ISSN 1543-4672

Medical Ethics

Fall 2006
Vol. 13, Issue 3

Quote to note

"Informed consent becomes pretty questionable when prisoners (who)…can't read…are signing a document it…takes a law degree to understand."

Professor Daniel S. Murphy
on Resuming Use of Prisoners
in Drug Trials

Inside

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The relationship between ethics and politics

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The term "bioethics" is by now well known to almost everyone in the United States and in many other countries. It is remarkable that despite the core discipline of bioethics, much of what we worry about most in public discourse arises from laws and court cases. Why do we focus on "ethics" when the grist for the bioethics mill is overwhelmingly a political or juridical event? I think that the answer lies in looking more closely at the relationship between ethical theory and political theory.

We fervently hope that progress on contentious social issues such as abortion, birth control, medical research and end-of-life decisions can be made through the methods of bioethics. We convene commissions, employ experts, develop consensus papers and submit court briefs. The stuff of such methodologies (for example, that of the dominant bioethics model of balancing among competing principles) remains quite mysterious, however. What produces agreement or lets us know when we have struck the proper balance? The essential claim I defend elsewhere is that nothing within the methods of bioethics determines consensus; any agreement is due to the fact that we share certain assumptions about the purposes of social life and the kind of lives suitable to members of society. We disagree because of our deep differences on political ideals.[1] A brief look at Aristotle, Locke and Mill will illuminate some of the alternative perspectives available to us.

Ethics in it earliest sense in Greek philosophy was focused on one core question famously raised by Socrates, "what is the best life for man?" Aristotle's answer was that is a life of virtue—a set of human excellences or skills that make life go well for the person because it makes possible a life of wise choices.

Aristotle held that good moral judgment consists in what would be exemplified in the choices of the *phronimos*—the man of mature practical wisdom—and that such judgment is inherently particularistic. Moral judgment is a matter of knowing what to do in concrete or particular cases, in which the correct choice involves a course of action "at the right time, with reference to the right objects, towards the right people, with the right motive, and in the right way."[2] For someone seemingly committed to this particularistic conception of moral judgment—which has many loyal followers today in feminist and casuist schools of bioethics—his account of the virtue of justice is somewhat surprising. Justice is the virtue central to the excellence of choice within the public sphere. At the heart of moral choice on matters of justice is an ability to make judgments with respect to the set of general rules applicable to all members of the society, and to set out its requirements in advance of their application. For all the Aristotelian emphasis on good judgment in concrete cases, the weight he places on the role of rules in the public sphere is striking.

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Ethics and politics—*continued from page 1*

Aristotle put forward what many regard as the first well-articulated conception of the rule of law. His idea is that, even if the locus of moral certitude among the most virtuous lies in highly particularized judgment, much of the moral life within the public sphere can be conducted only as a life ruled by common rules. Aristotle's conclusion was not merely a concession to the fact that most of us fall far short of the ideal of the *phronimos*. The main justification for the rule by rules is that social relations so organized contribute great value to our moral life that is not attainable otherwise. It means that social life itself is possible only if some important parts of our moral relationships are governed by general rules known to and applicable to all. It means also that the citizens have to deliberate together about the rules that bind us together as a community, so that, as Aristotle put it, we are not a mere aggregation or collection of individuals. The rule-guided life, despite its bluntness and loss of attention to particularities, requires deliberation about means and the underlying ends for which our common rules are instituted. Such activity itself develops moral excellences or skills to a degree not otherwise possible, and it provides us with a kind of good not otherwise attainable. It provides us with the good of membership in a common community bound together by more than the desire for mutual protection, common defense, or felicity of trade and commerce. Moreover, without substantial agreement on the ends of life, social life itself is at risk and the ability of individuals to lead lives of virtue is undermined. The ethical life was, for Aristotle, a life of political participation and statecraft necessary because it is the only sure way to both individual and communal virtue, which are inextricably linked.

Isaiah Berlin in his *Four Essays on Liberty* saw the Aristotelian view as a rival to modern accounts of political morality.[3] He defined political theory as a branch of moral philosophy that involves the study of the moral relationship between the individual and society. For bioethics, Berlin's definition is helpful. Bioethics as a field is more inclusive than traditional medical ethics—the ethics of professionals and patients. Issues of individual rights at the end of life, informed consent in scientific research, and control over reproduction raise questions of the morality of individual action, but they raise also a second-order set of questions about the moral authority of the state to regulate intimate aspects of the lives of its citizens.

Aristotle's arguments, as powerful as I believe them to be, leave us with sobering thoughts. Public deliberation leading to common rules of conduct, enforced by the state, makes perfect sense on an Aristotelian view. The modern political liberalism of today might well question such an enterprise. It recommends a form of limited government; it seeks to remove many decisions from the domain of collective deliberation and decision. Liberal argument of this kind has taken two different forms. For John Stuart Mill, the theoretical task is to identify some domain of preference or choice in which the individual is sovereign and the state has no authority to intervene.[4] The Millian approach is a fairly good characterization of what the U.S. Supreme Court attempted in its privacy doctrine with respect to reproductive decisions in *Roe v. Wade*.

The second strand of liberal argument associated with John Locke is different in its rationale.[5] Locke argued that there are some matters best left for individuals to decide on grounds of conscience. Note that his claim is not one of moral relativism or generalized skepticism about matters of right and wrong. Locke's argument is that human understanding is limited and what we can know with confidence in the moral life necessarily remains inadequate to resolve every matter of controversy that might arise in public life. Nor was Locke advocating a kind of individualism of the free marketplace in which the different choices people might make on some moral matters was a matter of personal preference. Locke advocated an individualism of conscience, which on his theological view, meant that some matters are ones each person ultimately must answer alone. Indeed, the primary opinion in *Planned Parenthood of Southeastern Pennsylvania v. Casey* purports to uphold the "essential holding in Roe," but it substitutes what it calls a conception of ordered liberty in which for some matters individuals are free to "define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." More than mere preference is assumed here; the Lockean idea is central that some choices are linked to one's own moral and theological bearings, and are not mere preferences.

We cannot realize the benefits that are only possible in the Aristotelian system and the benefits of adopting either Mill's or Locke's approach. Either we defer more to individual preference (as Mill would recommend), or to individual conscience (as Locke might argue), or we place our faith in public deliberation aimed at common rules. In short, we have to decide not only what we think about the moral status of certain behaviors, but also about what we think represents the proper moral relation between the state and the individual. If we follow Aristotle's deliberative recommendations, we will inquire into the ends or purposes of those rules, and we shall have to confront arguments that take us full circle back to a version of Socrates' question, "what is the best kind of life for humans?" My sense is that when we take such a path and we try to reach answers about how best to "balance" competing concerns within bioethics debates, we strike the balance we reach largely because we are driven in the direction we take by some underlying broader vision of the sort suitable for answering Socrates' question. If we follow Locke or Mill we will defer to the judgments of individuals on such matters, and we will do so on the basis of a theory of political morality very different from the Aristotelian approach. □

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[2]Aristotle. *The Nicomachean Ethics (Oxford World's Classics).* D. Ross, tr. Oxford: Oxford University Press; 1998.

