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Medical Ethics

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Quote to note

"If one starts by saying 'Morality is…,' nothing one says afterward seems quite right."

—Bernard Gert, PhD

Inside

This issue of *Lahey Clinic Journal of Medical Ethics* honors Bernard Gert, PhD (1934–2011), moral philosopher, Stone Professor of Moral and Intellectual Philosophy Emeritus at Dartmouth College, and longstanding member of our author family.

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Neuromarketing: At the intersection of technology, privacy and choice

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Research in brain imaging is increasingly advancing the understanding of human preference, desire and needs. While the neuroscience community is excited about this progress in the experimental context in which it is obtained, a few companies in the private sector have already taken up brain imaging methods to assist their clients to identify consumer preferences and shape product messages in what they call *neuromarketing*.

These neuromarketers may bypass focus groups and other conventional research techniques on the premise that peering into a consumer's brain using sophisticated technology is a better predictor of behavior than what a consumer predicts or admits to. Is it? Unlikely, without the old-fashioned behavioral data alongside; but even so, neuromarketing raises a range of interesting ethical challenges that fall along a continuum that begins with autonomy and choice, and could find exploitation at its endpoint.[1]

How did this all start? Neuromarketing made its debut in 2003, when Read Montague, a distinguished neuroscientist, then at Baylor College, applied functional MRI imaging (fMRI) to measure cerebral blood flow and oxygen utilization as participants viewed pictures of external stimuli, such as sweet beverages. Montague found that oxygen levels in brain regions associated with taste perception predicted subjects' preference for the products established in blind taste tests. When subjects were informed of the brand they were drinking, brain centers linked to emotion and cognitive control became disproportionately stimulated. The resulting headline: the culture of a brand can trump the power of taste buds. The message unleashed: individual preference may be manipulated covertly and in previously unimaginable ways.

On the surface, other reports seem to convey similar possibilities. Stanford neuroscientist Brian Knutson and his team, for example, used fMRI to study the expectation of pleasure in the context of online shopping and, by extension, the possibility to predict consumer behavior. In one study, Knutson and colleagues monitored brain activity in a simulated buying-experience paradigm as the participant-consumers selected and purchased a series of products.[2] They found that when subjects were

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attracted to a product, measurements of statistically high activity were made from the nucleus accumbens, a region of the brain often associated with the expectation of pleasure; evaluation of products with prices that were manipulated to be too high stimulated the insula, a region of the brain associated with the anticipation of painful stimuli.

David Heeger and his team at New York University have used both fMRI and eye movement measurements to explore viewers' emotional and cognitive responses to film.[3] In this offshoot of neuromarketing that they call *neurocinematics*, they demonstrated the potential of these techniques to help the movie industry better assess its products and, by extension, to potentially increase its grip on viewers' interest. Movie trailers, for example, like commercials for product advertising, might be better designed, or even tailored, to potential audiences. If Astolfi et al. are right, it is the prefrontal and parietal areas of the brain that play an active role in the coding of information retained by subjects such as that from commercials.[4] And taking this all a step further, Vecchiato et al. recently used brain electrical signals measured from Western (Italian) and Eastern (Chinese) participants to point to cultural differences in attention to and information processing of commercial materials, in this case to sensitivity to product brand (carbonated beverages again) and to the form of presentation of a product brand.[5]

Neuromarketing, alongside other endeavors such as *neuroeconomics* (economic decision making) and *social neuroscience* (social decision making), is clearly here to stay. Although there is a temptation to worry about the potential for the erosion of personal autonomy and subversive monitoring or manipulating of the brain, that worry is exaggerated. In reality, neuromarketing is about shaping the nature and appeal of products. It is based on brain data obtained largely from groups of people who volunteer to participate in studies that take place in highly constrained test environments. The combination of behavioral data and brain data is powerful, no doubt, and thus the potential for exploitation exists.

