its Oct. 24, 2002, issue.[1]

The decision to retract the study was made at the request of a number of the listed study authors who wrote the journal claiming their signatures had been falsified on documents submitting the article for publication and that they had not had the opportunity to review the original data nor seen any of the manuscripts.

In an editorial comment published on the publication's web site and to be published in the March 6 print edition, editors **Gregory D. Curfman**, MD; **Stephen Morissey**, PhD; and **Jeffrey M. Drazen**, MD, wrote:

"Of the eight persons named as authors of the article, some claimed that they had never reviewed the original data, and most claimed they had not seen or approved either the original version or one or more of the three revised versions of the manuscript. One author claimed that he had seen neither the original data nor any version of the manuscript. Thus, there was an egregious disregard of the principles of authorship, as specified by the International Committee of Medical Journal Editors."

According to the editors, a co-author falsified signatures of several of the authors without their knowledge during the review process. Falsified signatures appeared on the letters of transmission accompanying the original and revised versions of the manuscript.

The journal became aware of the falsifications only after the article was published and several listed co-authors wrote a letter asking that the study be retracted.[2] To prevent such occurrences in the future, the journal plans to inform all authors of record via e-mail when a manuscript bearing their name is received.

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- What is wrongful life?
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CME Questions

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9. According to research performed by neurolo gist Alan Shewmon:
A. The brain is the "central integrator" of all of the body's systems.
B. The brain is *not* the "central integrator" of the body's systems.
C. "Higher brain" or "neocortical" death should be the standard used in order to determine whether a patient can no longer recover.
D. None of the above

10. Legal scholar Gregory Crespi's organ futures proposal would explicitly allow:
A. People to sell their organs for cash.
B. People to designate an intermediary that would be empowered to sell their organs after the person's death in order to benefit the estate.
C. People to engage in a bidding process for organs over the Internet.
D. None of the above

11. The UNOS conference on organ donation request techniques:
A. Will help determine best practices when approaching families to request donation.
B. Will present the results of original research into different techniques used to request donation.
C. Will involve input from both transplant surgeons and the organ procurement community.
D. All of the above

12. According to the article, the Maine Rx program is designed to benefit:
A. Maine Medicaid recipients.
B. The uninsured.
C. Maine residents who do not have prescription drug coverage.
D. None of the above

Answers: 9-B; 10-B; 11-D; 12-C.