[3]Berlin I. *Liberty: Incorporating Four Essays on Liberty.* Oxford: Oxford University Press; 2002.

[4]Mill JS. *The Basic Writings of John Stuart Mill: On Liberty, the Subjection of Women and Utilitarianism.* New York: Modern Library; 2002.

[5]Locke J. *Two Treatises of Government.* Cambridge: Cambridge University Press; 1988.

Ask the ethicist:

Is this patient brain-dead?

Question: A 55-year-old woman was admitted for treatment of a small bowel infarction. Postoperatively, she suffered acute renal failure requiring dialysis, and a massive cerebral infarction producing increased intracranial pressure, coma, cerebral herniation and apnea. She did not have a DNR order. Neurologists performed a brain-death determination showing deep coma with no responses or movements and the absence of all brain stem reflexes. During apnea testing, she lost pulse and blood pressure from subcutaneous emphysema and pneumomediastinum that was presumed to have resulted from tracheal perforation by the oxygen catheter. Restoration of mechanical ventilation did not result in return of her pulse or blood pressure. Because the apnea testing was incomplete, she could not be declared dead by a neurological criterion. But the neurologist felt that she was almost certainly brain-dead and concluded that it was therefore futile to attempt to treat her subcutaneous emphysema and pneumomediastinum by chest tube placement or thoracotomy. Was she brain-dead and should any treatment have been attempted?

Response: Medical practice guidelines and statutes of death recognize two complementary standards for death determination: cardiopulmonary and neurological. By the cardiopulmonary criterion, a patient is dead who has suffered irreversible cessation of circulation and respiration. By the neurological (or "brain-death") criterion, a patient is dead who has suffered irreversible cessation of all clinical brain functions.[1] In the United States, most statutes of death employ the Uniform Determination of Death Act or a variant of it that permits physicians to use either criterion: cardiopulmonary when mechanical ventilation is not being used or planned, and neurological when it is used.[2] There is an important linkage between the two. The cardiopulmonary criterion is a valid determination of death because it leads to complete destruction of the brain.[3]

Tests for death are designed to show that the criteria of death are satisfied. The tests to show satisfaction of the cardiopulmonary criterion are the observed prolonged absence of breathing and heartbeat in a patient not receiving mechanical ventilation.[2] The tests to show satisfaction of the neurological criterion ("brain death") are more complicated. The patient must have a demonstrable anatomic pathologic condition that can fully account for the clinical signs. The patient must be comatose and ventilator dependent without movement; have absence of all brain stem reflexes mediated by the cranial nerves including pupillary light reflexes, corneal touch reflexes, vestibular-ocular ("ice water caloric") reflexes, and gag and cough reflexes to endotracheal tube suctioning; and must have total apnea. These findings must be proved to be irreversible.[4] Confirmatory lab and imaging tests can be performed in indeterminate cases to demonstrate the absence of intracranial blood flow or of brain electrical signals.[5]

Physicians must determine apnea properly by allowing the P_ACO_2 to rise to a level greater than 60 torr to maximally stimulate the brain stem respiratory centers, while protecting the P_ACO_2 from falling to dangerously low levels that could induce cardiac arrhythmia or hypotension.[6] The technique of apneic oxygenation usually is employed to achieve these goals.[7] The patient's ventilator settings are adjusted to restore P_ACO_2 to normal levels and oxygen concentration to 100% for at least 20 minutes. The 100% oxygen is passively infused under high flow through an endotracheal catheter or other means. The patient is removed from the ventilator and observed for any signs of respiratory activity as the P_ACO_2 increases over 5–10 minutes. Arterial blood gas determinations prove that the requisite P_ACO_2 level has been achieved. The test shows true apnea only when no respiratory effort at all is observed.[6] When the pre-test P_AO_2 cannot be raised to a level high enough to permit the apnea test to be performed safely, the augmented CO_2 apnea test can be performed, in which the patient is administered a higher concentration of CO_2 by ventilator.[8] This technique shortens the durationof apnea during the test and leads to fewer complications.[9]

The patient in this case satisfied some of the brain-death tests by having a proved brain disorder that could account for the irreversible cessation of all clinical brain functions, namely cerebral transtentorial herniation from increased intracranial pressure. She satisfied the clinical criteria by being comatose and having an absence of all brain stem reflexes. But tracheal perforation occurred, a rare complication of apnea testing,[10] that precluded an apnea determination, thus preventing brain death from being confirmed despite its very high likelihood. Given the clinical facts, it is likely that the patient would have fulfilled the apnea test and been declared brain-dead.

Her neurologist cited medical futility as the grounds for not attempting further resuscitative therapy. I agree with this decision because of the high probability she was brain-dead (despite the difficulty in proving it) and the vanishingly small chance that any therapy could reverse her circulatory collapse. And even if aggressive treatment could have restored her heartbeat, it only would have permitted completion of the brain-death determination, leading to her being declared dead anyway. Although medical futility remains a controversial justification for unilaterally withdrawing or withholding life-sustaining therapy in many conditions, most ethical analyses of this topic agree that impending brain death is a fully justified reason for not ordering aggressive therapy.[11]

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Outcome: The patient was declared dead. □

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Ask the ethicist—*continued on page 12*

The legal column:

Patient safety meets fraud and abuse

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Are health care providers different from plumbing contractors, and should mistakes or adverse outcomes be treated any differently in the two cases? Consider this scenario: you are a large third-party payer and contract for services. The provider causes an adverse outcome due either to negligence or an unanticipated complication.[1] Unaware of the adverse outcome, you receive a bill and pay the contractor. The contractor repairs the damage it originally caused, bills for the remediation, and the payer pays for it, not immediately making the connection with the initial, flawed service. Was there a legal and/or ethical breach by the contractor? Once you find out about it, do you have a remedy?

A nexus of patient safety and fraud/abuse has been targeted in recent health care litigation that may shake the finances and clinical practices of health care organizations. The hitherto obscure Medicare Secondary Payer Act (MSPA, 42 USC Section 1395 y C b) has recently been deployed by very experienced plaintiffs' attorneys against hospital systems.