However, neuromarketing is not about taking signals of brain physiology and invading personal privacy by interpreting from them individual intentions and motivations in the moment through mind reading. There is no buy button; that concept is more hype than here, and the jury is still out on overall, practical effectiveness. Our searches returned no published data on the improvement of product sales as a result of neuromarketing.

Nonetheless, through media attention and other means, neuromarketing has piqued the interest of many and the ire of others. It is in this context that we note five gap areas that imminently merit the scholarly attention of bioethicists (Murphy et al.[1]):

1. A code of ethics for neuromarketing companies that requires full disclosure of goals and results.
2. Collaborations to ensure both internal and external validity for meaningful and culturally respectful study results.[6]
3. Policies to protect research subjects—whether in the academic or commercial sector—when findings of potential clinical significance such as a tumor or vascular abnormality are detected incidentally during neuroimaging.
4. Methods for accurate media representation of neuromarketing studies.
5. Frameworks to protect vulnerable populations, such as children and people with mental illness, should neuromarketing-influenced advertising campaigns ever attain critical effectiveness.

Fisher et al. have led the way in addressing some of these bioethical issues. They found considerable heterogeneity of neuromarketing products, disproportionate media coverage compared to the paucity of peer-reviewed reports in the field, and involvement of experts from both the academic and for-profit sector.[7] They, like us, and others are cautious both about interpretation and implementation of neuromarketing data. These concerns are compounded by publications of scientifically dubious, non-peer-reviewed findings in major media. On September 30, 2011, the *New York Times* published an op-ed contribution by Martin Lindstrom that stated:

> Earlier this year, I carried out an fMRI experiment to find out whether iPhones were really, truly addictive…. In conjunction with the San Diego-based firm MindSign Neuromarketing, I enlisted eight men and eight women… [who] were exposed separately to audio and to video of a ringing and vibrating iPhone…. [M]ost striking of all was the flurry of activation in the insular cortex of the brain, which is associated with feelings of love and compassion. The subjects' brains responded to the sound of their phones as they would respond to the presence or proximity of a girlfriend, boyfriend or family member.… In short,…they loved their iPhones.

Lindstrom's article engendered an appropriate outcry by well-respected neuroimaging scientists (http://www.talyarkoni.org/blog/2011/10/01/the-new-york-times-blows-it-big-time-on-brain-imaging/).

To the extent that legitimate studies lend themselves to productively advancing the knowledge of the human brain or to understanding the motivating forces of human behavior,[8] to mitigating illness and to improving quality of life for people, we are fully supportive. Much work in the broad domain of neuroimaging does this. We are more concerned when we think about the potential for neuromarketing to go unchecked and unregulated, as did direct-to-consumer marketing of whole body CT and MRI in the 1990s. Through interdisciplinary partnership and well-focused efforts, the possibility exists to harness the full power of neurotechnology to positively improve decision making at all levels in our world today, not compromise it. □

[1]Murphy ER, Illes J, Reiner PB. Neuroethics of neuromarketing. *J Consumer Beh* 2008; 7: 293–302.

[2]Knutson B, Rick S, Wimmer GE, Prelec D, Loewenstein G. Neural predictors of purchases. *Neuron* 2007; Jan 4; 53(1): 147–156.

Neuromarketing—*continued on page 7*

Ask the ethicist:

Can a patient give valid consent to a phase 1 oncology trial?

Question: A 47-year-old woman presents with widely metastatic malignant melanoma that has progressed despite standard chemotherapy protocols. Her oncologist notified her that the regional cancer center was recruiting patients like her for a phase 1 clinical trial of an experimental drug that had shown promise in animals with malignancies. After a detailed consent discussion with the investigator and research nurse, it became apparent that the patient was not listening to the information being explained about serious side effects and the improbability of beneficial effects. The patient responded that she really didn't care to hear this information because she already had decided to enroll, feeling that she "had no choice" because she would die otherwise. The nurse was concerned that the circumstance of having no choice sounded implicitly coercive and therefore called into question the voluntariness and validity of her consent to participate. How would you counsel the nurse?

