The Journal of Clinical Ethics

VOLUME 18, NUMBER 2 SUMMER 2007

The Journal of Clinical Ethics

219 West Washington Street, Hagerstown, Md. 21740 U.S.A.
(240) 420-8850 • fax: (240) 420-0037 • *sales@clinicalethics.com*

The Journal of Clinical Ethics, ISSN 1046-7890, is published quarterly: spring, summer, fall, winter. Subscriptions are by volume year.

Subscribers who purchase electronic access will receive a License Agreement, and will receive instructions on activating the subscription. Electronic content corresponds to print content.

Subscriptions must be prepaid. All sales final. Prices subject to change without notice.

Send orders to *The Journal of Clinical Ethics,* at the address above, or to a subscription agent. Subscriptions at special rates (individuals, ASBH member) must be sent directly to the publisher. Claims must be filed within three months of publication, to the address above.

The Journal of Clinical Ethics is indexed on MEDLINE, Social Sciences Citation Index, Research Alert, Current Contents/Social & Behavioral Sciences, and Cumulative Index to Nursing & Allied Health Literature, and is a peer-reviewed, refereed journal.

2007 Subscription Prices	Print	Single-Site Electronic*	Print + Single-Site Electronic*
Institutional Level 1	**$150**	**$130**	**$170**
College or university without an advanced degree program; public library (non-research); private practice office.			
Institutional Level 2	**$200**	**$180**	**$220**
College or university with a graduate-level program; community hospital or clinic; VA hospital; non-profit organization or independent research library; small for-profit organization (under 50 employees).			
Institutional Level 3	**$250**	**$230**	**$270**
Healthcare network; government agency, or large resource institution; large non-profit; mid-to-large for-profit (50 to 500 employees).			
Individual Subscription	**$68**	**$62**	**$88**
Payment by personal check or credit card only. Must be sent to home address. Electronic access limited to 1 user, via password and ID number.			
ASBH Member Subscription	**$58**	**$53**	**$75**
15% off Individual Subscription price. Payment by personal check or credit card only. Must be sent to home address. Electronic access limited to 1 user, via password and ID number. ASBH Members must provide ASBH Member # to receive this rate.			

* Multi-site electronic access is available; contact Mary Gesford at the address above.
Subscriptions outside the U.S. add $10 per volume year for Surface Rate.

At the Bedside

"I'm Still Glad You Were Born" — Careproviders and Genetic Counseling

Edmund G. Howe

In this issue of *The Journal of Clinical Ethics,* in "Uncertainty and Moral Judgment: The Limits of Reason in Genetic Decision Making," Mary T. White asks several ethical questions involving genetics. The most important of these may be the extent to which we, as careproviders, should abandon our traditional allegiance to being ethically nondirective.

We should consider this change due to recent advances in genetics that have increased the benefits of genetic testing. This following case is an example: a 48-year-old woman tested positive for the BRCA1+ gene and so was considered to be at high risk of acquiring ovarian cancer, but she refused follow-up evaluation and care. Her genetic counselor chose to be radically directive, and called the woman regularly over 12 months, urging her to have further evaluation until eventually she sought treatment. It was found that she did have ovarian cancer, and her surgeons, fortunately, were able to remove it all before it spread.[1] Whether the counsellor should have taken this approach is open to question,[2] but in this case it may have been lifesaving.

We know that some patients make decisions that do not seem to be best from an objective point of view. Some patients' decisions do not even seem to reflect their actual desires. Why might this happen? In some instances, patients may be at great genetic risk, but engage in total denial. They may, like the 48-year-old patient, not take measures that could save their lives. Unlike that patient, they may not agree to genetic testing that could help them determine what else they should do. When we are more directive with patients, we may be able to help them overcome their denial, and so this approach seems worth consideration.

But there are also well-recognized risks that caused genetic counselors to be nondirective in the first place. For instance, it is feared that we may impose our own moral views on patients, which may violate their autonomy and harm their self-esteem. If patients feel anger or depression in response, this may change the decisions they make; for example, if they are angry, they may choose not to go for genetic testing because this is what we recommend. Or, when

Edmund G. Howe, MD, JD, is a Professor of Psychiatry and the Director of Programs in Medical Ethics at the Uniformed Services University of the Health Sciences in Bethesda, Maryland; and is Editor in Chief of *The Journal of Clinical Ethics.*

we are directive, some patients may feel that we are telling them what to do, and they may feel less self-esteem and not go for testing because they feel "down" on themselves. Some patients may be so offended that they won't return for follow-up counseling and suffer a worse ultimate outcome. Given these concerns, should we be more directive? And if we should, when?

Readers may ask why genetic counseling shouldn't be left to genetic counselors, who receive special training. The answer is that the number of patients who may need or benefit from genetic counseling is far greater than what we may assume, and the number of genetic counselors is far short of being able to meet patients' needs. As a result, in most cases, patients will depend on the careprovider they usually see for genetic counseling. How patients fare with genetic illness often is not determined by the seriousness of the disease — at least until its final stages — but rather how they perceive their own situation.[3] The implications of these findings for careproviders are immense: what we do may actually determine patients' outcomes, for better or for worse.

GENERAL PRINCIPLES

To help patients gain the most from genetic counseling, we should focus on establishing and maintaining our relationships with them and to maintaining their self-esteem. Without the relationships we may have no patients left to treat; patients who feel badly about themselves often make poor decisions. If we choose to be directive, we may violate patients' denial, and the patient/careprovider relationship may be "fatally" changed: patients may no longer feel safe enough to discuss their genetic options openly with us.

Patients may also feel that we "talk down" to them,[4] which may infantilize or anger them, and threaten their self-esteem. Perhaps the patients suffered some loss of self-esteem when they first learned that they might have a genetic illness (or be a carrier).[5] The loss may occur due to feeling a change in identity or feeling fear. Greater loss may occur if they later go for testing, whether the results are positive, negative, or uncertain. Patients who lose a relationship with a careprovider, or who lose self-esteem, may make decisions that are based not on what they really want, but on what they feel. They may seek out additional information from their careprovider, not to help make a decision, but to rationalize a decision they have already made based on emotional reasons.

Patients tend to make genetic decisions on the basis of their feelings, and, as Mary White notes, these decisions are often "non-rational." That patients tend to make genetic decisions based on non-rational or irrational feelings has led to an important finding: most patients must be emotionally engaged to benefit from genetic counseling.[6] This makes sense, as persons don't usually make personal decisions based solely on statistics. Thus, if patients make genetic decisions based on feelings, and the feelings are irrational, the only way to help patients may be to help them change their feelings. The best way may be to directly engage their emotions. Recent studies suggest that we can engage patients' emotions most effectively when we share a relationship with them that is safe and trusting.[7] There are ways that we can be directive and also reduce the risk of harming patients.[8] Two of these approaches are especially promising.

THE "MAGIC" OF SAYING *WHY*

Patients who face genetic illness state repeatedly that what they need most, in addition to genetic information, is emotional support from their careproviders (and others).[9] In general, if we can express any positive feeling — verbal or nonverbal — that is genuine and caring, it will enhance our relationship with patients and enhance their self-esteem. Although this is not difficult to do, we may not do it; all too often patients bitterly say their careprovider "doesn't seem to care." Showing that we care is especially important when we do genetic counseling and try to engage patients emotionally, even though this may be incompatible with conventional nondirective counseling.

An example of what I call the " 'magic' of saying *why*" makes this case. A patient called

me and said he had sudden strong impulses to take his life. He had been in a therapy group and there met a new best friend — actually, his sole friend. When he shared with the group that he and the other group member had become friends, the leader of the group told him that he could not continue to participate in the group and continue to meet outside the group with his friend. (This is a routine "rule" in certain kinds of group therapy, and the group leader probably provided guidelines when the group had started to meet, but the patient apparently missed that, and felt beat up.)

Over the phone, with the patient still feeling acutely suicidal, I tried to explain *why.* "It's a 'ground rule,' virtually always the case in groups like this. When your doctor said this to you, it wasn't at all personal. The assumption underlying this rule is: if any person from the group meets outside the group with a friend from the group, the friends may share what is most important with each other, but not with the whole group. Then, patients may not benefit from the group."

"Oh," he said after a silence, and then reported that his suicidal feelings had "disappeared."

If we aren't the kind of persons who experience such sudden, profound shifts in feelings, we may not know that this kind of shift can occur. Regardless, in patients whose emotions are labile, this kind of shift isn't uncommon. What I hope to show is the profound and possibly lifesaving results of taking time to explain *why.*

During genetic counseling, patients sometimes ask careproviders what they would do, if they were in the patients' situation.[10] Should we refuse to answer, patients may experience this as an assault, especially since they took the initiative and found the courage to ask. There are some examples in the medical literature that illustrate how we should not respond — although these responses may still be recommended today. One recommended response is to say: "I'm wondering if you wish that someone could tell you what to do." Another is: "What are you hoping that I'll say?" Still another is: "Perhaps you wish that I could tell you the 'right' answer."[11] These responses correctly intend to gain information, but they all risk harming the relationship and patients' self-esteem by conveying to them that we have more knowledge about the patients than they do, themselves. Based on our response, patients may feel that they are being talked down to.

Yet another recommended response is: "I'll answer, but only if you first explain to me your reasons for asking."[12] This is also a mistake, as it also may convey that we see ourselves as knowing more about patients than they know about themselves and, thus, are talking down to them. What can we do instead?

We could say we will share what we would do, but would like to ask first for the patient to identify what he or she hopes to gain. We can explain: "If I answer your question first, then you may not know what you are hoping I might say, and that information about yourself could be very important as we work together to enable you to decide what you want to do." We can say: "As you know, what I would do may be the total opposite of what you should do. Only you have lived in your shoes your whole life, so only you know what is most important to you."

A separate question is whether we should take the initiative to offer what we would do even when a patient doesn't ask. We can obviously ask every patient if she or he would find this helpful, which is clearly the opposite of being nondirective. We can even encourage patients to answer "no," and say, "I have a sense of what I might do if I were in your shoes. You might find that useful — or not. Maybe you feel you have all the information you want, and don't want to discuss anything else. If you think my telling you what I might do would help, I will. What would you like?"

Taking this approach serves several positive ends. First, the information may benefit the patient. Second, taking the initiative to offer advice to all patients avoids discriminating between patients who are assertive and ask for help and those who are not. Third, offering in this way has a personal, caring connotation. When we go further to try to maximize the

chance for a good outcome, it conveys to patients that we care about them.

THE MAGIC OF ANTICIPATING AND FOREWARNING

As noted above, should we choose to be more directive, it may adversely affect our relationships with patients or their self-esteem. A way to reduce this risk is to anticipate any ambiguous meanings in what we plan to say and forewarn patients that what we say could be misinterpreted. We can say that what we plan to say is directive and intended to be helpful, but it may seem as though we are trying to impose our own view. This may cause resentment, and given this, should we continue?

We have to anticipate that patients may misinterpret what we say and respond negatively whenever we do anything more than just provide information. This is particularly important in genetic counseling, which includes asking patients to reflect — asking questions about feelings they may want to deny, which can feel threatening.

As a hypothetical example, perhaps a patient is trying to decide whether to abort a fetus she has learned has a very serious genetic disease. She says to her careprovider, "I know that my having an abortion would be best for my family." Her careprovider, wanting to engage her emotionally, might ask, "But how about you?" because he noticed that she remained silent after speaking, suggesting that she was somehow stuck emotionally after saying this. In these kinds of situations, there are any number of mildly directive, more reflective questions we can ask patients to try to engage them emotionally.

But, as noted before, these kinds of questions may threaten a patient's denial. In the above example, for instance, the patient might experience her careprovider's prompting query as "pushing her," and as an attempt to impose his bias against her decision to have an abortion. To do our best for our patients, we must try to reduce the risk that a patient may make a wholly unwarranted inference. We can reduce the risk by trying to anticipate this and say something such as: "I want to ask you something that may feel as though I am pushing you a bit. Maybe you won't think that, but it's possible, even when that isn't my intent. You might feel resentful, because that's how we all work — we can't help it. So, knowing this, do you want me to go ahead and ask you a question that might cause some pain?"

Of course, if we ask this, some patients may answer falsely because they are exceptionally compliant. As Darlyn Pirakitikulr and Harold J. Bursztajn state in their article in this issue of *JCE,* "Pride and Prejudice: Avoiding Genetic Gossip in the Age of Genetic Testing," for example, "frightened and demoralized" patients find it "easier to go with the flow" than to initiate an objection. What this means is that some patients would find it hard or nearly impossible to say "no" when their careprovider asks, "Is it OK for me to ask you something that may hurt?" They may be like the 48-year-old woman who wouldn't go for treatment for her ovarian cancer, even though it was possible that she might die; she was denying that she was at high genetic risk. The hypothetical patient above who said she knew that having an abortion would be better for her family may not feel emotionally ready to discuss her own desire — if she has such a desire — to go against what she sees as her family's best interest and bear her child.

We may find that it is difficult emotionally to bear patients' avoidance. Yet, patients must be prepared for what they will experience, and we must be prepared to accept these kinds of situations and the helplessness that patients may feel in response. It is essential that patients know their full range of options and the risks of each option. When patients know this and then want no more discussion, we must accept that the best we can do may be to maximally support their denial, rather than confront it.[13]

Patients may have denial for many reasons. In the case of the patient with the BRCAI+ gene, the patient may have needed denial to retain her sense of hope.[14] We don't know whether the value of retaining hope (if that is the reason for the denial) should outweigh the potential gain of testing or treatment. I would suggest that to

prepare patients in the ways just suggested, but not go further, may be the best that we can do.

SPECIFIC APPROACHES

Patients and their careproviders may feel confident that they can know how patients will respond to agreeing to genetic testing, whether the findings are positive, negative, or uncertain. In fact, this may not be the case. For example, a patient may have great anxiety prior to being tested, but this higher level of anxiety about being tested may not predict how she or he will respond later, after receiving the testing results. The patient's anxiety may "go," actually, in the opposite direction.[15] Accordingly, we shouldn't ever conclude that a patient won't benefit from counseling, even if the patient appears to be and reports to be wholly calm. Rather, we should presume that, for most patients, genetic counseling will be significantly beneficial,[16] and we should tell patients that their prior feelings, no matter how calm, may be misleading. In any event, the following suggestions are meant to apply to all patients.

PATIENTS WHOSE FINDINGS INVOLVE MOSTLY THEMSELVES

Some of the following approaches apply to giving patients information. They are not about genetic risks, but about the risks for patients that are related to the process of deciding to be tested or to the consequences that may be experienced when choosing to be tested. Many may appear to be nondirective, as they involve only giving information, but this assumption is mistaken, as the connotation of the information may be highly directive. Thus, the general principles outlined above regarding directiveness apply.

Helping patients to consider counseling. A first concern is that a patient may not know that she or he could benefit from counseling and so, to their detriment, decline it. Accordingly, we should take the initiative to inform patients of the two empirical findings stated just above: (1) some patients may find the experience of deciding whether to undergo genetic testing and/or the findings emotionally extremely "difficult," but may not suspect this; (2) most patients may benefit from genetic counseling, both before and after testing, especially if they can become emotionally involved. We can tell patients that no matter how savvy they may be, when it comes to genetic illness, they may have some emotional fears that even they can't detect -- fears that are in an emotional "blind spot," so to speak. In this situation, the additional eyes and ears of a counselor may be helpful to them.

Helping patients to decide whether to seek testing. We may be tempted to urge patients to be tested when the results could benefit them greatly — perhaps even be lifesaving. If we express our own bias, even inadvertently, however, it may be counterproductive. Instead, we should tailor our interventions to the particular stage of awareness the patient has achieved. Earlier on, patients may simply not feel ready for testing. In this circumstance, the most helpful thing is to support patients' feeling that they need to wait. We can say that for now the most important thing is to retain hope and not pursue testing. We can add that the patient can change her or his mind later, and that this reconsideration may take some time.

If waiting may significantly increase patients' risk, we should ensure that they know this. It may be especially important to support patients at this time, particularly if others urge them to be tested against their will. It seems paradoxical that we can best help patients by respecting and supporting their choice, even when this is to avoid testing. If we do this while making patients aware of the risk, we may help them overcome their fear sooner. We may also help them avoid feeling shame; later, if they become ill, others may want to blame them for delaying testing, and the shame they may feel might harm them as much or more than their genetic illness.

We can also help patients by alerting them to the possible risks of seeking too much information. This may also seem counter-intuitive, as we may not be able to imagine that seeking out more and more information may, at some

point, become self-destructive. Patients may feel virtually driven to it. Patients who do this may be the opposite of those who are harmed from having too much denial; they may be "compulsive information seekers." Patients may become so frightened by the information they acquire that they can't get the information out of their minds. Simply stated, it "haunts" them. They seek out the "worst-possible scenarios" and then can't get them out of their minds.[17] This exhaustive worst-case scenario information may so overwhelm patients that they "shut down" emotionally. Then they may avoid testing, even though it is most beneficial.

As this may be the case, we should take the initiative to inform patients that, on the one hand, while it is important to consider possible worst outcomes, it is as important not do this to an excessive degree. We can tell patients that they may not be able to avoid "obsessing" about what they know, but they may be able to consciously stop seeking out more information. We can encourage patients to discuss any medical experiences that they or others may have had that have upset them. We can say that we urge this because those upsetting experiences may bias or even determine patients' decisions. Finally, we can ask specifically whether any of their own or other persons' medical experiences have upset them recently — say, in the last year.[18] If patients answer "yes," we should advise them to take more time to decide about being tested, as long as doing this wouldn't significantly increase possible risk.[19]

This is directive advice, and is based on the finding that most persons need at least a year to recover from very upsetting events, and if they have to make a decision before a year (or more) has elapsed, their upset feelings may dictate the choices they make.

Preparing patients for positive, negative, and uncertain results. Patients may become profoundly emotionally disturbed after receiving genetic results, whether these results are positive, negative, or uncertain.[20] It is empirically known in many clinical contexts that patients who are prepared and expect what may occur fare better than patients who are not prepared. This may especially be the case for patients who receive the worst possible news, but have been able to anticipate that this might occur. An example of this truism is patients with cystic fibrosis (CF), now the most common life-threatening genetic disease in the U.S. The statistical life expectancy for people with CF is now the middle or late thirties. Some people with CF do as well as others without the disease as they grow older, however, in large part because, in addition to support, they have learned what to expect and have had time to adjust.[21]

To sum up, when patients do decide to be tested, we can help them greatly by preparing them for the various possible results.

Positive results. The most important way we can help patients in the event they test positive for a genetic disease is to inform them that what patients experience, even when they have the most serious genetic disease, may depend more on how they perceive their disease than on the disease itself, at least until its final stages. It may have an exceptionally great impact to say this *before* patients go for testing. If it is related after patients test positive, patients may feel we are just saying this to help them feel better. Further, if it's said beforehand it may "pop" into patients' minds later, when they most need it.

Some patients, even those who have the most serious genetic diseases such as Huntington's, are able to find different and new sources of meaning and joy even after they learn they have such a disease. Patients may find new meaning in each moment of their lives that they hadn't and perhaps couldn't have before. They may also help others find new meaning as they cope with their disease with as much dignity as possible. For example, patients may want loved ones to have a positive memory of how they were, and hope to inspire them to cope as well with any adversities that they encounter.

By telling this to patients beforehand, we may plant the seeds of these thoughts. We can acknowledge with patients that these things may be easy for us to say, because we aren't about to be tested! And on this basis, it would be understandable if patients feel resentful about our comments. We should also acknowledge,

though, that we are sharing the information before the testing (1) because it's true, and (2) because patients may be better able to hear it before testing, rather than after. As I mentioned above, patients may remember this, and it may provide a ray of hope later on.

Another major way that we can help patients who test positive is to help them anticipate possible stigma, which may even occur within their own families. We can also tell patients that stigma may occur even if they are "only" a carrier. As Pirakitikulr and Bursztajn state, "lay people" often believe that "a mutation equates to the presence of a malady." Stigma is due to centuries of irrational attitudes. If we are able to address and even attack the irrationality of stigma before it occurs, its harmful effects may be disproportionately less. This claim may seem exaggerated, but recent empirical data indicate that even remarkably brief interventions by teachers can markedly change the invidious effects of both racial discrimination and gender discrimination. As a consequence, persons affected by stigma may do surprisingly better.[22] One writer reviewing the extent of this impact has described it as "remarkable." Another, an expert in this field, says that these studies go " 'far beyond what you might expect from the simplicity of the interventions.' "[23]

My favorite example illustrating this involves a patient who has an evident facial imperfection. When she was a child, other children mocked her, and she felt great hurt and shame. When she was 12, she described this to a doctor when they were in a room that had a blackboard with chalk. At hearing this, he grabbed a piece of chalk and threw it against the blackboard hard enough to shatter the chalk, and said, quietly, "Makes you feel angry, doesn't it." She never again felt the same sense of hurt or shame.

The "lesson" is unmistakable — when just one careprovider says something like this, it may be enough to change a patient's life.

Negative results. Patients may have exorbitantly painful emotions even after they receive negative testing results. There are many reasons; for example, they may remain unconvinced they do not have the disease. For this reason, some careproviders recommend that, routinely, when patients have negative results, careproviders should schedule a follow-up visit several months later.[24] At this visit, we can evaluate whether patients have had difficulty believing their negative results. If so, we can reaffirm the negative results. Patients may have painful feelings because someone related to them is positively affected. They may experience what is commonly called survivor guilt.[25] They may feel intense emotional pain in this situation because they have lost their (presumed) "shared genetic identity" with a loved one, and after testing negative they may feel more distant and estranged.

Or the negative results may destroy patients' prior "identity." Some patients assume that they have the genetic disease their parent had, will suffer from the illness, and perhaps die prematurely. For example, a patient psychologically identified with her mother, who had Huntington's disease. When she tested negative at age 20, she said, "the one constant thing in my life has now been taken away."[26] This belief isn't wholly rational. Still, patients may become emotionally convinced of this from the first time they learn that a parent is affected.

When patients learn that they aren't affected by the disease, it may shatter their prior beliefs regarding who they are and what they expect. They may, for example, never get married or have children, because they "know" that they have this disease.[27] If patients are told about these three possibilities before testing — that they may not believe negative test results, that they may feel much worse after testing due to survivor guilt, that they may lose a sense of themselves that they have had their whole life — it may help them to accept these feelings later, if they occur. More importantly, it may also help them to see these responses as "normal." They may then not experience, in addition to these other responses, the feeling of shame.

Uncertainty. Test results may be uncertain, which may occur in either of two ways: the predictive value of the results may be low, or "modern medicine" does not currently know what

the results mean. We can help patients prepare in either case. The first thing we should tell patients is that most patients find the feeling of uncertainty most difficult to bear. For example, patients who might have Huntington's disease may prefer the certainly of an unambiguous test result — even a positive result — than to live in uncertain fear.

For this reason, many patients choose to be tested. Some genetic tests may indicate that patients are at greater risk, but the extent to which this changes their possible outcome is marginal. Under these circumstances, patients may not gain much useful knowledge from testing, but knowledge of their increased risk may greatly increase their anxiety. As a result, patients may do better if they choose not to be tested. When the medical profession doesn't know what some genetic results mean, patients may face no known risk but may also feel markedly increased anxiety.

This anxiety may significantly interfere with the quality of their lives. So, in advance, we should inform patients how they may respond to whatever kind of uncertainty they can foresee, and this knowledge may or may not significantly influence their decisions. It may help them to accept that they may experience anxious feelings, and to not feel shame if they do. The seriousness of such feelings are illustrated by the experience of a man who was caring for his wife as she died. As time passed, he felt increasingly distressed and, in his words, "became unglued." He felt profound pain and grief on his wife's behalf, but he said that a greater and more unbearable feeling was shame that he wasn't "stronger." The feeling of shame caused him to have thoughts of ending his life, he said. (He didn't, and has since done well.)

PATIENTS WHOSE GENETIC FINDINGS INVOLVE OTHERS

When patients consider genetic testing, this testing often involves the interests of family members who are genetically related as well as patients' significant others and spouses. These concerns are much more complex in that they involve others.

Parents, siblings, and spouses. When a patient's decision to be tested involves other adults, it is ideal to be able to discuss key issues with all of those who are involved. We can try to persuade those who are involved to get together, and this may succeed in many cases. It may be very helpful for those involved to get together and improve their communication before the patient goes for genetic testing, because they may feel less stress prior to testing and more able to hear, as mentioned above.

The results of doing this may be disproportionately beneficial. For example, a man had been estranged from his father for 10 years, and when they first reconciled, the son spent their first hour together lambasting his father! For a decade, the father had spent all his holidays alone; after this meeting, however, the son, with his wife's agreement, has left her to join his father for every holiday. The effects of meeting to nurture loved ones' support for patients who may have genetic disease is similarly beneficial. As one teenager with cancer expressed it: "Well, you kind of knew that your family cared but they never really had a chance to show you. It kind of gives them a chance to show you."[28] Consequently, we should be directive and explore this initiative, and not be deterred if a patient is estranged from his or her loved ones.

Parents with serious genetic diseases may feel terrible because they will die prematurely.[29] We may be able to help parents and their children by enabling the parents to share this with adult children, if they haven't already. The principle is simple: Talk is likely to be better than no talk. If persons aren't speaking with each other, they most likely are holding their feelings within.

One of the greatest sources of distress in genetic testing is when siblings test differently.[30] If the siblings meet together before being tested, it may help them overcome this. Two sisters who had wholly different styles of coping were both at risk. They sought counseling together, before being tested. Now, both engage in optimal self-monitoring, and better still, perhaps, they report that "this conversation is part of their relationship."[31]

Meetings can also help greatly — often in a different way — for spouses, since their partners aren't genetically affected but live "side by side." For example, a wife was at high risk for breast disease but wouldn't go for genetic testing, and even refused to regularly examine her own breasts. The risk of not doing either of these was "lethal." She and her husband decided to go for counseling before she went for testing. In the end, she decided not to go for testing but agreed to examine herself every month. At her request, her husband reminds her to do so, "religiously."[32] It is particularly important for spouses to attend counseling when one may be at genetic risk, because the person who is at risk may be terrified that the partner will abandon her or him. This fear may be particularly pronounced if the person at risk observed this happening with an affected parent.[33] Even when a patient fears abandonment, we may be able to help the patient and her or his partner improve communication, which may wholly alter the couple's "fate."

Children. Our potential to positively affect what patients experience also exists when the other affected family members are children. An often agonizing issue for parents is deciding when to tell children that their parent has — or may have — a serious genetic disease. If the parent has this disease, the child may then have it as well. An example illustrating this wrenching dilemma is a parent who has myotonic dystrophy (MD). MD is an autosomal dominant disorder characterized by progressive muscle loss. Parents must tell a child that he or she also has MD when the child begins to show its manifestations, and this may be particularly difficult because MD may occur earlier with each successive generation.[34] Careproviders who encounter this situation might discuss three things with the parents.

The first is how the child will feel if the parents don't tell her or him in the longer run, but instead tell the child about this as early on as they can. This information may be most difficult for children to hear at any age, but, if parents don't share it with their child early on, in addition to feeling devastated, as the child will at some time in any case, the child may also feel bitter.[35]

The second is an argument that parents should not disclose that they and/or their child has or may have a serious genetic illness as early as they can. In most simple terms, parents might hold off because the information may cloud a child's capacity to experience joy in the present. This may be a reason that parents who are at genetic risk may not want to be tested. One mother said, for example, after she tested positive, " 'Now when I look at my daughters I see death on their faces.' "[36]

Third, if parents do tell their child, they may be able to support the child in ways that they otherwise couldn't. We could offer, as a group for consideration, children who have cystic fibrosis (CF) and their parents. Many of these children do well, although they usually know that they have this genetic disease from early on. The children come to know, also, that they will prematurely die.[37] When children who know that they have CF are younger, their parents can imbue them with unparalleled self-esteem. This is exemplified by a father who has MD and a 50 percent chance of passing it on to his children. He has two children without MD, but the third child has it. He told her, "Well, I'm still glad you were born."[38]

As children grow older and enter adolescence, it may be very painful to fear that no one will want to marry them. Parents who have discussed their genetic illness openly with their children may again inculcate exceptionally positive feelings. In this situation, parents may help their children acquire the sense that what may be most important is whom they would want to marry for themselves. This might not be someone who wouldn't want to marry them because of their illness; this might be someone who would want to marry them regardless of their genetic illness, but solely because of who they are. Parents may help their children use this as a sort of litmus test for whom they might want to marry. An example of a man who "passes the test" follows: he married a woman with MD and comments, " 'On my father's side,

there is deafness. . . . So it is just kind of, you know, nothing. You just come to accept flaws in people.' "[39] They plan to have children using prenatal testing, if they can.

Infants and fetuses. Parents may agonize over whether to have children who may have genetic illness, and what to do should they learn, during pregnancy or just after their child is born, that this is the case. If parents would be able to use pre-implantation genetic screening, we should take initiative to inform them about it, because they may not be aware that it exists.[40] Since some parents could find this offensive, we should use the general approach outlined above: we could tell parents why we raise this option and say that it is possible that they could take this the wrong way — namely, that we are implying that there is something wrong with a child who has a genetic disease. After we do these things, we should then ask the parents whether they want us to proceed. The hardest aspect may be that some parents will want to abort their child or let him or her die after birth, when we feel that although it is "legal," the parents' grounds for doing this aren't justifiable.[41]

Some reasons that parents may choose to let a fetus or infant die when he or she has genetic problems are more valid than other reasons. Parents may, for example, not want to have such a child due to feelings of shame. We may inform parents of this possibility; state why we do this; describe to parents how they may misinterpret our actions; ask them for permission to proceed. We can inform them that some parents, for unconscious reasons and without knowing it, may want to "extrude" such a fetus or infant from their family, so that their family can be "normal." We can pursue this further and say that if the parents feel this way, they may want to take more time with their decision, since feeling this way may be transient. They may regret it later if they make a decision too quickly.[42]

Still, we must keep in mind that some parents have greater capacities to raise children with serious genetic illness than others. The best any parent can do may be to decide what capacity she or he has, as best as possible. This may result in what may seem to be a repeat of what happened to a baby born with Down's syndrome and intestinal atresia at Johns Hopkins decades ago. The baby died due to water and food being intentionally withheld. I talked with a parent who made the same decision for an infant with most serious genetic disease. He held his son, day after day as he died, and as water and food were withheld. The baby, the father tells me, at the end, had the beginning of gangrene in his legs and stopped breathing, periodically, for many seconds. This may seem to be gruesome, but we must, above all else, fully support parents if and when this occurs. We should give our support even when parents legally can and do make decisions with which we strongly disagree. This may be among the most difficult tasks we ever are asked to perform. Still, as leading authorities in the area state, "the quality of the decision making process should not be assessed on the basis of its rationality, but on the basis of the parental emotional outcome."43

NOTES

1. E.T. Matloff, "Becoming a Daughter," *Journal of Genetic Counseling* 15, no. 3 (June 2006): 139-43.

2. See comment on this intervention in P.M. Veach, "Commentary on Becoming a Daughter: Trauma is a Powerful Teacher," *Journal of Genetic Counseling* 15, no. 3 (June 2006): 145-8.

3. See, i.e., S. McDaniel, "The Psychotherapy of Genetics," *Family Process* 44, no. 1 (March 2005): 25-44, p. 26, and P.E. Pfeffer, J.M. Pfeffer, and M.E. Hodson, "The Psychosocial and Psychiatric Side of Cystic Fibrosis in Adolescents and Adults," *Journal of Cystic Fibrosis* 2 (2003): 61-8, p. 63.

4. Feminist theory seeks to equalize power imbalance between therapists and clients. B.C. Thomas, P.M. Veach, and B.S. LeRoy, "Is Self-Disclosure Part of the Genetic Counselor's Clinical Role?" *Journal of Genetic Counseling* 15, no. 3 (June 2006): 163-77, p. 164.

5. K.S. Kendler et al., "Life Events, Dimensions of Loss, Humiliation, Entrapment, and Danger in the Prediction of Onsets of Major Depression and General Anxiety," *Archives of General Psychiatry* 69 (August 2003): 789-96.

6. S. Sarangi et al., "(Mis)alignments in Counseling for Huntington's Disease Predictive Testing: Clients' Responses to Reflective Frames," *Journal of Genetic Counseling* 4, no. 1 (February 2005): 135-55. See also, K.D. Valverde, "Why Me? Why Not Me?" *Journal of Genetic Counseling 1*5, no. 6 (December 2006): 461-3.

7. S. Sarangi et al., "Initiation of Reflective Frames in Counseling for Huntington's Disease Predictive Testing," *Journal of Genetic Counseling* 13, no. 2 (April 2004): 135-55.

8. R.J. Tassicker, "Psychodynamic Theory and Counseling in Predictive Testing for Huntington's Disease," *Journal of Genetic Counseling* 14, no. 2 (April 2005): 99-107.

9. Ibid.

10. Self-disclosure requests were more common from prenatal parents (34 percent) than they were from pediatric parents (6 percent). Thomas, Veach, and LeRoy, see note 4 above, p. 171.

11. Ibid., 174.

12. Ibid., 175.

13. "Resistance thrives when we and the patient are not allied around a common goal and are at different sates of change." D. Mee-Lee, "Engage Resistant Patients in Collaborative Treatment," *Current Psychiatry* 6, no. 1 (January 2007): 47-61, p. 51.

14. Valverde, see note 6 above, p. 463.

15. K.A. Rimes and P.M. Salkovskis, "Applying a Cognitive-Behavioral Model of Health Anxiety in a Cancer Genetics Service," *Health Psychology* 25, no. 2 (2006): 171-80, p. 172.

16. M. Keller et al., "Acceptance of and Attitude toward Genetic Testing for Hereditary Nonpolyposis Colorectal Cancer: A Comparison of Participants and Nonparticipants in Genetic Counseling," *Diseases of the Colon and Rectum* 47, no. 2 (February 2004): 153-62, p. 159.

17. See, e.g., A. Tluczek et al., "Newborn Screening for Cystic Fibrosis: Parents' Preferences Regarding Counseling At the Time of Infants' Sweat Test," *Journal of Genetic Counseling* 15, no. 4 (August 2006): 277-91, and P.A. Ubel, "Is Information Always a Good Thing?" *Medical Care* 40, no. 9 (supp.) (2002): V39-V44.

18. Sarangi, see note 7 above.

19. Ibid.

20. "Sharing the experiences of individuals who have previously undergone genetic testing with potential testees may be a useful strategy in this process, as normalizing reactions to health threats has been shown to be an important way of promoting good coping." N.A. Kasparian et al., "Better the Devil to Know? High-Risk Individuals' Anticipated Psychological Responses to Genetic Testing for Melanoma Susceptibility," *Journal of Genetic Counseling* 15, no. 6 (2006), *www.springlink.com.lrc1.usuhs.edu/content/m306wlk707r26282/fulltext.html,* accessed 12 January 2007.

21. Tluczek et al., see note 17 above, p. 278.

22. G. Cohen et al., "Reducing the Racial Achievement Gap: A Social-Psychological Intervention," *Science* 313, no. 5791 (1 September 2007): 1307-10; I. Dar-Nimrod and S.J. Heine, "Exposure to Scientific Theories Affects Women's Math Performance," *Science* 314, no. 5798 (20 October 2006): 435.