The first high-profile suit was filed in California Superior Court against a set of Tenet health care organizations (*Erin Brockovich ex rel vs. Tenet Healthcare Corporation, et al.*, 2006).[2] The suit alleges that the hospitals and their employees or agents caused harm to unnamed Medicare beneficiaries (by way of medical errors); that the health care organization knowingly billed Medicare for the initial services and then proceeded to provide remedial treatment and services to the same injured patients. The plaintiff, who is already a nationally recognized name in consumer litigation, then claims that Tenet billed Medicare for the remedial services and received additional Medicare reimbursements. The allegations in the complaint are not based upon the claims of a single patient or even a class of patients, but upon published data that errors for certain conditions exist in every facility, and that based on national data and other information, errors occur at the Tenet facilities. Based upon the allegations, discovery requests will likely seek specific information from the defendant.

Under the provisions of the MSPA, it can be argued that the hospital had the obligation to pay for the remediation, and that if it had been paid by Medicare, the defendant must have a means by which to track such payments and reimburse the federal government. The premise of the act is that Medicare is precluded from paying for certain services *if* "payment has been made or can reasonably be expected to be made under…an automobile or liability insurance plan…or under no fault insurance."

An underlying assumption of the Brockovich action is that medical errors that occur in a hospital may represent a personal injury to the patient for which some payment or remediation could reasonably be expected to be made under the provisions of some insurance (including a malpractice liability) policy. If, in the process of providing care, errors occur and remediation is included in the billing, then the provider is receiving payment for remediating an error during treatment of a potential insurance reimbursed service. Even if a malpractice case is not filed, health care providers should never expect to get paid to remediate their own errors, especially by the federal government. Payments made by Medicare to providers in the scenario suggested are deemed "conditional payments" for which repayments are required.

The provisions of the act become more interesting with respect to penalties and enforcement. The U.S. may collect double damages against the health care provider (which can be a hospital, clinic, physician or any billing clinical entity), and the act expressly provides for private causes of action and damages. The U.S. has an interest if it paid for the initial services through Medicare. Double damages are a form of punishment to the defendant in an action.

The implications of this first, loud salvo are profound for hospitals, Medicare and patients. The cause of action emulates aspects more common in "whistle-blower" actions in Medicare fraud and abuse cases. In these cases, somebody with inside knowledge of fraud or abuse can be the named plaintiff in a case against the alleged perpetrator. This whistle-blower is called the "relator." The relator whistle-blower is standing in the shoes of the government and may benefit by receiving a percentage of a settlement or recovery. But unlike the more common Medicare fraud cases, the MSPA plaintiff need not be an insider. The plaintiff can be any citizen acting privately on behalf of the federal government.

The action makes the reasonable assumption that some medical errors and adverse outcomes due to negligence of the provider have occurred within the hospital. While patient safety has assumed a prominent role in risk management program evolution, this litigation uses patient safety as its springboard—with one anticipated effect being that hospitals will pay far more attention to the causes of error once they are forced to pay for their own mistakes. For example, a Medicare beneficiary undergoes abdominal surgery for a bowel resection. Post-closure, and perhaps even post-discharge, an infection results. The patient is readmitted and the cause is determined to be a foreign object left in the abdominal cavity. The patient is brought back to surgery and the object is removed. The hospital (and perhaps even the surgeon and anesthesiologist) submits additional bills to Medicare for the remedial procedure and gets paid.

By billing for the remediation, not having a means by which to track such events, and not repaying Medicare for "conditional payments," there is an implication that there has been a degree of fraud on the part of providers who knowingly accepted Medicare payments for remediating their own mistakes. At stake could be penalty payments that are twice the amount of the bills submitted. And the federal government can look back three years and charge interest, retrospectively.

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Risks posed by new biomedical technologies: how do we analyze, communicate and regulate risk?

This is an edited transcript of a May 2006 symposium presented by the University of Minnesota's Consortium on Law and Values in Health, Environment & the Life Sciences, co-sponsored by the University's Joint Degree Program in Law, Health & the Life Sciences; Center for Bioethics; and Center for Environment and Health Policy. Full video of the symposium is available at http://www.lifesci.consortium.umn. edu/. This transcript was edited by Jordan Paradise, JD, Associate Director of Research & Education at the Consortium and Susan M. Wolf, JD, Chair of the Consortium.

E. Thomas Sullivan, JD, Senior Vice President for Academic Affairs and Provost, Julius E. Davis Chair in Law, University of Minnesota:

Biomedical research is moving forward at a furious pace, in our community, across the country and around the world. Leading public and private universities are developing important new interdisciplinary initiatives and joint ventures. With such extensive activity, we need to look ahead to emerging issues in biotechnology, particularlyas we move from research to effective therapies through translational research. There is an urgent need to ask the question posed by this symposium: How do we analyze, communicate and regulate risks posed by new biomedical technologies?

The answer will require interdisciplinary approaches. Formidable gains will be made by crossing professional divides and working together across cultures and beliefs. People will bring different perspectives to the analysis of risk. We need to use the tools of psychology to ask how the public understands and perceives risk. We need to use the tools of ethics to decide what risks should and should not be imposed on research subjects and patients. We need to use the tools of law to explore what oversight mechanisms will protect the public from inappropriate risks and negligent design or manufacturing of biomedical technology. This symposium is an opportunity to develop common concepts and a common language, and then to begin the difficult process of weighing and balancing. Debate and discussion are essential components of this process.

This symposium allows us to explore these questions across several biomedical technologies. By analyzing the successes—and the mistakes—of the past, we can responsibly shape our future. Past approaches to the risks posed by reproductive technologies or drug and device development may have important lessons to teach us as we try to grapple with the risks of emerging biomedical technologies such as enhancement technologies, nanotechnology and genomic medicine. Here, we have to consider risks we have yet to encounter. What new risks await us? How can we prepare for them? These are the right questions for a leading public research university to be asking. Our speakers today will help us to explore these important public policy questions.

Eric T. Juengst, PhD, Associate Professor of Biomedical Ethics, Case Western Reserve University School of Medicine, on Human Enhancement Technologies—Addressing Physical and Societal Risk:

One working definition of human enhancement technologies is artificial interventions designed to improve on the functionality of otherwise healthy human traits beyond the reference class, above normal functioning. Depending on the context, this may mean that you are enhancing yourself beyond your own genetic endowment, or beyond the normal range of your competitors and teammates in an athletic context, or out of your social class, or out of being a recognizable member of our species altogether. A lot of the interesting work in the field at the moment involves teasing apart what all these words, particularly philosophically laden words, might mean in a policy context.

In bioethics, we are not worried about the risks of positive thinking—practicing your music lessons to improve your performance ability, prayer as a tool for spiritual growth, caffeine, cosmetics or even cosmetic surgery. As all of these practices suggest, we live in a culture in which enhancement by itself, living up to our potential or improving ourselves, is not an unusual or, on the face of it, a bad thing.