Response: Phase 1 oncology trials raise a number of thorny ethical issues relating to the risk-benefit ratio of this type of research and the validity of consent. The trial in this case is a first-in-human study of an experimental anticancer agent. Because phase 1 trials are designed to assess safety and the appropriate dose for subsequent efficacy trials, some commentators describe them as lacking any prospect of benefit for patient-subjects. If there is no chance of benefit, then patient-subjects who enroll in these studies in order to seek medical benefit suffer from a *therapeutic misconception*, which raises serious doubts about the validity of their consent. This view is mistaken, however, because the potential for benefit derives from the anticipated outcomes of the study and not from the design or intent of the research.[1]

In some, comparatively rare, cases, phase 1 trials have demonstrated dramatic benefit in terms of complete tumor response (e.g., imatinib for chronic myeloid leukemia). However, on the whole, the chances of therapeutic benefit are quite low and risks from toxicity are not insignificant. A systematic review of phase 1 oncology trials from 1991 through 2002 found that the rate of complete and partial tumor responses was only 4.4 percent (1.5 complete and 2.9 partial) for first-in-human trials of chemotherapeutic agents. The risk of death from toxic events was 0.57 percent, and 15 percent of the patient-subjects experienced a grade 4 toxic event.[2] Because patients are eligible for phase 1 trials only if they have exhausted standard treatment options, even a small prospect of relatively short-term benefit can make trial participation reasonable for patients who are motivated to receive cancer-fighting treatment.[1]

While patient-subjects who are motivated to obtain therapeutic benefit may provide valid consent for phase 1 studies, the case under consideration raises specific concerns about the validity of consent. The patient communicated to the research nurse that she wanted to enroll in this study because she felt she "had no choice" but to enroll; otherwise, she was certain to die. The patient's statement was seen by the research nurse as implying that the request for consent was "coercive," thus undermining its validity. Does the patient's expressed motivation to enroll in this trial reflect coercion?

The Belmont Report, which describes "ethical principles and guidelines for the protection of human subjects of research," defines "coercion" as follows: "Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance."[3] The fact that the patient feels she has no choice but to enroll in the phase 1 study does not constitute coercion because there is no intentional threat of harm that compels enrollment. Patients with life-threatening conditions frequently choose surgery or other invasive treatments under circumstances in which they feel that "they have no choice," given the high likelihood of death without treatment. This is not thought to undermine the validity of consent; and the same should hold for research participation for prospective subjects who lack any other options for fighting cancer.

More worrisome is the concern of the research nurse that the patient was not listening to the information about the risks and the low probability of benefit. Absent attention to this information, the patient and prospective research subject is not giving informed consent. In the context of medical care when patients are being offered treatment options with a known favorable risk-benefit profile, it may be acceptable (and consistent with patient autonomy) for patients to waive information disclosure and leave the decision about treatment up to the doctor. In this phase 1 trial, however, the intervention is experimental and never before tested in humans. Any therapeutic benefit is highly uncertain; and patient-subjects may be exposed to considerable risks of toxicity. Waiver of informed consent does not appear reasonable in this situation.

The research nurse should explain that enrollment in a phase 1 oncology trial requires informed consent and accordingly insist that the prospective subject pay attention to the risks and low probability of benefit in order to enroll in the trial. The patient also should be informed regarding the alternative of palliative care, though this is unlikely to be an attractive option for a 47-year-old person who strongly desires to continue fighting her disease, with the hope of prolonging survival. It would be reasonable for this sort of trial to require that prospective subjects pass a test of comprehension regarding key aspects of the study, including risks and potential benefits.

Ask the ethicist—*continued on page 7*

The legal column:

Legal issues in health care quality reporting

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Patients who have long turned to doctors, nurses, friends and family members for advice about where to find the best care now have a new source of information: health care quality reporting. Quality ratings have proliferated despite evidence suggesting that fewer than 15 percent of American adults have consulted online rankings or reviews of providers.[1] The federal Department of Health and Human Services (HHS), state agencies (*see* http://hcqcc.hcf.state.ma.us/), and private organizations such as Massachusetts Health Quality Partners, *Consumer Reports*, HealthGrades, Yelp, and health insurers all provide quality information about hospitals, physicians or both.

