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Quote to note

"Education is a progressive discovery of our own ignorance."

—Will Durant

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Kidney donation from brain-injured patients before a declaration of death

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In the 1990s, donation after cardiac death (DCD) was reintroduced to the U.S. transplant community as a means to increase the number of kidneys and other organs for transplantation. DCD protocols give families of patients with severe and irreversible brain injuries an opportunity for organ donation. These patients, maintained on mechanical ventilation, do not meet the criteria for brain death. With the family's consent, arrangements are made for the withdrawal of life-sustaining therapy, usually involving extubation and discontinuation of intravenous fluids, feeding and medications. When the patient progresses to asystole within a suitable time frame (usually 60 to 90 minutes), and maintains asystole for five minutes, death is declared and organ recovery undertaken. Potential donors with long periods of organ ischemia are declined for organ donation and continue with end-of-life care, eventually sustaining cardiopulmonary arrest.

The DCD program has had great success with the number of DCD donors increasing more than 10-fold in the past decade. The outcomes of renal transplants from DCD donors have been satisfactory.[1] Nonetheless, there remains room for improvement. Among the many problems uniquely associated with DCD is the ischemia time inherent in the donation process, which leads to high rates of delayed renal allograft function. Also, some 30–40% of potential DCD donors, once extubated, fail to progress to asystole in a manner that would enable safe organ transplantation, and therefore no organs are recovered.

Many patients, the medical community and society stand to benefit from an improved model that permits more reliable organ recovery from neurologically devastated patients who would be considered for DCD protocols. The donor family would realize their goal of organ donation at a time of tragic loss, while patients with end-stage renal disease would benefit from transplantation and removal from more costly dialysis. Hospitals and organ procurement organizations would benefit by the efficient and predictable recovery of organs.

A new protocol for DCD

My proposed model uncouples organ donation from the donor's death. The process begins as before with the identification of an individual with good renal function and with severe, irreversible brain injury with no hope for purposeful or prolonged existence. The family decides to withdraw care with the expectation of the patient's imminent death. A DNR order is written. With the consent of the donor family, the patient is transported to the operating room for kidney recovery. Both kidneys are recovered in a controlled surgical procedure with vascular control, equivalent to bilateral nephrectomy in a neurologically intact patient. General anesthesia and standard analgesic care are administered, as would be given to a trauma victim with severe head injury undergoing surgery. The patient returns to the intensive care unit and end-of-life care is instituted, in a more relaxed time period without the

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requisite "rush" to the operating room following asystole. This protocol enables the family to grieve and spend time with the decedent after death.

Discussion

In its current form, DCD has gained the full support of the transplant community as well as the U.S. health care establishment. The Institute of Medicine endorsed the practice.[2] All hospitals are mandated to have a DCD protocol as a condition for Medicare participation and a DCD protocol is required by the Joint Commission.[3,4]

The broad goals of DCD are to obtain organs for transplantation and provide a respectful death for the donor. Secondary objectives are to provide the benefits of organ donation for the family of the decedent and for the organs to be of the highest quality for the recipient. These objectives are not met when the donor fails to progress to asystole in a manner suitable to allow organ recovery. More unfortunate is the common scenario in which the donation occurs, with disfigurement of the donor and hopeful expectations for the family, only to recover organs that are not transplantable, because of prolonged ischemia and other forms of preventable injury.

Thus, current protocols for DCD fail to satisfy the needs of the transplant community (healthy, transplantable kidneys) and donor family (organ donation, successful transplantation for the recipient, respectful death for the donor). Disadvantages to the organ recipient include delayed allograft function, continued dialysis, longer hospital stay, increased risk of acute rejection and higher costs. Donor families suffer when their emotional investment in organ donation is unfulfilled. Donor hospitals and staff are disheartened by wasted time and resources for evaluation and donor management culminating with often futile attempts at organ recovery.