Similar to what a judge once said about pornography we know a problematic enhancement when we see one. They are the enhancements that we gain not simply by practice or prayer but by drugs, devices, genomic medicine, nanotechnology, stem cell interventions, human gene transfer, reproductive technology and other biomedical tools. I think we will see most of these enhancement technologies arrive after approval and risk assessment through the normal biomedical research process, along one of two routes. Either they will arrive as a form of prevention, as part of the promise of personalized genomic medicine to address our health problems prophylactically, or in the guise of our old friend, the off-label use of medical treatments.

In 1995, LeRoy Walters developed the framework for the regulation of gene therapy. He said that out of the four things possible to do with human gene transfer, we should be doing only one—altering somatic cells for therapy, and not for enhancement. This line in the sand was accepted and adopted by the National Institutes of Health in establishing the federal risk assessment process for human gene transfer research. Today, however, most gene therapy protocols approved by the Recombinant Advisory Committee (RAC) are cancer vaccination protocols to boost the immune systems of research participants so they will be more capable of seeking out and destroying cancer cells than the immune systems of their reference class, the rest of us. In fact, compared to the rest of us, their immune systems have been enhanced, improving their ability to stave off cancer, much in the same way we upgrade our immune systems to stave off infection through vaccination.

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***Risks**—continued from page 5*

However, if we call this enhancement, then we've been doing enhancement all along, upgrading people's immune systems beyond their reference class in order to prepare for the insults of the environment. That is just prevention, and of course is what the cancer vaccinations are as well. If these techniques work with patients who have cancer, why not use such prophylaxis for the rest of us? Why not take your immune system in for an upgrade in order to prevent cancer in the future? That is the promise of personalized genomic medicine.

We may need to amend the definition of human enhancement technologies to exclude interventions that prevent health problems by reducing health risks below the normal range for the subject's reference class. Instead of saying we must worry about these enhancements, why not just extend the biomedical boundary to include prevention, and say that is not the kind of enhancement we are worried about? Under the auspices of prevention, many enhancements could come to us and their risks will be assessed in that context. As difficult as it is to assess the risks of preventions, at least we do have some experience with vaccine trials to begin the discussions.

The question arises whether there are any special risk-assessment issues for enhancement. In conducting quality control or risk assessment to anticipate off-label uses—whether in the context of clinical trials or sports medicine—we need to determine whether these applications are harmful. We need evidence; we need studies.

But how do we conduct this research to test for risks of enhancement? We are no longer balancing health risks against health benefits. We are balancing health risks against other kinds of benefits—social benefits—necessitating an algorithm for balancing incommensurable values. We will have to figure out what we mean by efficacy. We will have to consider whether there are vulnerable populations. For example, if youare an athlete in a forced-choice situation—either I use the performance enhancement or I sacrifice my competitiveness—joining a trial might be quite attractive.

Of course we will need to address the downstream social risks of enhancement. How do we assess the likelihood, severity and distribution of such risks? One thing we can predict is that social values will change, and we have an ability to influence that change. So what should our posture be? One possibility is prohibition: forbid enhancement and condemn those who do it.

Or we could draw from the environmental movement and use the precautionary principle—put the burden of proof on those who would want to pursue enhancement. That is the midrange, traditional, case-by-case technology assessment that the RAC has been doing and that other science-impact assessment enterprises have been engaged in.

I think we need something more. We should take a lesson from public health about addressing risk and accept the need for harm-reduction measures. We should prepare for the possibility that someone will use enhancement technologies without applying the precautionary principle by shoring up the protection of human rights in the face of new kinds of genetic differences. To protect the innocent from the downstream social consequences of enhancement, should we develop a convention against human rights abuses of human genetic research?

We need to consider the different ways in which human genetics research can be used and abused to foster forms of discrimination. This is the most urgent need, because it is in the more proximal consequences of genome research that these issues will first arise—the law enforcement and political uses of genetic profiling, public health uses of genetic screening tools, genetic discrimination in social institutions, and the debate over the use of race in genetic research. If we could address those issues and find a way to preserve our commitment to moral equality in the face of all kinds of differences, then I think we might successfully prepare for the day when, intentionally or not, we come to a new kind of human diversity.

R. Alta Charo, JD, Warren P. Knowles Professor of Law and Bioethics, University of Wisconsin-Madison, on Stem Cell Interventions and Regenerative Medicine—Risk and Politics:

The human embryonic stem cell field is one that has been characterized by excessive distortion, specifically with regard to information about risks and benefits of this research. Both sides have engaged in distortion for partisan purposes. The debate has become muddied rather than clarified, putting us at risk of oppressive political reactions.

Human embryonic stem cell research involves isolating material from the so-called inner cell mass of a human embryo, which is several days old, and culturing that material into a self-replicating but non-differentiating population of so-called embryonic stem cells. The vast majority of the time, people who want to work with embryonic stem cells want to work with stem cells arising from excess embryos remaining at IVF (in vitro fertilization) clinics whose progenitors have decided not to use them. This is the principal source of material for the derivation of new embryonic stem cell lines.

If you were a casual reader of the newspapers or a casual observer of the politics, you would get the mistaken impression that the primary source of embryonic stem cells will be from custom-made embryos. You would have that impression both because the news media has regularly conflated the technologies of cloning and stem cell research and also because so much of the debate lately seems to be about the risks associated with egg donation. Some have asserted that we would need hundreds of thousands of women providing hundreds of thousands of eggs at exorbitant cost and with exorbitant risk to the women themselves. This is an incredibly interesting shift in focus to the risks on the egg donors, even though it is at odds with the reality, which is that the new lines would come from surplus embryos in almost all cases of near-term research.

Human embryonic stem cells have largely been considered for tissue transplantation. This relies on the ability to use embryonic stem cells to grow tissue in a laboratory, which could then be transplanted into a person who has an injury or a disease, functioning to replace the defective tissue or supplement existing healthy tissue. This application relies upon a special characteristic of embryonic stem cells, the fact that we may direct them to become different sorts of tissue through differentiation.

One of the tactics used by people who oppose federal funding for embryonic stem cell research and often oppose its legality has been to assert that this kind of therapy is intrinsically risky. These opponents argue that the very flexibility of these cells, their ability to become different kinds of tissues, makes them dangerous, because they

might grow in an uncontrolled fashion once in the body and form tumors or other kinds of inappropriate tissues. The same people tout, by contrast, the value of adult stem cell therapy, pointing out that we have other kinds of stem cells in our bodies that are partially specialized and provide a perfectly adequate range of materials to use for research. They point excitedly to the fact that there is intriguing research suggesting we may be able to change the direction that these adult stem cells differentiate. And wouldn't this be great, because then we wouldn't need to use embryonic stem cells? But notice that the very plasticity that they are now suggesting may exist in adult stem cells is precisely the plasticity that they argued earlier made embryonic stem cells too dangerous for human therapies; that very plasticity is what would allow the stem cells, potentially, to differentiate in uncontrolled fashion and form tumors and other kinds of inappropriate tissue growth. So the language of risk is being used in ways that are scientifically inconsistent and probably more tied to the politics of the embryonic stem cell debate.