The information they provide varies considerably. HHS's Hospital Compare website, for example, includes measures of process (such as the percentage of heart attack patients given aspirin upon hospital arrival), outcomes (such as whether heart failure mortality rates are better, the same, or worse than the U.S. national rate), patient experience (such as the percentage of patients reporting that their nurses always communicated well), and patient safety (such as fall and injury rates). By contrast, Yelp contains individual patients' ratings on a five-star scale and patients' narratives about their experiences.

Quality ratings are controversial. If they accurately reflect quality, they may improve care by allowing patients to choose higher-quality providers, either on the patients' own initiative or at the behest of family members, physicians or insurers. They might also encourage physicians to improve the quality of their services. On the other hand, poorly constructed or misunderstood ratings could drive patients to worse, rather than better, providers. Ratings might also lead to problematic unintended consequences. For example, some providers might avoid sicker patients out of a concern that these patients' poor outcomes will worsen quality ratings. Providers focused on improving measured performance might overlook quality problems that exist but do not appear on the ratings scale. In addition, guideline-based performance measures might divert providers' attention from clinical or other factors that would call for a departure from the guidelines.

Evaluations of reporting systems have found both negative and positive effects. Many studies have identified weaknesses in quality ratings, and some have found problematic consequences.[2] Other studies have found favorable effects. A 2008 systematic review concluded that quality reporting leads hospitals to undertake quality improvement activities, but noted that in general, evidence of ratings' impact remains scant.[3]

Given the controversy surrounding these programs, it is not surprising that legal issues sometimes arise in connection with their operation. The law has shaped reporting initiatives in several ways. First, it establishes a framework for public reporting programs. State statutes have required reporting of provider-specific quality measures, hospital errors and hospital infection rates, for example.[4] The Patient Protection and Affordable Care Act (PPACA) mandates quality reporting programs for long-term care hospitals, inpatient rehabilitation hospitals and hospice programs. It also requires HHS to develop a Physician Compare website that in 2013 will include measures of quality and patient experience.

Second, the law helps to define the limits of quality reporting by private individuals and organizations. While the vast majority of online reviews of physicians are positive, patients occasionally criticize the care they received.[5] Some physicians have responded with threats of lawsuits; if a review contains a false statement of fact, as opposed to just the patient's opinion, a provider might be able to successfully sue the patient for defamation or libel. Other physicians have tried to avoid such reviews by asking patients to sign contracts in which they promise not to publish comments about the physician's services. Some also ask patients to transfer the copyright for any written comments they do make, a step intended to give the physician the right to demand the removal of publicly posted comments. Such agreements raise both ethical and legal concerns. In November 2011, a dental patient filed a lawsuit challenging this type of agreement based on principles of copyright law, contract law and consumer protection law.[6]

Health insurers' provider ratings have also led to legal challenges. In 2006, a Washington State health insurer used claims data to create a physician network based on certain quality and efficiency metrics. Concerned about the insurer's data and methodology, the Washington State Medical Association filed a lawsuit alleging defamation, breach of contract and violation of Washington's Consumer Protection Act. The parties eventually settled.

In 2008, the Massachusetts Medical Society brought a similar suit against two insurers and the Massachusetts Group Insurance Commission (the entity that purchases insurance for Massachusetts state employees); the Medical Society recently abandoned the case after a judge dismissed the Insurance Commission from the suit. In 2010, the California Medical Association challenged Blue Shield of California's Blue Ribbon Physician Recognition Program. In the spring of 2011, a judge dismissed the suit, finding that the plaintiffs had failed to address the argument that the First Amendment protected the ratings.