Under our current practice, all potential DCD donors succumb to cardiopulmonary arrest; however, many donors do not progress to asystole in a time frame that acceptably limits organ injury for transplantation. Furthermore, DCD is often not offered to "marginal" donors based on renal function, age or medical co-morbidities with the concern that the added ischemic insult will render the allograft unsuitable. It is estimated that a controlled premortem recovery of all patients who meet the criteria for DCD would nearly double the number of DCD kidneys available for transplantation. Additionally, the kidneys would be recovered in a controlled fashion, without ischemia and promptly transplanted similar to the optimal circumstance of kidney donation from a living donor.

The end-of-life care of the potential donor presents another set of challenges. Most families elect to be present during the extubation and through the final phase of the donor's life. Including families in the operating room is logistically challenging, unfamiliar and stressful. The environment is inhospitable and cold and does not foster a sympathetic approach to end-of-life care.[5] Ushering the family from the bedside upon declaration of death and prior to rapid cannulation can be awkward.

Thus, the organ recipient and the donor family stand to benefit significantly from a controlled organ recovery prior to end-of-life care. Barriers to implementing the proposed paradigm, therefore, center on the potential for harm to the brain-injured donor.

The legal framework for organ donation was established by the Uniform Anatomical Gift Act and the Uniform Brain Death Act.[6] Underlying these committee and legislative actions was an informal principle called the "dead donor rule," which states that organ donation cannot cause the donor's death.[7] Others have interpreted the rule to imply that donors of vital organs must be declared dead before organ removal.[8] This imprecision and lack of universal applicability has inspired some ethicists to advocate abandoning the dead donor rule altogether in DCD.[8,9] Two features of kidney recovery are unique to application of the dead donor rule. The first is that donation of a single kidney by a healthy individual is widely accepted and the minimal surgical risk is considered acceptable. The second is that nephrectomy is possible without the surgical intervention causing the donor's death.

The decision to proceed with kidney donation requires informed consent, a diagnosis of irreversible brain injury, a judgment of imminent death and an intention to institute end-of-life care. If the medical judgment of imminent death is correct, and the donor receives anesthetic and analgesic care as would be provided to any neurologically injured patient, then no harm can come to the donor. In the circumstance of surgery proximate to anticipated end-of-life care, the likelihood of causing consequential harm is negligibly small.

With what certainty do we know that cardiopulmonary death will ensue following the withdrawal of life-sustaining therapy? To date, no patient entered into consideration for DCD has been reported to have prolonged cardiac function or entered a persistent vegetative state. Cases of prolonged cardiac function after extubation beyond even 24 hours are exceedingly rare. Patients considered for DCD have severe deficits in neurological function and will not survive off mechanical ventilation. Furthermore, the care plan calls for end-of-life care inconsistent with measures to sustain life. The intended consequence of the extubation and withdrawal of care is the patient's death.

Medical interventions for people who are unconscious usually require guardian consent and must meet patients' best-interests standards.[10] However, for a patient who is suitable for DCD, there are no interventions that can benefit the patient except providing a dignified death. In these cases, the benefits of making organ donation a part of end-of-life care are realized by the donor's surrogate and associated family. The hope that a deceased family member can save the lives of other patients should not be dismissed. This benefit is best met by organ donation, successful outcomes for the recipients and a dignified death for their loved one. Current DCD policy fails to satisfy these criteria.

In is undeniable that the elaborate protocols for DCD often fail to result in successful organ recovery and always increase organ ischemia. Controlled kidney recovery from a living patient for the purpose of transplantation has been practiced safely for more than 50 years. The current proposal extends this practice to a unique category of living patient, one meeting criteria for terminal extubation. Kidney donation and end-of-life care are separated in time and place. Such a sequence respects the wishes of the decedent in cases of premortem desire to be an organ donor or the wishes of the family for successful organ donation to accompany compassionate end-of-life care for their loved one. The opportunity to achieve organ donation following fatal intracranial injury is usually a source of lasting pride and comfort for the grieving family. Because of the potential large benefit and the minimal risk of harm, the medical community should review this topic. □

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Ask the ethicist:

Conflicts in duty caused by expensive drugs

Question: An 81-year-old man was admitted to the hospital of a fixed-budget hospital system because of massive bleeding in his bladder from a clotting disorder caused by a circulating anticoagulant against factor VIII. Factor VIII treatment was unsuccessful. He was then prescribed an FDA-approved and appropriate treatment, NovoSeven, an exceedingly expensive therapy, which temporarily stopped the bleeding. The total cost of this treatment was about $250,000. Anticipating further bleeding, additional NovoSeven had to be obtained from other hospitals at a cost of more than $350,000. The attending physician knew that this huge expense would drain the hospital system pharmacy budget and thereby negatively impact other patients cared for by the system. The doctor wanted to give his patient the most effective treatment but was conflicted because of the potential harm this expenditure would cause to unidentified other patients in the health care system. How would you advise him?

Response: Despite spending more than $2 trillion per year on health care,[1] tens of millions of Americans lack health insurance and the United States lags far behind more frugal countries in important health outcome measures.[2] It is no surprise, then, that health care reform is hotly debated on the national stage, even as clinicians are increasingly asking the question at the bedside, "Is the potential benefit worth all we're spending?"

This case exemplifies the dilemma, but pertinent pieces of information are missing that may shed light on the solution. First, what was the patient's health status before the bladder hemorrhage? It would be more sensible to authorize another NovoSeven treatment if the patient had been relatively healthy than if he were suffering from a condition with a grim prognosis (such as metastatic cancer). Second, the statement that NovoSeven "temporarily" stopped the bleeding suggests that it is a stopgap measure, designed to keep the patient alive until the coagulopathy for some reason resolves. If so, how can we be certain that one more dose of NovoSeven will be curative, or might we soon be back in the same position when the effects of the *second* dose wear off?

These questions address the overall potential benefit from the proposed treatment. For no matter how much a treatment costs, if it does not provide benefit to the patient, it should not be offered.

Let us assume, then, that continued treatment with NovoSeven could benefit the patient in terms of improved function and/or prolonged survival. The next question is how such treatment might impact *other* patients in light of the costs of the NovoSeven. The ethical principle of justice dictates that similar patients be treated similarly, and thus it would not be ethical to provide state-of-the-art care to one critically ill patient while providing substandard care to another critically ill patient (assuming the same probability of improvement or recovery).

Critics often decry "wasteful" spending on health care—defined as expensive treatments with low probability of benefit—on the assumption that money saved in one area will be devoted to a more worthwhile pursuit. Dollars spent on rescuing a baby at the cusp of viability could be spent on maternal-child health programs, the argument goes. But absent a single-payer health care system, such broad claims do not hold. Money saved in one area might well be redirected to less noble pursuits, such as a bonus for the executive who denied the requested expenditure for NovoSeven treatment in the first place.

Here the fact that this is a "fixed-budget hospital system" is important. Most hospitals accept the fact that a portion of the care they provide will not be reimbursed as long as this percentage does not deplete the hospital's reserves. (As the saying goes, "No margin, no mission.") We would do well to ask how large the overall hospital budget is, in order to gauge the impact of an additional $350,000 in charity care for a single case. A large tertiary care center would be better positioned to absorb such financial impact than a critical access hospital.

If a previously ill patient likely would continue to hemorrhage even after another dose of NovoSeven, then a small rural hospital could justify withholding requested treatment because it would not help this patient in a meaningful sense and would indirectly harm other patients. However, a large urban center with a much larger budget for charity care could well afford to provide treatment to a previously well patient. Intermediate cases—such as a patient at a small hospital who likely would fully recover with further doses of NovoSeven—are especially challenging. Providing additional doses could negatively impact the care offered to other patients, and not providing them suggests that similar patients may be treated differently at certain hospitals. Both responses raise questions of justice, one of the core principles of medical ethics.

In such situations, the physician is torn between his fiduciary obligation toward his patient and his responsibility as a just steward of limited resources. I would, therefore, advise him or her first to estimate the likely short- and long-term benefits of the proposed treatment for this patient. The cost—which would depend on whether further doses of NovoSeven may become necessary—should then be reviewed in the context of overall hospital expenditures. A multidisciplinary group should be convened to review the proposed treatment, because the attending physician has an unavoidable conflict of interest by virtue of his competing obligations. Ideally, this group would formulate a thoughtful algorithm for dealing with dilemmas such as this, to ensure that all patients in similar situations are treated equally.