The stem cell debate is also characterized by unpredictable alliances, which partly explains the general paralysis in policy making. People who oppose abortion and the right to have an abortion are frequently of the view that the embryo is the moral equivalent of a fetus, so the destruction of an embryo is as morally weighty as the destruction of a fetus and, therefore, destruction of fetuses should be forbidden. For this group, it is very important to oppose embryonic stem cell research because of the way it takes advantage of embryos.

However, research by Kathy Hudson shows that people who oppose abortion are not uniformly opposed to the use of embryos in research.[1] The dominant factor, as important as or even more important than the attitude about embryos, is their attitude about human suffering. If you can demonstrate that there is a profound benefit to be achieved from the research and if they come from a religious tradition or a personal background that views suffering as something to be actively avoided—if they come from a tradition where healing people is more important than learning from suffering—then they will find themselves supporting embryonic stem cell research legality and even federal funding.

If you were working to oppose federal funding for embryonic stem cell research and if you understood your constituency, you would put forth an argument discounting the benefits of the research and heightening the perception of risks. This underlies the campaign to overemphasize the benefits of adult stem cell research and to suggest that it is moving ahead so quickly that we have no need for any alternative sources of research. It underlies the persistent claims that embryonic stem cell therapies from whatever source would be incredibly risky in humans. It underlies the argument that most embryonic stem cell research is going to take place in conjunction with cloning, adding yet more risk.

In the debate over embryonic stem cell research, we also find a co-opting of the rhetoric from the women's health movement and the far progressive left within the antiabortion community. A fringe element of the women's health movement has taken an extremely critical stance with regard to embryonic stem cell research, particularly with regard to cloning research. This is a group from the 1980s upset with reproductive technologies, not only because of lack of regulation, but also because this group saw in reproductive technology the view that women absolutely had to have children of their own bodies or they would not be fully formed women. This critique has been unsuccessful; these critics did not shut down the field or pass legislation to criminalize or heavily regulate practices that they most strongly criticized.

Judy Norsigian, a leader of the movement against the development of reproductive technology, has thus led a charge with a small number of women from the women's health community to promote the criminalization of cloning research in the U.S. and has joined forces with the most dedicated opponents of abortion rights. Indeed, it was Norsigian's presence in this kind of alliance that allowed people like Senator Sam Brownback from Kansas, a leading conservative in the U.S. Senate, to pitch his criminalization bill as something that was being supported by the women's movement. The mainstream women's movement was so perplexed by all this and without any opinion on it that they stayed completely silent and allowed the terrain of the women's position to be occupied by these rather fringe groups.

In the absence of good information, we have a political free-for-all. Indeed, both the complicated alliances and the absence of good information and the absence of a regulatory regimen that is comprehensible to the public has put us at risk of oppressive legislation that includes the criminalization of basic cloning research. The way to handle the risk of this kind of political overreaction, the last hope for staving off truly oppressive levels of regulation often based on bad science or distorted politics, has been to ask for a much more vigorous effort at self-regulation within the profession.

The embryo stem cell research debate is turning out to be far more complex than one might realize. In part it is complex precisely because of distorted information about the risks and benefits. In 1975 we saw the Asilomar crowd taking a tremendous step forward in assuaging public fears about risks by overregulating themselves in the conduct of early recombinant DNA research and then letting the world catch up. The question is whether or not we can successfully replicate that experiment without any help from the federal government to preserve a field from criminalization and wait until the public catches up.

Edward R.B. McCabe, MD, PhD,
Co-Director, UCLA Center for Society and Genetics, on Genomic Medicine—A Future Flooded with Risk Information:

To a geneticist, risk means prediction, and probabilistic prediction rather than an absolute prediction. We cannot offer absolutes to our patients, yet we are uncomfortable with nuance. Thus we may give misinformation to our patients based partly on lack of information, but partly on our nature—a desire for absolutes.

The difficulty of predicting risk is compounded by the complexity of systems biology (the study of the relationships and interactions between and among parts of biological systems) and by an incomplete understanding of genetic and environmental modifiers. Genotype (the genetic makeup of an individual, in the form of DNA) does not predict phenotype (the total physical appearance and makeup of an individual or a specific manifestation of a physical trait) even for rare single-gene simple Mendelian disorders (genetic disorders caused by the change in a single gene). Because of the complexity of the

***Risks**—continued on page 8*

Risks—*continued from page 7*

genome (the entire hereditary information of a biological organism encoded in the DNA), the proteome (the entire complement of proteins in a given biological organism or system) interacting with the transcriptome (the set of all messenger ribonucleic acid, or mRNA, molecules in a cell or set of cells), we are faced with interacting and dynamically coupled systems that are constantly changing. So if it is true for rare single-gene disorders that genotype does not predict phenotype, then clearly it is going to be true for the common, much more complex traits.

We have learned that individual biological molecules do not exist or function in isolation; we have to consider these proteins as parts of modular systems. Systems biologists would argue that these dynamic systems can be modeled and the models are amenable to mathematical analyses. Systems biology is moving biology from a descriptive science to a quantitative discipline. If we are going to translate biology into medicine, we must be able to quantify it.

Consider systems dynamics. We are not a random network. We are a hub-and-spoke network in terms of the biology in our cells. You can think of it as the "FedEx" system. If there is a blizzard in Boston, the rest of the system can still function as long as Memphis does not go down, which is the central hub of FedEx. With systems dynamics, you can take modules and build them up to be the biology of a cell or a complete organism. But that is extremely complex when we are just beginning to learn about the bare minimum of these with, say, cystic fibrosis (CF) and, in fact, cannot even link the CF protein and its modifier yet on one of these network diagrams.

Our knowledge is incomplete. Individual modifiers influence risk in a probabilistic manner and vary depending on genetic makeup. If we wish to understand risks, we need to take a whole-genome approach requiring information on large populations. For hemochromatosis, an iron-storage disease, a study was conducted on a population of 100,000 and erased some of the myths about genotype-phenotype relationships in that disease.[2]

So what are some of the challenges facing us? Pharmacogenetics, the interface of genetics and the medication environment, will be one of the first places where genomic medicine begins to impact routine medical care. In U.S. hospitals, the incidence of adverse drug reactions, or ADRs, is 6.7%. The incidence of fatal ADRs is 0.3%. The goal would be to use pharmacogenetics to predict and prevent ADRs and to optimize an individual's therapy.