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Ethics and the humanities:
Stitches

By David Small
New York: W. W. Norton & Company, 2009, 329 pages

Review by Jenny Blair, MD
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Silence and voicelessness pervade this haunting memoir of childhood cancer, *Stitches*. David Small, an illustrator, undertook in middle age the task of drawing a comics-style book about his thyroid cancer at age 14. With its moody pen-and-ink drawings and its laconic narration of a powerless child who loses and eventually finds his voice, the book is deeply affecting; it was a 2009 National Book Award finalist.

We meet Small as a six-year-old in 1950s Detroit, where his father is a radiologist. It is a time when radiologists are "soldiers of science" who use "miraculous wonder rays." Small's mother is chronically angry, stalking through the house in silent rages that are never explained or even acknowledged. Small learns early to avoid her and draws quietly by himself. Family dinners are tense and wordless affairs. Everyone in the house defies its stifling muteness with his own "language": Small's mother by slamming cupboards or weeping behind closed doors, his father by attacking a punching bag or tearing down the street on squealing tires, and his older brother by pounding a drum set.

Small, for his part, speaks out via illness: from infancy, he suffers from repeated respiratory and digestive problems. "Getting sick, that was my language," he writes. His own father undertakes to treat these ailments.

In the mid-1950s, at the age of 11, Small develops a lump on his neck. His mother's first reactions are to lament, "Can't anything ever go right for me?" and to bark at her bewildered son that doctors cost money. By the time his parents finally see fit to have the tumor removed, over three years have passed. He awakens from the operation to see his father, suddenly genial after a lifetime of coldness, leaning over his bed explaining that a specialist would remove "the thing, the, uh, the cyst" in a second operation. The same night, his mother comes into his hospital room and tells Small she will get him anything he wants.

At that moment, the night before the tumor is removed, Small at last speaks up, finding his voice just before the operation is to take it away again. He angrily reminds his mother that she burned the book he had been reading, *Lolita*. She responds by buying a second copy in the hospital gift shop and dumping it unceremoniously on his bed. Then she walks out.

After the operation, Small awakens, having lost his thyroid gland and one vocal cord. He finds himself unable to speak. "The fact that you now have no voice will define you from here on in, like your fingerprints, the color of your eyes, your name," he thinks on the drive home. "My silence was no longer a matter of choice." Yet that of the family continues. It is two weeks before he learns by snooping at his mother's desk that the lump in his neck was cancerous, and that is how he realizes that the family had expected him to die; his mother had come into his hospital room to grant him his last request. The secret of Small's diagnosis is the first of several devastating revelations the boy soon faces about his mother, his father, and the cause of his cancer.

Though it is a masterful portrait of a family and its secrets, the book also demonstrates with distressing clarity how illness can render its victim voiceless—and even more so when the victim is a child, especially a child in an uncommunicative family. The reverse, too, is true: voicelessness itself can lead to illness. In Small's case, this truth is borne out by both his childhood ailments and the mental turmoil he develops in the years that follow his diagnosis.

From the start, Small is marginalized from all decision making about his illness. The family friend who discovers his tumor talks over his head about it to his mother. At a yacht party, Small's father asks one of his colleagues, an ear-nose-and-throat surgeon, to look at the lump; the man grips Small's neck with a hairy hand, tells him to hold still, and tosses a recommendation back at the father.

Later, examining the x-rays, the surgeon assures Small's mother that the operation can take place whenever it is convenient for her. He closes the encounter with a toothy grin and a hearty question aimed at the boy's departing back:

"How does all that sound to you, sport?"

"Uh. OK. I guess."

"Teee-riffik!"

Apart from this worthless rhetorical flourish, no one asks the patient what he thinks. No one discusses its implications with him or seeks to calm his fears. And no one expects him to have any questions. His parents flatly refuse to discuss it. That Small's illness ended up damaging his larynx would seem a heavy-handed metaphor if the story weren't true.

But Small grows up to reject the silence. As a teenager, after he has developed hallucinations, nightmares, and has brushes with the law, he begins to see a psychotherapist.