I am generally opposed to "rationing at the bedside" precisely because it runs the risk of being applied selectively. But given the extreme cost of the proposed treatment—and assuming that subsequent doses might become necessary and the patient was not in immaculate prior health—if the multidisciplinary advisory group counsels in favor of withholding future NovoSeven treatment, I would concur with that advice.

Outcome: The patient's condition deteriorated for reasons unrelated to his bleeding disorder. His treatment level was lowered to "comfort measures only." No additional NovoSeven was given and he died soon afterward. □

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[1]Centers for Medicaid and Medicare Services. "National Health Expenditure Data," http://www.cms.hhs.gov/nationalhealthexpenddata/. Accessed November 9, 2009.

[2]Nolte E and McKee CM. Measuring the health of nations: Updating an earlier analysis. *Health Aff* 2008; 27: 58–71.

The legal column:

The new NIH stem-cell guidelines

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With the publication last summer of the National Institutes of Health (NIH) final guidelines for research using human stem cells,[1] the Obama administration laid the groundwork for an enormous expansion of federal investment in human embryonic stem cell (hESC) research. Under President George W. Bush, NIH funding was available only for research on stem-cell lines that preexisted the funding date of August 2001. That restriction was designed to prevent the availability of federal monies from encouraging the destruction of human embryos in the production of new lines. Under President Obama, however, federal funding will be available for research on stem-cell lines created from embryos left unused after a couple undergoes fertility treatments. The practical difference between the two policies is enormous: Under President Bush, there were only about 20 useful stem-cell lines eligible for federal research funding. Pursuant to the new guidelines, researchers have completed applications for funding approval on 107 lines, and a further 117 applications are in draft form.[2]

To qualify a stem-cell line for research funding, researchers must meet exacting new ethical standards for the line's "provenance" or origin. To be eligible, new stem-cell lines must have been derived from "excess" in vitro fertilization (IVF) embryos—embryos originally created using IVF for reproduction and no longer needed for that purpose.[3] The persons who sought fertility treatment must have given informed, written consent for the embryo to be used in research.[4] Documentation must be provided to show that: (1) the donors were given a full explanation of all potential alternative uses of the excess embryos; (2) they were not compensated in any way for the embryos; (3) their decision for or against research donation had no effect on their fertility treatment; (4) their consent to the research use of embryos was conducted separately from their consent to the fertility treatment; and (5) they were aware of their right to withdraw consent.[5]

The consent process itself must have informed the donors fully about what would happen to their embryos during the course of hESC research: (1) that the stem-cell lines created from their embryos might be kept and used for many years; (2) that their donation did not confer any medical benefit to them, nor any right to restrict who can benefit from the research; (3) that they would not share in any commercial development of their hESCs; and (4) whether researchers will have any information that could identify the donors.[6]

These ethical guidelines are more strict, particularly in their demand for documentation, than the most commonly used previously existing standards: those of the National Academies of Science,[7] of the International Society for Stem Cell Research[8] and of the various states that have been funding hESC research. As a result, many existing stem-cell lines fall short of the NIH informed-consent guidelines in one particular or another. In order to prevent massive disruption of ongoing hESC research, therefore, the new guidelines permit older stem-cell lines to be "grandfathered" into funding eligibility. Researchers can submit materials to an NIH working group, showing that their stem cell lines were created from leftover IVF embryos and that voluntary written consent was obtained from the embryo donors. If the working group is satisfied with the quality and documentation of the consent obtained, it can approve the stem-cell line for funding eligibility.[9] A similar process permits researchers working with stem-cell lines created outside the United States to prove that the consent standards of the countries in which those lines were created are sufficient to justify federal funding eligibility, even if they do not match U.S. standards exactly. A serious and as-yet-unresolved question is whether the lines fundable under President Bush—about a quarter of which have been shown to lack adequate consent[10]—will be among those "grandfathered in" or whether the longtime federal support for research on those lines will cease.