Many drug side effects are not probabilistic. We know a side effect reflects how that drug interacts with our genetics; we can relate many ADRs to individual genetic predisposition. This is where we will first see the promise of genomic medicine on predictive, preventive and personalized care.

But we need testing devices. Roche, working with Affymetrix, came up with a pharmacogenetic testing device called the AmpliChip CYP450, named for cytochrome P450, a family of enzymes that metabolize drugs. Approved by the Food and Drug Administration in January of 2005, it is the first microarray-based clinical test. (A DNA microarray is a 2D array of genes or gene fragments set on a solid surface, such as glass, plastic or silicon chip for use in monitoring gene expression levels.) Tests for genetic variation and genes in two of these P450 enzymes, CYP2D6 and CYP2C19, should affect a significant percentage of the drugs that we use: antidepressants and antipsychotics, anticonvulsants, cardiovascular medications, cancer chemotherapeutics, antimalarial drugs and others. In children, we prescribe doses based on the patient's size. But otherwise we use uniform dosing, treating everyone as if they were the same genetically and assuming identical metabolism. The AmpliChip CYP450 identifies the spectrum of variation in metabolism, poor metabolizers, intermediate metabolizers, normals, and ultrarapid metabolizers.

What are the consequences of this fact? If you are a poor metabolizer, you risk toxicity from prolonged or excessive drug levels. Ultrarapid metabolizers risk not achieving therapeutic levels. For pro-drugs, drugs that have to be metabolized to become an active drug, it is the opposite. If you are a poor metabolizer, then you cannot get to a therapeutic dose. If you're an ultrarapid, then you exceed a therapeutic dose. There are significant differences in metabolism.

The SNP-chip microarrays, the same kind of technology that's used for the CYP450 AmpliChip, can also be used for whole-genome approaches. We have single nucleotide polymorphisms, or SNPs, throughout our genome. They're not mutations but genetic markers. Microarrays were originally designed to identify variation in these SNPs in order to look at associations between SNPs and phenotypes, but can also be used to look at the presence versus the absence or the amplification of a genomic region. You can then also combine molecular cytogenetics—insertions and deletions in an individual's DNA—with identifications of the modifiers.

With this whole-genome approach, we can identify the patient's deletions and can combine that with the knowledge of polymorphisms, the SNPs in the deleted region and genome-wide. We can utilize this whole-genome information to improve prediction of the phenotype and all of the other SNPs. But with all of that, the risk predictions are still going to be probabilistic and not absolute. It's just the way biology is.

Systems biology is an attempt to begin to quantify the complexity of these dynamically coupled, robust networks. Limited information and methods at this time are the norm and so much remains unknown. There is an incredible volume of data. We have to use mathematical algorithms for analysis because the output is going to be enormous. We have to figure out ways of representing the output and the risk.

In summary, genomic medicine represents a future flooded with risk information. We already recognize that we do not know all of the information that we need to know to counsel our patients in the genetics clinic. This risk information in genetics is inherently probabilistic and not absolute. We must develop comprehensible representations of this risk information if we are going to be better able to transfer that information to the general pediatrician and the general practitioner for the care of their patients. Parents tell us they do not want us to dictate the care of their child. They want to be partners with us in the care of their child. So they want to understand this probabilistic information. Such efforts are going to require multidisciplinary teams—geneticists, mathematicians, engineers and others working together—to develop the tools for genomic medicine. □

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Ethics and the humanities:

Nobody ever said AIDS: stories and poems from southern Africa

Edited by Nobantu Rasebotsa, Meg Samuelson and Kylie Thomas
Cape Town: Kwela Books, 2004

Review by Rebecca Garden, PhD
Center for Bioethics and Humanities
SUNY Upstate Medical University at Syracuse

In the foreword to *Nobody Ever Said AIDS*, a groundbreaking anthology that establishes the literature of AIDS in Africa, South African short story writer and essayist Njabulo S. Ndebele quotes a leading human rights activist, Edwin Cameron, in calling for "sympathetic insight" into the AIDS pandemic in Africa, saying, "We need to respond with imagination and compassion to what is happening around us." Ndebele praises *Nobody Ever Said AIDS* as a necessary imaginative argument for an urgent response to the AIDS crisis, one that is more effective than a purely rationalist mode of argumentation because it is in the form of storytelling and other creative modes of writing. Ndebele describes the ability of short stories and poems to "open the space for us as readers to understand, to mourn, and to grieve for the collective losses facing us in southern Africa today" and to mediate "access to the social and interior worlds of their characters." In the way that American authors in the 1980s and '90s created a body of literature that broke the "silence that equals death" during the AIDS epidemic in the United States, now African authors and publishers have begun to represent to those outside of Africa the particularities and interior experiences of the pandemic, with the hope that these individual stories of AIDS will create understanding, sympathy and the action needed to effect social and political change.

Two million people died of AIDS in Africa last year; more than 12 million children have been orphaned by AIDS; fewer than one in five of the millions who need antiretroviral treatment are receiving it. *Nobody Ever Said AIDS* offers individual life stories and individuals' laments, arguments and critiques as a counterweight to the paralyzing blankness of these figures enumerating those living with HIV/AIDS. Roshila Nair thus begins her poem "Fanon's Land" with the lines: "Threadbare in the blood/bloody in the tongue/tongue-tied by the birth push,/we have washed up on a word/like an old bed sheet/wrung dry of the fight/on laundry day." Nair incorporates a critique into her lament: "love still finds me here/in the post-colonial hour,/here/among the politics of viruses/and neo-liberal economic policies,/here among the grand things that have curled around us/and sprouted wings."

The poem that begins the anthology and gives it its title, Eddie Vulani Maluleke's "Nobody Ever Said AIDS," addresses the issue of denial that characterizes the failure to confront HIV/ AIDS from within Africa and from without. Beginning with images of celebration prior to a full awareness of the crisis—"Oooh/1994/Friday night shebeen/Sis Thandeka's kitchen/ Singing loud and rich/To anyone who clapped"—the poem takes the reader through the increasing losses—"Jimmy/Petros/ And Jabu/All got sick/And skinny like broomsticks… And just drank and drank/Then they died of TB/In 1996./ TB?"—and the disaster of denial—"We all died/ Coughed and died/We died of TB/ That was us/Whispering it at funerals/ Because nobody ever said AIDS."