He writes, "And so we talked. After life in a house where silence reigned and free speech was forbidden, that office, three times a week, became a haven for me. There, things began to make sense…." Gradually, Small regains a measure of raspy speech and begins a career in visual art. "Art became my home," he writes, and it takes the place of the other house where he grew up amid so much misery. "Not only did it give me back my voice, but art has given me everything I have wanted or needed since."

Silence and illness, when taken together, can heighten each other's toxic effects. Patients already disempowered by illness lose a further measure of control when that illness is left undiscussed, as if it is taboo. This loss may disproportionately devastate a child, who enjoys so little autonomy to begin with. Giving patients a voice, as Small's therapist and his art finally do years later, is crucial to helping them overcome the damage that illness leaves behind. □

Dialogue:
Dilemma reduction

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Steven Ralston's article, "Multifetal pregnancy reduction" (*Lahey Clinic Journal of Medical Ethics*, fall 2011), is a model of clarity and ethical sensitivity. He lays out a solid, sensible way of framing the ethical dilemma. The dilemma comes down to balancing a woman's desire to have a child by means of infertility treatments with the knowledge that such treatments can produce multiple fetuses, thus threatening the health of both the fetuses and the mother. The mother is then sometimes left with the unpleasant, often disturbing, choice of running the risk of multiple births or having the pregnancy "reduced," that is, having one or more fetuses killed. A hard choice indeed, and often for the physician as well.

I want to suggest another way of framing the problem. It is one that falls into the category of ethical dilemmas we should not have in the first place, and with some changes in policy and economic arrangements, those dilemmas could be greatly minimized. Think of it as *dilemma reduction*. Two steps are necessary, one of them turning on what kind of a health problem we think infertility is, and the other on simply pursuing in a more vigorous way what appears to be a gradually emerging consensus on the need to minimize multifetal pregnancies. Both of those changes should be set within a context of taking seriously the killing of fetuses who have done no harm to the mother and whose only disability is that they are one (or more) too many.

Imagine by chance stumbling upon some morbidity statistics that showed a very large number of women afflicted with serious risks that reflect in great part behavioral and social determinants. But imagine, too, that one did not know who those women were. It would be reasonable, I propose, to classify their problem as a public health more than a medical issue. Why has that not happened with this group of women? For two likely reasons. One is that they are pregnant because of one form or another of assisted reproduction. Why is that? Because for a variety of reasons they could not otherwise bear a child. The second reason is that, for reasons heavily social and behavioral, not just medical, they have lived lives that put them at high risk for infertility.

An NIH website notes some 17 causes of female infertility, at least six of them falling into that public health category, and which I believe to be proportionately the most common. They include a delay in procreation into the mid-thirties or early forties, and the harm done by sexually transmitted disease. The delay of procreation is very much a function of the perceived—but quite justifiable—view that later rather than earlier procreation is necessary for educational and professional reasons, for economic security, and often because of difficulty finding a suitable mate, sometimes because of the delay.

The net result is that infertility, despite those causes, has been medicalized, aiming to find technical solutions instead of deploying public health mitigation efforts. In effect, the public health perspective has been given a kind of pass, a let's-not-go-there strategy, which would mean taking on such troublesome matters as women and work, procreative choice, sexual mores and so on.

Assisted reproductive technology (ART) offers a way around those dangerous topics, turning it into a conventional health problem, to be solved technologically. Health is the only moral category that is allowed into the discussion. We then end with the standard kinds of dilemmas: mother's health vs. fetal health, healthy births vs. compromised births, healthy babies vs. unhealthy ones—and we solve the problems with "pregnancy reduction," thought to be the best way to achieve the goal of good health for all. Well, not so good for the healthy aborted fetus, but presumably a price worth paying to achieve the health goal. "Health" is the privileged ethical concept, asked to do the moral heavy lifting.