23. R. Adler, "The Curse of Being Different," *New Scientist* 193, no. 2586 (13 January 2007): 17.

24. Valverde, see note 6 above, p. 463.

25. Ibid., 462.

26. Tassicker, see note 8 above, p. 102.

27. Ibid.

28. R. Woodgate, "The Importance of Being There: Perspectives of Social Support by Adolescents with Cancer," *Journal of Pediatric Oncology* 23, no. 3 (May-June 2006): 122-34, p. 129.

29. "The biggest concern is leaving your own children motherless." Valverde, see note 6 above, p. 463.

30. McDaniel, see note 3 above, p. 27.

31. Ibid., 36.

32. Ibid., 36-7.

33. Tassicker, see note 8 above, p. 105.

34. McDaniel, see note 3 above, p. 32.

35. "June felt outrage at her parents." Tassicker, see note 8 above, p. 104. See also K.

Holt, "What Do We Tell the Children? Contrasting the Disclosure Choices of Two HD Families Regarding Risk Status and Predictive Testing," *Journal of Genetic Counseling* 15, no. 4 (August 2006): 253-65.

36. McDaniel, see note 3 above, p. 30.

37. Tluczek et al., see note 17 above. CF is the most common life-threatening genetic disease in the U.S. (p. 278). The median survival age is now the late thirties (ibid.). See also Pfeffer, Pfeffer, and Hodson, note 3 above.

38. McDaniel, see note 3 above, p. 33.

39. Ibid., 35.

40. Pfeffer, Pfeffer, and Hodson, see note 3 above, p. 65.

41. Couples who have prenatal testing may have less difficulty when they have less certainty. Their "burden of decision-making" may then be less, and it may enable them to better " 'hope' for the best." H. Bijma et al., "Parental Decision-Making After Ultrasound Diagnosis," *Fetal Diagnosis and Therapy* 20, no. 5 (September-October 2005): 321-7, p. 323.

42. Ibid., 324.

43. Ibid., 325.

Features

The Role of Substituted Judgment in the Aftermath of a Suicide Attempt

Robert C. Macauley

CASE

A 73-year-old man has, by his own estimation, a poor quality of life. He's retired, recently divorced, and his activity is limited by congestive heart failure (CHF). He spends most of his day watching television. He has completed an advance directive (AD) which stipulates that he does not wish aggressive treatment (such as cardiopulmonary resuscitation — CPR — or intubation), should these ever be required. He named his eldest child as his primary healthcare agent.

He is involved in a car accident, and is now hospitalized with multiple injuries including a collapsed lung and disfiguring facial trauma that will require multiple surgeries . As he is currently intubated and sedated, the medical team turns to his family (especially the eldest child) for guidance. The family is convinced that the patient would not want continued aggressive treatment and requests that mechanical ventilation be stopped and that he be allowed to die in peace.

As far as ethical dilemmas go, this is a fairly mild one. It is well established in ethics and the law that competent patients have the right to refuse any treatment, including those that are life sustaining.[1] Appropriate surrogates may also exercise this right on behalf of patients who lack decision-making capacity (DMC).[2] According to both this patient's autonomous choice and the substituted judgment of his agent, life-sustaining treatment should be withdrawn and the patient should be allowed to die in peace. External assessments of what is in the patient's "best interest" never come into play, they are trumped by the patient's right of autonomy.

Things become much more complicated, though, if two aspects of the case are modified. Take the same patient — same age, social situation, and nature of injuries — but suppose that the patient's activity was limited by *depression* (rather than CHF), and his current injuries are the result of a *self-inflicted gunshot wound* rather than an automobile accident. In cases such as this, physicians commonly bypass both the autonomy and substituted-judgment standards and treat based on the lower "best interest" standard.[3] There are several reasons for this response. First, suicide is considered by many to be irrational (and therefore not a truly autonomous choice), and the overriding ethical duty thus becomes one of beneficence.[4] The patient's lack of DMC at the time of the suicide

Robert C. Macauley, MD, is Clinical Associate Professor of Pediatrics at the University of Vermont College of Medicine and Medical Director of Clinical Ethics at Fletcher Allen Health Care in Burlington, Vermont, *robert.macauley@uvm.edu.*

attempt would also call into question the reliability of the AD, as well as the substituted judgment offered by the family. Was the AD executed at a time of depressive incapacity? And is the family estimating what the *depressed* patient would want (which seems fairly clear from the suicide attempt), as opposed to the patient's autonomous wishes when he was not clouded by mental illness?[5]

Second, some argue that the high probability of recovery from the underlying illness (that is, depression) justifies aggressive treatment for the sequelae (in this case, the self-inflicted trauma).[6] Third, the patient may not have truly been trying to kill himself, but rather counted on the medical system to "save" him from a suicidal gesture.[7] And finally, there is the concern for professional complicity, for is the medical establishment not abetting the patient's self-destructive behavior by making it "easier" for him to succeed (by virtue of withdrawing supportive measures)? If maximal treatment ceased to be the standard of care, wouldn't we be making suicide more convenient and attainable because suicidal patients would then merely have to render themselves dependent on life support (if only transiently) to achieve their goal? Would suicide thus join the ranks of horseshoes and hand grenades as the only forums where closeness counts as success?

Ironies abound in this instinctual response. A person goes to great lengths to end his or her life, only to have the medical establishment go to even greater lengths to prolong it. Physicians strive to avoid complicity in suicide, even as those in one state (Oregon) are legally permitted to assist patients in actively ending their own lives.[8] And what originally seemed a very reasonable decision (that is, withdrawing life-sustaining treatment) is deemed ethically impermissible due to the mechanism of injury, even though the patient's preceding quality of life, advance directive, current condition, and physical prognosis are unchanged.

In this article I will argue that while maximal treatment following a suicide attempt is a worthy guideline, it should not be an absolute rule. A variety of factors — including overall prognosis, as well as prior psychiatric history and treatment — need to be considered, and, in select situations, a surrogate's request for limitation of treatment following a suicide attempt should be honored.

BACKGROUND

There are approximately 425,000 suicide attempts each year in the United States, leading to over 30,000 deaths. This represents approximately 1 percent of all deaths in the U.S., and constitutes the third most common cause of death in late teenagers, and the eleventh most common cause overall (eighth for men, sixteenth for women). There are also important gender differences: women are more likely to attempt suicide, but men are four times more likely to die from the attempt (largely based on the methods men opt to use).[9]

HIERARCHY OF ETHICAL DECISION MAKING

The traditional hierarchy of ethical decision making emphasizes the patient's autonomous choice, followed by substituted judgment, and finally the patient's best interest. In the immediate aftermath of a suicide attempt, it would seem reasonable to doubt the autonomous nature of a direct patient refusal of treatment, if one grants the inherent irrationality of suicide.[10] This is not to say that all such patients necessarily lack DMC, but rather that there exists strong *a priori* evidence for their incapacity, based on the fact of their suicide attempt. Thus it would be unreasonable to expect that they could fulfill the burden of proof to the contrary, particularly while dependent on life-sustaining treatment.

But what of the patient's AD? Rather than summarily discard it for either legal or ethical reasons, it would seem reasonable to investigate its context and "rationality," if you will. In terms of context, was the AD composed just prior to the suicide attempt, or long before? Are there discernible reasons that the patient communicated those specific treatment directives

at the time the AD was executed? An AD composed in the minutes prior to a self-inflicted gunshot wound would certainly be suspect, but one composed years earlier during a happy period of life in a noble attempt to spare one's family from excruciating decisions would not.

In terms of "rationality," one must examine the treatment directive in light of the patient's condition. A request for no aggressive treatment from an otherwise healthy 30-year-old would obviously raise suspicion. By contrast, an older patient with evolving co-morbidities might rationally elect to limit certain life-sustaining treatments in non-terminal situations. For an elderly patient with metastatic cancer to request to be "DNR" (do not resuscitate) seems eminently reasonable; indeed, to perform CPR on such a patient might feel profoundly wrong to the medical team, almost an assault. Yet if that same patient actively attempts to take his or her own life, and the "suicide attempt means full treatment" algorithm were followed, we might find ourselves acting maleficently toward a patient, ostensibly for the sake of his or her "best interest."

Some would also discard the substituted judgment of a healthcare agent in such a situation, arguing that since the patient would not be able to refuse treatment following a suicide attempt (because of presumed depression), neither would the agent. Thus Spike writes, "The agent has authority to make only those decisions the patient would have had the authority to make."[11] Yet this claim does not support his conclusion, for it misconstrues the patient's *authority* with his or her *ability.* As stated above, patients have the authority to offer an informed, autonomous refusal of life-sustaining treatment, but some patients (such as those who do not currently possess DMC) presently lack the *ability* to do so.[12] Thus while it is true that an agent's authority extends only as far as the patient's would have — and thus would exclude, for instance, a request for active euthanasia — the right of the agent to make decisions that the patient currently is unable to make is the very reason for appointing a healthcare agent in the first place.

If one admits that (1) an AD may, in certain cases, be a trustworthy guide to treatment; (2) the "best interest" standard may paradoxically lead to harmful, unwanted treatment; and (3) substituted judgment may indeed have a role in decision making following a suicide attempt; then the rule of maximal intervention in the aftermath of a suicide attempt cannot be universal. Therefore, we must delineate a method to identify the exceptions. The context and "rationality" of the AD have already been mentioned, but further considerations must be applied in the case of "substituted judgment" offered by agents or surrogates: (1) the characteristics of the underlying depression; (2) extrinsic factors influencing probability of improvement; and (3) the level of surrogate certainty as to what the patient would have wanted.

CRITERIA FOR APPLICATION OF SUBSTITUTED JUDGMENT

CHARACTERISTICS OF THE UNDERLYING DEPRESSION

In evaluating a suicide attempt, one must consider the duration and intensity of the underlying depression, as well as the extent of prior treatment, all of which have implications for the patient's prognosis. In terms of duration and intensity of depression, there is a significant difference between a situational sadness (as in the case of a young person responding to the recent breakup of a romantic relationship) and a long-standing major depression that meets *DSM-IV* criteria.[13] It is difficult to imagine honoring an AD or surrogate request for limitation of treatment in the former case.

One might also hypothesize that a patient who has never received treatment for depression is more likely to improve with psychiatric treatment than a patient who had exhausted all known options. This is not to say that the untreated patient would definitely improve, nor that the latter patient might not benefit from new and innovative interventions. In light of the ethical imperative of *primum non nocere* (first, do no harm), physicians are obligated both to give patients an opportunity to benefit from poten-

tially efficacious treatment, as well as to acknowledge the point at which the likely burdens of continued treatment (both somatic and psychiatric) may outweigh the potential benefits.

Ultimately, this criterion focuses on the patient's prognosis. And while the trajectory of depression is more uncertain than somatic ailments such as heart failure (which have quantitative measures such as ejection fractions that can be used to project the future course of the disease), it is no less debilitating. The default response of maximal treatment makes an implicit appeal to either a minimizing bias (which overlooks the profound implications of mental illness) or an optimistic one founded on the claim that "most suicidal patients have a reasonable chance for recovery."[14] If one accepts the intense burden of depression, and acknowledges that refractory cases do exist, then the inherent prognostic uncertainty should not preclude a clinician from making an educated forecast and formulating treatment plans accordingly.

It is worth noting that the best interest standard has traditionally been used to justify withdrawal of life-sustaining treatment for unrelievable *somatic* suffering, but not for psychiatric suffering. There are many possible reasons for this, most notably that many somatic ailments of this severity involve life-sustaining treatments that may themselves be limited. In the absence of unrelievable somatic suffering, though, physicians are reluctant to limit treatment due to the inherent uncertainty as to the "intractability" of psychiatric illness. Mental health advocates, for their part, are rightfully concerned about blanket assertions that it would be in a depressed patient's "best interest" to no longer be alive.

To be clear, I am not arguing that the best interest standard (as determined by an external observer) justifies withdrawal of life-sustaining treatment in the aftermath of a suicide attempt. Rather, I make the much weaker claim that the best interest standard does not automatically mandate *maximal* treatment in *every* such case. The patient's personal values — as expressed prior to decisional incapacity, and applied to both the somatic and psychiatric aspects of the current situation — may trump the presumption of full treatment.

EXTRINSIC FACTORS INFLUENCING PROBABILITY OF IMPROVEMENT

If one views depression from a multifactorial point of view, "extrinsic factors" must also be taken into account when formulating a prognosis. In this case scenario, the patient has multiple risk factors for depression, such as age and marital status. The patient may also have other unspecified co-morbidities and may be responding poorly to retirement. In situations such as this, in which the majority of extrinsic factors that influence (and are influenced by) the patient's depression are irremediable, one should be more likely to take seriously a substituted judgment that requests limitation of treatment.

In addition, various methods and severities of suicide attempts lead to different expected changes in their aftermath. In terms of recovery time and burden, for instance, a failed overdosage would likely have modest long-term consequences (assuming that kidney and liver function were intact). There would be good reason to expect that the patient could return to his or her previous quality of life — however that is defined or quantified — following discharge.

Gunshot wounds are a different story, however. The patient in this scenario is not only facing a protracted, intense, and emotionally and financially draining rehabilitative course, but also long-term social consequences. If he was already depressed, how much worse will his outlook be when he realizes the cosmetic implications of the gunshot wound to his face? Viewed holistically, these concerns represent further irremediable extrinsic factors that influence his probability of improvement.

At the same time, one must be vigilant against potential discrimination. Granted too much importance, this criterion might be used to disproportionately favor limitation of treatment in the aftermath of a suicide attempt by the elderly, divorced, poor, and otherwise in-

firm. Recognizing that physicians significantly underestimate a patient's quality of life (compared to self-report),[15] extrinsic factors must be considered in light of the other suggested criteria and the overall quality of life of the patient, as defined by the patient himself or herself.

LEVEL OF SURROGATE'S CERTAINTY ON WHAT THE PATIENT WOULD HAVE WANTED

Surrogate decision making is inherently fraught with uncertainty. Studies report that even under the best of circumstances, surrogates frequently advocate a different course of action than the patient would have wanted.[16] Often the medical team has no other choice, though, as the patient may never regain DMC, and a loved one's substituted judgment seems more faithful to the patient than a stranger's sense of the patient's best interest.

In this particular case, the process of substituted judgment is even more complex, as the surrogate must imagine what the patient — *at a time when he still had DMC* — would have wanted. A general policy of full treatment in the aftermath of a suicide attempt may, therefore, be attractive precisely because it eliminates the need for substituted judgment altogether, ultimately deferring critical decisions to the patient himself once he has (hopefully) regained the ability to make them. In yet another instance of irony, one might defend such a blanket policy of overriding a patient's past statements of refusal, and the surrogate's appropriate request for discontinuation of treatment, in the name of (future) autonomy.

As is often the case, the truth lies somewhere in the middle, between blind trust in a surrogate's substituted judgment and utter reliance on hoped-for restoration of the patient's own DMC. There may be situations in which the surrogate has solid reasons to believe that the patient — at a time of maximal autonomy and DMC — would not have wanted aggressive treatment under *any* circumstances. (The aforementioned hypothetical case of the elderly patient with metastatic cancer might be an example.) On the other hand, a surrogate's vague sense of what the patient probably would have wanted would not be so compelling. And a surrogate's request for withdrawal of life-sustaining treatment would generally be viewed with caution if the patient's level of consciousness were steadily improving and restoration of DMC appeared imminent.

AMOUNT OF PSYCHIC PAIN INVOLVED IN ASKING PATIENTS TO MAKE THE DECISION

These criteria are complex and nuanced, and thus one might be tempted to reject substituted judgment not because it is inapplicable, but simply because it is *impractical.* "Why not simply wait for the patient to regain DMC?" one might ask. Even those who favor mandatory maximal treatment for suicide attempts grant that eventually the patient should be allowed to make his or her own decisions once again, assuming his or her DMC is intact. Thus Bania and colleagues suggest, "Even though the cause of the patient's coma was self-inflicted, it does not invalidate the pre-suicidal wishes of the patient *after he or she is resuscitated from the suicide and is no longer being directly treated for the suicide.*"[17]

Such an approach, however, fails to take into account the psychic pain involved in asking the patient to make such a decision. To state the obvious, the patient wished to end his life.[18] To participate in decision making would require that he acknowledge that this attempt failed, and that he has been "at the mercy" of others — in the ambulance, emergency department (ED), and intensive care unit, unconscious and in various states of undress — for the intervening period of time. In addition, he is facing a future of rehabilitation and disfigurement, as previously noted. Finally, even if he were to subsequently request discontinuation of treatment unrelated to his suicide attempt, it is quite possible that his request would not be honored, out of concern for continuing depression and resulting incapacity.

While it may be noble, therefore, to attempt to involve the patient in decision making, there may be overriding concerns of nonmaleficence

to refrain from doing so. Moreover, it is unfair to ostensibly grant the patient the right to make his own treatment decisions, provided he decides in favor of recommended treatment. This makes a sham of the notion of patient autonomy, a noble concept that is better honored and protected through the substituted judgment paradigm suggested in this article, than in a question with only one acceptable answer.

CAVEATS

As stated above, one of the proposed justifications for maximal treatment of all patients following suicide attempts is the concern that the patient may not have intended to actually kill himself or herself. Certainly some methods of suicide are recognized to be much more "effective" than others,[19] with firearms 2.6 times more likely to be lethal than hanging/suffocation, and 270 times more likely to be lethal than intentional ingestion.[20] At first glance, one might tend to treat suffocations or ingestions more aggressively than gunshot wounds, as the latter would be thought to reflect a more "serious" attempt.

There are multiple problems with this interpretation, however. First, the average patient is unlikely to be familiar with epidemiological data regarding the relative lethality of suicide methods, and thus the chosen method may be a matter of convenience. Second, the possibility of gender bias must be considered, for while firearms account for the majority of male suicides, they represent less than one-third of female suicides.[21] It would be profoundly unjust to subject male patients to under treatment (or, conversely, female patients to over treatment) simply because men are roughly four times as likely to own a gun as women.[22]

Context must also be considered in applying the aforementioned criteria. In the ED setting, for instance, many facts are not yet in evidence, and the considerations enumerated here cannot be considered in full. Initially, then, the *status quo* practice of maximal treatment is reasonable. At the other extreme, well into the patient's course when he or she has been treated for the sequelae of the suicide attempt and his or her DMC has (hopefully) been restored, few would continue to limit the patient's right to make his or her own medical decisions.

The intervening period between initial resuscitation and eventual recovery — the focus of this article — is much more complex. The underlying motivation behind maximal treatment in every such case has been shown to be replete with ironies and given to compelling counter-examples. The consideration of the three proposed criteria — exercised with particular caution so as not to introduce social, health, or gender biases — offers a nuanced approach to surrogate decision making in the aftermath of a suicide attempt. These criteria can be used to identify the select clinical situations in which a surrogate's request for limitation of treatment should be respected.

AKNOWLEGMENT

The author would like to thank Robert Orr and Marcia Bosek for their helpful critiques, and Sanchit Maruti for his invaluable assistance in research and manuscript preparation.

NOTES

1. "The principle of patient autonomy requires that physicians respect the decision to forego life-sustaining treatment of a patient who possesses decision-making capacity." *Code of Medical Ethics of the American Medical Association* (Chicago, Ill.: American Medical Association Press, 2006), 75.

2. Compare with *In re Quinlan,* 355 A.2d 647 (N.J. 1976).

3. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics,* 5th ed. (New York, N.Y.: Oxford University Press, 2001), 98-104.

4. "There is a prevalent (and probably sound) view that a suicide attempt allows a presumption of psychiatric illness and that intervention over the patient's objection is justified." J. Spike, "Physicians' Responsibilities in the

Care of Suicidal Patients: Three Case Studies," *The Journal of Clinical Ethics* 9, no. 3 (Fall 1998): 311.

5. In purely legal terms, there is also the question of whether advance directives apply to situations of self-inflicted injury. One article asserts: "Advance directives . . . are considered to be legally binding when a patient presents with symptoms from a *naturally occurring disease process.* It is not the intent of any state to use these documents to assist a patient who has attempted to commit suicide. . . . Such a view would be considered violative of public policy." W. LeStrange and K. Porter, "Risk Management and Legal Principles," in *Goldfrank's Toxicologic Emergencies,* ed. L.R. Goldfrank et al. (New York, N.Y.: McGraw Hill, 2002), 1776 (italic added). I have not, however, been able to locate statutory evidence of this assertion.

6. "Physicians do not permit suicidal patients to refuse treatment, because most suicide attempts occur when judgment is impaired, and *most suicidal patients have a reasonable chance for recovery.*" R.K. Wagle et al., "An Ethical Dilemma: When the Family Wants the Withdrawal of Care," *Journal of Psychiatric Practice* 10, no. 5 (September 2004): 335 (italic added).

7. A recent study found that only 22 percent of suicide attempters wished that their attempt had succeeded, while 36 percent wished they hadn't made the attempt and were glad to be alive. G. Henriques et al., "Suicide Attempters' Reaction to Survival as a Risk Factor for Eventual Suicide," *American Journal of Psychiatry* 162, no. 11 (November 2005): 2180-2.

8. Albeit under strictly controlled circumstances, including the documented absence of depression. Oregon Death with Dignity Act, Oregon Revised Statute 127.800-127.995, see *http://egov.oregon.gov/DHS/ph/pas/docs/statute.pdf.*

9. WISQARS (Web-based Injury Statistics Query and Reporting System, 2006), Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, *www.cdc.gov/ncipc/wisqars,* accessed 4 January 2007.

10. The condemnation of suicide can be based on philosophical (e.g., Plato, Aristotle) or theological (e.g., Augustine, Aquinas) grounds. While this is the prevailing viewpoint in our culture, there are well known arguments to the contrary. The Stoics emphasized quality of life over duration. Thus Seneca: "Mere living is not a good, but living well. Accordingly, the wise man will live as long as he ought, not as long as he can." L.A. Seneca, *Moral Epistles,* vol. 2, trans. R.M. Gummere (Cambridge, Mass.: Harvard University Press, 1917-25), 57. Aquinas's condemnation of suicide as a violation of natural, moral, and divine law was answered point by point by Hume. And perhaps most famously, Existentialism stresses the question of continued existence. Thus Camus: "There is but one truly serious philosophical problem, and that is suicide. Judging whether life is or is not worth living amounts to answering the fundamental question of philosophy." A. Camus, "The Myth of Sisyphus," in *The Myth of Sisyphus and Other Essays* (New York, N.Y.: Alfred A. Knopf, 1955), 3.

11. See note 4 above.

12. Or, at the very least, the chance to prove that they possess the ability to make such decisions, all *a priori* evidence to the contrary.

13. *Diagnostic and Statistical Manual of Mental Disorders,* 4th ed. (Washington, D.C.: American Psychiatric Association, 2000).

14. See note 6 above.

15. Compare with K.A. Wilson et al., "Perception of Quality of Life by Patients, Partners and Treating Physicians," *Quality of Life Research* 9, no. 9 (November 2000): 1041-52.

16. D.I. Shalowitz, E. Garrett-Mayer, and D. Wendler, "The Accuracy of Surrogate Decision Makers: A Systematic Review," *Archives of Internal Medicine* 166, no. 5 (March 2006): 493-7.

17. T.C. Bania, R. Lee, and M. Clark, "Ethics Seminars: Health Care Proxies and Suicidal Patients," *Academic Emergency Medicine* 10, no. 1 (January 2003): 65-8 (italic added).

18. Assuming that this was a true suicide attempt rather than merely a suicidal gesture, and granting that this wish may not be deemed

truly "autonomous."

19. Both poetically and epidemiologically, as Dorothy Parker wrote in her poem, "Resume,"

> Razors pain you;
> Rivers are damp;
> Acids stain you;
> And drugs cause cramp;
> Guns aren't lawful;
> Nooses give;
> Gas smells awful;
> You might as well live.

D. Parker, "Resume," in *Enough Rope* (New York: Boni and Liveright, 1926).

20. E.D. Shenassa, S.N. Catlin, and S.L. Buka, "Lethality of Firearms Relative to Other Suicide Methods: A Population Based Study," *Journal of Epidemiology and Community Health* 57, no. 2 (February 2003): 120-4.

21. National Center for Injury Prevention and Control, *http://webappa.cdc.gov/sasweb/ncipc/leadcaus.html,* accessed 9 December 2006.

22. G.J. Wintemute et al., "Mortality Among Recent Purchasers of Handguns," *New England Journal of Medicine* 341, no. 21 (November 1999): 1583-9.

Commentary: Support for Case-Based Analysis in Decision Making after a Suicide Attempt

Tia Powell

A curious aspect of healthcare delivery in the United States may be summarized by the following motto: Do everything, but only after all hope is lost. Robert Macauley, MD, presents an interesting article on the subject of providing medical treatment after suicide attempts; the article raises issues related to advance directives, the assessment of capacity, and the limits of surrogate decision making. However, before addressing those topics, we must pause to reflect on the absurd imbalance between the treatment available to the patient after an attempt to die, rather than before. Many insurance plans offer severe limitations on treatment for mental illness; out-patient clinics for the severely mentally ill are closing at a rapid rate, as they do not generate profits.[1] Rates of suicide attempts remain too high; providing access to effective care at a stage before injury is an important goal for mental health policy. Although many have worked to decrease stigma and increase access to mental healthcare, there is still much too much to be done to provide treatment that will prevent suicide.

Nonetheless, we will always be faced with some suicidal patients, and thus with the question of how to determine appropriate medical treatment for a patient after a failed suicide attempt. Decisions in this context are made yet more complex by the aura of grief and anger generated by the patient's act of self-violence. Family members confront their sense of failure in preventing the attempted suicide; physicians battle a sense of futility in trying to preserve a life not valued by the patient. Suicidal patients themselves are most often in the throes of depression, substance abuse, and other significant mental illnesses. Each of these three groups — family, provider, and patient — faces significant challenges as they address their role in making medical decisions. The context of emergency treatment and difficulties in assessing decision-making capacity in the mentally ill add to the complexity of the issues.

Emergency treatment, irrespective of whether a suicide attempt is involved, is often provided without full informed consent either from the patient or a surrogate. Trauma victims are stabilized; in some cases it later turns out

Tia Powell, MD, is Executive Director of the New York State Task Force on Life & the Law, New York, *tpp03@health.state.ny.us.*

that an advance directive prohibited aggressive treatment. As the medical history and options are clarified, life-sustaining treatments or other interventions may be modified or withdrawn based on the fuller information that becomes available with more time. Many post-suicidal patients are trauma victims and thus their treatment follows the same pattern, with aggressive early attempts to preserve the patient's life pursued in the emergent situation, followed by exploration of various treatment options once the patient is stable. To some extent, aggressive treatment after a suicide attempt is a phenomenon more related to emergency treatment than suicidality *per se.* Acutely ill patients are stabilized if possible, and issues of decision-making capacity and continued treatment are addressed once the emergency is controlled.

Macauley questions whether maximal treatment following a suicide attempt is always appropriate. The suggestion that various factors should influence the choice of treatment is a common sense one, and one that is followed today in many facilities. In all cases, however, it is an emotionally and legally challenging process to weigh and balance factors related to surrogate decision making, mental illness, and prognosis. Not surprisingly, these cases frequently give rise to requests for ethics consultation and assistance from consultation-liaison psychiatry.

One such challenge is to discover who the appropriate decision maker is. A patient is not automatically deprived of decision-making capacity by virtue of a suicide attempt, although clinicians are understandably reluctant to defer to a suicidal patient's wishes to discontinue treatment. Even when denied the right to refuse some treatments, the patient may retain authority to make other decisions. Patients who remain alert enough to communicate require a careful assessment of their mental status, both to support the treatment of the probable underlying mental illness and to assess decision-making capacity. For patients who lack decision-making capacity, designated healthcare agents or other surrogates, when available, must step in to work with the healthcare team in making appropriate choices.

However, even once the correct decision maker is identified, these choices are far from simple. Decisions to withdraw and withhold life-sustaining treatment are often full of conflict, even without the added complication of a suicide attempt. Indeed, third-party requests to forego life-sustaining treatment are a common source of requests for ethics consultation, and appropriately, providers often request additional review of such a request. Bania and colleagues describe the familiar Jonsen-Siegler-Winslade approach to ethics consultation as a useful system for weighing different aspects of one such challenging case.[2] The question of how to separate the impact of suicidal thoughts from long-standing and legitimate beliefs about end-of-life care is exceedingly complex. A useful comparison is found in the work of Ganzini and Lee, who have published a number of studies documenting the relative stability of wishes regarding end-of-life care among elderly patients both when euthymic and depressed.[3] Their work has done much in the last decade and more to promote careful, case-by-case analysis of decision making that involves end-of-life choices, mental illness, and suicidality.

Practical options, too, play a role in decision making after a suicide attempt. For patients with a grim prognosis, either because of the suicide attempt itself or from other pre-existing health issues, physicians and surrogates can, and do, appropriately consider the likely efficacy and physical burden of a proposed medical intervention. Futile or nearly futile invasive treatments need not be imposed on a patient merely because that person has attempted suicide. Karlinsky and colleagues offered a sensitive discussion of these issues almost 20 years ago, which highlights the point that these dilemmas, sadly, are not new.[4]

The treatment of patients after a failed suicide attempt pulls together a number of contentious issues: assessment of capacity, mental illness, surrogate decision making, and the durability of patients' preferences over time and

in different states of health. Given the complexity of these issues, healthcare facilities today find that the best practice is to support a careful case-based review of the relevant factors. "Doing everything" for the suicidal patient means thinking carefully about the options, preferences, and best interest of that person, and devising a plan of care that is appropriate to this individual.

DISCLAIMER

The opinions expressed here are those of the author, and do not reflect the views of the New York State Task Force on Life & the Law or of New York State.

NOTES

1. P.S. Appelbaum, "The quiet crisis in mental health services," *Health Affairs* 22, no. 6 (November - December 2003): 281-2.

2. T.C. Bania, R. Lee, and M. Clark, "Ethics Seminars: Health Care Proxies and Suicidal Patients," *Academic Emergency Medicine* 10, no. 1 (January 2003): 65-8.

3. See, for instance: L. Ganzini et al., "The effect of depression treatment on elderly patients' preferences for life-sustaining medical therapy," *American Journal of Psychiatry* 152, no. 12 (December 1995): 1836-7; M. Lee and L. Ganzini, "Depression in the elderly: effect on patient attitudes toward life-sustaining therapy," *Journal of the American Geriatric Society* 40, no. 10 (October 1992): 983-8.

4. H. Karlinsky et al., "Suicide Attempts and Resuscitation Dilemmas," *General Hospital Psychiatry* 10 (1988): 423-7.

Flipping the Default: A Novel Approach to Cardiopulmonary Resuscitation in End-Stage Dementia

Angelo E. Volandes and Elmer D. Abbo

INTRODUCTION

Much of the recent attention on Alzheimer's disease has focused on potential cures from stem cell research, but has left largely neglected an issue that has been floating in medical circles for years: What constitutes appropriate care for patients with end-stage dementia (ESD)?[1] Over the coming years, patients with ESD from Alzheimer's disease will overwhelm the healthcare system. In 2000, according to the U.S. Census, 4.5 million patients had Alzheimer's dementia; that number is expected to surge to 13 million by 2050.[2] Since Alzheimer's accounts for approximately 60 percent of all patients with dementia,[3] we estimate about 7.5 million patients have some form of dementia today, and approximately 20 to 30 percent, or 2 million patients, have advanced forms of the disease.[4]

Angelo E. Volandes, MD, is on faculty in the General Medicine Unit at Massachusetts General Hospital/Harvard Medical School in Boston, *avolandes@partners. org.*

Elmer D. Abbo, MD, JD, is a Member of the Faculty in the Department of Medicine at the University of Chicago, *eabbo @medicine.bsd.uchicago.edu.*

We will first explore the present mechanisms by which care for the elderly with ESD is decided and the problems associated with these practices. Following the well-validated clinical definition, by "ESD" we mean a chronic state that is characterized by severe neurological incapacity as demonstrated by an almost complete loss of intelligible vocabulary, loss of ambulatory function, and complete dependence on others for one's basic needs, including feeding.[5] We will review the empirical evidence, which suggests that the large majority of patients would prefer not to receive cardiopulmonary resuscitation (CPR) in ESD as well as the evidence that such care is common. We suggest and explain the practical application of a default approach in which CPR in ESD is routinely withheld. Lastly, we will discuss how such a default can be justly applied.

ADVANCE DIRECTIVES AND SURROGACY

In a pluralistic society that values choice and tolerates difference, the individual is the ultimate decision maker in the care of her or his body.[6] When a patient is decisionally incapaci-

tated, such as a patient with ESD, the accepted practice is to utilize either an advance directive or a surrogate, practices that attempt to preserve the patient's autonomy.[7] Although shared decision making is commonly advocated,[8] the patient — or, when the patient is incapacitated, the patient's surrogate — retains practical veto power.[9] The courts have consistently upheld this principle of self-determination,[10] and legislation such as the Patient Self-Determination Act embodies this principle.[11]

However, serious questions have been raised regarding the use of advance directives and surrogate decision makers. Advance directives, as traditionally drafted, have not proven to be very effective and have been seriously questioned.[12] The vast majority of patients do not have an advance directive, and even when a directive is present, it often has a small effect on terminal care.[13] A traditional advance directive specifically refers to terminal illness and persistent vegetative states. Applying an advance directive to a patient with ESD is fraught with uncertainty. Patients with ESD qualify as being terminally ill but are not recognized as being so.[14] It is certainly possible that families interpret advance directives broadly, for example, by not pursuing hospitalization of a loved one.[15] But physicians have been reluctant to make such judgments. In addition, physicians have difficulty adhering to an advance directive unless it is supported by a surrogate.[16]

The alternative to an advance directive is a surrogate decision maker, who either attempts to make decisions for the incapacitated patient according to a substituted judgment or a best interest standard.[17] Surrogate decision making has been considered a vital component in the care of the decisionally incapacitated. To preserve the value of individual self-determination and autonomy, a surrogate, often a family member, is assumed to know best what an individual would have wanted.[18]

But surrogate decision making is also imperfect.[19] Proxies often do not know the patient's preferences, are selected for reasons unrelated to how well they know the views of the patient, and often make estimates of a patient's preferences that are little different from chance.[20] Surrogates sometimes also knowingly disregard a patient's preferences.[21]

The imperfect nature of surrogacy should not be surprising. Even competent patients often make decisions for themselves that are less than optimal due to difficulties in assessing risk, misinformation, denial, and distrust.[22] Decisions that have been placed in the hands of a surrogate are further complicated by an overwhelming sense of emotion as the surrogate struggles with feelings of guilt and the psychological desire to avoid being responsible for the death of a loved one.[23] Although a patient may be willing to have life-sustaining therapy withdrawn, surrogates are generally less willing to withdraw it for a relative.[24] Physicians have also noted that surrogates have difficulty letting a loved one go.[25] These guilt-based reasons, although compelling, fall far short of preserving autonomy by the substituted judgment standard.

The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT), which combined a prospective observational study of seriously ill patients with a multilayered, nurse-based communication intervention focused on documenting patients' preferences, demonstrated a disturbing disconnect between the kind of care that people want at the end of life and the care they actually receive.[26] Ironically, SUPPORT frequently relied on surrogates themselves to establish a patient's preferences, the very approach we question. The lack of an effect of the SUPPORT intervention on the use of aggressive interventions at the end of life may be partly explained by the fact that cognitively intact patients are certainly willing to accept some life-sustaining therapy regardless of their baseline quality of life.[27]

However, the evidence does strongly suggest a disconnect between preferences and practice in the case of patients with ESD. When the subjects in the studies described above were asked specifically about the use of CPR in the face of ESD, their responses were dramatically different than those for cognitively intact patients. Thus, an unchallenged role for advance

directives and surrogate decision making for patients with ESD is problematic because our standard methods of decision making may fail to secure patients' preferences.