An important feature of the new guidelines is that, once eligibility for federal funding has been established, all of the approved lines—new, "grandfathered" and non-American—will be listed on a public NIH registry.[11] That will make it much easier for researchers around the world to determine the ethical provenance of their stem-cell lines, and should make international trade in stem-cell lines and their derivatives much simpler.

As useful as the new guidelines appear to be, however, many researchers remain dissatisfied with them. First, the long-promised NIH money has not begun to flow as quickly as researchers had hoped it would—though at this writing, 40 lines have been found eligible for funding by the NIH working group.

More importantly, the Obama administration's guidelines—though much more liberal than President Bush's policy—are not as generous as many researchers had hoped they would be. An annual amendment to the appropriations bill, signed into law every year by presidents beginning with President Clinton in 1995, still prevents any federal money from being used in the creation of a new stem-cell line from a human embryo. More significantly, the Obama guidelines specifically prohibit the use of NIH funding for research on any hESC line not derived from a leftover IVF embryo. Scientists cannot seek NIH funding for research on stem-cell lines created in the laboratory for research purposes, whether by IVF, somatic cell nuclear transfer (SCNT) or parthenogenesis (development of an embryo without male fertilization).

Researchers see several advantages to using laboratory-created embryos in addition to excess IVF embryos. IVF can be used to create a research embryo with specific genetic or disease traits. SCNT—a method of creating an embryo by removing the nuclear genetic material from an egg and replacing it with the nuclear material taken from an adult donor cell—can be used both to generate stem-cell lines with particular diseases and to develop "custom" transplantable cells for the treatment of cellular disease.

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Ethics and the humanities:

A whole new life

By Reynolds Price
New York: Scribner, 1994, 224 pages

Review by Marilyn Chandler McEntyre, PhD
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At the height of his career as a writer and professor, Reynolds Price was hospitalized for what was found to be a 10-inch spinal tumor. It extended, he recalls, "from my neck-hair downward and too intricately braided in the core of my spinal cord to permit [the surgeon] to do much more than sample its tissue in several places." In the course of a 10-hour operation, the surgeon was able to remove only 10% of the gray mass. Price came to think of it as an eel pursuing its eerily quiet life in the cave-like seclusion of his body. Months went by before Price's brother relayed one doctor's grim assessment of what the pathology report meant: "six months to paraplegia, six months to quadriplegia, six months to death."

That was in 1984. A decade later Price published *A Whole New Life: An Illness and a Healing*—a rich reflection on years spent outliving that bleak prognosis. During those years Price's priorities shifted. His appetite for sex changed. He wrote more prolifically. He developed new kinds of intimacy. His dreams offered new insights. A visionary experience convinced him that he had been summoned to an arduous spiritual journey. At one level, the book follows a fairly recognizable pattern in pathography—a bumpy trajectory from symptoms to diagnosis to surgery and radiation to qualified recovery, new stages of accommodation, new treatments, a present life full of both pain and gratitude, and an uncertain future, faced with irony and hope. He even resorts to the war metaphor so common to cancer stories:

> …I'd missed the Second World War by some six years…. With college deferments I'd likewise missed Korea; and in the various Berlin confrontations and Vietnam, no branch of the service had wanted me. As a writer who admired the war stories and novels of so many soldier-authors, I'd often wondered to what extent my apparent luck was in fact a deprivation.
>
> Now at last I must enter what was plainly a war, with life-or-death stakes, and assume the fight in the only way I knew to fight—in the arts of picture-making and story-telling that I'd worked at since childhood…. So even that early, I'd cast myself as the hero of an epic struggle, and I saw both the ludicrous melodrama of that role and the urgent need for it.

Despite its limitations the metaphor served him well at the outset, providing incentive and focus as he crafted his survival strategies. Later, fierce determination softened into surprised acceptance of the costly months and years allowed him, in the course of which he continued the life he loved in a new key, his writing and teaching fueled by precious awareness broken open by loss and deepened by chronic pain.