The anthology lifts the discourse about HIV/AIDS out of the whispering and denial into fierce articulation. Stories like Leila Hall's "Girls in the Rear-view Mirror" represent individual subjectivities within abstractions such as "risk groups," in this case sex workers and truckers. Hall tells a story about Luis and Jotinha in Mozambique. Luis meets Jotinha at a truck stop and is taken by her serious expression and dark almond eyes. Luis pays for sex with Jotinha that night—he pays double for sex without a condom—and for other nights in the following years, during which time the two fall in love. Jotinha disappears and when she finally returns, she is dying. Luis refuses to see her, to speak to her, seeking her out only when it is too late. An acquaintance tells Luis that Jotinha died of AIDS, that she has a child and that the child is HIV positive. Hall frames Luis's response with a simple metaphor: "The thread began tying itself into a perfect knot. He tried to undo it, tried picking it with his fingernail, but it was too tight. There was suddenly a whole line of things, a whole network of people connected…Anger was boiling inside Luis." "Girls in the Rear-view Mirror" does not untie the knot of social relations that enables both community and communication of the disease. Rather, it ties its readers into the knot of relations as witnesses, involving them in the specificity of Luis's despair.

Nobody Ever Said AIDS records the way in which the oral tradition of storytelling in African culture responds to HIV/AIDS with Teboho Raboko's "Sefela—Migrant Worker's Poem," translated and transcribed from oral Sesotho, a language of Southern Africa. "Sefela" tells the story of the "Thin Death," also called "kill-all" and "lying-on-the-back-disease," and involves the reader in folk knowledge about the disease with the imperative direct address: "You can imagine how cruel the disease was." Another poem, "Just a Child," by Mthuthuzeli Isaac Skosana, similarly hails the reader as a witness to the epidemic: "I'm just a child/not prescribed as a cure/I'm not your HIV medication/even my scream could not stop you/your ears are my witness/I'm just a child."

The stories and poems in *Nobody Ever Said AIDS* not only break the silence the separates Africans from those outside Africa who have the power to assist them, they also fill that silence with subjective experience, revealing the interior worlds, the first-person observations and ideas of those who live with the disease in one form or another. These subjective experiences engage our imagination, our sympathy and ideally our will to bear witness to and to alleviate the suffering caused by HIV/AIDS in Africa. □

Dialogue:

Holding mechanisms responsible

Times are tough for those who suppose that the mind is something categorically other than the body. Neuroscience increasingly reveals that the physical brain carries out those higher mental functions traditionally attributed to the immaterial soul: feeling, thinking, planning and moral decision-making.[1] If we tie our status as morally responsible beings to something non-physical that supposedly evades scientific explanation—consciousness, for instance—we are skating on thin ice. Those inclined to science, not mind-body dualism, must find a basis for moral agency that is compatible with being strictly physical creatures.

In "Free Will and Moral Responsibility in the Age of Neuroscience" (*Lahey Clinic Medical Ethics*, Spring 2006), bioethicist Walter Glannon denies that he is a dualist, but nevertheless he says consciousness transcends materiality: "The brain is subject to material analysis, but the mind is not. The essence of mind is consciousness." To declare that the mind, and in particular consciousness, is beyond the reach of scientific physicalism is a very strong claim indeed, and premature, given the tendency of science to explain heretofore mysterious phenomena. But for Glannon, we must be more than physical creatures to count as moral agents, and consciousness seems to fill the bill.

What motivates Glannon, I suspect, is what philosopher Daniel Dennett has called the fear of "creeping mechanism"[2]: if we are, even in our highest capacities, merely the working out of mechanistic causality (neural mechanisms, in this instance) then on what basis can we consider ourselves deserving of praise and blame? If, as Glannon says, "Moral responsibility for our behavior presupposes free will, which in turn presupposes the requisite control," then it might seem consciousness only gives us the requisite control if it is not reducible to deterministic, cause-effect relationships instantiated by the brain. But are we conscious creatures more than very complex mechanisms? And need we be more than mechanisms to possess the sorts of control capacities that confer responsible agenthood?

Such questions have exercised philosophers for millennia, but the recent advent of science has shifted the debate considerably in favor of a materialist understanding of the mind, what Francis Crick called the "astonishing hypothesis."[3] Of course, it is not that human beings or human choice-making disappear on a neuroscientific account—we and our capacities do not get explained *away*. But scientific explanations do not (and cannot) appeal to anything that is categorically non-physical, nor can they posit some inner homunculus pulling the strings, since that simply begs the question of explaining the homunculus. In principle, there is a complete causal story to be told about human action that runs from perceptual input to behavioral output, a story that need not invoke an immaterial agent exerting freely willed control independent of the brain's workings. If we are to hold one another responsible on a scientific understanding of ourselves, then it seems the brain's control capacities must suffice.

It is important to see that control, not any exemption from determinism, is the key factor in being a responsible agent. Imagine there were some random, indeterministic element that affected your behavior—for instance, a cosmic ray triggered a neural spike that then caused you to raise your hand. Could you take credit or blame for that action? Obviously not. As philosopher David Hume pointed out more than 250 years ago, what we want is for our character and motives to determine behavior, not anything random, so determinism is a *necessary condition* of responsibility.[4] If, as seems the case, our character and motives are themselves fully determined by factors that ultimately we had no control over (our genetics, upbringing, peer group, etc.), they are still the main proximate causes of our behavior. Seeing this, we can properly say, "I control my actions, not anyone else," at least in cases when no one is compelling us to act against our will.

But, we might well ask, is the *I* in this deterministic picture anything more than what the brain, ensconced in the body, does? After all, it certainly *seems* as if I am more than a physical thing, more than a well-organized collection of deterministic, behavior-controlling neural algorithms. And if that is all I am, why should we praise or blame something that is ultimately just the unfolding of complex causal processes?

Here we have reached the nub of the twin questions of consciousness and responsibility, where commonsense intuitions about control conflict with the somewhat disconcerting findings of neuroscience. As the famous experiments by Benjamin Libet mentioned by Glannon show, conscious choices can have causal antecedents in unconscious brain processes, so consciousness is not necessarily a privileged initiator of voluntary behavior. Further, and perhaps even more tellingly, the neuroscientific consensus is that consciousness itself is completely dependent on neural processes. It is not something that plays an independent causal role in controlling behavior above and beyond what your neurons do, rather it *supervenes* (as philosophers put it) on what neurons do.[5]

To see the force of this, imagine building a robot that learns to avoid hurting itself. You design what we might call "hot stove" circuits that, in the event of damaging behavior, cause the robot to remove itself from danger and lower the probability of repeating the behavior. Now, if this circuitry works well to keep the robot from harm, why do human beings need, in addition, the conscious experience of pain? After all, our neural circuits pull our hands off the stove even in advance of feeling pain, and we know that learning occurs by means of neural mechanics such as gene expression, neurotransmitter release, adjustments in the strength of synaptic connections, and perhaps the development of circuits that cause us specifically to avoid hot stoves. What essential role in governing behavior does conscious pain play that is not being played by these mechanistic, "robotic" control capacities? It is not at all obvious what phenomenal consciousness—the subjective, qualitative feel of experience—is *for*, causally speaking.[6]

Philosophers and neuroscientists say, well, maybe pain just *is* a certain subset of physical processes in action, for instance, the firing of C-fiber neurons, or maybe it just is the carrying out of certain damage-minimizing functions, whether performed by neurons or

silicon chips. Or, perhaps it is something extra *produced* by physical processes or functions.[7] But on all these accounts, pain per se still does not seem to play an irreplaceable role in generating behavior since again, it is the neural mechanisms that actually produce movement. In which case, to get back to Glannon's thesis, perhaps we are mistaken to think that conscious experience, even that which accompanies higher cognitive functions, has much to do with giving us the behavioral control required for responsibility.