PREFERENCES FOR CPR IN DEMENTIA

A review of the existing literature indicates that a large majority of the patients queried do not want CPR in dementia, including ESD. We searched Medline and conducted a search of paper bibliographies and identified studies that evaluated the use of CPR in patients with dementia. We excluded studies that evaluated preferences in states of coma or permanent unconsciousness. We included all studies that mentioned dementia, even if they did not specify the degree of dementia.

We found 15 studies that suggest that a large majority of patients do not want CPR in dementia,[28] and only three studies that supported a preference for CPR in dementia (see table 1).[29] We categorized the studies by severity of dementia to illustrate the increasing numbers of people who preferred no life-sustaining treatments in ESD. We roughly categorized the severity of dementia as follows:

- A person with early dementia has deficits in performing complex tasks of daily life such as balancing a checkbook;
- A person with moderate dementia requires assistance with activities of daily living such as bathing;
- A person with severe or ESD has speech limited to a few words and is unable to ambulate.[30]

The studies varied in the manner in which the subjects' preferences were obtained; some questioned subjects directly regarding the use of CPR, while others used phrases such as "life-prolonging care" (see table 1).

As mentioned above, we did find three studies that found less agreement on preferences for treatment in states of dementia. In a study by Seckler and colleagues, only 32 percent of the patients queried did not want CPR in the setting of moderate dementia, in a racially diverse sample.[31] Caralis and colleagues found only 38 percent of 49 non-Hispanic Whites, 26 percent of 51 African-Americans, and 11 percent of 39 Hispanics did not want CPR in dementia (not otherwise described).[32] Reilly and colleagues evaluated 218 elders about moderate dementia and found only 46 percent of patients did not want CPR.[33]

Most of the studies were performed in elderly patients whose opinions are more likely to be shaped by experience and knowledge about dementia. One study did report that knowledge and experience with Alzheimer's disease was associated with a desire to avoid CPR in dementia.[34] It is also interesting that two studies reported individuals were more willing to provide CPR to others than they were willing to accept it for themselves.[35]

Although most of the studies did not directly specify or describe a state of ESD,[36] we presumed that individuals who do not desire CPR in mild or moderate states of dementia would also choose not to have CPR in ESD. In fact, one study reported that patients were less willing to accept CPR as dementia advanced.[37] Thus, we suspect that preferences against CPR would have been even stronger if cases of ESD were clearly described.

The majority of the studies were conducted in English-speaking countries, specifically the United States, England, Canada, and Scotland. The studies were also limited in that they were done in predominantly White populations; thus, firm conclusions could not be drawn about preferences in dementia for minority populations. Studies published in the early 1990s suggested that members of minority groups, mostly African-Americans and Latinos/Latinas, may have different cultural frameworks from which to understand end-of-life decision making.[38] But simply because members of minority groups may work from within a different cultural framework does not necessarily mean that their preferences regarding advanced dementia will be different from the preferences of Whites. In the study by Caralis and colleagues, 90 of 140 subjects were either African-American or Latino/

TABLE 1 Summary of Studies Evaluating Patients' Preferences of Life-Sustaining Therapy in Dementia

Study	Year	*N*	Characteristics	Age	Race	No CPR
ESD						
Michelson et al.	1991	44	NH, US	83 ± 6	NR	64%
Gjerdingen et al.	1999	84	NH, OP, US	80 ± 9	99% White	96%
Finucane et al.	1988	34	OP, US	73.4 mean	NR	74%
Ebell et al.	1990	339	OP, US	63.8 mean	NR	4.1/5.0[1]
Pearlman et al.	2000	342	OP,[2] NH, US	= 65 & > 65[3]	NR	± 70 to 80%[4]
Moderate dementia						
Lo et al.	1986	94	OP, US	= 65 & > 65[5]	NR	71%
Everhart et al.	1990	30	VA ICU, US	64 ± 9	90% White	63%
Seckler et al.	1991	69	OP, US	78	39% White;	
					50% AA; 11% Latino/Latina	32%
Robertson	1993	322	OP, Scotland	< 60 & = 60	NR	75%
	1993	196	OP, Scotland	< 60	NR	73%
	1993	126	OP, Scotland	= 60	NR	78%
Harrison et al.	1995	163	OP, Canada	42 ± 17.5	NR	80%
Gjerdingen et al.	1999	84	NH, OP, US	80 ± 9	99% White	93%
Reilly et al.	1995	218	OP, US	69 median	96% White	46%
Berger et al.	1998	37	NH, US	81.9 mean	97% White	4.8/5.0[6]
Mild dementia						
Malloy et al.	1992	201	OP, US	76 mean	NR	69% to 86%[7]
Gjerdingen et al.	1999	84	NH, OP, US	80 ± 9	99% White	76%
Dementia (unspecified)						
Gunasekera et al.	1986	134	OP, England	80.7	NR	76%
Emanuel et al.	1992	507	OP, US	= 65 & > 65[8]	majority White	72%
Morgan et al.	1994	100	OP, England	80.4	NR	76%
Griffith et al.	1995	661	OP, US	= 65 & > 65	93% White	78%
	1995	535	OP, US	= 65	93% White	76%[9]
	1995	126	OP, US	> 65	93% White	85%
Caralis et al.	1993	139	OP, US	53 ± 15	35% White;	38%
					37% AA;	26%
					28% Latino/Latina	11%

NOTES

1. Likert scale: 1 = definitely want, 5 = definitely do not want.
2. Diverse patient populations including young adults, older well adults, persons with chronic illness, terminal cancer, acquired immunodeficiency syndrome, stroke survivors, and nursing home residents.
3. Mean not reported.
4. Range across multiple subpopulations reported graphically. Exact values not reported.
5. Mean not reported
6. Likert scale: 1 = definitely want, 5 = definitely do not want. Average of three results over six months reported.
7. CPR aggregated with range depending whether intervention posed in negative, neutral, or positive fashion.
8. Mean not reported.
9. Calculated.

KEY

AA African-American
CPR cardiopulmonary resuscitation
ESD end-stage dementia
ICU intensive care unit
NH nursing home
NR not reported
OP out-patient
US United States
VA Veterans Administration

Latina. After discussing preferences for life-prolonging treatments, regardless of how ill they were, 61 percent of the subjects did not want life-prolonging treatment.[39] A more recent study that included a sizable number of minority subjects and clearly specified ESD also suggests that when the health state of ESD is accurately communicated and described, minority patients differed little from Whites regarding their preferences for medical care.[40]

CPR IN END-STAGE DEMENTIA

Despite this strong consensus to forgo CPR in ESD, patients with ESD continue to receive CPR out of proportion to their preferences.[41] Ahronheim and colleagues evaluated the frequency of aggressive interventions in patients who died in an acute care hospital and found that out of 80 patients with advanced Alzheimer's, 24 percent received CPR. The evidence of the use of life-sustaining procedures on patients with ESD in nursing homes is no less disturbing. Although the use of CPR is rare in nursing homes,[42] in a study on the use of CPR in nursing homes in Milwaukee from 1986 to 1989, Duthie and colleagues found that 38 percent of the patients who received CPR had dementia.[43] When the charts were abstracted, the authors were struck by the degree of disability and the burden of illness from which these patients suffered, suggesting that the patients had advanced disease.

Mitchell and colleagues sampled 1,609 patients with advanced dementia who were living in nursing homes and found that 45 percent had a "full code" in the final months of life; 95 percent of these patients died within three months of their last formal assessment.[44] The fact that almost half of such patients were full code so close to death suggests that many received CPR in a state in which the majority of patients would not have wanted it. We recognize that there are no data directly linking the preferences of individual patients prior to the onset of their dementia and the receipt of unwanted procedures later in a state of ESD. Such data would be difficult to obtain, but long-term follow-up studies would be highly useful. Nevertheless, in light of the proven unreliability of advance directives and surrogate decision making to secure the wishes of patients, the relatively high rates of these procedures when most patients would not have wanted them suggests a failure of our current approach.

Traditionally, medicine's default for patients with ESD continues to be life-prolonging care.[45] To not receive life-sustaining therapy, a patient must opt-out either by directly using an advance directive or by relying on a surrogate, a tenuous proposition. And so, contrary to the preferences of a large majority of patients, many patients with ESD receive CPR at the end of life. Our current *modus operandi* is to disrespect the wishes of a large majority of patients with ESD. It is time for a new approach.

FLIPPING THE DEFAULT

We reaffirm that the preferences of patients ought to be maintained. We certainly do not recommend a return to a more paternalistic model of the doctor-patient relationship in which the patient's principal role was to follow "doctor's orders."[46] We acknowledge that surrogate decision making attempts to preserve individuals' preferences in decisionally incapacitated patients.[47] Despite its flaws, we recognize that surrogacy will remain the dominant method of decision making for decisionally incapacitated patients. In the vast majority of cases involving decisionally incapacitated patients, in which we have little evidence to believe that surrogacy is harming patients, surrogacy makes sense. But in the case of patients with ESD, many of whom are likely to receive CPR at the end of life, we need better approaches to assist surrogate decision making.

So what can clinicians do to minimize the inappropriate use of CPR? First and foremost, clinicians need to improve their communication skills or enlist the help of others trained in palliative care to help patients make these decisions.[48] We hope the evidence presented encourages clinicians to address these issues in the early stages of dementia and to document

those preferences. Advance directives remain a viable mechanism to secure patients' preferences, but they must be improved and specifically tailored to address patients' preferences in ESD. We feel that all patients in the early stages of dementia should be required to complete an advance directive.[49] In addition, advance directives must be seen as more than just a document for patients to sign, but as documentation of a deliberative process between the patient and a knowledgeable health professional.[50] We certainly need more innovation and research in this area, as well as novel forms of communication.[51] Nevertheless, given past experience with advance directives and their need for significant improvement, there are legitimate concerns about relying on advance directives, particularly in the near future, to promote fidelity to patients' preferences.

We are concerned that applying our traditional default toward the use of CPR in patients with ESD has untoward effects. Presently, unless a patient has completed an advance directive that specifically limits medical treatment such as CPR, or the patient's surrogate has made a similar request, medicine's "default" is to provide CPR. This default, to implement the use of CPR in the vast majority of illness, is appropriate precisely because it is what a large majority of people want.[52] But applying this same default to providing CPR for patients with ESD is flawed when a large majority of patients would not have wanted it.

Choosing defaults for emergency procedures, like CPR, is a reality that every healthcare system must face; healthcare systems must set emergency defaults.[53] Despite functioning in a system that respects individuals' preferences, a healthcare system must choose default rules for emergency procedures such as CPR when there is little time for deliberation with patients or surrogates. When a healthcare system chooses a particular default while allowing an individual's choice, it only makes sense to consider what the majority of patients would want. Default rules ought to be chosen to favor behaviors that maximize the welfare of patients.[54]

In the case of patients with ESD, the overall welfare is improved by maximizing individuals' preferences and avoiding unwanted procedures at the end of life. Our present default is to provide CPR to all patients. We propose that this be changed to a default against the routine use of CPR in patients with ESD unless an advance directive or a surrogate specifically requests it. Since most people queried have stated preferences against the use of CPR in ESD, it makes sense that when choosing a default to apply in emergency situations, such as when a surrogate is unavailable or the preferences of a patient are unknown, that the default reflect what the large majority of patients appear to prefer. Setting the default *against* the use of CPR in ESD would be consistent with what most patients have stated they would prefer, while it would allow the minority of patients to express their preference. Flipping the default maximizes welfare by respecting the preferences of most patients to a much greater extent than a default that favors the use of CPR for patients with ESD. A healthcare system's choice of which default to choose ought to reflect the majority of individuals' preferences while it allows for minority's preference.

We limit our proposal to CPR, which often includes mechanical ventilation, since defaults are put in place for procedures that are considered emergent, when discussion is not possible. Most procedures other than CPR are not emergent, and consent may be obtained from the surrogate. To maximize patients' welfare by respecting the stated preferences of the majority, the assumption should be that CPR is not desired in ESD. Since the majority of studies were conducted in the United States, and a default ought to reflect the preference of the majority in a particular system, we limit our argument to healthcare systems in the United States.

Of course, there will be some patients who will desire CPR in ESD and their welfare will be curtailed by such a flipping of the default. However, a default to not offer invasive medical procedures such as CPR that allows a patient to request those procedures will avoid such an infringement on patients' welfare. Such a change in the default maximizes patients' wel-

fare while it preserves individuals' liberty, insofar as persons are able to act according to their own conception of the good by opting out of the default.[55]

Flipping the default at the health policy level should be reflected at the clinical level. Surrogates would continue to play an important role in end-of-life decision making, but the framing of such discussions would be conducted very differently. For example, traditionally, a surrogate is asked, "If your father's heart were to stop and he needed CPR, is this something that he would have wanted?" With a new default, the clinician would approach the surrogate and say, "Most patients state they would not want CPR for a life-threatening illness if they have advanced dementia such as your father. Based on that, we generally do not provide these interventions to patients with advanced dementia. If you believe your father would have wanted this procedure, we will honor that. But you must specifically tell us that, for us to provide it."

This reframing of the question relieves surrogates from feeling guilty about not providing all interventions to their loved one and, we suspect, would significantly influence their decisions in a nonpaternalistic fashion that maximizes welfare. We feel strongly that the current default to provide all life-sustaining care shapes decision making in favor of such care. Withholding or withdrawing care is a highly emotional and guilt-laden process for surrogates. A default that relieves some of the emotional responsibility for the majority of surrogates will improve their adherence to the patients' preferences.

We do recognize that medical urgency in life-threatening situations, however, requires some type of advance notice to surrogates so that instructions requesting all life-prolonging care can fairly be provided. But emergent cases at the time of admission, in which a history of ESD is confirmed and in which no surrogate is available, should be treated according to our proposed default. When a patient with ESD arrives in an emergency room from a nursing home at 3:00 a.m. in cardiac arrest, we should not innocently agree to perform CPR now and sort out the ethical issues "in the morning," since this disrespects the wishes of the majority of patients. We reject the argument that it is better to resuscitate a patient with ESD and assess whether the patient did not want treatment than to avoid an unwanted death. On this approach, one risks a day or two of unwanted treatment to avoid an unwanted death. As physicians, we feel that the additional suffering for the patient is abusive and an injustice, when it is well documented *ex ante* that most patients would not want such treatment. Even when a surrogate is later identified, the difficult and unreliable task of representing another's interests has been further clouded by the need to make an active decision to withdraw care.

We recognize that this approach may appear to lead to a premature death for some patients. Regardless, we are more troubled by the potentially abusive care that many patients with ESD today receive in these situations despite the fact that most competent people, when asked hypothetically, say that they would reject such care for themselves.

Using our proposed default, surrogates would remain active decision makers, but their evidentiary task would no longer be whether their loved one desired the curtailment of life-supporting care, but rather, whether their loved one asked for life-supporting care. The burden of evidence would no longer be on the surrogate to provide evidence that a patient did not want CPR; instead, the evidentiary burden would be to prove that the patient wished to have CPR in ESD. In *Cruzan,* Justice Brennan argued a similar point in regard to the state's evidentiary requirements for the default in care of patients in a persistent vegetative state: "[The state's] rule of decision imposes a markedly asymmetrical evidentiary standard. . . . No proof is required to support a finding that the decisionally incapacitated person would wish to continue treatment."[56] If most patients do not desire life-sustaining procedures in ESD, then it should be incumbent upon the surrogate to argue for life-sustaining treatment when it is desired.

In most cases, activation of the default in the absence of any discussions with a surrogate would, in fact, be rare. Patients living in the

community and presenting to the emergency room are usually accompanied by family members who are available to help make decisions. For patients in nursing homes, advance notice of the default policy could easily be provided to surrogates. In those rare cases in which we have no advice from a surrogate, it makes sense to rely on what the majority of others say that they would want.

A flipping of the default can already be found in some nursing homes in which the default position is a do-not-resuscitate (DNR) policy.[57] In a study by Kane and Burns of 342 of 404 nursing homes in Wisconsin, 4 percent did not offer CPR, 23 percent would not initiate CPR themselves but would call emergency services if it was requested in advance, another 15 percent would initiate CPR only if it was requested in advance, and 57 percent would provide CPR unless it was specifically rejected.[58] Of the 95 facilities that did not provide CPR, the most common reason cited was poor outcome. The second most common reason cited was concern about suffering.

Although it is similar to the approach taken by nursing homes that require an opt-in strategy, our proposal is novel in two fundamental ways. First and most importantly, our proposal is based on maximizing patients' welfare by focusing on the stated preferences of the majority of patients, not on efficacy and potential futility. "Futility" refers to offering care that is highly unlikely to lead to a desired result.[59] In the case of futile medical procedures, the physical pain that may be inflicted is felt to be unwarranted, given the probable negligible benefit. We agree with other commentators that there is little consensus on what constitutes futility, and that the concept appears to have more use for physicians than for patients or their families.[60] At worst futile care is nonbeneficial — but it is not harmful. Previous arguments against the use of invasive life-sustaining interventions in ESD were arguments based on futility. For example, a consensus against the use of feeding tubes in patients with ESD has developed,[61] but these arguments have been based on the belief that tube feedings in patients with ESD do not provide any benefit since they do not prolong survival.[62] Gillick has proposed a similar flipping of the default in regard to tube feedings based on efficacy and potential futility.[63] Others have also suggested that an opt-in strategy in regard to CPR in nursing home patients may best serve patients because of concerns of futility.[64] Our argument suggests a change in the default based on maximizing patients' welfare by avoiding potential maltreatment of the elderly, a more pressing claim.

Finucane has also eloquently articulated the complex problems presented at the end of life in patients with ESD, with which we similarly struggle.[65] He has also suggested that a policy against CPR in nursing homes would be reasonable and compassionate, based on the complex and unfortunate realities of end-of-life care in the debilitated elderly, but he leaves the policy question unresolved because such compassion seems to conflict with our long-standing values to prolong life.[66] The policy solution, grounded in maximizing welfare by honoring patients' preferences, is clear. We need to change our default approach for patients with ESD.

Second, we limit our alternative default to patients with ESD. Basing defaults generally in end-of-life care has been previously proposed.[67] These defaults and nursing home opt-in policies are not sufficiently selective. We limit our recommendations to patients with ESD, for whom the case for potential abuse is the strongest. Mild and moderate dementia are excluded, based on the findings previously discussed. Acute loss of cognition from stroke is excluded, since some recovery is certainly possible. Patients in other end-of-life situations, such as those involving cancer, cardiac, and respiratory disease, have expressed the desire to receive life-sustaining measures.[68] In addition, these patients are generally competent far into the advanced stages of their disease, and so have sufficient opportunity to articulate their end-of-life wishes, or for physicians and surrogates to learn them.

The natural trajectory of ESD — toward further deterioration — also distinguishes these patients from other chronically decisionally

incapacitated patients, such as those with persistent vegetative states, for which current approaches may still be appropriate.[69] Similarly, pediatric populations, such as neonates and children with severe mental retardation, are different in that they are perceived to be at the beginning of their life trajectory and have not yet developed or never will develop the mental capacity to articulate their own preferences.

OBJECTIONS

We will identify and address several major arguments against changing the default. First, some may claim that changing the default in ESD returns us to unilateral paternalism, but such an accusation is unfounded. If patients do not want invasive procedures in ESD and we perform such procedures on them, we will violate a foundational pillar on which medical ethics and healthcare law rest, namely, patient self-determination. To do so is to actively bring harm upon nonconsenting individuals; to not change the default would be wrongly paternalistic, as it assumes that most patients desire all life-sustaining invasive procedures when our best evidence tells us otherwise. Those who strongly feel that life should be prolonged over other goals may seek that option from their physicians. When a patient or surrogate wants such care, even assuming it has the faintest possibility of benefit, the patient is entitled to such care in our current system. Physicians look to the patient or the surrogate to make decisions regarding treatment and its chance of success. Our proposal works from within that framework. Our approach, as opposed to an absolute ban on life-sustaining procedures in ESD, retains patients' right to formulate an advance directive, and thus is consistent with federal law.[70] We recognize, however, that our proposal may require statutory changes in some states that have wrongly paternalistic approaches.[71]

Second, a charge of a "tyranny of the majority" is also unwarranted.[72] The present default position to perform invasive procedures that are not preferred by the majority of patients instead produces a "tyranny of the minority." There is a legitimate concern, however, regarding the effects of our default approach on members of racial or ethnic minority groups. First, there is a higher prevalence of dementia in minority communities.[73] Second, it has been documented in some studies that African-Americans may have different preferences for end-of-life treatments,[74] although one recent study suggests that members of minority groups, when appropriately informed about ESD, state preferences that differ little from those of Whites.[75] Nevertheless, our approach provides an opportunity to preserve and respect cultural variation by allowing patients to opt-out of the default, for example, by completing an advance directive. A similar line of reasoning can be used for patients who have religious beliefs that would be contrary to a changed default. Variations in preference are respected because patients retain the right to opt-in for CPR.

A potential objection to this opting-out strategy is that members of minority groups, particularly African-Americans, are commonly thought to be less likely to complete advance directives. Although numerous studies in the past have found this to be the case,[76] the largest and best study to date looking at the rates of advance care planning reported no difference in the rates at which advance directives were completed.[77] This study was conducted at 34 randomly selected senior centers in New York City, with 700 community-dwelling adults 60 years or older: 239 were African-American, 237 were Latino/Latina, and 224 were White. Furthermore, a growing consensus within the medical and geriatrics community advocates for advance care planning in the earliest stages of dementia, and this helps to address that concern.[78]

Another potential objection is that members of minority groups may eventually comprise the majority of the patient population. In that case, if members of minority groups indeed favor aggressive care for patients with ESD — a doubtful occurrence — would we again flip the default? We find this suggestion highly unlikely. The medical profession has refocused its understanding of ESD as a terminal condition akin to cancer.[79] As palliative care concepts continue

to permeate the medical profession, it is less likely that patients, minorities or not, will insist on aggressive care in ESD.[80] But, if the majority of patients in a society favor a medical procedure, then society ought to set the default to favor delivery of that procedure to maximize the welfare of the public.

Some may also question whether a majority — but not unanimous opinion — is enough to justify changing the default in favor of withholding CPR in patients with ESD, particularly because withholding CPR is irreversible, and will likely lead to death. Although, as previously mentioned, we suspect that studies that better informed subjects about ESD would have demonstrated an even higher rate of refusal,[81] we feel the default can justifiably be changed when a large majority of individuals do not favor such treatment. More importantly, the action of performing life-sustaining therapy in many patients who would not have wanted it must be viewed as causing harm, even when the therapy was later quickly withdrawn. Causing such harm at the end of life is also irreversible, and the value placed on avoiding that harm should not necessarily be less than the value placed on preserving life.

Another objection raises concerns regarding the validity and stability of patients' expressed preferences. There are important philosophical concerns regarding what a patient wants, and what the patient says she or he wants, and whether a patient's previous competent self may have any moral bearing on the patient's present decisionally incapacitated self. These questions are well beyond the limits of this discussion.[82] Nevertheless, from a clinical perspective, an individual's previously expressed wishes are widely held as the ethical standard for all decision making, and this standard supports the legal rationale for advance directives and decision making in other nonmedical contexts.[83] Furthermore, we have used data that are primarily from patients who are elderly or who have experienced serious illness, which lends greater probative value to their expressed views, based on their thoughtfulness and maturity when their preferences were stated, a criterion also used by the courts.[84] Concerns regarding the stability of patients' preferences have also been evaluated in at least six studies in both healthy and sick patients. Most of the studies reported that patients' preferences remained largely stable (approximately 80 percent stable) over follow up of one month to two years.[85]

Some may charge that a "slippery slope" will extend the alternative default beyond patients with ESD. We respectfully disagree. There are numerous instances in medicine in which criteria must be met to be included or excluded from diagnostic consideration or treatment. We envision similar strict criteria for patients with ESD, including evidence of the chronic nature of illness, loss of meaningful speech, complete dependence on others, and a battery of diagnostic tests to rule out other reversible causes.[86] These factors are easily identifiable and recognizable to experienced physicians; ESD is not a subtle diagnosis. Furthermore, these diagnostic criteria are not always documented in the medical record. With a change in the default, we anticipate that documentation of this criteria will improve dramatically. We believe that requiring adequate documentation to meet the criteria would prove an adequate safeguard to prevent misapplication of the default to other patients.

Some may accuse us of advocating for the default approach as a pretext to save healthcare resources, but that is not our concern here. It cannot be denied that resources are disproportionately consumed at the end of life.[87] However, healthcare costs are driven by many diseases that are not directly associated with dementia.[88] We do not suspect that any resource savings that may result would significantly stem the tide of healthcare inflation.[89] More importantly, we are much more concerned about the use of resources by patients who did not want them, rather than the use of resources that produce marginal benefit. Surely, we can agree that using resources on patients who did not want them is simply wasteful.

Additionally, some may argue that policies should focus on educating and changing clinicians' practices while encouraging patients in

early stage dementia to complete advance directives. We are not so optimistic. For the last two decades, millions of dollars have been directed toward changing clinicians' practices at the end of life and encouraging patients to complete advance directives. So far, the results are mixed. Although it would be valuable to direct more resources toward these ends, we feel that more extreme measures at the policy level are warranted. Flipping the default would not only change physicians' practices, but also encourage those patients who wish aggressive care to complete advance directives.

Lastly, some may argue that changing the default is tantamount to abandoning such patients, but the reality is that it does not lead to abandonment. These patients represent a unique class of vulnerable patients who are prone to abuse and deserve protection. Our policy aims to provide this general protection while allowing individual exception. Of course, we do not know how such a change might influence the care given to patients with ESD, particularly patients who lack a surrogate. However, even patients who do not have a surrogate are best served by a policy based on the majority's preferences. More importantly, all patients with dementia, regardless of end-of-life decisions, deserve aggressive care focused on comfort and their personal needs. This care can hardly be mistaken for abandonment.[90]

CONCLUSION

We hope that a transparent deliberation among physicians, patients, and families will take place in which discussions, however difficult, of the care of patients with ESD will be addressed. Present defaults and policies that rely on advance directives and surrogate decision making are less than perfect and may lead to mistreatment of the elderly with ESD. This mistreatment can be minimized by a change in the default for the delivery of care to patients with ESD. To continue the status quo is to dishonor the preferences and dignity of some of our most vulnerable patients.

ACKNOWLEDGMENTS

We would like to thank Muriel Gillick and Greg Sachs for comments on previous versions of this article.

NOTES

1. L. Volicer et al., "Hospice Approach to the Treatment of Patients with Advanced Dementia of the Alzheimer Type," *Journal of the American Medical Association* 256 (1986): 2210-3; N. Rango, "The Nursing Home Resident with Dementia: Clinical Care, Ethics, and Policy Implications," *Annals of Internal Medicine* 102, no. 6 (1985): 835-41; D. Hilfiker, "Allowing the Debilitated to Die: Facing Our Ethical Choices," *New England Journal of Medicine* 308 (1983): 716-9.

2. L.E. Hebert et al., "Alzheimer Disease in the US Population: Prevalence Estimates Using the 2000 Census," *Archives of Neurology* 60, no. 8 (2003): 1119-22.

3. B.J. Gurland et al., "Rates of Dementia in Three Ethnoracial Groups," *International Journal of Geriatric Psychiatry* 14, no. 6 (1999): 481-93.

4. See note 2 above; E. von Strauss et al., "Aging and the Occurrence of Dementia: Findings from a Population-based Cohort with a Large Sample of Nonagenarians," *Archives of Neurology* 56, no. 5 (1999): 587-92.

5. B. Reisberg, "Dementia: A Systematic Approach to Identifying Reversible Causes," *Geriatrics* 41, no. 4 (1986): 30-46.

6. T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 2001); E. Emanuel, *The Ends of Human Life: Medical Ethics in a Liberal Polity* (Cambridge: Harvard University Press, 1991); G. Dworkin, *The Theory and Practice of Autonomy* (New York: Cambridge University Press, 1988).

7. A. Meisel and K.L. Cerminara, *The Right to Die* (New York: Aspen, 2004); D. Orentlicher, "Advance Medical Directives," *Journal of the American Medical Association* 263 (1990):

2365-7; A. Buchanan and D. Brock, *Deciding for Others: the Ethics of Surrogate Decision Making* (New York: Cambridge University Press, 1989).

8. D. Brock, *Life and Death: Philosophical Essays in Biomedical Ethics* (New York: Cambridge University Press, 1993).

9. D.E. Meier and R.S. Morrison, "Autonomy Reconsidered," *New England Journal of Medicine* 346 (2002): 1087-9.

10. *Cruzan v. Director,* Missouri Dept. of Health, 497 U.S. 261 (1990); *In re Conroy,* 486 A.2d 1209 (N.J. 1985).

11. 42 U.S.C. 1395cc(f), 1396a(w) (2002).

12. J.M. Teno et al., "Do Advance Directives Provide Instructions that Direct Care? SUPPORT Investigators, Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment," *Journal of the American Geriatrics Society* 45, no. 4 (1997): 508-12; J.M. Teno et al., "Do Formal Advance Directives Affect Resuscitation Decisions and the Use of Resources for Seriously Ill Patients? SUPPORT Investigators, Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment," *The Journal of Clinical Ethics* 5, no. 1 (Spring 1994): 23-30; M. Danis et al., "A Prospective Study of Advance Directives for Life-sustaining Care," *New England Journal of Medicine* 324 (1991): 882-8; L.J. Schneiderman et al., "Effects of Offering Advance Directives on Medical Treatments and Costs," *Annals of Internal Medicine* 117, no. 7 (1992): 599-606; P.H. Ditto et al., "Advance Directives as Acts of Communication: A Randomized Controlled Trial," *Archives of Internal Medicine* 161, no. 3 (2001): 421-30; S.H. Miles, R. Koepp, and E.P. Weber, "Advance End-of-life Treatment Planning: A Research Review," *Archives of Internal Medicine* 156, no. 10 (1996): 1062-8; D.M. Cox and G.A. Sachs, "Advance Directives and the Patient Self-determination Act," *Clinics in Geriatric Medicine* 10 (1994): 431-43; A. Fagerlin and C. Schneider, "Enough: The Failure of the Living Will," *Hastings Center Report* 34, no. 2 (2004): 30-42; J.M. Teno, "Advance Directives: Time to Move on," *Annals of Internal Medicine* 141, no. 2 (2004): 159-60.

13. Teno et al., "Do Advance Directives Provide Instructions that Direct Care?" see note 12 above; Teno et al., "Do Formal Advance Directives Affect Resuscitation Decisions and the Use of Resources for Seriously Ill Patients?" see note 12 above; Schneiderman et al., "Effects of Offering Advance Directives on Medical Treatments and Costs," see note 12 above.

14. S.L. Mitchell, D.K. Kiely, and M.B. Hamel, "Dying with Advanced Dementia in the Nursing Home," *Archives of Internal Medicine* 164, no. 3 (2004): 321-6.

15. H.B. Degenholtz, Y. Rhee, and R.M. Arnold, "Brief Communication: The Relationship Between Having a Living Will and Dying in Place," *Annals of Internal Medicine* 141, no. 2 (2004): 113-7.

16. S.B. Hardin and Y.A. Yusufaly, "Difficult End-of-life Treatment Decisions: Do Other Factors Trump Advance Directives?" *Archives of Internal Medicine* 164, no. 14 (2004): 1531-3.

17. Orentlicher, "Advance Medical Directives," see note 7 above; Buchanan and Brock, *Deciding for Others,* see note 7 above.

18. R.M. Arnold and J. Kellum, "Moral Justifications for Surrogate Decision Making in the Intensive Care Unit: Implications and Limitations," *Critical Care Medicine* 31, no. 5 (2003): S347-53; D. Brock, "What Is the Moral Authority of Family Members to Act as Surrogates for Incompetent Patients?" *Millbank Quarterly* 74, no. 4 (1996): 599-618.

19. E.J. Emanuel and L.L. Emanuel, "Proxy Decision Making for Incompetent Patients: An Ethical and Empirical Analysis," *Journal of the American Medical Association* 267 (1992): 2067-71.

20. Teno et al., "Do Formal Advance Directives Affect Resuscitation Decisions and the Use of Resources for Seriously Ill Patients?" see note 12 above; P.M. Layde et al., "Surrogates' Predictions of Seriously Ill Patients' Resuscitation Preferences," *Archives of Family Medicine* 4, no. 6 (1995): 518-23; M.B. Gerety et al., "Medical Treatment Preferences of Nursing Home Residents: Relationship to Function and Con-

cordance with Surrogate Decision-makers," *Journal of the American Geriatric Society* 41, no. 9 (1993): 953-60; A.B. Seckler et al., "Substituted Judgment: How Accurate Are Proxy Predictions?" *Annals of Internal Medicine* 115, no. 2 (1991): 92-8; N.R. Zweibel and C.K. Cassel, "Treatment Choices at the End of Life: A Comparison of Decisions by Older Patients and Their Physician-selected Proxies," *Gerontologist* 29, no. 5 (1989): 615-21; J. Suhl et al., "Myth of Substituted Judgment: Surrogate Decision Making Regarding Life Support Is Unreliable," *Archives of Internal Medicine* 154, no. 1 (1994): 90-6.

21. M.K. McNabney, M.H. Beers, and H. Siebens, "Surrogate Decision-makers' Satisfaction with the Placement of Feeding Tubes in Elderly Patients," *Journal of the American Geriatrics Society* 42, no. 2 (1994): 161-8.

22. H.C. Sox et al., *Medical Decision Making* (Woburn, Mass.: Butterworths, 1988); C. Schneider, *The Practice of Autonomy* (New York: Oxford University Press, 1998); D.A. Redelmeier, P. Rozin, and D. Kahneman, "Understanding Patients' Decisions: Cognitive and Emotional Perspectives," *Journal of the American Medical Association* 270 (1993): 72-6; P.A. Ubel, "Is Information Always a Good Thing? Helping Patients Make 'Good' Decisions," *Medical Care* 40, no. 9 (2002): V39-44.

23. D.W. Molloy et al., "Decision Making in the Incompetent Elderly: 'The Daughter from California Syndrome'," *Journal of the American Geriatrics Society* 39, no. 4 (1991): 396-9; E.J. Emanuel and L.L. Emanuel, "The Health Care Proxy and the Living Will," *New England Journal of Medicine* 325 (1991): 893-4; E.W. Lariviere, "Limiting Specific Interventions in Advance Directives," *Journal of the American Medical Association* 267 (1992): 51.

24. J.J. Fins et al., "Contracts, Covenants and Advance Care Planning: An Empirical Study of the Moral Obligations of Patient and Proxy," *Journal of Pain and Symptom Management* 29, no. 1 (2005): 55-68; S.R. Steiber, "Right to Die: Public Balks at Deciding for Others," *Hospitals* 61, no. 5 (1987): 72.

25. T. Kizhakekuttu, L. Meyer, and L. Cation, "Knowledge, Attitudes and Practices of Residents and Attending Physicians Regarding End of Life Issues," *Society of General Internal Medicine* Abstract Number 126198 (2004), *http://www.blackwellpublishing.com/sgim/abstract.asp?id=19174,*accessed 29 November 2004.

26. The SUPPORT Principal Investigators, "A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients, The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT)," *Journal of the American Medical Association* 274 (1995): 1591-8.