Though the narrative participates in pathographic conventions, it is hardly conventional. Indeed, one might read it not primarily as a story of illness, but as a meditation on the mystery of creativity. It is as much about how Price learned to reclaim his calling as it is about suffering and survival. In fallow periods, capable only of lying in bed, he listened to music "as if it were literally life-or-death food," letting the harmonies reach "the core of my spine."

Later, able to sit up and hold a pencil and inkbrush, he took to drawing, rather than returning to the novel he had abandoned. He drew his "eel," and hung it where he could see it as he turned to other subjects, including a series of "meditations on the face of Jesus" that included "ferocious Christs like wilderness prophets with baleful eyes" and "unbearded young Christs barely sighting their fate, compassionate healers, numinous shamans, elder brothers and implacable judges." He wrote poems, from a place just beyond the reach of prose, as a record of days lived on budgeted energy and spent partly in the grudging idleness of exhaustion. He kept accounts of his "stupefying battery of drugs" and their dubious effects: dexamethasone, cimetidine and later amitriptyline, tryptophan, baclofen. Eventually, he returned to the fiction and essays that had always been his strongest way of meeting the world with his imagination. He has since produced 13 volumes, despite insomnia, bouts of depression, physical setbacks that confined him to a wheelchair and aching periods of loneliness.

It is easy to say such a book is inspiring. It may be more useful to consider how it informs and complicates our understanding of what compassionate care entails. From the testimonies of those who live with pain we learn what helps. For Price help came in the discernment of friends who brought their own kinds of gifts—silence from some, conversation from others, merciless reminding, late-night videos, groceries, overnight stays on the sofa, companionship in hospital halls. And in work—writing between mandatory rest periods, and teaching, where, in addition to adulation he received the "peculiarly tough and steady dose of daily judgment which students readily provide." Literature helped; lines like this one from *King Lear* saw him through hard moments: "The worst is not / So long as we can say 'This is the worst.'" Dreams helped, with strange intimations and usable information that lent direction to his enforced introspections. And help came in two waking visions that left him with a palpable sense of divine presence.

In his final reflections, Price acknowledges how mysteriously curse and blessing have intertwined in the long aftermath and how pain has taught him to love even a difficult life. Still in a wheelchair, having suffered some irreversible losses, he reports with amazement that recent scans show his spine clear of cancer—a level of cure one friend called "miraculous." He makes no direct comment upon that claim, but does recall that when his physician heard it, he responded, grinning, "You could say that." □

Dialogue:

The technology cost blues

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Americans want desperately to believe that health care reform is just a matter of eliminating waste and increasing efficiency. This dearly held view, according to Daniel Callahan (*Lahey Clinic Journal of Medical Ethics*, Fall 2009), is a delusion. The real problem is that we are addicted to technology, and while technology may be phenomenally beneficial for some, it is useless for others, harmful for a few and extremely costly for all. Callahan has been trying to persuade us to face this problem head-on since he published *Setting Limits* in 1987,[1] but we have been remarkably resistant to any consideration of limiting treatment.

For a short while it looked as though the situation might change, as the media devoted increasing attention to the problem of marginally effective treatment with a huge price tag. In the summer of 2008, the *New York Times* ran a long article about the use of bevacizumab (Avastin), a form of "targeted chemotherapy" that may cost as much as $100,000 a year.[2] Two weeks later, the *Times* featured another article about the growing use of invasive and expensive medical devices in very elderly people, presenting the example of a 99-year-old patient who was treated with an implantable defibrillator.[3] In both cases, the journalists recognized the problems engendered by spending so much money on interventions when success may be measured in months of additional life. But they concluded that Americans will never willingly forgo access to potentially beneficial treatment. Also in the summer of 2008, Federal Reserve Chairman Ben Bernanke told Congress in no uncertain terms that rising health care costs were the principal cause of the country's budget problems.[4] Then in January 2009, Peter Orszag, at the time head of the Congressional Budget Office, made a splash by asserting that it was health care costs that were going to bankrupt the United States.[5] It seemed that we might be entering a new era of restraint after all. But when congressional committees began laying out their proposals for reforming the health care system, even the most oblique mention of rationing unleashed a storm of protest. This ranged from the preposterous claims about "death panels" to tirades against comparative effectiveness studies on the grounds that they might lead health plans to drop coverage for treatments that they deemed ineffective.