An obvious way to reduce the need for ART is earlier procreation, getting it back into the twenties and early thirties. That would require a much-improved workplace for young women, aiming at not professionally penalizing them for having children, and providing strong financial and other forms of support for childcare once they have reentered the workplace. The corporate support for such policies would require some government subsidy. Not only would such policies be good for the health of mothers, it would civilize the workplace, bridging the gap between home and work. I realize that sounds utopian, but it is hard to say that the present arrangement of medicalization is the ideal solution.

The most important risk is that of multiple fetuses. As Dr. Ralston notes, "The more fetuses (and placentas) in the uterus, the higher the risks of almost every known pregnancy complication." He adds, "It behooves us to . . . strive for a reduction in the number of high-order multiple pregnancies produced through assisted reproductive technologies." A number of countries have moved in that direction in recent years, and the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology have issued guidelines to push in that direction also.

One obstacle is that, while IVF, as an assisted-reproductive technology, allows for more control of the number of implanted embryos, it is used less than non-ART techniques. The latter involves ovarian stimulation to produce eggs; but when insemination

occurs, there is no effective way to control the number of embryos that may be created and implanted. Part of the effort to reduce multiple pregnancies is to move toward more IVF procedures, which can be facilitated by greater patient knowledge of the hazards of multiple gestation, and by better financial support for the procedure to reduce financial incentives to implant more than one embryo.

While I have been a longtime supporter of a woman's legal right to choose abortion, I have no less held firm to the conviction that it is an ethical decision, not simply an amoral "personal decision." There is no room to make that argument here. But a clue to the likelihood that many people, otherwise pro-choice, have such a response in this context is surely suggested when Dr. Ralston notes, "It is a stressful clinical scenario that requires patience, finesse and empathy on the part of the entire health care team caring for these couples."

Surely it is not stressful because it is a surgical procedure, but simply because it is the choice of one life over another life, lives that on the face of it are equal in their potential for birth and a life. If it makes sense to long for a dilemma reduction on occasion, this is one of them.

Response: I agree with Professor Callahan that these dilemmas could be made less common with public health interventions and policy changes. Infertility, however, will remain a clinical entity because most of the causes of infertility are beyond a woman's control and often reside in their male partners. Moreover, infertility was a problem for couples well before the social changes that have allowed women to delay childbearing.

From a practical standpoint, safer medical practices that reduce the risk of multiple pregnancies are much more likely to have an impact on the incidence of triplets and high-order multiples than are social policies. As Professor Callahan notes, in the U.S., safer practices in IVF have been promoted by leading medical organizations such as the American Society of Reproductive Medicine and the Society for Assisted Reproductive Technologies, though other countries have addressed the problem—perhaps more effectively—legislatively and through central management of health care. But it is the use of ovarian hyperstimulation agents and not IVF that accounts for most high-order multiples in this country, and modifying physician practices with these medications is more difficult to accomplish. □

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

Outcome: After the usual informed consent process, the patient enrolled in the clinical trial. □

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Permit No. 57

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Noting the disclaimers accompanying the blue ribbon designation, he also found that the plaintiffs had failed to show that the public was deceived by the ratings, or even that it had relied on them.

While the outcomes of these suits highlight the challenges of using the law to limit ratings programs, insurers have taken some steps toward alleviating provider concerns. The Washington suit settlement called for the insurer to disclose its methodology and to permit physicians to appeal their scores. More recently, the New York Attorney General entered into agreements with major insurers that laid out basic requirements for ratings methodologies and ratings transparency, and required insurers to contract with an independent ratings examiner for review of the insurers' programs. Concerns about these programs remain, but there is now a framework to begin to address them.

In December 2011, the federal government issued regulations permitting the release of Medicare data to private organizations for the purpose of measuring provider performance, a step that will promote the growth of quality reporting. As these programs spread and evolve, and as ratings start to play a more significant part in payment and regulatory systems, ensuring rating accuracy will become increasingly important. The law will undoubtedly play a role in this process. Ultimately, though, the continued involvement of providers, patients, payers and researchers in the development of quality reporting programs will be critical to ensuring that these programs serve patients well. □

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