27. Gerety et al., "Medical Treatment Preferences of Nursing Home Residents," see note 20 above; T.R. Fried et al., "Understanding the Treatment Preferences of Seriously Ill Patients," *New England Journal of Medicine* 346 (2002): 1061-6; M. Danis et al., "Patients' and Families' Preferences for Medical Intensive Care," *Journal of the American Medical Association* 260 (1988): 797-802; L.A. O'Brien et al., "Nursing Home Residents' Preferences for Life-sustaining Treatments," *Journal of the American Medical Association* 274 (1995): 1775-9; T.J. Starr, R.A. Pearlman, and R.F. Uhlmann, "Quality of Life and Resuscitation Decisions in Elderly Patients," *Journal of General Internal Medicine* 1, no. 6 (1986): 373-9; M.D. Silverstein et al., "Amyotrophic Lateral Sclerosis and Life-sustaining Therapy: Patient Desires for Information, Participation in Decision-making, and Life-sustaining Therapy," *Mayo Clinic Proceedings* 66, no. 9 (1991): 906-13.

28. R.A. Pearlman et al., "Preferences for Life-Sustaining Treatments in Advance Care Planning and Surrogate Decision Making," *Journal of Palliative Medicine* 3, no. 1 (2000): 37-48; N.P. Gunasekera et al., "Elderly Patients' Views on Cardiopulmonary Resuscitation," *Age and Ageing* 15, no. 6(1986): 364-8; T.E. Finucane et al., "Planning with Elderly Outpatients for Contingencies of Severe Illness: A Survey and Clinical Trial," *Journal of General Internal Medicine* 3, no. 4 (1988): 322-5; B. Lo, G.A. McLeod,

and G. Saika, "Patient Attitudes to Discussing Life-sustaining Treatment," *Archives of Internal Medicine* 146, no. 8 (1986): 1613-5; M.A. Everhart and R.A. Pearlman, "Stability of Patient Preferences Regarding Life-sustaining Treatments," *Chest* 97, no. 1 (1990): 159-64; M.H. Ebell et al., "The Do-not-resuscitate Order: Outpatient Experience and Decision-making Preferences," *Journal of Family Practice* 31, no. 6 (1990): 630-6; C. Michelson et al., "Eliciting Medical Care Preferences from Nursing Home Residents," *Gerontologist* 31, no. 3 (1991): 358-63; L. Emanuel et al., "Advance Directives for Medical Care — A Case for Greater Use," *New England Journal of Medicine* 324 (1991): 889-95; T.R. Malloy et al., "The Influence of Treatment Descriptions on Advance Medical Directive Decisions," *Journal of the American Geriatrics Society* 40, no. 12 (1992): 1255-60; G.S. Robertson, "Resuscitation and Senility: A Study of Patients' Opinions," *Journal of Medical Ethics* 19, no. 2 (1993): 104-7; R. Morgan et al., "Views of Elderly Patients and Their Relatives on Cardiopulmonary Resuscitation," *British Medical Journal* 308 (1994): 1677-8; C. Harrison et al., "Should People Do Unto Others As They Would Not Want Done Unto Themselves?" *The Journal of Clinical Ethics* 6, no. 1 (Spring 1995): 14-9; C.H. Griffith et al., "Knowledge and Experience with Alzheimer's Disease: Relationship to Resuscitation Preference," *Archives of Family Medicine* 4, no. 9 (1995): 780-4; J.T. Berger and D. Majerovitz, "Stability of Preferences for Treatment Among Nursing Home Residents," *Gerontologist* 38, no. 2 (1998): 217-3; D.K. Gjerdingen et al., "Older Persons' Opinions About Life-sustaining Procedures in the Face of Dementia," *Archives of Family Medicine* 8, no. 5 (1999): 421-5.

29. Seckler et al., "Substituted Judgment: How Accurate Are Proxy Predictions?" see note 20 above; P.V. Caralis et al., "The Influence of Ethnicity and Race on Attitudes Toward Advance Directives, Life-prolonging Treatments, and Euthanasia," *The Journal of Clinical Ethics* 4, no. 2 (Summer 1993): 155-65; R.B. Reilly, T.A. Teasdale, and L.B. McCullough, "Projecting Patients' Preferences from Living Wills: An Invalid Strategy for Management of Dementia with Life-threatening Illness," *Journal of the American Geriatrics Society* 42, no. 9 (1994): 997-1003.

30. S.G. Sclan and B. Reisberg, "Functional Assessment Staging (FAST) in Alzheimer's Disease: Reliability, Validity, and Ordinality," *International Psychogeriatrics* 4, no. 1 (1992): 55-69.

31. Seckler et al., "Substituted Judgment: How Accurate Are Proxy Predictions?" see note 20 above.

32. Caralis et al., "The Influence of Ethnicity and Race on Attitudes Toward Advance Directives, Life-prolonging Treatments, and Euthanasia," see note 29 above.

33. Reilly, Teasdale, and McCullough, "Projecting Patients' Preferences from Living Wills," see note 29 above.

34. Griffith et al., "Knowledge and Experience with Alzheimer's Disease," see note 28 above.

35. Morgan et al., "Views of Elderly Patients and Their Relatives on Cardiopulmonary Resuscitation," see note 28 above. Harrison et al., "Should People Do Unto Others As They Would Not Want Done Unto Themselves?" see note 28 above.

36. See note 5 above.

37. Gjerdingen et al., "Older Persons' Opinions About Life-sustaining Procedures in the Face of Dementia," see note 28 above.

38. Caralis et al., "The Influence of Ethnicity and Race on Attitudes Toward Advance Directives, Life-prolonging Treatments, and Euthanasia," see note 29 above; L.J. Blackhall et al., "Ethnicity and Attitudes Towards Life Sustaining Technology," *Social Science and Medicine* 48, no. 12 (1999): 1779-89.

39. Caralis et al., "The Influence of Ethnicity and Race on Attitudes Toward Advance Directives, Life-prolonging Treatments, and Euthanasia," see note 29 above.

40. A.E. Volandes et al., "Using Video Images of Dementia in Advance Care Planning," *Archives of Internal Medicine* 167, no. 8 (2007): 828-33.

41. Mitchell, Kiely, and Hamel, see note 14 above; J.C. Ahronheim et al., "Treatment of the Dying in the Acute Care Hospital: Advanced Dementia and Metastatic Cancer," *Archives of Internal Medicine* 156, no. 18 (1996): 2094-100; E. Duthie et al., "Utilization of Cardiopulmonary Resuscitation in Nursing Homes in One Community: Rates and Nursing Home Characteristics," *Journal of the American Geriatrics Society* 41, no. 4 (1993): 384-8; S.L. Mitchell et al., "Clinical and Organization Factors Associated with Feeding Tube Use Among Nursing Home Residents with Advanced Cognitive Impairment," *Journal of the American Medical Association* 290 (2003): 73-80.

42. Duthie et al., "Utilization of Cardiopulmonary Resuscitation in Nursing Homes in One Community," see note 41 above; T.E. Finucane et al., "The Incidence of Attempted CPR in Nursing Homes," *Journal of the American Geriatrics Society* 39, no. 6 (1991): 624-6.

43. Duthie et al., "Utilization of Cardiopulmonary Resuscitation in Nursing Homes in One Community," see note 41 above.

44. Mitchell, Kiely, and Hamel, see note 14 above.

45. T. Finucane, "Thinking About Life-sustaining Treatment Late in the Life of a Demented Person," *Georgia Law Review* 35, no. 2 (2001): 691-705; T.E. Finucane and G.M. Harper, "Attempting Resuscitation in Nursing Homes: Policy Considerations," *Journal of the American Geriatrics Society* 47, no. 10 (1999): 1261-4.

46. Brock, see note 8 above; J. Katz, *The Silent World of Doctor and Patient* (Baltimore: Johns Hopkins University Press, 2002).

47. Buchanan and Brock, *Deciding for Others*, see note 7 above; Arnold and Kellum, "Moral Justifications for Surrogate Decision Making in the Intensive Care Unit," see note 18 above; Brock, "What Is the Moral Authority of Family Members?" see note 18 above.

48. R.S. Morrison and D.E. Meier, "Palliative Care," *New England Journal of Medicine* 350 (2004): 2582-90.

49. E.D. Abbo and A.E. Volandes, "A Forced Choice: The Value of Requiring Advance Directives," unpublished manuscript; readers may contact the authors for additional information.

50. B. Lo and R. Steinbrook, "Resuscitating Advance Directives," *Archives of Internal Medicine* 164, no. 14 (2004): 1501-6.

51. Volandes et al., see note 40 above.

52. Gerety et al., "Medical Treatment Preferences of Nursing Home Residents," see note 20 above; Fried et al., "Understanding the Treatment Preferences of Seriously Ill Patients," see note 27 above; Danis et al., "Patients' and Families' Preferences for Medical Intensive Care," see note 27 above; O'Brien et al., "Nursing Home Residents' Preferences for Life-sustaining Treatments," see note 27 above; Starr, Pearlman, and Uhlmann, "Quality of Life and Resuscitation Decisions in Elderly Patients," see note 27 above; Silverstein et al., "Amyotrophic Lateral Sclerosis and Life-sustaining Therapy," see note 27 above; D. Brock, "Borderline Cases of Morally Justified Taking Life in Medicine," in *Intending Death: The Ethics of Assisted Suicide and Euthanasia,* ed. T.L. Beauchamp (Upper Saddle River, N.J.: Prentice Hall, 1996), 131-49.

53. C.R. Sunstein and R.H. Thaler, "Libertarian Paternalism Is Not an Oxymoron," *University of Chicago Law Review* 70, no. 3 (2003): 1159-202.

54. Ibid.

55. D. Thompson, *Political Ethics and Public Office* (Cambridge: Harvard University Press, 1987).

56. *Cruzan v. Director,* Mo. Dep't of Health, 497 U.S. 261, 318 (1990) (Brennan, J., dissenting).

57. Finucane and Harper, "Attempting Resuscitation in Nursing Homes," see note 45 above; M.R. Gillick, "Rethinking the Role of Tube Feeding in Patients with Advanced Dementia," *New England Journal of Medicine* 342 (2000): 206-10; R.S. Kane and E.A. Burns, "Cardiopulmonary Resuscitation Policies in Long-term Care," *Journal of the American Geriatrics Society* 45, no. 2 (1997): 154-7.

58. Kane and Burns, "Cardiopulmonary Resuscitation Policies in Long-term Care," see note

57 above.

59. L.J. Schneiderman, N.S. Jecker, and A.R. Jonsen, "Medical Futility: Its Meaning and Ethical Implications," *Annals of Internal Medicine* 112, no. 12 (1990): 949-54.

60. P.R. Helft, M. Siegler, and J. Lantos, "The Rise and Fall of the Futility Movement," *New England Journal of Medicine* 343 (2000): 293-6.

61. S.G. Post, "Tube Feeding and Advanced Progressive Dementia," *Hastings Center Report* 31, no. 1 (2001): 36-42; Gillick, "Rethinking the Role of Tube Feeding," see note 57 above; T.E. Finucane, C. Christmas, and K. Travis, "Tube Feeding in Patients with Advanced Dementia: A Review of the Evidence," *Journal of the American Medical Association* 282 (1999): 1365-70; F. Angus and R. Burakoff, "The Percutaneous Endoscopic Gastrostomy Tube: Medical and Ethical Issues in Placement," *American Journal of Gastroenterology* 98, no. 2 (2003): 272-7.

62. S.L. Mitchell, D.K. Kiely, and L.A. Lipsitz, "The Risk Factors and Impact on Survival of Feeding Tube Placement in Nursing Home Residents with Severe Cognitive Impairment," *Archives of Internal Medicine* 157, no. 3 (1997): 327-32; S.L. Mitchell, D.K. Kiely, and L.A. Lipsitz, "Does Artificial Enteral Nutrition Prolong the Survival of Institutionalized Elders with Chewing and Swallowing Problems?" *Journals of Gerontology* 53, no. 3 (1998): M207-13; L.M. Murphy and T.O. Lipman, "Percutaneous Endoscopic Gastrostomy Does Not Prolong Survival in Patients with Dementia," *Archives of Internal Medicine* 163, no. 11 (2003): 1351-3.

63. Gillick, "Rethinking the Role of Tube Feeding," see note 57 above.

64. P.N. Bruce-Jones, "Resuscitation Decisions in the Elderly: A Discussion of Current Thinking," *Journal of Medical Ethics* 22, no. 5 (1996): 286-91; S.C. Zweig, "Cardiopulmonary Resuscitation and Do-not-resuscitate Orders in the Nursing Home," *Archives of Family Medicine* 6, no. 5 (1997): 424-9.

65. Finucane, "Thinking About Life-sustaining Treatment Late in the Life of a Demented Person," see note 45 above.

66. Finucane and Harper, "Attempting Resuscitation in Nursing Homes," see note 45 above.

67. L.L. Emanuel and E.J. Emanuel, "Decisions at the End of Life: Guided by Communities of Patients," *Hastings Center Report* 23, no. 5 (1993): 6-14; J. Lindgren, "Death by Default," *Law and Contemporary Problems* 56, no. 3 (1993): 185-254; C.A. Marco and R.M. Schears, "Societal Opinions Regarding CPR," *American Journal of Emergency Medicine* 20, no. 3 (2002): 207-11.

68. Gerety et al., "Medical Treatment Preferences of Nursing Home Residents," see note 20; Fried et al., "Understanding the Treatment Preferences of Seriously Ill Patients," see note 27 above; Danis et al., "Patients' and Families' Preferences for Medical Intensive Care," see note 27 above; O'Brien et al., "Nursing Home Residents' Preferences for Life-sustaining Treatments," see note 27 above; Starr, Pearlman, and Uhlmann, "Quality of Life and Resuscitation Decisions in Elderly Patients," see note 27 above; Silverstein et al., "Amyotrophic Lateral Sclerosis and Life-sustaining Therapy," see note 27 above.

69. *Cruzan v. Director,* Missouri Dept. of Health; *In re Quinlan,* 355 A.2d 647 (N.J.).

70. 42 U.S.C. 1395cc(f), 1396a(w) (2002); R.S. Kane, "Considering CPR Policy," *Journal of the American Geriatrics Society* 48, no. 5 (2000): 595.

71. Lo and Steinbrook, "Resuscitating Advance Directives," see note 50 above; American Bar Association Commission on Legal Problems of the Elderly, "Health care power of attorney and combined advance directive legislation," 2004, *http://www.abanet.org/aging/update.html,* accessed 29 October 2004.

72. J.S. Mill, *On Liberty* (Ontario: Broadview Press, 1999).

73. Gurland et al., see note 3 above; M.X. Tang et al., "Incidence of AD in African-Americans, Caribbean Hispanics, and Caucasians in Northern Manhattan," *Neurology* 56, no. 1 (2001):49-56.

74. Caralis et al., "The Influence of Ethnicity

and Race on Attitudes Toward Advance Directives, Life-prolonging Treatments, and Euthanasia," see note 29 above; F.P. Hopp and S.A. Duffy, "Racial Variations in End-of-life Care," *Journal of the American Geriatrics Society* 48, no. 6 (2000): 658-63; Blackhall et al., "Ethnicity and Attitudes Towards Life Sustaining Technology," see note 38 above; H.R. Degenholtz et al., "Persistence of Racial Disparities in Advance Care Planning Documents Among Nursing Home Residents," *Journal of the American Geriatrics Society* 50, no. 2 (2002): 378-81; G.P. Eleazer et al., "The Relationship Between Ethnicity and Advance Directives in a Frail Older Population," *Journal of the American Geriatrics Society* 44, no. 8 (1996): 938-43; E.D. McKinley et al., "Differences in End-of-life Decision Making Among Black and White Ambulatory Cancer Patients," *Journal of General Internal Medicine* 11, no. 11 (1996): 651-6; S.T. Murphy et al., "Ethnicity and Advance Care Directives," *Journal of Law, Medicine and Ethics* 24, no. 2 (1996): 108-17; Volandes et al., see note 40 above.

75. Volandes et al., see note 40 above.

76. D.E. Meier et al., "Marked improvement in recognition and completion of health care proxies: a randomized controlled trial of counseling by hospital patient representatives," *Archives of Internal Medicine* 156 (1996): 1227-32; R.S. Morrison et al., "Barriers to completion of health care proxies: an examination of ethnic differences," *Archives of Internal Medicine* 158 (1998): 2493-7.

77. R.S. Morrison et al., "High rates of advance care planning in New York City's elderly population," *Archives of Internal Medicine* 164 (2004): 2421-6.

78. G.A. Sachs, "Dementia and the Goals of Care," *Journal of the American Geriatrics Society* 46, no. 6 (1998): 782-3; C.E. Gessert et al., "Planning End-of-life Care for Patients with Dementia: Roles of Families and Health Professionals," *Journal of Death & Dying* 42, no. 4 (2000): 273-91.

79. Mitchell, Kiely, and Hamel, see note 14 above.

80. B. Lo et al., "Discussing Palliative Care with Patients: ACP-ASIM End-of-life Care Consensus Panel, American College of Physicians-American Society of Internal Medicine," *Annals of Internal Medicine* 130, no. 9 (1999): 744-9; D. Cook et al., "Withdrawal of Mechanical Ventilation in Anticipation of Death in the Intensive Care Unit," *New England Journal of Medicine* 349, no. 12 (2003): 1123-32; R.S. Morrison and D.E. Meier, "Clinical Practice: Palliative Care," *New England Journal of Medicine* 350, no. 25 (2004): 2582-90.

81. Volandes et al., see note 40 above.

82. Buchanan and Brock, *Deciding for Others,* see note 7 above; E.R. Koppelman, "Dementia and Dignity: Towards a New Method of Surrogate Decision Making," *Journal of Medicine and Philosophy* 27, no. 1 (2002): 65-85; R. Dresser, "Missing Persons: Legal Perceptions of Incompetent Patients," *Rutgers Law Review* 46, no. 2 (1994): 609-719; R. Dworkin, *Life's Dominion: An Argument About Abortion, Euthanasia, and Individual Freedom* (New York: Vintage, 1993).

83. Presidents Commission for the Study of Ethical Problems in Medicine and Behavioral Research, *Deciding To Forgo Life-sustaining Treatment: Ethical, Medical, and Legal Issues in Treatment Decisions* (Washington, D.C.: U.S. Government Printing Office, 1982); B.A. Rich, "Advance Directive Instruments for End-of-life and Health Care Decision Making," *Psychology, Public Policy, and Law* 4, no. 3 (1998): 610-28.

84. See note 10 above.

85. Silverstein et al., "Amyotrophic Lateral Sclerosis and Life-sustaining Therapy," see note 27 above; Everhart and Pearlman, "Stability of Patient Preferences Regarding Life-sustaining Treatments," see note 28 above; Berger and Majerovitz, "Stability of Preferences for Treatment Among Nursing Home Residents," see note 28 above; K.E. Rosenfeld et al., "Factors Associated with Change in Resuscitation Preference of Seriously Ill Patients, The SUPPORT Investigators, Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments," *Archives of Internal Medicine* 156, no. 14 (1996): 1558-64; M. Danis et al., "Stabil-

ity of Choices About Life-sustaining Treatments," *Annals of Internal Medicine* 120, no. 7 (1994): 567-73; L.L. Emanuel et al., "Advance Directives: Stability of Patients' Treatment Choices," *Archives of Internal Medicine* 154, no. 2 (1994): 209-17.

86. Reisberg, see note 5 above.

87. C. Hogan et al., "Medicare Beneficiaries' Costs of Care in the Last Year of Life," *Health Affairs* 20, no. 4 (2001): 188-95.

88. B.G. Druss et al., "The Most Expensive Medical Conditions in America," *Health Affairs* 21, no. 4 (2002): 105-11; J.W. Cohen and N.A. Krauss, "Spending and Service Use Among People with the Fifteen Most Costly Medical Conditions, 1997," *Health Affairs* 22, no. 2 (2003): 129-38.

89. B.C. Strunk and P.B. Ginsburg, "Tracking Health Care Costs: Trends Turn Downward in 2003," *Health Affairs* (2004), *http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.354v1,* accessed 29 October 2004; K.E. Thorpe, C.S. Florence, and P. Joski, "Which Medical Conditions Account for the Rise in Health Care Spending?" *Health Affairs* (2004), *http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.437v1,* accessed 29 October 2004.

90. T.E. Quill and C.K. Cassel, "Nonabandonment: A Central Obligation for Physicians," *Annals of Internal Medicine* 122, no. 5 (1995): 368-74.

Proactive Ethics Consultation in the ICU: A Comparison of Value Perceived by Healthcare Professionals and Recipients

Felicia Cohn, Paula Goodman-Crews, William Rudman, Lawrence J. Schneiderman, and Ellen Waldman

INTRODUCTION

Since its introduction into the practice of medicine, ethics consultation has been perceived as useful in addressing conflicts regarding medical treatment decisions, particularly in the context of end-of-life care.[1] Yet traditional approaches to ethics consultation remain reactive, rather than proactive. That is, consultations usually do not occur until disputants have already begun to maneuver themselves in an adversarial way, and one or both sides decide to call in the ethics team for help in coping with a fully materialized conflict.

Communication in these circumstances becomes more difficult, suggesting the need for a different approach. Recent investigations suggest the need for more timely and effective end-of-life care discussions. These discussions would optimally include the following:

- Communication about poor prognosis and the failure of treatments;
- Treatment choices and the patient's/family's responses to them;
- The values of the patient/family and their role in selecting among clinical pathways;
- Advance care planning;
- Coping strategies for grief and anger;
- Anticipatory mourning;
- The meaning of illness and suffering.[2]

Although several retrospective studies analyze the effectiveness of traditional ethics consultations, empirical research on ethics consul-

Felicia Cohn, PhD, is Director of Medical Ethics at the University of California, Irvine, Department of Medicine, School of Medicine, *fcohn@uci.edu.*

Paula Goodman-Crews, LCSW, is a Bioethics Consultant at Kaiser Permanente in San Diego, California.

William Rudman, PhD, is Professor of Health Information Systems at the University of Mississippi Medical Center, School of Health-Related Professions, in Jackson.

Lawrence J. Schneiderman, MD, is a Professor in the Departments of Family & Preventive Medicine and Medicine at the University of California, San Diego.

Ellen Waldman, JD, LLM, is a Professor at Thomas Jefferson School of Law in San Diego.

tation and end-of-life care is limited.[3] Research has generally described the demographics of patients involved in requests for ethics consultation, the ethical questions raised, and the satisfaction levels of health providers and family members with the process. As a whole, physicians requesting ethics consultations have been satisfied with this process, as 70 percent to 90 percent of the physicians queried report that consultation was valuable in one or more aspects of patient care. Reported rates of satisfaction by families have been considerably lower, in the range of only 50 percent.[4]

Proactive approaches have not been the focus of extensive study. Still, what little research exists suggests that proactive ethics consultation may provide a more effective mechanism for facilitating communication and addressing ethical conflicts than more reactive approaches. Lilly and colleagues compared usual care with a proactive, multi-disciplinary method of communicating and concluded that an intensive communication process is associated with a decreased use of critical care resources in accord with patients' preferences.[5] Fins and colleagues examined current care practices in the absence of proactive intervention and observed a troubling "lack of clarity about goals of care, habitual adherence to established routines of hospital practice . . . or a therapeutic disposition to maintain treatment in order to preserve life."[6] Dowdy and colleagues reported more frequent decisions to forgo life-sustaining treatment and reduced length of stay in the intensive care unit (ICU) for proactive consultation groups, as compared to other groups, and offered anecdotal observations that proactive consultation encouraged members of healthcare teams to place increased value on collaboration and to address ethical issues in a more timely manner.[7] In a single-site randomized controlled pilot study, Schneiderman and colleagues found that more than 70 percent of the patients and families queried agreed or strongly agreed that proactive ethics consultation was helpful in analyzing, resolving, and educating about ethical issues, and that the process was fair, supportive, and informative.[8]

To assess the impact of ethics consultation on the interaction between family members, and healthcare providers concerning end-of-life care decisions, we examined data collected during a larger study of a proactive model of ethics consultation in an adult ICU.[9] Our study found that healthcare providers and family members both experienced proactive ethics consultation as helpful in facilitating communication and decision making in an ICU setting. It should be noted, however, that healthcare providers' ratings of the process were more positive in many categories than those reported by participating family members, a finding that warrants more attention, inquiry, and research.

METHODS

The collection of data and the study process for the multi-site, randomized controlled trial Impact of Ethics Consultation in the ICU study has been previously described.[10] The study received approval from the institutional review boards (IRBs) at each of the seven sites involved. The patients who had been identified as potentially having a values conflict who were targeted in the protocol were randomized into control and intervention arms. The subsequent ethics consultations that were requested and provided for the control patients did not alter this original assignment, nor did a refusal to participate in an ethics consultation. The potential conflicts deemed appropriate for inclusion in the study included those among healthcare team members, between patient/family/friends, or between healthcare providers and the patient/family/friends regarding the pursuit of aggressive life-sustaining treatment, identifying the patients' best interests, recognizing futile treatment, or choosing a surrogate decision maker. The consultation, although it was not standardized across the study sites, adhered to a general process model of ethics consultation, including review of the medical record, discussion with healthcare team and family members, assessment of the issues, timely meetings as appropriate, and recommendations for next steps. The consultations were offered in re-

sponse to latent or manifest conflicts, rather than specific requests for ethics consultation, and will otherwise be referred to as *proactive ethics consultation.* Among the issues addressed were relevant medical factors, a patient's known or inferred values and preferences, quality of life considerations, and other contextual factors of importance. The consultant(s) helped frame the issues, facilitated understanding of the conflict or recognition of ethical questions, identified common ground, and adopted other consensus-seeking strategies. Follow up by the ethics consultant(s) occurred as needed to provide ongoing support to the process, and evaluation was undertaken during case review by the ethics committee.

Members of the two groups in the intervention arm of the study were interviewed following each patient's death or discharge. Structured and open-ended questions were directed to primary healthcare providers and to the patient/surrogate/family/friend identified by the healthcare team as the most appropriate decision maker. In all cases, the persons who were interviewed had participated in the ethics consultation. The interviewed subjects were asked to respond by means of a structured Likert scale to questions regarding the efficacy of the consultation (specifically whether the consultation was helpful in identifying, analyzing, and resolving ethical issues), whether it was stressful, informative, supportive, and whether it facilitated enhanced communication. Spontaneous comments were encouraged and recorded during all of the interviews. The data regarding the subjects' satisfaction were collected to confirm empirical findings in the primary study, that a reduction of nonbeneficial treatment was not coerced, imposed, or otherwise a source of distress. The interview instrument is available upon request.

Interview data were analyzed first by examining any descriptive patterns that were found in subjects' responses to questions focused on the clinical value, educational benefits, and general satisfaction with the ethics consultation. Second, responses from family members (n = 108) and healthcare providers (n = 255) were compared for differences in beliefs about the importance of, and satisfaction with, ethics consultation. As the data were ordinal and not normally distributed, the Mann Whitney U test was used to test for concordance and statistical significance between family members and healthcare providers on each of the ethics value indicators.

RESULTS

Interviews were completed with healthcare professionals for all patients in both of the intervention arms of the study. Among the patients/surrogates, 111 of 122 (91 percent) of the interviews were conducted. Analysis indicates that healthcare providers and family members found the ethics consultations helpful (92.3 percent, 87.0 percent), informative (81.1 percent, 88.0 percent), supportive (93.3 percent, 88.0 percent), fair (92.9 percent, 84.3 percent), and respectful of personal values (92.4 percent, 85.1 percent). Furthermore, 73 percent of the healthcare providers and 71.2 percent of the family members did not find the ethics consultation to be stressful. Both healthcare providers and family members valued the educational benefits of the ethics consultation. Again, healthcare providers and family members found the ethics consultation to be helpful in identifying ethical issues (87.7 percent, 86.7 percent), analyzing ethical issues (86.5 percent, 84.6 percent), and resolving ethical issues (73.9 percent, 71.2 percent). Similarly, healthcare providers and family members found ethics consultation to be beneficial in helping to educate all parties (80.0 percent, 81.9 percent) and in helping parties present their personal point of view (80.9 percent, 84.5 percent). Finally, the majority of both clinical caregivers and family members agreed with the decision reached in the ethics consultation (81.3 percent, 71.8 percent) and would seek out further ethics consultations in similar situations (95.2 percent, 80.4 percent) as well as recommend ethics consultation to others (98.0 percent, 80.4 percent). The educational benefits of ethics consulting are reported in table 1. Healthcare providers and family

members strongly valued the problem-solving component of ethics consultation. There were no statistical differences between healthcare providers and family members in beliefs concerning the educational value of ethics consultation.

The data on subjects' reports of general satisfaction with ethics consultation and whether healthcare providers or family members would recommend ethics consultation for future questions or disputes are presented in table 2. Both healthcare providers and patient/family perceived similar degrees of changes in the treatment plan following ethics consultation, although the actual changes were not verified in this study. Healthcare providers were significantly more likely than family members to agree with the decision of the ethics consultation, seek out ethics consultation in similar situations, and recommend ethics consultation to others.

The data on healthcare providers' and family members' beliefs concerning the value of ethics consultation in creating a helpful and supportive environment are reported in table 3. Healthcare providers said that ethics consultation was significantly more helpful, supportive, and fair than did family members. Healthcare providers also said that ethics consultation was significantly less stressful than did family members. There was no difference between the responses of healthcare providers and family members on whether they found ethics consultation informative and respectful of values.

DISCUSSION

This study examines the perceived value of proactive ethics consultation in the ICU and suggests that such consultations are helpful in educating and informing participants about the issues at stake. Both healthcare providers and family members reported that ethics consultation helped them to identify, analyze, and resolve ethical questions and conflicts. On a 5-point Likert scale, mean values for both healthcare providers and family members ranged from 3.88 to 4.27 on these items. Early identification of and attention to ethical issues appears to have increased opportunities to express beliefs and feelings, raise questions, and resolve conflicts (mean values ranged from 4.15 to 4.43).

Notably, the ratings of healthcare providers and family diverged in a number of areas. Although both healthcare providers and family

TABLE 1 Educational Value of Ethics Consultation in Problem Solving: Comparison of Healthcare Professionals and Family Members

	Healthcare Professionals	Family Members
Identifying ethical issues	4.27	4.10
Analyzing ethical issues	4.26	4.12
Resolving ethical issues	3.93	3.88
Educating you and the family	4.15	4.12
The consultation was informative	4.19	4.30
Helping present your view	4.10	4.13

* $p \geq .05$ ** $p \geq .01$ (neither apply in this table)
The responses were on a Likert scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

TABLE 2 Impact of Ethics Consultation on the Decision-Making Process: Comparison of Healthcare Professionals and Family Members

	Healthcare Professionals	Family Members
I agreed with the decision reached in the ethics consultation	4.25**	3.92
The treatment plan changed significantly after the ethics consultation	3.34	3.31
I would seek an ethics consultation in similar circumstances again	4.54**	4.15
I would recommend an ethics consultation to others	4.59**	4.20

* $p \geq .05$ ** $p \geq .01$
The responses were on a Likert scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

members had positive responses to the interview questions, the data indicates that healthcare providers felt the consultation to be more beneficial than did family members (table 3). For example, both healthcare providers and patients/surrogates valued the consultation for helping to identify and resolve ethics issues at an individual level. However, healthcare providers rated the efficacy of the consultation in these clarifying and dispute-resolving categories more highly than did family members. The mean values for family members ranged from 4.14 to 4.27, as compared with healthcare providers who had mean scores ranging from 4.37 to 4.44 (table 2). Although our data does not indicate a definitive explanation, one interpretation of this difference, based on our experience, is that ethics consultation helps healthcare providers to diffuse responsibility for making end-of-life care decisions and provides an infrastructure that allows for and supports communication with patients/families at the end of life. Ethics consultation creates time, space, and a formal mechanism for the sharing of divergent experiences and expectations. This process helped to dissipate misunderstandings and to encourage mutually informed medical decision making among parties who felt supported by the process.

Ethics consultants are able to serve as a source of ongoing support in difficult and often contentious decision-making processes. Providing such support to patients/families often falls to healthcare professionals and may be neglected or inadequate for a family's needs. Healthcare professionals themselves are often without any formal support mechanism. Thus, ethics consultants support healthcare professionals in at least three ways, as the help to:

1. Delineate and work logically through entangled ethical issues,
2. Establish a place for difficult communications that are arguably part of their jobs,
3. Identify and address healthcare professionals' own ethical beliefs and conflicts.

This, in part, may explain the consistent findings that healthcare professionals value the dispute resolution aspect of ethics consultation more highly than patients/families do, although further research is needed to verify this.

Finally, our findings suggest that healthcare providers and family members value the educational aspect of the ethics consultation equally. The findings reported in table 1 indicate that the mean value that subjects assigned to ethics consultation as informative and educational ranged from 4.10 to 4.30. As noted, previous studies, and ours to a lesser degree, have indicated that healthcare providers tend to value ethics consultations more than patients/families, making this the most surprising finding of the study (see table 1). The ethics consultants involved in the study believe this was due to their efforts to identify issues before a crisis point and to tailor ethics consultation to the idiosyncratic needs of those involved. The consultants reported ongoing contact with family members beyond the formal consultation meeting, including calls or meetings to discuss new medical findings as well as personal perspectives and ethical questions. Family members may have perceived this additional source of information and communication to be a benefit that enhanced their impression of ethics consultation.

TABLE 3 Value of Ethics Consultation in Creating a Helpful and Supportive Environment When Dealing with End-of-Life Crises: Comparison of Healthcare Professionals and Family Members

	Healthcare Professionals	Family Members
The consultation was helpful	4.44**	4.14
The consultation was stressful	2.21**	2.95
The consultation was supportive	4.43*	4.27
The consultation was fair	4.37**	4.15
The consultation was respectful of my values	4.40	4.25

* $p \geq .05$ ** $p \geq .01$

The responses were on a Likert scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

Although findings from the study show some benefits of proactive ethics consultation, they are limited to the adult ICU setting in hospitals that have active ethics committees/consultants. This study does not address the quality of care issues that may affect those perceptions, nor does it address the role of other consultants, such as palliative care physicians or social workers. It is difficult to know whether these results would be repeated in hospitals whose ethics consulting services did not have the same knowledge, skills, and experience required to participate in this study.[11] In addition, while some consultations were requested simultaneously or subsequent to enrollment in the study, our findings, in the main, come from consultations that were catalyzed by latent or manifest ethical issues identified, at least initially, by study personnel. No survey was conducted among patients in the control group (those not assigned to receive ethics consultation), and could not have been without interfering with the design of the study, so no comparison can be made with this group. Negative feedback from study participants is addressed elsewhere.[12] Further study is needed to assess the relative merits of this proactive style of consultation against the more traditional, by-request consultation model and against the perceptions of patients who were not offered consultation.

We speculate that if proactive ethics consultation were part of routine care for patients who are nearing the end of their lives, it would yield significant benefits on two levels. First, physicians in our study reported that ethics consultation helped facilitate helpful conversations with patient/families in the end-of-life setting. Families of critically ill patients often identify communication as a vital skill for health professionals, describing it as more important than their perception of clinical skills.[13] Consequently, it seems likely that the inclusion of ethics consultation in routine end-of-life care would both increase the frequency of the conversations deemed important by families and improve their timeliness. A routine practice of ethics consultation for patients nearing the end of life could also result in more informed and shared responsibility in the decision-making process.