To continue our thought experiment, imagine our robot is designed to learn appropriate behavior by being responsive to voice commands. If it "misbehaves"—for instance, rudely cuts in front of a guest to get us a drink—we say "no, robot, no!" which triggers hot-stove circuitry, making it less likely to be rude in the future. Similarly, saying "good robot!" upon successful behavior will strengthen propensities we want to encourage, such as common courtesy. Now, we do not have to suppose our robot is conscious to see that, in a primitive sense, we are holding it responsible and accountable—applying rewards and sanctions—in order to shape its behavior.

This example suggests that our responsibility practices vis-à-vis one another make sense even if consciousness turns out not to play an essential, special role in regulating behavior. As an agent with very complex and sensitive control capacities instantiated by my brain—the deterministic result of my genetic endowment interacting with my upbringing—I am exquisitely responsive to the prospect of rewards and sanctions, whether verbal, monetary or otherwise. Moral norms control me in ways that only my properly functioning neural wiring makes possible, which is why it makes sense to hold me responsible. Rewards and sanctions are justly applied to me since I have those neural capacities that *define moral agenthood.* Those with defective capacities (the insane) or undeveloped capacities (children before the age of reason) are not capable of having their behavior controlled in this fashion, so it is unjust to hold them responsible as moral agents. Consciousness does not explain this crucial moral distinction (since we are all conscious), only the differing control capacities instantiated by specific brain structures, for example, the frontal cortex. When assessing criminal and moral responsibility—to distinguish the mad from the bad—we can use as benchmarks the neural parameters of normal adult self-control, for instance as suggested by neurophilosopher Patricia Churchland.[8]

But even if the capacity for responsible agency is based in neural mechanisms, we are of course essentially conscious beings, capable of joy and suffering. Since we want to minimize suffering, our responsibility practices should be as humane as possible. Understanding that people are fully determined to become who they are helps undercut retributive attitudes based on the idea that people just *choose* their bad character and actions, using a free will that transcends causality.[9] Acknowledging the causal roots of responsible action, we will also want to promote physical and social conditions that increase the likelihood that children grow up with intact, norms-responsive brains,[10] and that they will *want* to behave ethically. Both our inclination to punish as a first resort, and the need to punish as a last resort, might diminish should we adopt a fully naturalistic, physicalist view of ourselves. Thus can neuroscience contribute to the creation of a less punitive society. □

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Legal—*continued from page 4*

But are potentially offending health care organizations exclusively to blame? The Office of the Inspector General (OIG) within the Centers for Medicare and Medicaid Services (CMS) has the express obligation to establish regulatory compliance requirements for the MSPA—especially in cases where there may have been previous instances of settlement or judgment associated with fraud or abuse. There is no evidence that the OIG or hospitals have had MSPA and its implications on their radar screens or even in a set of policies and procedures in place to address this kind of event. And if the OIG failed to enforce a statutory provision overtly, should unsuspecting hospitals suddenly be held to a new standard? Or is this a natural evolution of fraud and abuse litigation with patient safety serving as a new cause of action?

A fundamental logic underlying the recently filed Brockovich case is that you should not have to pay me to fix something I broke. And that if I have been mistakenly getting paid by a public source, I should pay back the money. Further, if I knew (or should have known) that I was making (causing) medical errors, and then knowingly billing for remediation, I should be subject to some punitive payment as well (payment of double the amount billed as damages). Finally, even though the provisions of the MSPA have been obscure and do not appear to have been applied either in regulatory circumstances or in previous litigation, the law is on the books and has been for many years. And from a prudent purchaser's perspective, it may be hard to argue against—especially if it goes before a jury.

The plaintiff's attorneys intend to initiate hundreds of these kinds of lawsuits nationwide and probably expect settlement offers and federal involvement to protect defendants formally from any

Legal—*continued on page 12*

Ask the ethicist*—continued from page 3***

[9]Melano R, Adum ME, Scarlatti A, Bazzano R, Araujo JL. Apnea test in diagnosis of brain death: comparison of two methods and analysis of complications. *Transplant Proc* 2002;34:11–12.

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Legal*—continued from page 11***

additional damages once a settlement and recovery have been arranged. The evidence in support of the filing of the suits is likely to come from several potential sources. First, there are numerous published studies that speak to the incidence and prevalence of medical errors. The rates and prevalence of these errors have been analyzed using data from the U.S. Agency for Healthcare Research and Quality, which has developed, tested and validated a set of measures called patient safety indicators (PSIs), which can be applied to state databases for purposes of assessing expected levels of medical errors. In addition, after a lawsuit is filed, it is likely that the discovery process will demand specific information from defendant hospitals about their clinical data experiences, data systems and compliance with the MSPA. Finally, it is likely that individual Medicare beneficiaries who have been subject to medical errors will step forward, demand full access to their detailed medical records and provide a basis for establishing a potential "class" of injured patients for whom other medical records could be subpoenaed in order to demonstrate a "pattern of behavior."

The potential fallout from these cases may affect skilled nursing facilities, ambulatory surgical centers, multispecialty groups and even solo practitioners. The scope of litigation could then expand beyond Medicare into Medicaid. There is even a potential spillover into commercial insurance products, which may seek to apply the principle in civil actions as fraud (which may carry a possible treble damage payment in some jurisdictions).

Even without a federal, statutory basis for a cause of action, any prudent consumer would balk at paying a contractor to remediate faulty work. As this and other cases evolve, health care providers may want to brace for the consequences, which could be severe in financial terms. But as many patient safety experts have allowed, the best way to avoid malpractice litigation in the first place is to reduce the incidence of errors. □

[1]An "unanticipated result" that is not reasonably foreseeable is generally not subject to a claim of negligence. But one that may have been foreseeable could be a medical error versus a bad outcome.

[2]Darcé K. Celebrity Brockovich plaintiff in two suits here. *San Diego Union Tribune*. June 25, 2006. Available at: http://www.signonsandiego.com/news/business/20060625-9999 1b25suits.html. Accessed September 22, 2006.

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Generous funding for *Lahey Clinic Medical Ethics* is made in memory of Harold Karp, by the Karp Family Foundation.

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