Is there a way out? Is there any possibility of Americans confronting the "beloved beast," as Callahan puts it—medical technology, which, if unchecked, could result in health care consuming 37% of gross domestic product in 2050?[6]

Perhaps addressing waste and inefficiency is not as bankrupt an option as Callahan suggests. Maybe we could all have implantable cardiac defibrillators and targeted chemotherapy for cancer, prolonging life by at most a few months, if only we got rid of fraud on the one hand and delivered health care more efficiently on the other. There is some evidence that these two strategies may be more helpful than Callahan acknowledges.

In the realm of fraud and abuse—the most attractive line of attack because the only losers are criminals who defraud Medicare and Medicaid—$17 billion per year could be saved if all fraud were eliminated.[7] Government has devoted remarkably little effort and even fewer resources to going after the perpetrators, some of whom have elaborate systems for billing Medicare for bogus services ostensibly rendered to patients (some of whom are dead) by doctors (some of whom do not exist). In the realm of waste, we can make a modest dent in the cost of care by avoiding duplicate ordering of tests and using enhanced physician-to-physician communication via electronic medical records. While these strategies alone are unlikely to generate enormous cost savings, we may have a significant effect on cost if by "waste" or "inefficiency" we mean using an expensive treatment when a cheaper one would work just as well. Conducting research to determine which of various treatments offers the greatest benefit per dollar expended, and effectively promoting the winners in such studies, could well have a sizable impact on costs, just as substituting generic drugs for brand-name equivalents lowers costs.

If we accept this more expansive definition of efficiency, we need to identify how to ensure that doctors, hospitals and other health care providers practice efficiently. It turns out that we already have pockets of efficient medical care in the United States and that Elliott Fisher and colleagues at the Center for Health Policy Research at the Dartmouth Institute for Health Policy and Clinical Practice know exactly who and where they are.[8] In particular hospitals and in certain regions of the country, the cost per patient is as little as half that of the highest-spending regions. Most striking, health outcomes are comparable and, in some cases, better in the lower-spending areas than in the higher-spending areas. The explanation is not simply that the patients are sicker in the higher-spending regions (though this contributes to the differential spending), but rather that their doctors order more tests, refer patients to more specialists and do more procedures, in situations where they are "discretionary," that is, where the optimal strategy is unknown.[9] Fisher reasons that if medical centers throughout the United States were more like Group Health Cooperative in Puget Sound, Washington, or the Mayo Clinic in Rochester, Minnesota, than like UCLA Medical Center in California, we would cut annual health care expenditures by 30%. That translates into a $128 billion saving for the Medicare program alone. The way to achieve this transformation, Fisher argues, is to create integrated medical systems in which care is coordinated (a new delivery system) and to provide incentives to use evidence-based medicine (a new payment system).

But the intriguing aspect of the apparent success of Group Health in delivering top-notch, affordable medical care is not that it uses evidence-based medicine and others do not. Precisely the point is that the MRI scans and referrals to cardiologists that drive up the cost of care are *discretionary*: Hence, neither Group Health nor any one else

knows the optimal number of tests or referrals. But in the face of uncertainty, the Group Health doctors somehow make decisions that lead to good outcomes for their patients without incurring excess costs. The absence of a perverse economic incentive (i.e., a reimbursement system that stimulates greater test ordering by benefiting physicians financially) is surely part of the explanation for how that works. But that cannot be the whole story. Physicians in the high-spending areas refer patients to specialists even when they do not stand to benefit personally from such referrals—kickbacks for referrals are illegal. They order tests and procedures even when they are not themselves performing the interventions. Group Health has created a *culture of medicine* in which physicians practice a unique style of medicine.[10] We can only speculate how exactly the physicians achieve this, but perhaps they deal with uncertainty by spending time talking to their patients about the risks and benefits of interventions and recommending a conservative approach. Perhaps they deal with the inevitability of death by advocating a palliative approach near the end of life.