Comments from the healthcare providers we interviewed highlight the challenge of communicating effectively with patients and families in end-of-life circumstances and the role that ethics consultation can play in not only supporting communication, but facilitating it. For example, one clinician noted that one so-called ethical dispute was really a problem of communication rather than ethics. Another commented that "Consults helped facilitate proactive communication." Another physician elaborated: "The ethics consultation process was helpful in educating [the MD] on how to approach ethics conflicts in the future and how to obtain consults at the hospital in the future. [I am] very impressed with the efficiency, knowledge, and compassion with which this case/ethics consult was handled." Another commented that the consult "highlights the importance of collaborating as a team and helping let the family express their concerns as well." Another noted: "The family was driving me nuts — everyone — The wife was not coping. Consultant really helped organize the information. [The family] did not understand, even though all the doctors had told them."

Communication in the ICU is hindered by the often sudden transition to an intensive care setting, associated patient/family turmoil, and a multitude of physician specialists who may have no established relationship with the patient. The lack of evidence-based treatment protocols and the indistinct legal and ethical norms that guide treatment decisions for care at the end of life for patients with chronic, progressive illness can cause physicians to be uncomfortable regarding treatment planning. When the discussion of treatment goals or prognosis is haphazard, provoked by imminent crisis, and poorly articulated, the stage is set for conflicts over the care plan. Conflicts about continuing treatment, sometimes characterized as futility issues, may be based in a failure of communication and a subsequent discordance in expectation between or among healthcare providers and/or families.[14]

Ethics committees/consultants may play a key role in assisting healthcare professionals to anticipate ethical issues, facilitate discussion, and support the medical decision-making process. Traditionally, the burden for decision making, including the process of negotiation with patients/families, has rested primarily on physicians' shoulders. The stress on families associated with medical decisions has long been recognized,[15] but the impact on clinicians is less noted, perceived instead, perhaps, as an inherent part of the job. This study suggests that the consistent use of proactive ethics consultation is one successful strategy to enhance communication and decrease the discomfort felt by both clinicians and family members.

CONCLUSION

This study suggests that proactive ethics consultation supports enhanced communication and provides a tangible educational support infrastructure for patients/families and healthcare professionals in the ICU. Ethics consultants can facilitate medical decision making in a difficult communication process, and share responsibility or burdens related to end-of-life care decision making that clinicians, particularly physicians, have traditionally borne alone. We believe this is a previously under appreciated and essential role for ethics committees/consultants.

Although this study seems to support the beneficial role of proactive ethics consultations, further study is needed to assess the impact of ethics consultation, proactive and traditional, on the medical culture that surrounds end-of-life care specifically, and communication more generally. This study suggests a significant starting point for such evaluation.

ACKNOWLEDGMENT

The research discussed in this article was supported by a grant from the Agency for Healthcare Research and Quality, grant number 1 R01 HS10251.

NOTES

1. M.P. Aulisio, E. Chaitin, and R.M. Arnold, "Ethics and palliative care consultation in the intensive care unit," *Critical Care Clinics* 2 (2004): 505-23.

2. P.S. Mueller et al., "Ethical issues in geriatrics: a guide for clinicians," *Mayo Clinic Proceedings* 79 (2004): 554-62.

3. J. Carlet et al., "Challenges in end-of-life care in the ICU: Statement of the 5th International Consensus Conference in Critical Care: Brussels, Belgium, April 2003," *Intensive Care Medicine* 30 (2004): 770-84; D.G. Larson and D.R. Tobin, "End-of-life conversations: evolving practice and theory," *Journal of the American Medical Association* 284, no. 12 (2000): 1573-8; R.D. Orr and R.M. Perkin, "Clinical ethics consultations with children," *The Journal of Clinical Ethics* 5, no. 4 (Winter 1994): 323-8; R.D. Orr and E. Moon, "Effectiveness of an ethics consultation service," *Journal of Family Practice* 36, no. 1 (1993): 49-53; J. La Puma et al., "An ethics consultation service in a teaching hospital: Utilization and evaluation," *Journal of the American Medical Association* 260, no. 6 (1988): 808-11; J. La Puma et al., "Community hospital ethics consultation: evaluation and comparison with a university hospital service," *American Journal of Medicine* 92, no. 4 (1992): 346-51; R.D. Orr et al., "Evaluation of an ethics consultation service: patient and family perspective," *American Journal of Medicine* 101, no. 2 (1996): 135-41; B.M. Yen and L.J. Schneiderman, "Impact of pediatric ethics consultations on patients, families, social workers, and physicians," *Journal of Perinatology* 19, no. 5 (1999): 373-8.

4. Orr and Moon, "Effectiveness of an Ethics Consultation Service," see note 3 above; La Puma et al., "An Ethics Consultation Service in a Teaching Hospital," see note 3 above; La Puma et al., "Community Hospital Ethics Consultation: evaluation and comparison," see note 3 above; Orr et al., "Evaluation of an Ethics Consultation Service," see note 3 above; Yen and Schniederman, "Impact of Pediatric Ethics Con-

sultations," see note 3 above; Orr and Perkin, "Clinical ethics consultation with children," see note 3 above; M. Craig and T. May, "Evaluating the outcomes of ethics consultation," *The Journal of Clinical Ethics* 17, no. 2 (Summer 2006): 168-80; G. DuVal et al., "A national survey of U.S. internists' experiences with ethical dilemmas and ethics consultation," *Journal of General Internal Medicine* 19, no. 3 (March 2004): 251-8.

5. C.M. Lilly et al., "An intensive communication intervention for the critically ill," *American Journal of Medicine* 109, no. 6 (2000): 469-75.

6. J.J. Fins et al., "End-of-life decision-making in the hospital: current practice and future prospects," *Journal of Pain Symptom Management* 17, no. 1 (1999): 6-15.

7. M.D. Dowdy, C. Robertson, and J.A. Bander, "A study of proactive ethics consultation for critically and terminally ill patients with extended lengths of stay," *Critical Care Medicine* 26, no. 2 (1998): 252-9.

8. L.J. Schneiderman, T.P. Gilmer, and H. Teetzel, "Impact of ethics consultations in the intensive care setting: A randomized, controlled trial," *Critical Care Medicine* 28, no. 12 (2000): 3920-4.

9. L.J. Schneiderman et al., "Effect of Ethics Consultations on Non-Beneficial Life-Sustaining Treatments in the Intensive Care Setting: A Multi-Center, Prospective, Randomized, Controlled Trial," *Journal of the American Medical Association* 290, no. 9 (2003): 1166-72.

10. Ibid.

11. American Society for Bioethics and Humanities, *Core Competencies for Health Care Ethics Consultation, The Report of the American Society for Bioethics and Humanities* (Glenview, Ill.: American Society for Bioethics and Humanities, 1998).

12. L.J. Schneiderman et al., "Dissatisfaction with Ethics Consultation: The Anna Karenina Principle," *Cambridge Quarterly* 15, no. 1 (Winter 2006): 101-6.

13. J.R. Curtis et al., "The family conference as a focus to improve communication about end-of-life care in the intensive care unit: opportunities for improvement," *Critical Care Medicine* 29, no. 2 (2001 supp.): N26-33.

14. J.J. Fins and M.Z. Solomon, "Communication in intensive care settings: The challenge of futility disputes," *Critical Care Medicine* 29, no. 2 (2001 supp.): N10-5.

15. T.J. Prendergast and K.A. Puntillo, "Withdrawal of life support: intensive caring at the end of life," *Journal of the American Medical Association* 288, no. 21 (2002): 2732-40.

Genetic Testing

Uncertainty and Moral Judgment: The Limits of Reason in Genetic Decision Making

Mary Terrell White

Since the inception of the Human Genome Project, the question of how genetic information should be used responsibly has generated a great deal of speculation and scholarship.[1] Although genetic testing offers unprecedented opportunities for choice and control in disease management and human reproduction, it has many critics who fear that over time, the indiscriminate use of genetic information may result in various kinds of harms to individuals and society. Responsible use of these new diagnostic technologies is therefore essential if genetic testing is to be successfully integrated into clinical medicine. But establishing normative standards of genetic responsibility has proved challenging.

A number of scenarios illustrate some common dilemmas individuals and couples may face today.

Mary Terrell White, PhD, is an Associate Professor in the Department of Community Health at Wright State University School of Medicine in Dayton, Ohio, *mary.t.white@wright.edu.*

- Suppose a person is known to have a family history of disease. Does he or she have a responsibility to be tested for disease susceptibility?
- If a person tests positive, should he or she be expected to change behaviors or accept medical treatment to lower disease risks? Should a person be penalized or otherwise held accountable if she or he chooses not to do either?
- Suppose a person tests positive for a known disease-bearing mutation. Does the person have a responsibility to warn his or her relatives that they too may be at risk?
- If a woman or couple is thought to be at risk of having a child with a genetic abnormality, does the woman have a moral responsibility to undergo prenatal testing?
- If an abnormality is found, does the couple have a responsibility to continue or terminate the pregnancy?
- If both members of a couple are suspected carriers of genetic disease, do they have a responsibility to be tested prior to attempt-

ing reproduction? If they both test positive as carriers, does this information impose any new responsibilities on them?
- If a person is known to have a genetic predisposition for an occupational disease, does he or she have a moral obligation to seek other kinds of work?

Each of these scenarios suggests that genetic testing provides specific and clinically meaningful information that can be used in ways that can be considered morally responsible. However, in practice, genetic information is usually presented in terms of probabilities or risks, as uncertain rather than definitive information. Moreover, studies in genetics and other disciplines have reported that decisions made under conditions of uncertainty may be influenced by a variety of nonrational factors, including heuristics and emotion. In this discussion, I explore whether and how genetic decisions that are influenced by nonrational factors can be considered responsible. I begin by summarizing some of the primary causes of genetic uncertainty followed by a discussion of how nonrational cognitive factors, specifically heuristics and emotion, may shape decision making. I then explore the implications of these nonrational factors for genetic decision making. I conclude with a number of questions regarding the nature of moral judgment when knowledge is uncertain.

SOURCES OF GENETIC UNCERTAINTY

The mapping and sequencing of the human genome has been more or less completed, but we are still far from understanding how our approximately 25,000 genes contribute to human development and behavior and how genetic activity is affected by factors external to the human organism. In addition, decisions of whether or not to test and what to do with test results often involve a range of psychosocial concerns, compounding uncertainty. Despite the many unknowns, several kinds of genetic testing have entered mainstream medical practice.

The most common form of genetic testing is amniocentesis, which is performed prenatally, and examines fetal cells for chromosomal abnormalities. Amniocentesis is usually recommended for couples who are considered to be at high risk of having a child with a genetic disorder, based primarily on the mother's age and medical history. Whether to accept the test is itself a question for many women. Because a slight risk of spontaneous abortion accompanies the test, the risk of a birth defect must be weighed against the risks imposed by the test. If a genetic abnormality is found, its significance may be unclear. Some chromosomal abnormalities are relatively benign, others are incompatible with life, and many have a wide range of expression. Diagnosis of a disorder also raises questions about what a child with a disability might require of prospective parents and their existing children, what the child's medical needs and prospects might be, whether the family will be able to provide adequate support for the child, and how others might respond to a decision to continue the pregnancy. None of these questions has clear or obvious answers.

Other kinds of genetic tests look for mutations — abnormal patterns — in the nucleotide sequences that make up the functional "code" of the human genome. These tests may be used to confirm a suspected diagnosis in children, to diagnose late-onset disease susceptibility, or rarely, to diagnose disease-bearing mutations in embryos created through *in vitro* fertilization prior to implantation. Single-gene diseases are the easiest to detect, but if a disease has a wide range of expression, the severity of symptoms over a lifetime cannot be determined from the diagnosis and may be highly variable. But most genetic diseases are multifactorial, caused by a combination of genetic, environmental, and behavioral factors. Tests for these diseases vary in their predictive utility, depending on what is known about the frequency of the gene in the population at risk, the proportion of people with the mutation in whom symptoms will eventually develop, and variation in how those symptoms are expressed. Because the predictive values of genetic tests are derived from studies of

high risk populations, they are subject to change with continued research. For multifactorial diseases, particularly those that manifest in adults, a positive diagnosis therefore only indicates an increased risk for disease over a patient's lifetime. But even when risk assessments are quite high, because multifactorial disease is not determined by genetics alone, there will always be some people who test positive who will never develop disease. A positive diagnosis is thus rarely conclusive evidence of disease. Testing also carries risks of employment or insurance discrimination, concerns for the health of family members, and possible social or psychological burdens, all of which may compound uncertainty for the decision maker.

NONRATIONAL FACTORS IN GENETIC DECISION MAKING

A person usually seeks genetic testing because he or she is concerned about a risk. A woman may become pregnant at an older age and worry about her risks of having a child with chromosomal defects. A middle-aged man may have a family history of colon cancer and wonder how to minimize his risks. An employee in an industrial setting may be concerned about his or her susceptibility to occupational hazards. Whatever the situation, when faced with a genetic risk, an individual will first have to decide whether or not to seek genetic testing. This decision will be shaped by the state of genetic knowledge regarding the disorder, the way the person perceives his or her risks relative to other life stresses and values, and how the person's physician responds to his or her concerns. If testing is pursued, test results will likely be presented in terms of numerical risk factors or probabilities of developing disease, which must then be interpreted by the clinician and the patient prior to further action. In these ways, genetic testing almost always involves some interpretation of risks.

Risk assessments for genetic diseases are developed from correlations between family histories, genetic diagnoses, and the incidence of disease across large populations. But while these assessments provide meaningful indicators of disease risks in populations, it is often difficult for individuals to interpret numerical risks with respect to their own circumstances. Generally speaking, people experience risk as the possibility of a loss. The significance of the risk reflects the magnitude of the potential loss combined with the likelihood that the loss will occur. But individuals differ over what they consider a loss, the significance of that loss, and their perception of its likelihood. In this way, a risk has little or no objective value; it becomes meaningful only as it is interpreted by an individual.

Although perception of risk has been extensively studied across a range of disciplines, there is still much that remains unknown. What is clear, however, is that the interpretation of risk and probabilistic information is far from an exclusively rational process. Genetic counselors assume that the more accurately a risk is conveyed, the better prepared a client will be to make the right decision for him or her. They are aware that how a risk is "framed" contributes to how it is interpreted, and for this reason make an effort to present risks and probabilities in a number of ways: as a single figure or as part of a sequence, in comparison to other risks, and verbally as well as numerically expressed.[2] Differentiating between risks of different magnitude can be difficult. Whether one has a 50 percent risk or 85 percent risk of developing a disease over a lifetime may make very little difference to the person faced with the risk; instead, he or she may construe the risk simply as "high" or "low," or as something that either will or will not happen.[3] Moreover, risks are always understood relative to other goals and uncertainties. For this reason, some people may dismiss a long-term genetic risk when short-term demands of a job or family are pressing.[4]

Studies in social psychology and neuroscience have demonstrated that under conditions of uncertainty, a number of heuristics and emotional responses may strongly influence decision making.[5] Three such heuristics have been described as representativeness, availability, and anchoring.[6] *Representativeness* refers to the

extent to which interpretations of risk may be narrowly based on limited or anecdotal experience, neglecting the range of variation across populations. For example, prospective parents whose fetus is diagnosed prenatally with Down syndrome may consider whether to continue or terminate the pregnancy. If they only know one person with Down syndrome, they may assume all people with Down syndrome exhibit characteristics similar to that person, and base their decision on how they feel about that individual. But the symptoms of Down syndrome range from mild to severe, and the likely form of expression cannot be inferred from the diagnosis. In this way, the couple may be misled by excessive reliance on their limited experience.

Availability has to do with the tendency to judge the likelihood of an event by the vividness with which an impression of the event comes to mind. Factors that contribute to availability include the magnitude of the consequences of the event, how recently the event occurred, and the frequency of the event. For example, a person exposed to a disease in family members, friends, or acquaintances is likely to have a heightened perception of his or her own risks for that disease.[7] Similarly, diseases that receive a lot of media attention, such as breast cancer or AIDS, also carry heightened availability. As a result, risks for these diseases are often overestimated relative to more common risks such as heart disease or car accidents.[8] Conversely, those with no prior experience with a disorder may find it difficult to imagine what the disorder might mean, or why they might want to pursue testing. Availability may therefore heighten or diminish perceptions of risk, depending on each person's experience.

Anchoring refers to a person's baseline knowledge about a risk. For some people, anchoring may be the most powerful influence on their perception of risks because long-held beliefs, even when mistaken, can be difficult to shake. This is illustrated in a study of genetic counseling in which approximately half of the patients' beliefs about their genetic risks before genetic counseling remained unchanged after counseling.[9] The strength of anchoring can be particularly distressing for people who are convinced that they either do or do not have a gene for a particular disease and who seek testing to confirm their hunches. Receiving news to the contrary can require a monumental reshaping of one's identity and prospects.[10]

In addition to these heuristics, emotional factors can contribute to decisions in a variety of ways. People faced with a genetic decisions have been found to use emotional feedback as information, exploring how they imagine they would feel — joyful, despondent, regretful, and so forth — by creating best- and worst-case scenarios.[11] This kind of "anticipated emotion" can be a powerful determinant of decisions.[12] The emotional foundation of personality may also make a difference — a person's general sense of optimism, confidence in "luck," belief that "it won't happen to me," or distaste for preventive measures, may diminish his or her perceptions of risks, while anxious individuals may overestimate their risks or underestimate their ability to cope with what they consider a "bad" outcome.[13] It is also noteworthy that genetic decisions are always stressful and often must be made quickly, which may result in efforts to avoid making a decision or a panic response that impairs judgment.[14]

Fear may be the most powerful emotional contributor to genetic decision making and is rarely avoidable, if only because so much of genetic testing is done for purposes of reassurance. The rational component of fear may be characterized as prudence — as reasonable precaution in the face of the unknown. The irrational dimensions of fear are potentially far more powerful. Some fears are experienced viscerally, as an "anticipatory emotion" that may overwhelm reason altogether.[15] Fear of public speaking, fear of heights, fear of snakes — for people who have these kinds of fears, no amount of intellectualizing can overcome them. Conceivably, some people may have this kind of fear response upon learning of their genetic risks and diagnoses.

Fear may also include anxiety over the unknown — the extent to which a hazard is considered novel, invisible, or delayed in produc-

ing harmful effects. Fear may also be experienced as "dread," referring to a person's perceived lack of control and the catastrophic potential of a situation.[16] Because genetic decisions are unfamiliar to most people, have sometimes invisible or delayed effects, and yet may have catastrophic consequences over which individuals have little or no control, these kinds of fear responses may strongly influence genetic decision making. Fears may include fear of the genetic risk, of the child who is different, the future that is not turning out as expected; fear for one's health, one's marriage, one's employment, one's life; fear of the judgment of others, of stigma, embarrassment, and rejection. And fear is subject to the same kinds of cognitive errors as perceptions of risks — it can be overblown or underestimated, depending on a person's experience, emotional makeup, and personality.

To summarize, responses to uncertainty generally represent a balance between a person's desire for a particular outcome and desire for security. How this balance is struck will be a measure of how each risk is interpreted, which in turn reflects the decision maker's prior knowledge and experience, contextual circumstances, personality, and the extent to which cognitive biases and emotional responses govern choices. Due to the range and variability of the factors that contribute to risk assessment, the same genetic information will mean different things to different people and decisions will vary correspondingly. Remarkably, most people are highly confident of their ability to make the right decision, even when the facts are uncertain.[17]

GENETIC RESPONSIBILITY: A MATTER OF INTERPRETATION

Prior to genetic testing, most people meet with a healthcare professional who provides genetic counseling. Genetic counseling is primarily a process of sharing information, in which a counselor solicits information on a person's family and medical history, assesses his or her genetic risks, and discusses the risks and benefits of testing. When test results are received, the counselor then explains their significance as accurately as possible and helps the counselee with any questions and concerns. The counselor's role in decision making is somewhat restrained. In the United States, the current policies and practices that surround genetic testing have been dominated by concern for the highly personal nature of genetic information coupled with the emphasis on individual liberty and rights that pervade American culture and law. Ensuring genetic privacy is therefore a paramount concern, as is a determination to avoid the coercive practices of the eugenics era a century ago. For these reasons, genetic counseling has evolved as a nondirective practice, meaning that counselors offer information and psychological support but rarely offer advice, respecting the right of their counselees to make their own decisions. Only when there is clear medical benefit to be derived from a particular choice are counselors likely to offer guidance or make recommendations. Decisions are thus driven primarily by how decision makers interpret their risks and alternatives in view of their unique circumstances, goals, and values. This approach minimizes the possibility of coercion and, it is widely believed, enables each counselee to make the decision that seems best for him or her.

A nondirective stance with regard to genetic decision making thus offers no normative guidelines or blueprints for responsible decisions. But if decision making is largely a matter of individual interpretation, which in turn may be shaped by nonrational factors, in what way can genetic decisions be considered morally responsible? At its core, moral judgment calls for the intentional use of reason to guide one's actions, reason typically being understood as the dispassionate and impartial exercise of one's intellect.[18] However, the burgeoning literature in cognitive science and decision making indicates that cognition calls on far more than rational processes,[19] including more than 30 different heuristics that are known to contribute to medical judgment.[20] How should these findings be incorporated into theories of morality and ethics? At issue is the perceived value of non-

rational cognition — whether heuristics and emotional responses are believed to add useful insights that are not available by reason. If they are useful responses, how ought we to incorporate these insights in moral decision making? If not, how shall we minimize their influence? Can we even reliably distinguish between rational and nonrational modes of thought?

Cultural attitudes toward uncertainty and risk taking impose additional moral considerations. For example, in affluent industrialized societies, we are encouraged to try to minimize uncertainty and control risk as much as possible. In the United States, our massive insurance industry is predicated on these values; our laws, social conventions, and reliance on the accountability of individuals and institutions all speak to our distaste for the unpredictable. And because uncertainty is portrayed as something to be avoided, failure to avoid it carries moral weight. This is clearly evident in healthcare, in which both physicians and patients who take unnecessary risks may be seen as irresponsible. Sometimes risk taking is necessary, and when it is done on behalf of others, it is often praised, regardless of the outcome. However, if the risk is unnecessary, or seems to benefit only the risk taker or results in burdens to others, taking risks may be judged more harshly.

But for many people, uncertainty is a fact of daily life. Hunger, homelessness, illness, violence — when these are present, mere survival requires taking calculated risks. When uncertainty is unavoidable, constant, and potentially life-threatening, there may be less of a moral burden associated with taking inadequate precautions or failing to assess risks accurately. Religious beliefs may also help some people cope with risks by portraying uncertainty as something to be embraced or endured through faith in providence or the will of God. In such circumstances, religious beliefs may provide a source of guidance and strength, but may also diminish one's sense of responsibility for the consequences of a choice. Perceptions of uncertainty itself are therefore value-laden, depending on one's culture, circumstances, and whether opportunities to manage risk are available.

As described above, fear may also exert a powerful effect on genetic decisions. Fear is not a virtue, and decisions based on fear are rarely praised. But some fears may be legitimate. For example, in the United States, financial support and services for children with disabilities is limited and dwindling. The rising costs of health insurance make it inaccessible to increasing numbers of people, which hinders their ability to use disease prevention strategies. Legal protection from genetic discrimination is still far from comprehensive and existing laws have not been adequately tested in the courts. Indeed, people have been known to refuse disease susceptibility testing because they fear losing a job or insurance discrimination following testing.[21] Studies suggest discrimination in insurance and employment already occurs[22] and existing legal constraints may not prevent it in the future.[23] Given all this, how should fear be acknowledged in genetic decisions? Moreover, because the social policies and practices of a society affect how choices are perceived, do these also bear some responsibility for the kinds of decisions that are made? Western ethics places the locus of moral responsibility on individuals, but individual choices inevitably reflect the surrounding context. To what extent should society as a whole be considered accountable for how genetic technologies are used?

Lastly, if genetic decisions cannot be said to be fully rational, should genetic counseling remain nondirective? Genetic counselors have long been aware that heuristics and emotion affect perceptions of and responses to risk, but at present, they do not consciously or systematically attempt to limit or constrain the kinds of factors that their counselees bring to bear on their decisions or the kinds of decisions made. Should counselors intervene when they feel that a counselee's decision is inappropriately influenced by nonrational factors? How can a counselor judge this? If counselors attempt to redirect a decision, might they be seen as manipulative? As experts who know more than their

counselees about the significance of genetic information, to what extent should genetic counselors have a role in the kinds of uses to which genetic technologies are put and the kinds of decisions that are made?

CONCLUSION

Genetic decisions must thus be seen as a balancing act in which each individual balances his or her hopes, beliefs, and values against uncertainties and fears. This balancing act is primarily an act of interpretation that involves a host of medical, psychosocial, and moral factors, many of which are subject to biases and distortion due to the strategies we use to make sense of uncertainty. Where the balance will fall depends on each individual and his or her life story. With rare exceptions, most people will believe their decisions are morally responsible.

But recognizing that decisions may even partially based on nonrational considerations raises a number of questions. First is the question of what it means to make a moral judgment. We speak of "moral reasoning" as a rational process that is based on an impartial analysis of facts and values. Can a decision be considered morally responsible if it is shaped, perhaps even primarily, by nonrational factors?

Second, how might or ought we to frame, articulate, and acknowledge uncertainty as a contributing factor in moral judgments? How do cultural values and expectations contribute to responses to uncertainty? What can we claim about the demands and expectations of moral responsibility in the genetics arena, where information is almost always uncertain?

Third, what do we need to know about how fear contributes to genetic decisions? What kinds of fear are morally legitimate? If fears significantly reflect persons' anticipated social consequences of testing, should the locus of responsibility rest solely on the individual? How do public policies influence perceptions of risk, and correspondingly, what role has society in promoting responsible genetic decisions?

Finally, and most immediately, how ought those who provide genetic counseling acknowledge and respond to those factors that contribute to nonrational decisions? What is (or ought to be) counselors' role in promoting responsible decisions, and how ought they best to go about fulfilling it?

My goal in this article has been to introduce some of the literature on the limits of rationality to broader discussions of genetic responsibility and bioethics. To date, discussions of genetic responsibility have focused primarily on legal rights and protections for individuals and groups, and have neglected the lived experience of people who make genetic decisions. There is ample evidence that these decisions are not based entirely on factors that are amenable to rational analysis. The successful integration of genetics in healthcare and society will require that we learn much more about how nonrational forms of cognition affect moral judgment. It is possible that a greater understanding of these relationships may even prove useful beyond the genetics arena.

NOTES

1. Human Genome Project Information: Ethical, Legal and Social Issues, *www.ornl.gov/sci/techresources/Human_Genome/elsi/elsi.shtml,* accessed 24 March 2005.

2. S. Shiloh and M. Sagi, "Effect of Framing on the Perception of Genetic Recurrence Risks," *American Journal of Medical Genetics* 33 (1989): 130-5; D.C. Wertz, J.R. Sorenson, and T.R. Heeren, "Clients' Interpretation of Risks Provided in Genetic Counseling," *American Journal of Human Genetics* 39 (1986): 253-64.

3. A. Lippman-Hand and F.C. Fraser, "Genetic Counseling — the Postcounseling Period: 1. Parents' Perceptions of Uncertainty," *American Journal of Medical Genetics* 4 (1979): 1-71.

4. P.G. Frets et al., "Factors Influencing the Reproductive Decision after Genetic Counseling," *American Journal of Medical Genetics* 35 (1990): 496-502.

5. G.F. Loewenstein et al., "Risk as Feelings," *Psychological Bulletin* 127, no. 2 (2001): 267-86; A.R. Damasio, *Descarte's Error: Emotion, Reason, and the Human Brain* (New York:

Putnam, 1994); A. Tversky and D. Kahneman, "Judgment under Uncertainty: Heuristics and Biases," in *Judgment under Uncertainty: Heuristics and Biases,* ed. D. Kahneman, P. Slovic, and A. Tversky (Cambridge: Cambridge University Press, 1982), 3-20.

6. Tversky and Kahneman, see note 5 above.

7. G. Rees, A. Fry, and A. Cull, "A Family History of Breast Cancer: Women's Experiences from a Theoretical Perspective," *Social Science and Medicine* 52 (2001): 1433-40.

8. P. Slovic, B. Fischhoff, and S. Lichtenstein, "Cognitive Processes and Societal Risk-Taking," in *Cognition and Social Behavior,* ed. J.S. Carroll and J.W. Payne (Hillsdale, N.J.: Lawrence Erlbaum Associates, 1976), 165-84.

9. Wertz, Sorenson, and Heeren, see note 2 above.

10. M. Huggins et al., "Predictive Testing for Huntington Disease in Canada: Adverse Effects and Unexpected Results in Those Receiving a Decreased Risk," *American Journal of Medical Genetics* 42 (1992): 508-15.

11. Lippman-Hand and Fraser, see note 3 above.

12. Loewenstein et al., see note 5 above.

13. P. Slovic, B. Fischhoff, and S. Lichtenstein, "Facts versus Fears: Understanding Perceived Risk," in *Judgment under Uncertainty: Heuristics and Biases,* see note 5 above, pp. 463-89.

14. S. Shiloh, "Decision-Making in the Context of Genetic Risk," in *The Troubled Helix: Social and Psychological Implications of the New Human Genetics,* ed. T. Marteau and M. Richards (Cambridge: Cambridge University Press, 1996), 82-103.

15. Loewenstein et al., see note 5 above; Damasio, see note 5 above.

16. Loewenstein et al., see note 5 above.

17. Slovic, Fischhoff, and Lichtenstein, "Facts versus Fears," see note 13 above.

18. J. Rachels, *The Elements of Moral Philosophy* (Philadelphia: Temple University Press, 1986), 11.

19. The studies cited here are a very small sampling of this literature: Tversky and Kahneman, see note 5 above; P. Croskerry, "The Importance of Cognitive Errors in Medicine in Diagnosis and Strategies to Minimize Them," *Academic Medicine* 78, no. 8 (2003): 775-81; Loewenstein et al., see note 5 above; Damasio, see note 5 above.

20. Croskerry, see note 19 above.

21. E.A. Petersen et al., "Health Insurance and Discrimination Concerns and BRCA1/2 Testing in a Clinic Population," *Cancer Epidemiology Biomarkers and Prevention* 11, no. 1 (2002): 79-87; K.A. Apse et al., "Perceptions of Genetic Discrimination among At-Risk Relatives of Colorectal Cancer Patients," *Genetics in Medicine* 6, no. 6 (2004): 510-6.

22. L.N. Geller et al., "Individual, Family, and Societal Dimensions of Genetic Discrimination: A Case Study Analysis," *Science and Engineering Ethics* 2, no. 1 (1996): 71-88.

23. J.A. Alper and J. Beckwith, "Distinguishing Genetic from Nongenetic Medical Tests: Some Implications for Antidiscrimination Legislation," *Science and Engineering Ethics* 4, no. 2 (1998): 141-50.

Pride and Prejudice: Avoiding Genetic Gossip in the Age of Genetic Testing

Darlyn Pirakitikulr and Harold J. Bursztajn

INTRODUCTION: THE PROMISE OF GENETIC INFORMATION

Genetic testing holds increasing promise. As accurate, comprehensive, and inexpensive genetic testing becomes increasingly available, it becomes possible to measure the probability and magnitude of various maladies, making detection, treatment, and prevention all the more effective. So great is the promise that recently there have been increasing calls for including genetic information as a dimension even in revisions of the standard diagnostic nomenclature of such a far-afield specialty as psychiatry, as it proceeds with its fifth edition of the *Diagnostic and Statistical Manual* (*DSM V*).[1]

MEDICAL INFORMATION GOES CYBERSPACE

However, the advent of the age of routine genetic testing for medical and behavioral conditions, together with the increasing computerization of information and its transmission in cyberspace, raises security concerns that sensitive information not be used in ways that could be harmful; should security fail, it is important that methods of collecting information not compound the loss of privacy with helplessness and distrust, which are the special handmaidens of loss in the context of unconsented-to risk.[2]

Genetic information has often been seen as immutable character — with character's aura of destiny around it. Long before there was the concept of genes, Cassius comments on character to Brutus in Shakespeare's *Julius Caesar,* "The fault, dear Brutus, is not in our stars, But in ourselves."[3] All too often we now misunderstand genes as having the character of stars within us that determine our destiny. Even as genetic advances bring a deeper scientific and clinical understanding of the complexity of genetic influences on behavior, such reductionist fatalism regarding the role of heredity in char-

Darlyn Pirakitikulr is a First-Year Student at Boston University School of Law.
Harold J. Bursztajn, MD, is an Associate Clinical Professor of Psychiatry, and is Co-Founder of the Program in Psychiatry and the Law at the Beth Israel Deaconess Medical Center Department of Psychiatry at Harvard Medical School, *hbursztajn@hms.harvard.edu.*

acter and choice is likely to persist and grow. Thus, safeguards need to be put in place to make certain that a patient's personal genetic information will not be disclosed to others without the patient's informed consent. Further, although genetic information is often subject to distortion and stigmatization due to its aura of destiny and inevitability, in and of itself it is ambiguous,[4] and as genetic information grows, it will be impossible to segregate it neatly from other medical information, and there will be a great deal of room for distortion and mischief to make their presence felt.

Information that is the result of genetic testing needs to be handled with caution, as careless dissemination of personal information can create an environment in which nothing is sacred, which can cause patients to feel helpless and that they have lost their identity. Currently, under the Health Insurance Portability and Accountability Act (HIPAA), patients' confidential health information may be disclosed for medical operations without their informed consent. It appears that these informed consent provisions have been dropped as a kind of social policy experiment, which should, itself, have required informed consent.[5]

While the notion of "genetic discrimination" is relatively new, there are hundreds of instances in which individuals were denied employment or lost their health and life insurance based on perceived genetic abnormality.[6] "Genetic gossip" created by widespread circulation of individual genetic information can result in "genetic reductionism," which neglects the important role that the environment plays in the expression (or repression) of genetic potential. Genes are but one determinant of behavior — and genes alone cannot determine how individuals will grow and develop.

Nonetheless, all too often, sound bites trump complexity. Thus, when genetic information circulates as genetic gossip, it is not likely that its subtlety and complexity will be expressed as clearly as in a recent study by researchers at the University of California Los Angeles — who report that an individual's early or current environment can reverse the effect of a genetic variant linked to depression.[7] While individuals who are homozygous carriers of the short allele (s/s) of the serotonin transporter gene-linked polymorphic region (5-HTTLPR) may be at increased risk for depression, they were found to exhibit significantly less depressive symptomatology if they reported a supportive early environment or recent positive experiences.

GENETIC INFORMATION MEETS GENETIC REDUCTIONISM

Genetic discrimination touches on many issues, including individuals' right to privacy and what this right includes, the possible consequences of the sharing of genetic information, and the current protections that the law provides — or fails to provide — to protect individuals' genetic information. Moreover, when an individual's genetic information is disclosed, the information may stigmatize not only the affected individual but his or her family members.

An individual's right to privacy is protected under common law, and arguably under the first five amendments to the Constitution of the United States. However, with the advent of technology that is capable of determining an individual's genetic makeup, it becomes necessary to determine whether this right to privacy includes the right to genetic privacy. For example, in 1995, employees of the Lawrence Berkeley Laboratory filed a class action lawsuit alleging that the laboratory had tested them for various medical conditions without their knowledge or consent. Specifically, the employees accused the laboratory of performing genetic testing for sickle cell trait, in addition to testing for venereal disease and pregnancy.

This case was heard on appeal by the United States Court of Appeals for the Ninth Circuit,[8] which ruled that the laboratory may have violated the employees' constitutional right to privacy by performing genetic testing without their prior consent. The case was sent back to the district court level for retrial. Subsequently, in August 2000, Lawrence Berkeley Laboratory agreed to settle the lawsuit for $2.2 million and agreed not to test employees for pregnancy, syphilis, or sickle cell trait.

As technology improves and genetic tests become less expensive, individuals are increasingly at risk of having their genetic information exposed. This genetic information in turn can be used to discriminate against people who carry a gene that is tied to a specific disease. This can be particularly problematic because it may severely decrease an individual's prospects for employment, ability to secure insurance, or limit other opportunities in life, even when the person is clinically healthy and displays none of the symptoms of genetic disorder. As Sheri A. Alpert notes, "At its best, genetic information is highly probabilistic in nature. . . . The main difficulty with the nature of genetic information is that few lay people actually understand that probabilistic aspect, often believing instead that the presence of a mutation equates to the presence of a malady."[9] In effect, the individual can become a victim of the folk beliefs and stereotypes that surround genetics and mental illness.[10]

Given the fact that human beings use heuristics — fast and frugal simplifying strategies for survival — we avoid information overload in the midst of ambiguity and uncertainty when speed is of the essence. Yet, given the structure of memory, such heuristically governed first impressions may often be our last impressions.[11] Thus, for uninformed third parties, a "genetic predisposition" may translate to inevitable impairment, regardless of the individual's environment and choices. Such fatalism can easily feed prejudice that is founded on distortion of the meaning of heredity; such prejudice is invariably easier to maintain regarding others than it is regarding oneself. Allowing uninformed third parties to have unwarranted access to genetic information may not only undermine the goal of a just and fair society, but also create a self-fulfilling cycle of deepening and increasingly anachronistic genetic fatalism.

THE PROBLEM WITH HIPAA

As the breadth of genetic knowledge continues to grow, it is not surprising that there are new complaints regarding genetic discrimination. Without adequate safeguards in HIPAA that require informed consent for the release of medical information, we can expect more cases similar to that of the Burlington Northern Santa Fe Railway (BNSF), in which the U.S. Equal Employment Opportunity Commission (EEOC) filed a suit against the BNSF for secretly testing its employees for hereditary neuropathy with liability to pressure palsies (HNPP), a rare genetic condition that causes carpal tunnel syndrome as one of its many symptoms.[12] The BNSF claimed that the testing was a way of determining whether the high incidence of repetitive-stress injuries among its employees was work-related or not. However, beyond simply testing for HNPP, company-paid doctors also were instructed to screen for several other medical conditions such as diabetes and alcoholism. BNSF employees were not told that they were being genetically tested, and an employee who refused testing was threatened with possible termination.

While in this instance the lawsuit was settled, without adequate privacy protections employees are likely to eventually find themselves in job environments in which they are not aware that their genetic information is being secretly accessed, and decisions such as promotion or retention may be made on covertly or subtly discriminatory grounds.

Current privacy protections are inadequate. While HIPAA provides some protection from discrimination, the protections it offers are incomplete. Much more is needed to ensure that genetic information is securely safeguarded. HIPAA does not prohibit the use of genetic information as a basis for charging a group more for health insurance. As a result, individuals who are genetically predisposed to certain conditions may be charged premiums that are so expensive that they are, in effect, uninsurable. HIPAA does not limit the collection of genetic information by insurers, nor does it prohibit insurers from requiring individuals to take a genetic test. Because of this, an insurer can demand a genetic sample from an individual as a prerequisite to becoming insured. Further, HIPAA does not limit the disclosure of genetic

information by insurers: once an insurer acquires an individual's genetic information, there is the risk that it may disseminate the information to other parties. Finally, HIPAA does not apply to individual health insurers unless they are covered by its portability provision. The public's fears of irrational and rational discrimination by insurers are not unjustified, and should be addressed.[13]

CONCLUSION: THE LESSONS OF HISTORY AND PSYCHOLOGY

Historically, genetic stereotypes have been used to reinforce prejudice.[14] This abuse has been exacerbated by a psychological tendency to continue in patterns of behavior.[15] If genetic information is not protected, the problem will worsen. It is of paramount importance that patients who are at risk of this abuse retain control of medical information that can be easily distorted and used for prejudicial purposes.[16]

The current system burdens patients with "opting out" of the system of shared medical information. There is a difference between opting out of having personal information shared and being asked to give informed consent.[17] Patients who are frightened and demoralized may find it easier to "go with the flow." Patients who depend on their doctors for treatment may find a request for permission to release genetic information that has not yet been collected too abstract to be meaningful.[18] Thus, only a meaningful informed consent process for release of medical — and especially genetic — information, after the information has been obtained, can safeguard a vulnerable patient's autonomy[19] and only with such a process can the consent that is given be considered authentic.

As technology becomes more advanced and genetic information becomes more readily available, it becomes increasingly important to address the shortcomings of HIPAA. Without adequate privacy protection, the individuals who are most vulnerable to genetic discrimination are those most likely to be the victims of discrimination by employers who gain covert access to medical records — and these individuals lack appropriate legal recourse to timely and effective relief and remedy. As time goes on, an increasing amount of sensitive mental health treatment is being provided in general medical settings; in the same way, it is likely that an increasing amount of genetic information will be exchanged in these same settings.

In practice it is unlikely that general medical records can be purged of either sensitive mental health or genetic information, or that a Chinese wall, or information barrier, can be built between sensitive and nonsensitive medical information. Thus, there is a strong need to avoid genetic gossip, given the increasing presence of genetic information in routine medical charts, and the tendency for such information, when packaged categorically as encoded in electronic medical records, to be easily distorted by third parties and easily disseminated more widely than ordinary narrative medical information that is found in paper charts.

This is not to say that the privacy of genetic information should always be paramount, at all costs. As Stephen G. Pauker and Susan P. Pauker note, "When considering restrictions on information transfer, based either on HIPAA or on the precepts of medical ethics, one basic rule should be remembered: *Patient care and safety come first.* HIPAA contains explicit exclusions for treatment, payment, and health care operations: PHI [personal health information] that is required for these three purposes is exempt from HIPAA's restrictions."[20] Even from a cost/benefit perspective, however, we must re-examine the utility of the informed consent process in terms of promoting a more reliable patient history, empowering vulnerable patients, and promoting an ongoing doctor-patient alliance.

Acting today to provide an ounce of genetic privacy by re-establishing general HIPAA informed consent provisions for the release of any patient's medical information is consistent with good clinical care and patient safety. There is no convincing evidence that reinstituting informed consent provisions will make payment processes or healthcare operations unwieldy. Because covered entities need to ask patients to sign HIPAA notices, for the same amount of

effort, they can also ask for patients' consent. Furthermore, failing to use an informed consent process for the release of medical records containing genetic information may lead to an increased tendency toward "group think," such as overconfidence in interpreting often-ambiguous genetic information.[21] In such a situation, clinically useful information regarding genetic potential can be reduced to the equivalent of sound bites. When such clinically useful information is diluted in this way, the seeds of stereotyping and discrimination are sown. An ounce of genetic privacy, achieved via informed consent, is worth more than any pound of genetic discrimination cure tomorrow by the U.S. Equal Employment Opportunity Commission or the judiciary.

ACKNOWLEDGMENTS

The authors would like to thank Eric Drogin, Gary Zalkin, and Richard Sobel for their helpful editorial comments.

NOTES

1. M.A. Fauman, "Defining a DSM Infrastructure," *American Journal of Psychiatry* 163 (2006): 1873-4.

2. H.J. Bursztajn et al., *Medical Choices, Medical Chances: How Patients, Families, and Physicians Can Cope With Uncertainty* (New York: Routledge, Chapman & Hall, 1990); B. Woodward, "The Computer-Based Patient Record and Confidentiality," *New England Journal of Medicine* 333, no. 21 (1995): 1419-22.

3. W. Shakespeare, *Julius Caesar,* ed. J. Mobley (Chicago: Lorenz, 2006).

4. N.C. Manson, "What is Genetic Information, and Why is it Significant? A Contextual, Contrastive, Approach," *Journal of Applied Philosophy* 23, no. 1 (2006): 1-16.

5. H.J. Bursztajn and A. Brodsky, "Clinical dilemmas and interventions in caring for patients in managed health care," *General Hospital Psychiatry* 21 (1999): 239-48; *http://www.forensicpsych.com/articles/artCaptive2.html;* "Amicus Curiae brief for the Program in Psychiatry and the Law," *Citizens for Health v. Secretary of Health and Human Services* (U.S. No. 05-1311).

6. L. Low, S. King, and T. Wilkie, "Genetic discrimination in life insurance: empirical evidence from a cross sectional survey of genetic support groups in the United Kingdom," *British Medical Journal* 317 (1998): 1632-5.

7. S.E. Taylor et al., "Early Family Environment, Current Adversity, the Serotonin Transporter Promoter Polymorphism, and Depressive Symptomatology," *Biological Psychiatry* 60 (2006): 671-6.

8. *Norman-Bloodsaw v. Lawrence Berkeley Laboratory,* 135 F.3d 1260 (9th Cir. 1998).

9. S.A. Alpert, "Protecting Medical Privacy: Challenges in the Age of Genetic Information," *Journal of Social Issues* 59, no. 2 (July 2003): 301-22.

10. R. Sobel and H.J. Bursztajn, "Ban Genetic Discrimination," *Boston Globe,* 7 August 2000, A15.

11. Bursztajn et al., *Medical Choices,* see note 2 above.

12. *EEOC v. Burlington N. Santa Fe Ry. Co.,* No. C 01-4013-MWB (ND Iowa 2001).

13. M.R. Anderlik and M.A. Rothstein, "Privacy and Confidentiality of Genetic Information: What Rules for the New Science?" *Annual Review of Genomics and Human Genetics* 2 (2001): 401.

14. S.L. Gilman, *Difference and Pathology: Stereotypes of Sexuality, Race, and Madness* (Ithaca, N.Y.: Cornell University Press, 1985).

15. A.G. Greenwald and M.R. Banaji, "Implicit Social Cognition: Attitudes, Self-Esteem, and Stereotypes," *Psychological Review* 102, no. 1 (January 1995): 4-27.

16. H.J. Bursztajn and A. Brodsky, "Authenticity and autonomy in the managed care era: forensic psychiatric perspectives," *The Journal of Clinical Ethics* 5 (1994): 237-42.

17. D. Kahneman and A. Tversky, "Prospect Theory: An Analysis of Decision under Risk," *Econometrica* 47, no. 2 (March 1979): 263-92.

18. D. Pirakitikulr and H.J. Bursztajn, "The

Grand Inquisitor's Choice: Comment on the CEJA Report on Withholding Information from Patients," *The Journal of Clinical Ethics* 17, no. 4 (Winter 2006): 307-11.

19. Bursztajn and Brodsky, see note 16 above.

20. S.G. Pauker and S.P. Pauker, "Privacy vs. Safety: Is the Tradeoff a Bug or a Feature of HIPAA," May 2004, *http://www.webmm.ahrq.gov/case.aspx?caseID=57.*

21. I. Janis, *Victims of Groupthink* (Boston: Houghton Mifflin, 1972).

Law

Legal Trends in Bioethics

Sigrid Fry-Revere,
with the research assistance of
John Joseph Leppard, IV, Molly Elgin,
William Bryce Hankins, III, and Scott Ryan Grandt

GENERAL INTRODUCTION

The laws governing bioethics issues are confusing and sometimes contradictory because of several types of tensions inherent in our legal system. Legislatures and courts work in different time frames and with different priorities. The U.S. constitutional guarantees of separation of church and state and individual rights make bioethics issues involving personal, moral, or religious convictions particularly contentious.

Each state also has its own constitutional protections, some of which clearly mirror those in the federal Constitution and others that don't.

Legislatures and courts play different roles in our constitutional republic. Legislatures are by nature democratic and can react relatively quickly to changes in the political climate. Courts, on the other hand, are inherently antidemocratic. As a matter of fact, their main constitutional function is to protect the rights established by our various constitutions from violation by legislative action. Courts are also inherently conservative in their reaction to events because they are bound by precedents and procedural processes that are designed to assure that major philosophical changes happen gradually.

Legislatures and courts, in the area of bioethics, also act under the existence of two contrary presumptions. Legislatures tend to act with a presumption in favor of prevailing moral beliefs. The courts, on the other hand, have the structural and theoretical obligation to protect individuals from majoritarian decisions that unnecessarily violate their constitutionally protected freedoms. They also have an obligation to uphold the separation of church and state.

Readers who learn of cases, laws, or regulations that they would like reported in this column are encouraged to e-mail Sigrid Fry-Revere at *sfryrevere@cato.org.*

Sigrid Fry-Revere, PhD, JD, is Director of Bioethics Studies at the Cato Institute, Washington, D.C., *sfryrevere@cato.org.* **John Joseph Leppard, IV, Molly Elgin, William Bryce Hankins, III,** and **Scott Ryan Grandt** are Interns at the Cato Institute.

So, in bioethics cases, courts often have to deal with preventing governments, either through legislation or other state action, from imposing moral or religious preferences on individuals who might not agree. Thus courts tend to show greater deference to individual choice than legislatures do, and tend to become more cautious the more divisive the issue.

An understanding of these inherent tensions between legislative and judicial action and the various individual interests being balanced by the courts will make it easier to understand legal trends in bioethics.

Please note that cases, laws, and regulations listed in earlier columns will not be repeated unless there has been a change in status since the last reporting period. Updates on previously reported cases, laws, and regulations are marked with an asterisk (*).

INTRODUCTION TO *JCE* SUMMER 2007

The most significant development reported here actually took place after the January to March reporting period for this issue, but it is nevertheless included, given its importance. The U.S. Supreme Court ruled on *Gonzales v. Carhart* on 18 April 2007. Both the ruling and the dicta in this case will have far-reaching implications in years to come, not only for abortion rights, but for the medical profession as a whole.

The Court's specific ruling was that the federal Partial-Birth Abortion Ban Act of 2003 was constitutional. In so ruling, it held that any law restricting abortion rights would pass constitutional muster as long as it was reasonable. This is a lower standard than the heightened scrutiny standard the Court applied in earlier abortion cases, and it shifts the burden from the government having to prove a law doesn't violate rights to the citizens who feel their rights have been violated. This will make it harder for individuals who believe their rights have been violated to succeed.

In arriving at its ruling, the Court expanded the government's role in regulating the physician-patient relationship. The following are a few quotes from the majority opinion that could be used by legislatures and courts to "second guess" a physician's medical judgment. The opinion states, "There can be no doubt the government 'has an interest in protecting the integrity and ethics of the medical profession.' " Citing *Washington v. Glucksberg,* 521 U.S. 702, 731 (1997). It is hard to imagine what types of laws and regulations could not be justified on such grounds. The opinion also states, "The State has an interest in ensuring so grave a choice is well informed." It is easy to imagine other grave medical choices in which the State may have an interest. It is reasonable, the Court tells us, for Congress to regulate a procedure that "undermines the public's perception of the appropriate role of a physician during the delivery process, and perverts a process during which life is brought into the world." This could easily be just as true of end-of-life decisions as of those made at the beginning. Finally, we are told, "Considerations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends." This suggests legislatures and courts can restrict the use of medical procedures on moral or other reasonable grounds even if the alternatives are not quite as safe. See "The Rights of Maturing Individuals and Their Parents" below for more detail on the *Carhart* decision.

Another issue that has received considerable attention is whether or not vaccination against the human papillomavirus (HPV) should be mandatory. Most of the bills on this topic have stalled because someone has raised at least one of the following objections: (1) vaccination against a sexually transmitted disease might increase promiscuity, (2) the vaccine has been insufficiently tested, and/or (3) the mandate is being encouraged for political/financial reasons rather than true concern for the health of young women. The motives of some legislators were impugned when it was discovered that Merck, the sole manufacturer with FDA approval to market an HPV vaccine, had not only been actively lobbying to have the vaccine mandated,

but that the company had also made campaign contributions to politicians who could be influential in getting such mandates passed. Furthermore, some legislators were clearly supporting a mandate so that the federal government, which helps pay for mandatory childhood vaccines, would pick up at least part of the tab for state vaccination programs.

Other significant developments include an increased effort on the part of legislatures to grapple with how to solve the organ shortage and the ethics of stem-cell research. It is interesting to note how different the approaches can be from state to state.

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

PRE-BIRTH (ABORTION, FETUSES, EMBRYOS, AND STEM CELLS)

Abortion is clearly on the minds of U.S. lawmakers and courts. There has been a staggering surge in abortion-related legislation introduced in this legislative session, and at this writing the U.S. Supreme Court has just handed down its ruling in *Gonzales v. Carhart.*

Most of the legislative measures listed below are considered "anti-abortion" measures, but please note that there were almost as many typically called "pro-choice" measures introduced. Many pro-choice measures aren't listed because they involve funding educational programs and access to medical services for poor women. Such measures are certainly of interest, but, because of sheer volume, this report focuses only on bills that either curtail or increase rights independent of financial ability to pay.

It is worth paying careful attention to the terms used in each of the bills. For example, bills defining personhood at fertilization could, in addition to affecting abortion rights, potentially also lead to the prohibition of certain contraceptives and/or infertility treatments. And bills banning cloning could, in addition to banning cloning for purposes of human reproduction, also ban embryonic stem-cell research involving somatic cell nuclear transfer.

Finally, please note that the abortion debate is waged on several fronts, so also see sections below on "Informed Consent" and "Conscientious Objections" for more abortion-related cases, laws, and regulations.

Recent Cases, January 2007 - March 2007

***Federal.** Although this decision was handed down outside the time frame of the "Legal Trends" for the summer issue of *JCE,* I could not let this column go to press without including the most important abortion decision in decades. On 18 April 2007, the U.S. Supreme Court handed down its ruling in the combined cases of *Gonzales v. Carhart* and *Gonzales v. Planned Parenthood.* They are cited only by the name of the first case. The Court overturned two circuit court decisions and found the Partial-Birth Abortion Ban Act of 2003 constitutional. The federal act in question is now the law of the land. No state can allow Partial-Birth Abortions unless it is to save the life of the woman having the procedure.

The Federal Act. The Partial-Birth Abortion Ban Act of 2003 is very specific regarding what type of abortion procedure is prohibited. Not all D&Es are prohibited, only "intact D&Es," also known as "dilation and extraction," "D&X," or "intact D&X." The act is also very specific about the criteria for violations to exist. The *alive* fetus must have been delivered to the point where its entire head is outside the body of the mother, or, in the case of a breech presentation, any part of the fetal trunk past the navel is outside the mother before it is killed by an *overt* act of the healthcare professional doing the abortion. Any procedure in which the fetus has not been delivered to these anatomical benchmarks is not prohibited. Note, since the fetus must be alive when it reaches the indicated anatomical landmarks, an intact D&E in which the fetus is dead before it reaches these landmarks is not prohibited. Further, since the healthcare provider must have the intention of performing an intact D&E, there is no liability if the procedure accidentally becomes an intact D&E. The intention issue is a difficult one, because some procedures

are typically followed right from the beginning of the procedure only if an "intact" D&E is intended. The act's language and the Court's interpretation of the act seem to define an "intact" D&E as one that has reached the specified landmarks; however, this leaves open the possibility that there is such a thing as what might be technically an "intact" D&E that is not illegal because the required anatomical benchmarks have not been reached. Finally, it is important to note that the act specifically excludes the abortion recipient of any potential liability under the act. Partial-Birth Abortion Act of 2003, 18 U.S.C. § 1531 (2000 ed., Supp. IV).

The Court's Majority Opinion. The federal Partial-Birth Abortion Ban Act of 2003 is constitutional. The decision was 5 to 4. Justice Anthony Kennedy wrote the opinion joined by Chief Justice John Roberts and Justices Antonin Scalia, Clarence Thomas, and Samuel Alito. The majority opinion found that the act is not void for vagueness, not invalid on its face, and does not impose an undue burden due to overbreadth. This is the first time since *Roe v. Wade* that the Court has upheld a restriction on abortion that does not include an exception for the health of the mother. The major significance of this ruling is the deference it shows legislative action. The opinion states:

> We assume the following principles for the purposes of this opinion. Before viability, a State may not prohibit any women from making the ultimate decision to terminate her pregnancy. It also may not impose upon this right an undue burden, which exists if a regulations' purpose or effect is to place a substantial obstacle in the path of a woman seeking an abortion before the fetus attains viability. On the other hand, regulations which do no more than create a structural mechanism by which the State, or the parent or guardian of a minor, may express profound respect for the life of the unborn are permitted, if they are not a substantial obstacle to the woman's exercise of the right to choose.
>
> . . .
>
> The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it.
>
> . . .
>
> Where it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn.
>
> . . .
>
> Considerations of marginal safety, including balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends. [Citations and internal quotation marks omitted.]

In addition to a clear deference to legislative action, the majority opinion also shows a lack of deference to individual healthcare providers and their ability to judge what is in the best interest of patients.

The Court's Dissenting Opinion. Justice Ruth Bader Ginsburg wrote a dissenting opinion in which Justices John Stevens, David Souter, and Stephen Breyer joined. Those dissenting would have found the act unconstitutional. The opinion criticizes the majority for relying on "rational grounds" for upholding state action when in earlier cases the Court has used the standard of "heightened scrutiny." They also object to the majority's deviation from *Casey. Planned Parenthood of Southeastern Pa. v. Casey,* 505 U.S. 833 (1992). In that case, the Court ruled that "state regulation of access to abortion proce-

dures, even after viability, must protect the health of the woman" (internal quotation marks omitted). The dissenters argue that the majority's deference to the legislature in overriding constitutional rights deteriorates the gains U.S. society has made in recognizing women as protected by that Constitution and as individuals with the full rights of citizenship.

> There was a time, not so long ago, when women were regarded as the center of home and family life, with attendant special responsibilities that precluded full and independent legal status under the Constitution. Those views, this Court made clear in *Casey,* are no longer consistent with our understanding of the family, the individual, or the Constitution. Women, it is now acknowledged, have the talent, capacity, and right to participate equally in the economic and social life of the Nation. Their ability to realize their full potential, the Court recognized, is intimately connected to their ability to control their reproductive lives. Thus, legal challenges to undue restrictions on abortion procedures do not seek to vindicate some generalized notion of privacy; rather, they center on a woman's autonomy to determine her life course, and thus to enjoy equal citizenship stature.
>
> In keeping with this comprehension of the right to reproductive choice, the Court has consistently required that laws regulating abortion, at any stage of pregnancy and in all cases, safeguard a woman's health. [Citations and internal quotation marks omitted.]

The As-Applied Challenge. The majority opinion states the act would be unconstitutional if it exposed women to significant health risks. The Court did not find that a prohibition against intact D&Es created such a risk, but it did acknowledge that "preenforcement, as-applied challenges to the Act," could be filed as a proper way to protect the health of women should there be "discrete and well defined instances a particular condition has or is likely to occur" where use of intact D&E must be used to protect the health of the mother. While the majority opinion allows for such challenges, it is unclear what such a lawsuit would look like. The dissent asks, "Surely the Court cannot mean that no suit may be brought until a woman's health is immediately jeopardized by the ban on intact D&E." *Gonzales v. Carhart,* 550 U.S. ___(2007). I'm sure the answer will be forthcoming soon, since lawsuits challenging the act on as-applied basis are undoubtedly already being planned.

Arizona. On 23 January 2007, a state court of appeals unanimously upheld a lower court ruling that the state county sheriff's policy of only transporting female inmates to medical facilities for abortions when medically necessary was an unconstitutional burden on the right to an abortion. Defendants are seeking an appeal. *Doe v. Arpaio,* Ariz. S. Ct., 1 CA-CV 05-0835; 2007 Ariz. App., LEXIS 8 (23 Jan. 2007).

***California.** A unanimous California Court of Appeals affirmed the lower court's ruling as to the validity of California's Proposition 71. Proposition 71, approved by California ballot initiative during the 2004 general election, provides $3 billion in funding for stem-cell research over 10 years. *California Family Bioethics Council v. Independent Citizen's Oversight Committee,* Cal. Ct. App., No. A114195, 2/26/07; *People's Advocate v. Independent Citizens Oversight Committee,* Cal. Ct. App., No. A114282, 2/26/07. Plaintiffs are planning to appeal. Tansey, Bernadette, "Court Backs Stem Cell Funding Plan: Research Money From Prop. 71 Still Held Up Pending Appeals," *San Francisco Chronicle,* 22 April 2007; *http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2006/04/22/MNGH9IDLVO1.DTL,* accessed 23 April 2007.

***Kansas.** Potential action. State Attorney General Phill Kline has twice tried to file charges against physician George Tiller for allegedly performing 15 illegal late-term abortions in 2003. Each time, the criminal charges were thrown out by Sedgwick County, Kansas, District Judge Paul Clark on jurisdictional grounds, that is, Kline doesn't have authority to file such charges. Kline promises to continue to investigate. Phill Kline lost the Kansas Attorney Gen-

eral race in November 2006 to Democrat Paul Morrison, a vehement supporter of abortion. *http://www.lifesite.net/ldn/2006/nov/06110904.html,* accessed 11 April 2007. See related legislation under Kansas below.

***Michigan.** The Michigan Civil Rights Commission issued a declaratory ruling in August 2006 that prescription contraceptives must be covered by employers who provide prescription drug coverage in their health plans. Not to do so is a violation of the Elliott-Larsen Civil Rights Act, which prohibits sex-based discrimination. The ruling allows an exception for nonprofit "religious employers." *Michigan Civil Rights Commission, Declaratory Ruling on Contraceptive Equity,* 21 August 2006 at *http://www.chetlyzarko.com/Declaratory%20Ruling %207-26-06.pdf,* accessed 25 January 2007.

New Jersey. A suit was filed in State Superior Court of Essex County against the Metropolitan Medical Associates in Englewood by Rasheedah Dinkins who alleges that clinic physicians provided "negligent, careless and reckless care" because of alleged complications due to the abortion. After the procedure, she felt pains and went to Newark Beth Israel Medical Center where she was unconscious for more than three weeks, had two strokes, and underwent a hysterectomy. *Rasheedah Dinkins v. Metropolitan Medical Associates, Metropolitan Surgical Associates, Inc., Keith Gresham, M.D., Nicholas Kotopoulos, M.D.,* Esx. L-1688-07 (1 March 2007). Based on a complaint filed with the New Jersey Department of Health and Senior Services by Newark Beth Israel Medical Center, the abortion clinic was closed after an inspection revealed several health and record keeping violations that will need to be corrected before the clinic can reopen. R. Padawer, "From Abortion to 4-Week Coma, Case Triggered Probe, Closing of Englewood Clinic," *The Record,* 1 March 2007, pg. A01, accessed 27 April 2007.

Recent Laws and Regulations, January - March 2007

Alabama. Three bills were introduced in the state legislature to restrict abortions. One was introduced that defines personhood beginning at fertilization. A second, also in the state house, criminalizes abortions with the exception of cases where the woman's life is in danger or cases of rape or incest. A third, introduced in the state senate, would prohibit abortions except for the "extreme case where the pregnancy threatens the life of the mother." H.B. 128, H.B. 329, S.B. 59, 2007 Gen. Assem., Reg. Sess. (Ala. 2007).

A bill was introduced in the state house to prohibit the cloning of human beings. The Regenerative Medicine Enhancement Act would also provide for penalties and civil fines for violations. H.B. 28, 2007 Leg., Reg. Sess. (Ala. 2007).

Arizona. A bill was introduced in the state house making appropriations to the Department of Health Services for a regenerative tissue repository and for research in regenerative medicine involving non-embryonic stem-cell research. H.B. 2770, 48th Leg., 1st Reg. Sess. (Ariz. 2007).

Arkansas. A bill was introduced in the state house that would protect embryonic stem-cell research, including somatic cell nuclear transfer. The Regenerative Medicine Enhancement Act also bans human reproductive cloning. H.B. 2806, 86th Gen. Assem., Reg. Sess. (Ark. 2007).

California. The state assembly passed a bill that involves significant ongoing funding from the California General Fund in the form of grants to umbilical cord blood banks. A.B. 34, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

Colorado. Two bills were introduced in the state senate dealing with the personhood status of a fetus. One would make abortions criminal unless necessary to prevent the death of the mother. The other amends the state criminal code to define the fetus as a separate victim apart from its mother in homicide cases. S.B. 143, S.B. 71, 66th Gen. Assem., Reg. Sess. (Colo. 2007).

Connecticut. A bill was introduced in the state house to amend the state criminal code to include "unborn person" as a person under the code. H.B. 6067, Gen. Assem., Jan. Sess. (Conn. 2007).

Delaware. Two bills were introduced in the state legislature to encourage certain stem-cell research within ethical guidelines. The house

bill would allow research on donated embryos under 14 weeks old, ban human reproductive cloning, and establish a committee to develop and adopt guidelines for publicly funded research involving the derivation or use of human embryonic stem cells. The senate bill focuses on banning human reproductive cloning. H.B. 76, S.B. 5, 144th Gen. Assem., Reg. Sess. (Del. 2007).

Florida. Two virtually identical bills were introduced in the state legislature to amend the state criminal code to define an "unborn child" as a separate victim from the pregnant woman carrying the child. H.B. 71, S.B. 234, 109th Gen. Assem., Reg. Sess. (Fla. 2007).

Two virtually identical bills were introduced in the state legislature to establish the Stem Cell Research and Ethics Advisory Council. The "Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act" provides for both a donated funds program and a research grant program from the Biomedical Research Trust Fund. Funding is limited to adult stem cells, amniotic, cord blood, and placental stem cells and does not include embryonic stem cells. H.B. 1065, S.B. 2496, 2007 Leg., Reg. Sess. (Fla. 2007).

Two virtually identical bills were introduced in the state legislature to allow funds from the Biomedical Research Trust Fund to be used on embryonic stem cells. H.B. 555, S.B. 0750, 2007 Leg., Reg. Sess. (Fla. 2007).

Georgia. A state house resolution was introduced in the state house to place on the November 2008 ballot an initiative that would define personhood as beginning at fertilization. There is no language in the bill indicating exceptions when an abortion might be permitted. H.R. 536, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

A bill was introduced in the state house that would impose a near total criminal ban on abortion. The bill provides for an exception if a physician makes a medically justified effort to save the lives of both the mother and the fetus and the fetus does not survive. The bill also provides for a penalty of life in prison or the death penalty for both women and doctors found in violation of the law. H.B. 1, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

A bill was introduced in the state senate to establish the Newborn Umbilical Cord Blood Bank to encourage non-embryonic stem-cell research. S.B. 148, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Hawaii. Two virtually identical bills were introduced in the state legislature that would ban partial-birth abortions. H.B. 787, S.B. 129, S.B. 129, H.B. 787, 24th Leg., Reg. Sess. (Haw. 2007). (The bills are no longer necessary since the U.S. Supreme Court in *Gonzales v. Carhart* upheld the federal ban on partial-birth abortions.)

Two bills were introduced in the state senate to amend the state criminal code to consider the "unborn child" as a separate victim in an assault against a pregnant woman. S.B. 206, S.B. 1903, 24th Leg., Reg. Sess. (Haw. 2007).

Two bills were introduced in the state house that would permit all forms of stem-cell research. The state house version has been referred to committee. The senate version has been deferred until next year's session. H.B. 364, H.B. 1261, 24th Leg., Reg. Sess. (Haw. 2007).

***Illinois.** Two bills were introduced in the state house in December 2006: The first would allocate $25 million annually for the next five years to stem-cell research, including embryonic stem-cell research. The second would ban human cloning and the sale of human embryos. These bills died at the end of the session. H.B. 1039, H.B. 1038, 94th Gen. Assem., Reg. Sess. (Ill. 2006).

A bill was introduced in the state senate that would ban abortions at as early as 12 weeks. There is no exception for protecting the mother's life or health after the 12th week of pregnancy. S.B. 100, 95th Gen. Assem., Reg. Sess. (Ill. 2007).

A bill was introduced in the state house to allow pharmacies to dispense emergency contraceptives to women without a prescription. H.B. 1077, 95th Gen. Assem., Reg. Sess. (Ill. 2007).

Kansas. Two bills were introduced in the state legislature to amend the definition of person for purposes of the criminal code to include

"unborn child." H.B. 2006, S.B. 2, 82nd Leg., Reg. Sess. (Kan. 2007).

The Kansas House Federal and State Affairs Committee voted to approve a resolution that would force Attorney General Paul Morrison to reinstate the criminal charges against physician George Tiller for allegedly performing illegal late-term abortions. See original legal action reported above. H.R. 6018, 82nd Leg., Reg. Sess. (Kan. 2007).

Five bills were introduced in the state house that relate to stem-cell research. The first would ban somatic cell nuclear transfer. The second would ban the funding of embryonic stem-cell research. The third would ban the creation of chimeras. The fourth encourages non-embryonic stem-cell research by offering a 50 percent tax credit for donations to the adult stem-cell research fund. And the fifth would ban cloning. H.B. 2252, H.B. 2255, H.B. 2403, H.B. 2291, H.B. 2098, 82nd Leg., Reg. Sess. (Kan. 2007).

Kentucky. Two abortion-related bills were introduced in the state legislature. A house bill would "ban state constitutional protection for a woman's right to choose." A senate bill would amend existing abortion waiting requirements to require a 24-hour period between when a woman receives state-mandated information and performance of the abortion procedure. H.B. 251, S.B. 179, 2007 Leg., Reg. Sess. (Ky. 2007).

Massachusetts. Two bills were introduced in the state legislature to repeal a pre-*Roe v. Wade* criminal ban on abortion. H.B., 173, S.B. 831, 185th Gen. Assem., Reg. Sess. (Mass. 2007).

***Michigan.** Four bills were introduced in the state legislature to codify the above described Michigan Civil Rights Commission's declaratory ruling into law. H.B 4295, H.B. 4296, S.B. 41, S.B. 42, 94th Leg., Reg. Sess. (Mich. 2007).

A bill introduced in the state senate would allow for embryonic stem-cell research by amending the current state code to allow the use of human embryos for non-therapeutic research. S.B. 52, 94th Leg., Reg. Sess. (Mich. 2007).

Minnesota. Three bills were introduced in the state legislature to place an initiative on the ballot for November 2008 to amend the state constitutional provision protecting a woman's right to choose an abortion. S.B. 1235, S.B. 1234, H.B. 2378, 85th Gen. Assem., Reg. Sess. (Minn. 2007).

Mississippi. A bill was signed into law by the governor that would implement a near total ban on abortions in Mississippi in the event that *Roe v. Wade* is ever overturned by the U.S. Supreme Court. The law would only allow abortions in the case of rape, incest, or to prevent the mother's death. S.B. 2391, 2007 Reg. Sess. (Miss. 2007).

Missouri. A bill was introduced in the state house to ban abortions in all cases except when the woman is in danger of death. H.B. 990, 94th Gen. Assem., Reg. Sess. (Mo. 2007).

Nevada. A bill was introduced in the state senate to amend the state criminal code to include "unborn child" as a separate victim apart from the pregnant woman. S.B. 299, 74th Gen. Assem., Reg. Sess. (Nev. 2007).

New Hampshire. A bill was introduced in the state house to amend the state homicide code to include "unborn child" as a possible victim. H.B. 177, 160th Gen. Assem., Reg. Sess. (N.H. 2007).