The lesson from the Dartmouth Atlas[11] and from the studies of Medicare fraud is not that we can have as much technology as we want. But neither is it that we have to face difficult decisions about limiting the creation, introduction and diffusion of technology. Rather, the lesson is that we can build a better health care system modeled on organizations such as Group Health within which expensive technology of only marginal benefit is far less likely to be offered, or demanded, than in the current system. Without explicitly addressing the issue of limiting the use of medical technology, we can nonetheless create an *environment* in which the pursuit of marginal benefit is the exception rather than the rule. This approach, to be sure, will not eliminate the use of extremely costly technology that offers a small possibility, say, of prolonging life by a month or two. We will continue to have requests for ethics consultations at our hospitals in situations where patients, or more often their anxious families, insist on treatment the medical staff regards as futile. But these requests will be rare. Without invoking strategies such as introducing cost-effectiveness analysis into Medicare's decisions about reimbursing expensive technology or shifting research priorities away from innovation and toward public health, we will have tamed the beast.

[1]Callahan D. *Setting Limits: Medical Goals in an Aging Society.* New York: Simon and Schuster; 1987.

[2]Kolata G, Pollack A. Costly cancer drug offers hope, but also a dilemma. *New York Times.* July 6, 2008.

[3]Hartcollis A. Price seen in medical effort to treat the very old. *New York Times.* July 18, 2008.

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Response: Muriel Gillick raises two questions that bear on her optimism that difficult decisions might be avoidable. What can we believe and what can we hope for? Can we believe those who expect that a reform bill will make it through Congress? Can we believe that they will hang on to some of their early commitments, such as a beefed-up Medicare payment commission and a public option plan to promote competition with private insurers? The prospects are not good for either.

I am not sanguine that strong measures will be put in place to control cost. The Centers for Medicare & Medicaid Services noted projected Medicare savings of $493 billion in the Senate bill—and then judged many of its projections

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***Legal**—continued from page 4*

Parthenogenesis produces an embryo-like body from an unfertilized egg. A human parthenote cannot develop into a viable embryo, but can be used to generate stem-cell lines. Such lines would be a perfect genetic match for the egg donor, permitting cellular transplantation without rejection. Parthenote cells might also be easier to match with others besides the egg donor; because they have only one genetic "parent," parthenote cells inherit only half as many of the histocompatibility antigens that create transplant-incompatibility problems.

Given this promise, why did the Obama administration shy away from funding embryos created in the laboratory? The answer is twofold: First, there is less national consensus on the ethics of creating embryos for research than on the research use of leftover IVF embryos. Second, laboratory embryo creation requires a woman to donate an egg for research. Egg donation involves extensive hormonal treatments and invasive surgery, and raises difficult questions about risk, financial compensation and commodification—questions the NIH decided to avoid.

Nothing in the guidelines prevents ineligible research from proceeding with private or state funding. Expect states and foundations to refocus their hESC-funding programs on the gaps left by the new Obama policy. □

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Dialogue—*continued from page 7*

as unlikely. And they will take 10 years to come to fruition, assuming none are rescinded along the way.

Dr. Gillick finds hope in the possibilities exhibited by such institutions as the Mayo Clinic and Group Health of Puget Sound and by the analysis provided by the Dartmouth Atlas. Yet no one seems to have a good idea how to get their organizational structure and culture out to national health care, and some ideas to do so have run into political opposition as well.

Perhaps we can avoid difficult decisions in the future, but I believe it is necessary to get that possibility discussed now to make it more acceptable if and when that unpleasant day arrives—as I think it will, and soon. The baby boomers by the millions are on the way. □

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Lahey Clinic Journal of Medical Ethics encourages reader participation. We welcome comments for our "Dialogue" column and invite submission of ethical dilemmas for "Ask the ethicist." Send correspondence and requests for complimentary subscriptions to David Steinberg, MD.

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