New York. Two bills were introduced in the state legislature to amend the criminal code to include "unborn child at any stage of gestation" in the definition of person. S.B. 3117, A.B. 5777, 230th Gen. Assem., Reg. Sess. N.Y. 2007).

Three bills were introduced in the state legislature that would allow nurses and pharmacists to dispense emergency contraceptives without a prescription. S.B. 3579, S.B. 1940, A.B. 5569, 230th Gen. Assem., Reg. Sess. (N.Y. 2007).

A bill was introduced in the state senate authorizing stem-cell research, requiring informed consent, and prohibiting human reproductive cloning. S.B. 01257, 230th Reg. Sess. (N.Y. 2007).

A bill was introduced in the state senate to create the New York Stem Cell Research Institute. S.B. 02923, 230th Reg. Sess. (N.Y. 2007).

North Carolina. Two bills were introduced in the state legislature to amend the criminal code of North Carolina to include "unborn child" as a separate victim than the pregnant

woman carrying the child. H.B. 263, S.B. 295, 148th Gen. Assem., 2007 Sess. (N.C. 2007).

A bill was introduced in the state senate that would appropriate $8 million to the Wake Forest Soldier Regenerative Medicine Institute for stem-cell research. S.B. 715, 148th Gen. Assem., 2007 Sess. (N.C. 2007).

North Dakota. A bill was introduced in the state house to impose a total ban on abortions. H.B. 1489, 61st Gen. Assem., Reg. Sess. (N.D. 2007). Another bill was introduced that would impose a similar ban but allows an exception if the woman's life is in danger. H.B. 1466, 61st Gen. Assem., Reg. Sess. (N.D. 2007).

A bill was introduced in the state senate that defines personhood as beginning at fertilization. S.B. 2400, 61st Gen. Assem., Reg. Sess. (N.D. 2007).

A bill was introduced in the state house that bans abortions except if the woman's life is in danger but would only go into effect if *Roe v. Wade* is overturned by the U.S. Supreme Court. H.B. 1466, 61st Gen. Assem., Reg. Sess. (N.D. 2007).

Oklahoma. A bill was introduced in the state house that would make the state's pre-*Roe v. Wade* abortion ban enforceable if the case is overturned. In the meantime it would ban all abortions unless the mother's life is in danger. H.B. 1014, 51st Gen. Assem., Reg. Sess. (Okla. 2007).

Two bills were introduced in the state legislature that prohibit the distribution of mifepristone, a medical abortion pill. S.B. 715, H.B. 2181, 51st Gen. Assem., Reg. Sess. (Okla. 2007).

A bill was introduced in the state senate to allow government officials to search offices and medical files of abortion providers without cause, warrant, or announcement. S.B. 617, 51st Gen. Assem., Reg. Sess. (Okla. 2007).

A joint resolution was introduced in the state legislature that would allow researchers to perform any stem-cell research permitted under federal law, but the measure also bans cloning. H.J.R. 1010, 51st Leg., 1st Sess. (Okla. 2007).

Oregon. Three bills were introduced in the state house to amend the state criminal code definition of a human being to include "unborn child." H.B. 3272, H.B. 3240, H.B. 2802, 74th Leg. Assem., Reg. Sess. (Or. 2007).

The state house passed a bill amending existing emergency room law to allow dispensing emergency contraceptives to women over 18 without a prescription. H.B. 2154, 74th Leg. Assem., Reg. Sess. (Or. 2007).

A bill was introduced to establish the Human Stem Cell Research Committee and the Human Stem Cell Research Fund. The committee would create guidelines for stem-cell research, while the fund would obtain public and private funds for the purpose of dispensing grants. H.B. 2801, 74th Leg. Assem., Reg. Sess. (Or. 2007).

Two bills were introduced in the state house that would make human cloning a crime. H.B. 2662, H.B. 2929, 74th Leg. Assem., Reg. Sess. (Or. 2007).

Pennsylvania. A bill was introduced in the state senate to amend the state criminal code to include "unborn child" as part of the definition of person. S.B. 589, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

Rhode Island. Two bills were introduced in the state house to amend the state criminal code to include "unborn child" in the definition of "another." H.B. 5261, H.B. 5234, Gen. Assem., Jan. Sess. (R.I. 2007).

Two bills were introduced in the state legislature that would make the protections under *Roe v. Wade* permanent. S.B. 119, H.B. 5462. Gen. Assem., Jan. Sess. (R.I. 2007).

South Carolina. Four bills were introduced in the state legislature defining personhood as beginning at fertilization. H.B. 3284, H.B. 3697, S.B. 313, S.B. 3815, 117th Gen. Assem., 1st Reg. Sess. (S.C. 2007).

Two bills were introduced in the state house that would define person to include "unborn child" under the state's civil and criminal codes. H.B. 3019 (civil), H.B. 3171 (criminal), 117th Gen. Assem., 1st Reg. Sess. (S.C. 2007).

A bill was introduced in the state senate to allow embryonic stem-cell research but banning the buying and selling of pre-implantation embryos. The Biotechnology Act of 2008 would also ban human cloning. S.B. 0173, 117th Gen. Assem., 1st Reg. Sess. (S.C. 2007).

South Dakota. A bill passed the state house that would impose a ban on abortions except when the mother's life is in danger or in cases of incest or rape. If enacted by the state senate and signed by the governor, the measure will be automatically included on the 2008 general election ballot. H.B. 1293, 82nd Leg. Sess. (S.D. 2007).

Texas. Two bills were introduced in the state legislature that ban abortions unless necessary to prevent a woman from dying. This law would take effect if *Roe v. Wade* is overturned by the Supreme Court. H.B. 175, S.B. 186, 80th Leg. (Tex. 2007).

Five bills and a resolution were introduced in the state legislature relating to stem-cell research. Two identical bills ban human cloning and other uses of human tissue by institutes of higher education, but do not restrict nuclear transplantation to develop therapies. Another also bans cloning more generally. A fourth bill would create a program to provide grants and loans to institutions of higher education and advanced medical research facilities to conduct stem-cell research. And a house bill would establish the Texas Institute of Regenerative Medicine, authorize the issuance of bonds for the purposes of the institute, and prohibit the legislature from prohibiting stem-cell research. H.B. 1829, S.B. 56, H.B. 2704, H.B. 1486, H.B. 537, H.J.R. 43, 80th Leg. (Tex. 2007).

Utah. A bill was introduced in the state house to ban all abortions except if the woman's life is in danger, certain limited health circumstances, and if the pregnancy is a result of rape or incest. Law becomes effective if *Roe v. Wade* is overruled. H.B. 235, 57th Leg., Gen. Sess. (Utah 2007).

Virginia. A bill was introduced in the state house that would ban abortions except to prevent the death of the mother. The law would go into effect if the U.S. Supreme Court overturns *Roe v. Wade.* H.B. 2124, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

A bill was introduced in the state house that defines personhood as beginning at fertilization. H.B. 2797, 2007 Gen. Assem., Reg. Sess. (Pa. 2007).

Two bills were introduced in the state house that would amend homicide laws to allow fetuses or "unborn children" to be considered victims of a crime separate of the pregnant women who carry them. H.B. 1631, H.B. 2532, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

Five bills were introduced in the state house regarding stem-cell research. Two would allow embryonic stem-cell research within the guidelines established by an oversight committee established by the bills. A third would assure returns on venture capital investments in biotechnology. A fourth provides funding for stem-cell research. And a fifth offers a tax credit for contributions to stem-cell research. H.B. 2857, H.B. 1768, H.B. 1697, H.B. 1939, H.B. 2820, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

Washington. Two bills were introduced in the state house relating to stem-cell research. One creates a human stem-cell research advisory committee and establishes funding for stem-cell research. Another would restrict funding to research not involving somatic cell nuclear transfer. H.B. 1163, H.B. 173, 60th Leg., Reg. Sess. (Wash. 2007).

West Virginia. Three bills were introduced in the state legislature to ban abortions. One would ban all abortions with no health exception. The other two would ban abortions as early as 12 weeks with no exceptions. H.B. 2036 (general ban), H.B. 3058, S.B. 695 (after 12 weeks), 78th Leg., Reg. Sess. (W. Va. 2007).

A bill was introduced in the state house to include "unborn child" as part of the definition of "human being" for purpose of the state homicide laws. H.B. 2140, 78th Leg., Reg. Sess. (W. Va. 2007).

Wyoming. A bill was introduced in the state senate that would amend state homicide laws to include an "unborn child" as a separate victim from the pregnant woman carrying the child. S.B. 118, 59th Leg., Reg. Sess. (Wyo. 2007).

Interesting Developments in Other Countries

Mexico. Lawmakers in Mexico City are considering legalizing abortions within the first

three months of pregnancy. Hector Tobar, "Mexico City Lawmakers Begin Hearings on Bill that Would Allow Abortion During First Three Months' Gestation," *Los Angeles Times,* 29 March 2007.

Rwanda. Lawmakers are considering a measure that would limit couples to three children. "Rwandan Lawmakers Drafting Measure That would Limit Couples to Three Children, Official Says," *Reuters South Africa,* 15 February 2007.

AFTER BIRTH (PREMATURE INFANTS, NEWBORNS, AND CHILDREN)

The battle over abortion continues to cause fluctuations in the specific requirements for parental consent and notification laws. It is worth asking whether these debates adequately consider the best interests of the young women affected. More than half of the U.S. states require parental consent before a minor can get a tattoo or a body piercing. In some of those states, no such consent is required for an abortion. Is there, or can there be, any consistent criteria for determining when a minor is old enough to make decisions on his or her own? Should the seriousness, the inherent health risk, or the permanence of the decision play a role in determining whether notice or consent is required? If yes, then do these factors make notice and consent requirements more or less reasonable?

Recent Cases, January 2007 - March 2007

***Illinois.** The Illinois Supreme Court issued rules necessary to implement the state Parental Notice of Abortion Act. Ill. S. Ct. M.R. 21173 in January. But the act still remains unenforceable. The state's attorney general has filed a motion to have those rules put in place, but the matter is still pending.

***Missouri.** Case pending. In *Planned Parenthood of Kansas and Mid-Missouri, Inc., et al. v. Jeremiah W. (Jay) Nixon, et al.,* the Missouri Supreme Court heard arguments challenging the Missouri parental consent law that gives parents and prosecutors the right to sue adults who help minors get an abortion without complying with state parental consent laws, which require either direct parental consent or court approval. The challenge is based on whether the "aid and assist" language in the law includes speech, and therefore is a violation of state-protected right to free speech. The case was heard 15 November 2006. A decision is expected at some point before the end of the summer. *Planned Parenthood of Kansas and Mid-Missouri, Inc., et al. v. Jeremiah W. (Jay) Nixon, et al.,* No. SC87321 (Motion filed 13 November 2006).

Recent Laws and Regulations, January - March 2007

Connecticut. A bill was introduced in the state house that mandates parental notice prior to a minor obtaining an abortion. H.B. 5807, Gen. Assem., Jan. Sess. (Conn. 2007).

Georgia. A bill was introduced in the state house that would require parental notice before minors could receive contraception. H.B. 526, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Hawaii. Three bills were introduced in the state legislature requiring parental notice, and one requiring parental consent before a minor can obtain an abortion. H.B. 786, S.B. 1904, S.B. 205, H.B. 788, 24th Leg., Reg. Sess. (Haw. 2007).

Missouri. A bill was introduced in the state house to require parental consent for access to contraceptives. H.B. 617, 94th Gen. Assem., Reg. Sess. (Mo. 2007).

New Hampshire. A bill passed the state house and is now before the state senate to repeal existing parental notification laws. H.B. 184, 160th Gen. Assem., Reg. Sess. (N.H. 2007).

New York. Two abortion consent-related bills were introduced in the state assembly. One would require parental notice and the other parental consent prior to a minor receiving an abortion. A.B. 2560, A.B. 3217, 2007-2008 Gen. Assem., Reg. Sess. (N.Y. 2007).

North Carolina. Two abortion consent-related bills were introduced in the state legislature. The house bill would require parental notice when minors were granted access to contraceptives. The senate bill would require that parental consent to an abortion be either personally signed or notarized. H.B. 103, S.B. 481, 148th Gen. Assem., Reg. Sess. (N.C. 2007).

Oregon. A bill was introduced in the state house to require parental notice prior to a minor receiving an abortion. H.B. 3234, 74th Gen. Assem., Reg. Sess. (Ore. 2007).

Tennessee. Two bills were introduced in the state legislature to require parental notification when a minor seeks an abortion. H.B. 1441, S.B. 1795, 105th Gen. Assem., Reg. Sess. (Tenn. 2007).

Vermont. A bill was introduced in the state house to mandate parental notice before a minor receives an abortion. H.B. 473, 69th Leg., Reg. Sess. (Vt. 2007).

Washington. A bill was introduced in the state house that would mandate parental notice before a minor could receive an abortion. H.B. 1321, 60th Leg., Reg. Sess. (Wash. 2007).

West Virginia. Seven bills were introduced to modify parental notice laws. Two eliminate the option that parental notice can be given by phone and increase the waiting period between notice and the abortion procedure to 48 hours. A third requires that parental notice be notarized. A fourth requires written parental consent. A fifth allows a physician bypass provision but requires 48 hours notice. And two eliminate the physician bypass option and modify the time in which a judge must rule if a minor seeks waiver of the notice requirement — one lengthens the period from 24 hours to three days, the other lengthens the period to five days. H.B. 3128, S.B. 544 (48 hour prior notice; no phone notice); H.B. 3187 (notarized parental notice); H.B. 2219 (written parental consent); H.B. 2037 (allows a physician bypass 48 hour notice); H.B. 2151 (3 days), S.B. 72 (5 days), 2416 78th Leg., Reg. Sess. (W. Va. 2007).

VACCINES

Mandatory childhood vaccine is one of those issues in which the rights of parents and the state sometimes collide. There is a growing general mistrust of both pharmaceutical companies and the government, leading some parents to question their motives when issues involving mandatory childhood vaccine are raised. Some parents object on religious grounds, some on moral grounds, some because they see the specific vaccination program under discussion as a waste of money, some because they believe the drug hasn't been tested enough, and others because they simply feel it is their prerogative as parents to decide. All these issues are being raised with respect to mandating the HPV vaccine, and many legislators who originally rushed to introduce bills to mandate the vaccine are now having second thoughts.

Recent Laws and Regulations, January - March 2007

Federal. The Centers for Disease Control and Prevention (CDC) adopted the recommendation of its Advisory Committee on Immunization Practices to routinely give the human papillomavirus (HPV) vaccine to girls/women between the ages of nine and 26. John Abramson, the chair of this committee, has stated publicly that he does not support mandating the vaccine. See *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm,* accessed 27 April 2007; Gregory Lopes, "CDC Doctor Opposes Law for Vaccine," *Washington Times,* 27 February 2007, *http://www.washtimes.com/business/20070226-115014-2031r.htm,* accessed 27 April 2007.

In the U.S. House of Representatives a bill was introduced that would prohibit federal funds to be used by states who make the HPV vaccine mandatory. H.R. 1153, 110th Cong. (1st Sess. 2007).

Arkansas. On 26 March a state senate committee voted down a bill that would have restricted the amount of mercury allowed in vaccines. S.B. 911, 86th Gen. Assem., Reg. Sess. (Ark 2007).

California. A bill was introduced in the state assembly that would require all girls entering the sixth grade to receive the HPV vaccine. The bill includes an opt-out provision. A.B. 16, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

Colorado. The state house committee approved a bill that would require middle school girls to receive the HPV vaccine. The bill includes an opt-out provision and requires health insurers to cover the cost of HPV vaccines. H.B. 1301, 66th Gen. Assem., 1st Reg. Sess. (Colo. 2007).

Connecticut. Three HPV-related bills were introduced in the state legislature. One would require all 12-year-old girls to be vaccinated. A second would require the state's insurance program to cover HPV vaccines for low-income families. And a third would require the health department to develop HPV immunization standards. H.B. 6085, H.B. 5485, S.B. 86, 2007 Gen. Assem., Jan. Sess. (Conn. 2007).

District of Columbia. The city council voted to preliminarily approve a bill that would require girls entering the sixth grade to receive the HPV vaccine. The provision has an opt-out provision. B17-0030, 17th Council Period (D.C. 2007).

Florida. A bill was introduced in the state house to require all girls entering the sixth grade to receive the HPV vaccine. There is an opt-out provision. H.B. 561, 2007 Leg., Reg. Sess. (Fla. 2007).

Georgia. A bill was introduced in the state house to require all girls entering the sixth grade to receive the HPV vaccine. There is an opt-out provision. 2007. S.B. 155, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Indiana. A bill was signed by the governor on 26 March 2007 that requires school systems to report the number of girls who have received the HPV vaccine. S.B. 327, 115th Gen. Assem., 1st Reg. Sess. (Ind. 2007).

Kansas. A bill was introduced in the state house that would require all girls entering the sixth grade in the state's public schools to receive an HPV vaccine. The bill includes an opt-out provision. H.B. 2227, 82nd Leg., Reg. Sess. (Kan. 2007).

Kentucky. The state house passed a bill that would require middle school girls to receive the HPV vaccine. The bill includes an opt-out provision. H.B. 345, 2007 Leg., Reg. Sess. (Ky. 2007).

Maryland. A bill was signed by the governor that would establish a HPV vaccine subcommittee in the Cervical Cancer Committee of the Maryland Comprehensive Cancer Control Plan; provide for the membership and duties of the HPV vaccine subcommittee; and require the HPV vaccine subcommittee to submit an annual report to the Cervical Cancer Committee by 1 September 2007. H.B. 1049, 2007 Gen. Assem., 423rd Sess. (Md. 2007).

Massachusetts. The governor announced a plan that would make the HPV vaccine both optional and fully funded by the state as part of this year's budget proposal; *http://www.medicalnewstoday.com/medicalnews.php?newsid=64304,* accessed 27 April 2007.

Michigan. Two bills were introduced in the state house dealing with HPV vaccines. One would require parents to provide school officials with a statement from a physician indicating whether or not a sixth grade girl has received an HPV vaccine. The other would mandate the vaccine, but also includes an opt-out provision. H.B. 4164, H.B. 4140, 94th Leg., Reg. Sess. (Mich. 2007).

Minnesota. Lawmakers in both chambers introduced bills to mandate the HPV vaccine for all girls ages 12 and older. Both bills have opt-out provisions. H.B. 530, S.B. 243, 85th Leg., Reg. Sess. (Minn. 2007).

Nevada. A bill was introduced in the state senate that would require insurance companies to cover the cost of HPV vaccinations. S.B. 409, 74th Gen. Assem., Reg. Sess. (Nev. 2007).

New Mexico. A bill was passed by the state legislature that would require all girls entering the sixth grade to receive an HPV vaccine, but the bill was "pocket vetoed" by Governor Richardson on 17 March 2007. S.B. 1174, 48th Leg., 1st Sess. (N.M. 2007).

New York. A bill was introduced in the state senate that would require the HPV vaccine for females born after 1 January 1996. The bill includes an opt-out provision. S.B. 4394, 2007 Leg., 230th Reg. Sess. (N.Y. 2007).

Ohio. A bill was introduced in the state house that would require girls entering sixth grade to be vaccinated against HPV. The bill has an opt-out provision. H.B. 81, 127th Gen. Assem., Reg. Sess. (Ohio 2007).

South Dakota. The governor signed into law a bill that provides $9.2 million to voluntarily vaccinate at no cost to South Dakota's females between the ages of 11 and 18. H.B. 1061, 82nd Leg. Sess. (S.D. 2007); act of 26 March 2007, ch. 201, 2007 S.D. Laws (to offer an HPV vaccine

initiative, transfer funds, and declare an emergency).

Texas. The governor mandated by executive order that all girls entering the sixth grade receive the HPV vaccine, but that order is being challenged by the legislature and the Texas Attorney General. Tex. Exec. Order RP65, 2 February, *http://www.governor.state.tx.us/divisions/press/exorders/rp65,* accessed 27 April 2007.

Vermont. A bill was introduced in the state house that would require girls entering the sixth grade to be vaccinated against HPV. The bill does include an opt-out provision. H.B. 256, 69th Leg., 2007 Sess. (Vt. 2007).

Virginia. The governor signed into law a bill requiring all sixth grade girls to be vaccinated against HPV. The bill includes an opt-out provision. The bill was chaptered on 11 April 2007. H.B. 2035, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

INFORMED CONSENT

There have been many questions of late regarding the risks and benefits of vaccines and whether certain vaccines should be mandated, or if just the information parents need to make an informed choice should be mandated. Those vaccine-related laws are reported here, but abortion-related laws dominate the informed consent section of this issue of "Legal Trends." Since the Supreme Court's decision in *Carhart,* a proliferation of state laws governing the informed consent process can be expected. States have required specific disclosures during the informed consent process before, but I predict that they will rely on *Carhart* to greatly increase their interventions in the physician-patient relationship, particularly where abortions and end of life decisions are concerned.

Recent Cases, January 2007 - March 2007

Eighth Circuit Court of Appeals. In *Planned Parenthood Minn. v. Rounds,* the court of appeals (Minnesota, Nebraska, North Dakota, South Dakota, Eastern and Western Districts of Arkansas, Northern and Southern Districts of Iowa, Eastern and Western District of Missouri) enjoined the implementation of amendments to an **Ohio** state abortion law requiring that special informed consent provisions be met unless the abortion is necessary due to medical emergency. The special provisions in question require abortion providers to notify patients that "the abortion will terminate the life of a whole, separate, unique, living human being" and to certify that the pregnant woman has read, and that the physician believes her to understand, the information imparted. Plaintiffs sought the injunction, claiming the law compelled providers to articulate the state's abortion ideology and philosophy in violation of the First and Fourteenth Amendments. The injunction prevents enforcement of the law while it is adjudicated. The court simultaneously enjoined a similar **South Dakota** law. 467 F.3d 716; 2006 U.S. App. LEXIS 26914 (30 October 2006). The 8th U.S. Circuit Court of Appeals agreed to hear the case on 11 April 2007.

***Louisiana.** In *Brown v. Louisiana, State of,* the Louisiana Court of Appeals reversed and remanded a trial court's summary judgment. The court found that a failure to inform a patient of more conservative medical approaches to a hysterectomy could be a violation of informed consent, justifying damages for negligence. The issue needs to go to a jury and cannot be decided by summary judgment. The case was returned to the district court for jury selection and awarding of damages. A hearing is scheduled for 29 June 2007. No. 06-709 (La. Ct. App. 2 November 2006).

***Texas.** In *Gray v. Woodville Health Care Center,* the Court of Appeals of Texas, Eighth District, held that a family didn't have a case for malpractice or wrongful death. The court did not discuss informed consent or the meaning of "hospice" care, but analyzed the case purely along traditional notions of malpractice. The facts, however, clearly indicated a misunderstanding as to the meaning of "hospice" care. The family consented to having the patient transferred to hospice, but was shocked to find that the patient died the day after transfer; in their minds it was negligent for the patient's physician to order most treatments stopped in

conjunction with the transfer. 2006 Tex. App. LEXIS 6904 (3 August 2006). Petition for review was denied by *Gray v. Evans.* 2007 Tex. LEXIS 18 (5 January 2007).

A lawsuit was filed alleging that Governor Rick Perry violated state law by exceeding his authority when he mandated that Texas sixth graders be vaccinated against the HPV vaccine. *John and Jane Does 1-3 v. Rick Perry,* 1d. No. 07-000-553 (Travis County, Texas; filed 22 February 2007).

Recent Laws and Regulations, January - March 2007

Connecticut. Three abortion-related bills were introduced in the state legislature. A house bill would require that prior to the performance of an abortion, a physician or counselor must provide the woman seeking an abortion with an ultrasound photograph of the fetus for the purpose of helping women make informed decisions about abortion. Two senate bills would assure that sexual assault victims receive information about and access to emergency contraception. H.B. 6108, S.B. 1343, S.B. 685, Gen. Assem., Jan. Sess. (Conn. 2007).

Florida. Two virtually identical bills were introduced in the state legislature to assure that sexual assault victims receive information about and access to emergency contraception. H.B. 1191, S.B. 1156, 109th Gen. Assem., Reg. Sess. (Fla. 2007).

Georgia. A bill passed the state house that would require every woman seeking an abortion to undergo and review an ultrasound of her fetus before an abortion may be performed. After passing, it was sent to the senate, which made the ultrasound or sonogram voluntary; however, the physician must either offer to perform one or provide the patient with a list of providers, facilities, and clinics that can perform the procedure. The senate is insisting upon its version, which the house is now considering. 147, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Hawaii. Four bills were introduced in the state legislature to assure that victims of sexual assault receive information and access to emergency contraceptives. H.B. 762, H.B. 466, S.B. 1110, H.B. 1067, 24th Leg., Reg. Sess. (Haw. 2007).

Indiana. Two bills were introduced in the state senate to amend the language of current abortion informed consent requirements. Both laws also require an 18-hour mandatory waiting period between the time when the woman receives such information and the actual abortion procedure. S.B. 172, S.B. 135, 115th Gen. Assem., Reg. Sess. (Ind. 2007).

Kentucky. A bill requiring physicians to provide a patient with information pertaining to fetal pain at various stages of an abortion procedure passed the state senate on 1 March 2007 and has been delivered to the House Committee on Health and Welfare. Specifically, the bill would require physicians to administer anesthetic to a fetus of 20 weeks gestational age or older prior to performing an abortion and include fetal pain information as part of the informed consent process. Under the bill, any violation of these requirements is a Class D felony. S.B. 80, 2007 Leg., Reg. Sess. (Ky. 2007).

Maine. A bill was introduced in the state legislature to increase awareness about cervical cancer and the HPV vaccine. L.D. 137, 123rd Leg., Reg. Sess. (Me. 2007).

Massachusetts. A bill was introduced in the state house to amend existing pre-abortion requirements to require a 24-hour period between when a woman receives state-mandated information and performance of the abortion procedure. H.B. 1687, Gen. Assem., Reg. Sess. (Mass. 2007).

Minnesota. Two bills were introduced in the state legislature that would assure that sexual assault victims receive information and have access to emergency contraceptives. S.B. 1266, H.B. 1442, 85th Gen. Assem., Reg. Sess. (Minn. 2007).

Missouri. A bill was introduced in the state house that would require women to view an ultrasound as part of the informed consent process prior to an abortion. H.B. 1225, 94th Gen. Assem., Reg. Sess. (Mo. 2007).

New Hampshire. A bill was introduced in the state house that requires specific content for informed consent disclosure prior to an abor-

tion and a 24-hour waiting period between when the woman receives such information and the procedure. H.B. 744, 160th Gen. Assem., Reg. Sess. (N.H. 2007).

New York. A bill was introduced in the state assembly to create provisions for advance directives concerning the disposition of cryopreserved embryos and gametes. A.B. 2531, 2007 Leg., 230th Reg. Sess. (N.Y. 2007).

A bill was introduced in the state assembly that requires specific informed consent and a 20-hour waiting period between when a woman receives the required information and the abortion procedure. A.B. 5720, 230th Gen. Assem., Reg. Sess. (N.Y. 2007).

North Carolina. The state senate passed a bill that requires school officials to provide the parents and guardians of children in grades five through 12 information about the HPV vaccine. S.B. 260, 148th Gen. Assem., 2007 Sess. (N.C. 2007).

Two bills were introduced in the state legislature to assure that victims of sexual assault receive information and access to emergency contraception. H.B. 961, S.B. 968, 148th Gen. Assem., 2007 Sess. (N.C. 2007).

Oklahoma. A bill was introduced in the state senate that would assure that victims of sexual assault receive information and access to emergency contraceptives. S.B. 105, 51st Gen. Assem., Reg. Sess. (Okla. 2007).

Oregon. A bill was introduced in the state house that dictates the content of informed consent and requires that there be a 24-hour waiting period between when information is disclosed and an abortion procedure. H.B. 3415, 74th Leg. Assem., Reg. Sess. (Or. 2007).

Pennsylvania. Two bills were introduced in the state legislature to assure that victims of sexual assault receive information about and access to emergency contraceptives. H.B. 288, S.B. 730, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

Rhode Island. Two bills were introduced in the state legislature that would require specific information to be disclosed during the informed consent process and a 24-hour waiting period between such disclosure and the abortion procedure. H.B. 5849, S.B. 472, Gen. Assem., Jan. Sess. (R.I. 2007).

South Carolina. A bill was introduced in the state house requiring a 24-hour waiting period between required informed consent disclosure and the abortion procedure. H.B. 3766, 117th Gen. Assem., 1st Reg. Sess. (S.C. 2007).

Another pair of bills was introduced that would require women who are seeking abortions to view an ultrasound of their baby as part of the informed consent process. S.B. 84, H.B. 3355, 117th Gen. Assem., 1st Reg. Sess. (S.C. 2007).

South Dakota. A bill passed the state senate that allows a healthcare facility to refrain from providing emergency contraception or even information about emergency contraception. S.B. 187, 82nd Leg. Sess. (S.D. 2007).

Tennessee. Two bills were introduced in the state legislature to ensure that sexual assault victims receive information about emergency contraceptives, but the bill does not require the provision of emergency contraceptives, and it includes exemptions from the rule for certain hospitals. H.B. 1989, S.B. 2073, 105th Gen. Assem., Reg. Sess. (Tenn. 2007).

Texas. A bill was introduced in the state senate that requires doctors to tell women seeking an abortion that the state will pay them $500 if they choose to put their child up for adoption instead of having an abortion. S.B. 1567, 80th Leg. (Tex. 2007).

A bill was introduced in the state house to ensure that sexual assault victims receive information and access to emergency contraceptives. H.B. 2161, 80th Leg. (Tex. 2007).

Virginia. A bill was introduced in the state house that requires specific disclosure as part of informed consent and a 24-hour waiting period between disclosure and an abortion procedure. H.B. 2301, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

A bill passed the state house that requires all women considering an abortion to undergo an ultrasound. H.B. 2808, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

West Virginia. A bill was introduced in the state house to modify existing informed con-

sent requirements and require a 24-hour waiting period between disclosure and an abortion procedure. H.B. 2439, 78th Leg., Reg. Sess. (W. Va. 2007).

A bill was introduced in the state house that requires all women seeking an abortion to undergo an ultrasound procedure, whether medically indicated or not. H.B. 2031, 78th Leg., Reg. Sess. (W. Va. 2007).

A bill was introduced in the state house to assure that sexual assault victims receive information and have access to emergency contraceptives. H.B. 2134, 78th Leg., Reg. Sess. (W. Va. 2007).

Wyoming. A bill was introduced in the state house that would require specific informed consent and a 24-hour waiting period between disclosure and an abortion procedure. H.B. 144, 59th Leg., Reg. Sess. (Wyo. 2007).

ORGAN AND TISSUE PROCUREMENT

Recent Cases, January 2007 – March 2007

***Federal.** Ongoing case. The Eighth U.S. Circuit Court of Appeals (Minnesota, Nebraska, North Dakota, South Dakota, Eastern and Western Districts of Arkansas, Northern and Southern Districts of Iowa, Eastern and Western District of Missouri) in *Wash. U. v. Catalona* is reviewing the lower court's ruling that Washington University in St. Louis owned the tissue samples that William J. Catalona, MD, had collected for prostate cancer research while at the university. The U.S. District Court for the Eastern District of Missouri held that the informed consent documents signed by Catalona's patients, which specifically gave the doctor the patients' tissue samples and included the patients' right to withdraw from the study and request that their tissue samples be destroyed, were "inconsequential" in its decision to grant full property rights to the university. Appeal No. 06-2286 (8th Cir. 15 May 2006). The case was argued 13 December 2006. A decision should be forthcoming shortly. Appeal No. 06-2286 (8th Cir. 13 December 2006).

California. San Louis Obispo police and the Medical Board of California are investigating a transplant surgeon for allegedly hastening the death of a patient in order to harvest his organs more quickly. Hootan Roozrokh, MD, is being investigated for violating a California law that prohibits transplant surgeons from directing the care of potential donors while the patient is still in treatment. Roozrokh allegedly directed the administration of "excessive" doses of pain medication while the potential organ donor was still in the operating room. The case was referred to the San Louis Obispo District Attorney and it is currently under review; as yet, no formal charges have been filed.

***Massachusetts.** Ongoing case. In *Gonzales et al. v. Katz et al.,* a probable case of first impression, an organ bank is being sued because the recipient of an organ contracted a rare form of cancer, allegedly from the organ supplied by the bank. Both the recipient and the donor died of the same rare form of cancer. In this part of the case, the court refused to dismiss the case on grounds that the good faith immunity provision of the Massachusetts Promotion of Anatomical Science Act did not apply in this case. The act does not apply to the clinical process by which the medical suitability of organs is determined but rather to those authorizing and receiving anatomical gifts. 21 Mass. L. Rep. 351; 2006 Mass. Super. LEXIS 358 (Mass. Super. Ct. 19 July 2006). A hearing was held on 11 April 2007 to refine the issues to be addressed. The firm representing the plaintiff is in the process of issuing depositions. A hearing is expected later this summer.

Recent Laws and Regulations, January - March 2007

Federal. The Charlie Norwood Living Organ Donation Act, which clarifies that "paired donations" do not violate the National Organ Procurement Act's prohibition against receiving "valuable consideration" for organs, passed in the U.S. House and was placed on the Senate Legislative Calendar on 14 March 2007. H.R. 710, S. 487, 110th Cong. (1st Sess. 2007).

The Centers for Medicare and Medicaid Services (CMS) announced on 22 March 2007 new rules that would withhold Medicare funding

from transplant programs that were "poor or marginal performers." These regulations will be effective as of 28 June 2007. 42 *CFR* Parts 405, 482, 488, and 498.

The United Network for Organ Sharing (UNOS) is drafting a proposal to maximize the number of years of life gained from donated kidneys by favoring younger recipients over older ones. Once finalized, this proposal would need to be approved by the Department of Health and Human Services (DHHS). Meckler, Laura, "Donor Organs May Go to Youngest On Wait List," *Associated Press,* 10 March 2007.

Arkansas. On 29 March 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. Ark. Stat. tit. 12, §§ 12-325 (2007).

Idaho. On 23 February 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. Idaho. Stat. tit. 39, § 3703 (2007).

Iowa. On 5 April 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. Iowa Stat. tit. 4, § 142(c).

***New Jersey.** A bill passed the state legislature that would require the New Jersey Motor Vehicle Commission to share organ donor information with federally designated organ procurement organizations. The governor has indicated that he will sign the bill. S.B. 1760, 211th Leg., Reg. Sess. (N.J. 2006)

Also in New Jersey, a bill was withdrawn from further consideration that would have amended the New Jersey Anatomical Gift Act to require that those involved in organ procurement not ask for an anatomical gift if they have reason to believe that the gift would be contrary to the decedent's wishes or religious beliefs. The amendment further would have barred the anatomical gift if a person who is listed in the state list of potential surrogates indicates that such a gift would be contrary to the decedent's wishes or religious beliefs. S.B. 2378, 211th Leg., Reg. Sess. (N.J. 2007)

New Mexico. On 3 April 2007 the 2006 Revised *Uniform Anatomical Gift Act* became law. N.M. Stat. tit. 7, § 7242 (2007).

North Dakota. On 9 April 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. N.D. Stat. tit. 23, § 0601 (2007).

***South Carolina.** A bill was introduced in the state senate that would require all patients to indicate, at the time of admission to a hospital, whether or not they are an organ or tissue donor, or both, and, if not, whether the patient or the patient's family would be willing to discuss organ or tissue donation, or both, should the patient become a potential donor during his or her stay in the hospital. The bill was referred to the Committee on Medical Affairs on 9 January 2007. S.B. 131, 117th Gen. Assem., Reg. Sess. (S.C. 2007).

A bill was introduced in the state senate that would allow prison inmates to donate organs and bone marrow in exchange for commuted sentences. S.B. 417, 117th Gen. Assem., Reg. Sess. (S.C. 2007).

South Dakota. On 26 March 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. S.D. Stat. tit. 34, § 2640 (2007).

Utah. On 7 March 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. Utah. Stat. tit. 26, § 2800 (2007).

Virginia. On 11 April 2007 the governor signed into law the 2006 Revised Uniform Anatomical Gift Act. Vir. Stat. tit. 32, §§ 1-290.

UNCONVENTIONAL TREATMENT

Recent Cases, January 2007 - March 2007

Federal. On 21 February 2007 a suit was filed by the Americans for Safe Access against the DHHS and the U.S. Food and Drug Administration (FDA) in an Oakland California federal district court for allegedly violating the federal Administrative Procedure Act by publicly releasing "false and misleading statements" about the benefits of the use of medical marijuana. The suit is calling for the DHHS and the FDA to retract and correct statements that there are no sound scientific studies supporting the medical use of marijuana. The government's response is due 25 May 2007. *Americans for Safe Access v. Department of Health and Human Services and Food and Drug Administration,*

No. 007-01049 (C.D. Ca., Filed 21 February 2007).

Recent Laws and Regulations, January - March 2007

Federal. The FDA is considering regulations to expand its current Compassionate-Use Programs that make experimental drugs available to individuals or groups under certain circumstances. The rules make drugs available during all stages of development, including during Phase I testing, and allow manufacturers to charge the cost of making and providing the drugs, but not to make a profit. Such regulations would allow patients to use drugs before safety trials have been completed (Phase I) and before testing for efficacy has even begun (Phase II). "Expanded Access to Investigational Drugs for Treatment Use," 71 *Fed. Reg.* 75147 (14 December 2006).

Rhode Island. The state legislature is considering a bill that will permanently legalize medical marijuana use in the state. Such use was already legal under a law passed in January 2006, but that law was set to expire on 30 June 2007 unless the legislature acted. H.B. 6005, Gen. Assem., Jan. Sess. (R.I. 2007).

Washington. A bill received its first reading in the Health Care and Wellness Committee on 18 January 2007 that requires the state department of health to determine the quantity of marijuana that could be considered a reasonable 60-day supply. The existing law, Initiative 692, passed with 59 percent voter approval in 1998. It allows doctors to recommend but not prescribe marijuana for people suffering from intractable pain, but only allows a 60-day supply to be possessed by any individual at one time. This bill is intended to create a clear line for law enforcement and individual patients. The bill is currently back in the senate to be voted on as amended by the house. H.B. 1395, 60th Leg., Reg. Sess. (Wash. 2007).

LIFE-AND-DEATH DECISIONS

Two major developments stand out in this area of the law for this quarter. The first is that several states have adopted, or are considering adopting, the new Uniform Anatomical Gift Act. Those new laws are reported under the "Organ and Tissue Procurement" section of this column. The other development is electronic registries for advance directives. Those laws, and some others of interest, are reported here.

Recent Cases, January 2007 – March 2007

Florida. On 20 March 2007, a Palm Beach County jury awarded $150,000 in damages to the family of a patient who was kept alive by artificial means contrary to the wishes expressed in her advance directive. *Linda Scheible, as Personal Representative of the Estate of Madeline Neumann, deceased v. The Joseph L. Morse Geriatric Center, Inc., Jaimy H. Bensimon, M.D.,* 21569 F. Supp. 919 (Fla. 2007).

***New York.** In *In re Guardianship of Chantel Nicole R,* the Supreme Court of New York, Appellate Division, First Department ruled that the Mental Hygiene Legal Service (MHLS) had the authority to commence a special proceeding to object to a mother of a mentally retarded child making medical decisions for her daughter concerning life-sustaining treatment. 821 N.Y.S.2d 194; 2006 N.Y. App. Div. LEXIS 10922 (21 September 2006). An appeal was dismissed without costs, by the court *sua sponte,* upon the grounds that no substantial constitutional question is directly involved. 8 N.Y.3d 840; 862 N.E. 2d 784; 2007 N.Y. LEXIS 107 (16 January 2007).

Recent Laws and Regulations, January - March 2007

California. A bill was introduced in the state assembly called the California Compassionate Choice Act. A.B. 374, 2007-2008 Leg., Reg. Sess. (Cal. 2007). The act would allow adults to request that medication be prescribed to provide comfort and to assure a peaceful death if suffering becomes unbearable. The act would also establish procedures by which to implement such requests.

***Georgia.** A bill passed in the state house that revises Georgia's advance directive laws. Among other things, the bill combines Georgia's

living will and durable power of attorney provisions into one form. The state senate added an amendment providing for the creation of a web site for the purpose of providing consumers information on the cost and quality of healthcare in Georgia. The senate passed an amended version of the bill. The senate version will still have to be approved by the house or some other compromise will be needed before this piece of legislation can be sent to the governor for signature. H.B. 24, H.B. 24/SCSFA/1, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Hawaii. A bill was introduced in the state house to allow aid in dying. It is stuck in committee and can no longer come to a vote this legislative session. H.B. 675, 24th Leg., Reg. Sess. (Haw. 2007).

Kansas. A bill was introduced in the state assembly that creates a presumption that all state residents would want artificial nutrition and hydration even if there are known desires to the contrary, unless there is clear and convincing evidence of an express, informed wish to withdraw nutrition and hydration in the "applicable circumstances." A.B. 2176, 82nd Leg., Reg. Sess. (Kan. 2007).

New Hampshire. A bill was introduced in the state house that prohibits lifesaving treatment from being withdrawn from developmentally disabled persons or persons who once were mentally competent but have lost that competency. Life-sustaining treatment could not be withdrawn even if the patient had previously indicated such wishes while competent. H.B. 244, 160th Gen. Court, Reg. Sess. (N.H. 2007).

A bill was introduced to require the original copy of an advance directive for it to be followed. H.B. 244, 160th Gen. Court, Reg. Sess. (N.H. 2007).

***New Jersey.** Two virtually identical bills were introduced in the state legislature that would require surrogate decision makers to make healthcare decisions in accordance with a patient's religious beliefs. A.B 3514, S.B. 2380, 212th Leg., Reg. Sess. (N.J. 2006).

***Texas.** A bill was introduced in the state senate that, among other things, provides for transferable physicians' orders, and prohibits healthcare providers or insurance companies from requiring advance directives as a condition for receiving healthcare services. S.B. 28, 80th Leg. (Tex. 2007).

A bill was introduced in the state house that clarifies that advance directives can be used to request continuation of life-sustaining treatment. H.B. 1094, 80th Leg. (Tex. 2007).

Vermont. The state legislature voted down the Patient Control at the End of Life Act. The act would have decriminalized aid in dying. H.B. 44, S.B. 63, 69th Leg., Reg. Sess. (Vt. 2007).

Wisconsin. A bill was introduced in the state senate that permits an individual, of sound mind and over 18 years of age, to request, in writing, medication from a physician for the purpose of ending his or her life. S.B. 151, 2007 Reg. Sess. (Wis. 2007).

Interesting Developments in Other Countries

Canada. Ramesh Sharma, MD, of Vernon, British Columbia, has pleaded guilty to counseling or aiding suicide under Sec. 241 of The Criminal Code of Canada. He could be imprisoned for up to 14 years. He will be sentenced on 11 June 2007. Hilary White, "Canadian Doctor Pleads Guilty to Attempted Assisted Suicide Charge," *LifeSiteNews.com,* 4 April 2007, accessed 28 April 2007.

THE RIGHT TO ACCESS AND CONTROL MEDICAL INFORMATION

Recent Cases, January 2007 – March 2007

***California.** Ongoing litigation. *Taus v. Loftus, et al.* is a case in which a child abuse victim gave permission (at age 17) — and so did her father — for the young woman to be interviewed, and for the taped interview to be shown for "educational purposes." A case study was published that referenced "Jane Doe," but other identifying information was disclosed about the young woman when the researcher gave presentations about the case, including videotaped interviews with the subject in which the subject's first name was used by the researcher, and the city where the subject lived as a child

was disclosed. Based on this information, in conjunction with information disclosed in the researcher's published case study, reporters discovered more about the case and published allegedly defamatory remarks about the subject and the researcher's claims regarding her recovery of repressed memories. 2005 Cal. App. Unpub. LEXIS 3048, 22 media L. Rep. 1545. *Taus v. Loftus, et al.,* 2006 CA S. Ct. S133805. On appeal, the opinion was affirmed in part and reversed in part, and the matter is remanded to the court of appeals for further proceedings. 2007 Cal. LEXIS 2340 (26 February 2007) (Case # S133805).

Recent Laws and Regulations, January - March 2007

Federal. A bill was introduced in the House that, among other things, will encourage the use of electronic health records. Hillary Rodham Clinton has pledged to reintroduce a similar bill in the Senate. H.B. 1952, 110th Cong. (1st Sess. 2007). Colby Itkowitz, "Clinton to Reintroduce Health IT, Respite Care Proposals," *Congressional Quarterly,* 17 February 2007, HealthBeat.

Connecticut. The state will use a $5 million grant to develop and implement an electronic health records system for 35,000 Medicaid beneficiaries. Abram Katz, "State switching to electronic med records," *New Haven Register,* 29 January 2007, *http://www.nhregister.com/site/index.cfm?newsid= 17777112&BRD=1281&PAG=461&dept_id=517515&rfi=8,* accessed 29 April 2007.

***Iowa.** A bill to implement electronic health records systems incrementally throughout the state died in committee. H.B. 2637, 81st Gen. Assem., 2nd Sess. (Iowa 2005).

Oklahoma. A bill was introduced to allow government officials to search offices and medical files of abortion providers without cause, warrant, or announcement. S.B. 617, 51st Gen. Assem., Reg. Sess. (Okla. 2007).

Vermont. The Vermont Department of Health has established an electronic registry for advance directives. The Vermont Advance Directive Registry can only be accessed by authorized healthcare providers, funeral directors, and crematory operators. Any information sent over the internet will be encrypted. Vt. Stat. Ann. tit. 18, § 231 (2007).

MEDICAL TESTING

Concerns about the disclosure of genetic testing and the effect such disclosures has prompted several lawmakers to introduce legislation to prevent genetic discrimination.

Please note there are also testing-related developments reported in the HIV section of this column.

Recent Laws and Regulations, January - March 2007

Federal. Two bills were introduced in Congress that would make it illegal for an employer or health insurer to access genetic information and then make either insurance coverage or decisions regarding the hiring, firing, or promotion of an employee based on such information. The House bill was passed and the Senate version is expected to pass shortly. H.B. 493, S.B. 358, 110th Cong. (1st Sess. 2007).

Connecticut. A bill was introduced in the state house that would require newborns be given a deoxyribonucleic acid (DNA) test and that the results be entered upon the birth record and shared with the child's parents. H.B 5743, 2007 Gen. Assem., Jan Sess. (Conn. 2007).

***Ohio.** A bill was introduced in the state house that would limit the liability of hospitals, among other things, for the genetic screening of newborns. The bill died at the end of the last general assembly. H.B. 692, 162nd Gen. Assem., Reg. Sess. (Ohio 2006).

New York. Two bills were introduced in the state legislature that would create a genetics advisory council. The council would be charged with advising the governor and legislature on issues relating to genetic tests, access to information, privacy, and counseling. A.B. 03284, S.B. 01633, 2007 Leg., 230th Reg. Sess. (N.Y. 2007).

DECISION-MAKING CAPACITY/ COMPETENCY

Recent Laws and Regulations, January - March 2007

***Federal.** The U.S. DHHS Centers for Medicare and Medicaid Services (CMS) published its final rule on patients' rights with respect to the use of restraints and seclusion on 8 December 2006. These rules became effective 6 February 2007 and apply to all participating Medicare and Medicaid hospitals, including short-term, psychiatric, rehabilitation, long-term, children's, and alcohol/drug treatment facilities. The rule expands the category of practitioners who may conduct patients' evaluations when restraint or seclusion is being used, and includes special notice requirements regarding patients' care, records, and the right to be free of the use of inappropriate restraints or seclusion. The rule also includes stricter reporting requirements for deaths associated with the use of restraints or seclusion. 71 *Fed. Reg.* 71378 (8 December 2006).

HOSPICE, PALLIATIVE CARE, AND PAIN CONTROL

Recent Laws and Regulations, January - March 2007

Federal. A bill was introduced in the U.S. Senate called the Unborn Child Pain Awareness Act. The act would require medical officials to notify expectant mothers seeking abortion that their unborn child may experience pain while in utero. The bill is currently in committee. S. 356, 110th Congress, Reg. Sess. (2007).

On 21 December 2006 President Bush signed into law the Lifespan Respite Act, which provides $289 million for training and recruiting workers and volunteers, and educating family caregivers about their services. "Bush signs Ferguson's respite care bill," *Associated Press,* 21 December 2006.

New York. A bill was introduced in the state assembly called the Palliative Care Education and Training Act, which provides funds to educate healthcare providers, among other things, about pain management. A.B. 2974, 2007 Leg., 230th Reg. Sess. (N.Y. 2007).

DEFINITION OF DEATH

Recent Cases, January 2007 – March 2007

***Texas.** *Grotti v. State of Texas,* 2006 Tex. App. Lexis 10018 (17 November 2006). The court overturned a jury verdict that held that a doctor had caused a patient's death by occluding the patient's endotracheal tube (ET) after 60 minutes of coding the patient with little success. At the time of the occlusion, the patient's respiration had slowed to three or four respirations per minute; she had no heart sounds or pulse, but some electrical activity on the monitor. The court found that (1) the evidence contrary to the verdict demonstrates that the patient experienced irreversible cessation of her spontaneous respiratory and circulatory functions prior to 21:50 (the time of the occulation), and (2) her respiratory efforts between 20:50 and 21:50 were insufficient to maintain life. It is pretty clear, given the facts of this case, that there wouldn't have been a trial if the defendant doctor had simply withdrawn the patient's ET tube, rather than holding her finger over it until the patient stopped moving. (The physician had occluded the ET tube for five minutes.) The case was remanded for a new trial.

OVERSIGHT: PATIENT TRUST

Recent Cases, January 2007 – March 2007

Federal. The Inspector General of the DHHS, Daniel Levinson, has reopened the cases of 103 National Institutes of Health (NIH) scientists, most of whom only received reprimands and warnings after an ethics probe in 2006 revealed possible conflict of interest. After the earlier probe, only a few scientists were sanctioned. One researcher pled guilty to a misdemeanor conflict of interest charge and was sentenced to forfeit $300,000 and to do community service.

Another was suspended from NIH work for 45 days. Some others received suspensions of just a few days. Criticism from members of the U.S. House Energy and Commerce Committee spurred Levinson to reopen the investigation. The inspector general has also agreed to review current conflict-of-interest policies regarding scientists who do not work at NIH but receive federal grant money.

Louisiana. The state supreme court vacated on 9 February 2007 two lower court rulings that the state's $500,000 cap on damages in medical malpractice lawsuits was unconstitutional. The court held the cap was not at issue and remanded the cases for further consideration on the appropriate questions. *Susan Arrington, et al. v. Galen-Med, Inc., et al.,* Nos. 06-C-2923, 06-C-2944, 06-C-2968 (La. 2007); *Charles and Sharon Taylor, Jr. v. Dr. Richard J. Clement and The Louisiana Patient's Compensation Fund,* Nos. 06-C-2518, 06-C-2581, 06-C-2600 (La. 2007).

Recent Laws and Regulations, January - March 2007

Federal. On 12 February 2007, a resolution was reintroduced that would create a "patients' bill of rights" that would allow patients to sue health-maintenance organizations for improper medical decisions. H.R. 979, 110th Leg., Reg. Sess. (2007).

The DHHS Office for Human Research Protections has released updated guidelines for clinical trials sponsored or supported by DHHS. Now all "unanticipated problems" must be reported. An unanticipated problem is a sub-class of adverse event. Most adverse events are not unanticipated. "An unanticipated incident, experience, or outcome will generally warrant consideration of substantive changes in the research protocol or informed consent process/ document or other corrective actions in order to protect the safety, welfare, or rights of subjects." An incident is an unanticipated problem "if it is of an unexpected nature, severity or frequency given the research procedures described in the IRB-approved research protocol or informed consent form and taking into account the characteristics of the subject population; if it is or may be related to participation in the clinical trial; and if it may place trial participants or others at greater risk of physical, psychological, economic or social harm than was previously known." "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events," 15 January 2007, *http://www.hhs.gov/ohrp/policy/ AdvEvntGuid.htm#Q1,* accessed 27 April 2007.

Alabama. A bill was introduced to require the reporting and disclosure of hospital infection rates, "Hospital Infections Disclosure Act." S.B. 409, 2007 Leg., Reg. Sess. (Ala. 2007).

Arkansas. The "Health Facility Infection Disclosure Act of 2007," that requires the reporting and disclosure of hospital infection rates, was signed into law on 3 April 2007. H.B. 2735, 86th Gen. Assem., Reg. Sess., (Ark. 2007).

***California.** A bill was introduced in the California Assembly to establish an Office of Patient Advocate in the State Department of Public Health. The bill passed out of the Health Committee on 7 March 2007 and was re-referred to the Appropriations Committee. It has not yet been scheduled for a hearing. 2007 Text A.B. 52 (4 December 2006); A.B. 52, 2007-2008 Gen. Assem., Reg. Sess. (Calif. 2007).

Delaware. A bill was introduced in the state house to require the reporting and disclosure of hospital infection rates. HB 47, 144th Gen. Assem., Reg. Sess. (Del. 2007).

Massachusetts. A bill was introduced in the state senate to require the reporting and disclosure of hospital infection rates. S.B. 1269, 185th Gen. Court, Reg. Sess. (Mass 2007).

Michigan. A bill was introduced in the state house to require the reporting and disclosure of hospital infection rates. H.B. 4158, 2007 Leg., Reg. Sess. (Mich. 2007).

Minnesota. A bill was introduced in the state house that would require the reporting and disclosure of hospital infection rates. H.F. 1076, S.F. 755, 85th Leg., Reg. Sess. (Minn. 2007).

Oregon. Two virtually identical bills were introduced in the state legislature that would

require the reporting and disclosure of hospital infection rates. H.B. 2524, S.B. 960, 74th Leg. Assem., Reg. Sess. (Or. 2007).

Texas. Two virtually identical bills were introduced in the state legislature that would require the reporting and disclosure of hospital infection rates. H.B. 1398, S.B. 288, 80th Leg. (Tex. 2007).

Washington. A bill passed the state legislature that would require the reporting and disclosure of hospital infection rates. The bill is currently awaiting the governor's signature. H.B. 1106, 60th Leg., Reg. Sess. (Wash. 2007).

HIV

Recent Cases, January 2007 – March 2007

California. On 13 April 2007 the California District Court dismissed a suit filed by the AIDS Healthcare Foundation against Pfizer in Los Angeles Superior Court for allegedly promoting the recreational use of its erectile dysfunction drug Viagra. The complaint alleges that the drug is portrayed as a "party drug" that can improve the sex life of healthy men and that such use is not approved by the FDA. *AIDS Healthcare Foundation v. Pfizer,* No. CV07-1154 (C.D. Cal. Filed 22 January 2007).

Recent Laws and Regulations, January - March 2007

Federal. In January a resolution was introduced in the U.S. House to allow the distribution of condoms in prisons. On 2 February the bill was referred to the Subcommittee on Crime, Terrorism, and Homeland Security. H.R. 178, 110th Leg., Reg. Sess. (2007).

By the end of 2007 all states and D.C. will be required to report their HIV cases by name, not anonymously, if they wish to receive funding from the DHHS under the Federal Ryan White Grant Program. 42 U.S.C. § 201.

The FDA is considering changing its policy that prohibits men who have sex with men from ever donating blood. The American Red Cross, the American Association of Blood Banks, and America's Blood Centers believe it would be more reasonable to prohibit such men from donating only if they have had sex with another man within 12 months instead of ever in their lifetime. *FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era,* Wednesday, 8 March 2006, Lister Hill Auditorium, National Institutes of Health, Bethesda, Maryland.

Arkansas. On 9 March 2007 the state legislature enacted a bill that would require state prison inmates to receive an HIV test before being released. H.B. 1444, 89th Gen. Assem., Res. Sess. (Ark. 2007).

California. A bill was introduced in the California Senate that would allow HIV-positive men to use their own sperm in fertility treatments. There is a process by which the sperm can be washed. S.B. 443, 2007-2008 Leg., Reg. Sess. (Calif. 2007).

Georgia. The state legislature passed a bill that would require doctors to offer all pregnant women an HIV test. Women can opt out of the test, but such refusal becomes part of their medical record. H.B. 429, 149th Gen. Assem., Reg. Sess. (GA 2007).

Illinois. A bill to allow condom distribution in prisons died in committee. H.B. 686, 95th Gen. Assem., Reg. Sess. (Ill. 2007).

Maine. A bill was introduced to amend the state's HIV testing laws to bring them in line with the September 2006 recommendations of the Centers for Disease Control and Prevention (CDC), which suggest that HIV testing become a part of routine medical care. The proposed Maine bill would drop the requirements for written consent and pre-test counseling that now exist under state law. The bill has an opt-out provision. S.P. 180, 123rd Maine Senate, Reg. Sess. (ME 2007).

Interesting Developments in Other Countries

Kazakhstan. In Kazakhstan, 21 doctors are on trial for medical malpractice because they provided HIV-tainted blood transfusions to 100 children at a children's hospital, who subsequently tested positive for HIV. Ilan Greenberg,

"Doctors, and a Medical Procedure, on Trial in Kazakhstan," *New York Times,* 20 March 2007, *http://web.lexis- nexis.com.spot.lib. auburn.edu /universe/document?_ m=60ed914f881f58e3cd 2100b490666e3d&_d,* accessed 25 April 2007.

Libya. Five Bulgarian nurses and a Palestinian doctor have filed an appeal with the Libyan Supreme Judiciary Council to overturn a death sentence handed down by a lower court. The healthcare workers were convicted of intentionally infecting 426 children at Al Fateh Children's Hospital in Benghzi Libya with HIV-contaminated blood products and were sentenced to death by firing squad. The Libyan Supreme Judiciary Council is the court of final appeal and is expected to render a decision this summer; *http://www.kaisernetwork.org/daily_ report.cfm?DR_ID=43062&dr_cat=1,* accessed 20 March 2007.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

U.S. conscientious objector laws have their routes in the U.S. Bill of Rights First Amendment Free Exercise Clause and variations thereon that exist in the states. The basic rule is that governments can't force individuals to do things they believe to be against their religion or to be otherwise immoral. Generally, an accommodation for those who raise a conscientious objection must be made unless their exercise of that freedom would directly put someone else at risk. This is why conscientious objection, which is rarely a problem in most contexts, can quickly become problematic in healthcare, where a person's access to care may be affected.

It is important to note that the prohibition is against governments, not private individuals, and perhaps the best first step toward dealing with such issues is through contract and notice. Healthcare providers can contract to have their moral views on certain issues respected by not requiring that they perform certain procedures or discuss certain medical options, but then patients need to be given notice of that particular healthcare provider's position or be provided access to a different non-objecting healthcare provider.

Recent Laws and Regulations, January - March 2007

Colorado. On 15 March 2007 the governor signed into law a bill which requires that sexual assault victims receive information about emergency contraceptives. Hospitals are not required to provide the contraceptives, but must provide information regarding such contraceptives. Pharmacies that do not wish to provide emergency contraceptives need not do so, but must post a sign stating that emergency contraceptives are not available through that pharmacy. There are also provisions allowing for individual conscientious objectors to provide information about emergency contraception. S.B. 60, 66th Gen. Assem., Reg. Sess. (Co. 2007).

Missouri. Four bills dealing with conscientious objections were introduced in the state legislature. The first two bills would allow pharmacists and related professionals to refuse to provide or dispense contraceptives in most circumstances. But the other two bills would require a pharmacist to fill any valid prescription. H.B. 412, S.B. 285, H.B. 156, S.B. 72, 94th Gen. Assem., Reg. Sess. (Mo. 2007).

A bill was introduced in the state house to allow for conscientious objection to participation in any medical services in most circumstances. The Missouri bill also allows insurance companies to refuse to provide coverage for any service that conflicts with the entity's policies. H.B. 434, 94th Gen. Assem., Reg. Sess. (Mo. 2007).

New York. Two bills were introduced in the state senate that would prohibit pharmacists from refusing to provide or dispense contraceptives in most circumstances. S.B. 2317, S.B. 2344, 230th Gen. Assem., Reg. Sess. (N.Y. 2007).

Oklahoma. A bill was introduced in the state senate that would require pharmacies and pharmacists to fill all valid prescriptions. S.B. 555, 51st Gen. Assem., Reg. Sess. (Okla. 2007).

Pennsylvania. Two bills were introduced in the state legislature that would require a pharmacy or pharmacists to fill valid prescriptions.

H.B. 730, H.B. 316, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

Rhode Island. A bill was introduced in the state senate that would allow healthcare providers to refuse to perform abortions or sterilizations on moral grounds. S.B. 452, Gen. Assem., Jan. Sess. (R.I. 2007).

Two bills were introduced in the state legislature that would allow certain individuals to refuse to perform any medical services in most circumstances. S.B. 452, H.B. 5274, Gen. Assem., Jan. Sess. (R.I. 2007).

South Carolina. Two bills were introduced in the state legislature that would allow certain individuals to refuse to participate in medical services in most circumstances and to allow pharmacists and related professionals to refuse to dispense contraceptives. H.B. 3283 (general), S.B. 126 (pharmacy related), 117th Gen. Assem., Reg. Sess. 117 (S.C. 2007).

Texas. Two bills dealing with conscientious objections were introduced in the state legislature. A house bill would allow pharmacists to refuse to provide or dispense contraceptives in most circumstances, and a senate bill would require pharmacists to fill all valid prescriptions. H.B. 589, S.B. 1591, 80th Leg. (Texas 2007).

Vermont. A bill was introduced in the state house that would allow certain individuals and entities to refuse to perform medical services under most circumstances. It also allows insurance companies to refuse to cover any services that conflict with the entities' conscience or religious beliefs. H.B. 315, 69th Gen. Assem., Reg. Sess. (Vt. 2007).

Virginia. A bill was introduced in the state house that would require pharmacies to fill valid prescriptions. H.B. 2842, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

West Virginia. Five bills dealing with conscientious objections were introduced in the state legislature. The first four bills would allow hospitals, pharmacists, and related professionals to refuse, under most circumstances, to dispense substances that could be used as part of an abortion-related procedure. The last bill would prohibit the same from refusing to provide or dispense contraceptives. H.B. 2903, S.B. 639 (hospitals), H.B. 2092, S.B. 743 (pharmacists), H.B. 2416, 78th Leg., Reg. Sess. (W. VA. 2007).

HEALTHCARE COVERAGE ISSUES

Recent Cases, January 2007 – March 2007

Federal. The **Eighth Circuit** Court of Appeals ruled on 15 March 2007 that the Union Pacific Railroad Company did not violate the Pregnancy Discrimination Act when it decided that its health plan would not cover the cost of contraception. The court ruled that the plan was not discriminatory because it did not pay for any form of contraception, whether used by men or women. *Brandi Standridge v. Union Pacific,* 479 F.3d; 2007 U.S. App. LEXIS 4914.

Recent Laws and Regulations, January - March 2007

Federal. A resolution was introduced in the U.S. House that would require insurers to cover mental illness at the same level as they cover physical illness. H.R. 1424, 110th Leg., Reg. Sess. (2007).

The DHHS Centers for Medicare and Medicaid Services (CMMS) is considering revising an earlier interim final rule that required documentation of citizenship before the infants of undocumented immigrants could receive Medicaid services.

A bill was introduced in the U.S. House that would provide universal health insurance to all U.S. residents. The AmeriCare Health Care Act would create AmeriCare, a program that would use Medicare to provide health insurance to U.S. citizens who don't receive coverage through their employers and whose annual income falls below 300 percent of the federal poverty level. H.R. 1841, 110th Leg., Reg. Sess. (2007).

Arizona. A bill was introduced in the state senate that would require the state to provide no-cost prenatal care to women whose household incomes are below 185 percent of the federal poverty level. This is an increase in cover-

age for those women with household incomes between 133 percent and 185 percent of the poverty level. S.B. 1361, 48th Leg., Reg. Sess. (Ariz. 2007).

Connecticut. A bill was introduced in the state house to implement universal healthcare coverage in Connecticut. H.B. 6655, 2007 Gen. Assem., Reg. Sess. (Conn. 2007).

Illinois. A bill called the "Illinois Healthcare For All Act" was introduced in the state senate to expand the state insurance plan. S.B. 5, 95th Gen. Assem., Reg. Sess. (Ill. 2007).

Minnesota. A bill was introduced in the state house that would provide universal health coverage by 2011. H.F. 1856, Leg. 85, Reg. Sess. (Minn. 2007).

Rhode Island. Regulations took effect on 1 April 2007 that would require state hospitals to provide care free of charge to any uninsured resident with an income at or below 200 percent of the federal poverty line. Stat. aait. 23, § 1714.

Virginia. A bill was introduced in the state senate that would require health insurers to cover the cost of stem cell transplants. S.B. 991, 2007 Gen. Assem., Reg. Sess. (Va. 2007).

Washington. Two bills were introduced in the state legislature that would phase in universal health coverage over a five-year period. S.B. 5930, H.B. 2098, 60th Leg., Reg. Sess. (Wash. 2007).

OWNERSHIP OF HUMAN GENETIC MATERIAL

Recent Laws and Regulations, January - March 2007

Federal. A resolution was introduced in the U.S. House that would prohibit the patenting of human genetic material. The Genomic Research and Accessibility Act was refereed to the Subcommittee on Courts, the Internet, and Intellectual Property. H.R. 977, 110th Leg., Reg. Sess. (2007).

Editorial Policy and Instructions for Authors

The Journal of Clinical Ethics accepts original manuscripts, case reports, commentaries, and letters to the editor. It is a double-blinded, peer-reviewed journal. Authors may contact the editorial staff from 9 a.m. to 3 p.m. Eastern Time weekdays at the following address:

The Journal of Clinical Ethics
219 West Washington Street
Hagerstown, Md. 21740 U.S.A.

Phone: (240) 420-0036
Fax: (240) 420-0037
E-Mail: *editorial@clinicalethics.com*

Manuscripts that have not been solicited by the journal will be reviewed by the editorial staff for general quality and suitability before they are sent to two reviewers. The review process generally requires six to eight weeks. The editorial staff may accept or reject manuscripts based on their quality, suitability, and the needs of the journal.

HOW TO SUBMIT A MANUSCRIPT

Submission of manuscripts to *The Journal of Clinical Ethics* should include the following items, sent to the address above:

- A cover letter,
- A word-processed file,
- Signed copyright release forms (mailed or faxed only),
- Copies of permissions to reproduce published material, when applicable.

A COVER LETTER

Authors should send a cover letter with their submission to the journal, which should include the following:

- The title of the article, which should be concise but informative,
- The name by which each author is known, with his or her highest academic degree(s) and institutional affiliation,
- The name of the department(s) and institution(s) to which the work should be attributed,
- Disclaimers, if any,
- The name, address, phone number, and e-mail address (if possible) of the author responsible for correspondence about the manuscript,
- Source(s) of support in the form of grants, equipment, drugs, or all of these,
- Acknowledgments (see below), if any,
- Permission to use cases, if any (see "Privacy" below).

A WORD-PROCESSED FILE

The journal uses IBM (PC)-based software; authors may mail disks with a word-processed version of their manuscript in PC WordPerfect or MSWord, or may e-mail a file attachment in these formats — or in Mac MSWord — to the editorial offices at the address above.

The names of the authors, their affiliations, or any acknowledgments or other information that will identify the authors must be removed from the word-processed file, including running headers or footers. Use one common font in a moderate size, for example, Times 10 point, throughout the article.

SIGNED COPYRIGHT RELEASE FORM(S)

The journal publishes materials that have not been published previously, and requires authors to assign copyright to the journal before the peer-review process begins. Should the manuscript not be accepted for publication, copyright will be returned to the author or authors. Authors retain the right to

use their materials in future projects. Each coauthor must sign a release form; authors in different locations may submit separate forms. Forms may be mailed or faxed; electronic signatures in e-mailed documents are not acceptable. Forms may be obtained from the editorial office or the journal's webpage, *www.clinicalethics.com*.

ETHICAL ISSUES

The Journal of Clinical Ethics acknowledges the continuing evolution of editorial ethics, and the editorial staff invites the discussion and development of the policies outlined below with its readers and the larger community.

ACKNOWLEDGMENTS

Authors should list contributors who do not meet the criteria for authorship, such as a person who provided purely technical help or writing assistance, or a department chair who provided only general support, in an acknowledgment. Financial and material support should be acknowledged, as should groups who contributed materially.

ADVERTISING

The journal does not accept paid advertising.

AUTHORSHIP

All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article. Those who have contributed only materially to the production of the manuscript should not be included as authors (see "Acknowledgments" above).

CONFLICTS OF INTEREST

Authors. Authors are responsible for recognizing and disclosing financial and other conflicts of interest that might bias their work. They should acknowledge in the manuscript all financial support to the work and any other financial or personal connections to the work. Authors have an ethical obligation to submit creditable manuscripts; as persons directly responsible for their own work, authors should not enter into agreements that interfere with their control over the decision to publish the manuscripts that they write.

Reviewers. External reviewers should disclose to editors any conflict of interest that could bias their opinion of a manuscript, and should disqualify themselves from reviewing a manuscript when appropriate. Reviewers should not use knowledge of a work before publication to further their own interests.

PERMISSION TO USE THE WORK OF OTHERS

Authors who use the written or graphic work of another must obtain permission from the owner of the work, and acknowledge the source fully. Submissions of manuscripts must include copies of written permission to reproduce published material, to use illustrations, report information about identifiable people, or to name people for their contributions. In submitting a manuscript, authors accept liability for any infringement of copyright and for any proceedings in damages against the publisher that may arise from the publication of their manuscript.

PRIVACY

Authors. The identity of authors and any identifying information are removed from manuscripts when sent for review. Manuscripts are reviewed with respect for authors' confidentiality and are privileged communications; the editorial staff will not disclose information about manuscripts to anyone other than a reviewer or the author.

Reviewers and the editorial staff will respect authors' rights by not publicly discussing their work or appropriating their ideas before a manuscript is published. Reviewers are not allowed to make copies of a manuscript for their files and may not share a manuscript with others, except with the permission of the editorial staff.

Patients and third parties. Patients and third parties have a right to privacy that must not be infringed without their informed consent. This right is in tension with the traditional and valuable use of the cases of actual patients. As always, the primary considerations are to promote the welfare of patients, respect patients as persons, and avoid causing harm — and also to further ethical discourse. *JCE* acknowledges that it is not always possible, or desirable, to obtain truly informed consent from patients or their families, and offers the following guidelines for authors.

- Information from an actual patient should be included only when it is essential to a case presentation; that is, when the use of a fictional case will not suffice. Authors may decide how and how much to alter information depending on

its critical relevance to the case. Authors should omit non-essential identifying detail, but also respect the life narrative of the patient, and avoid altering or falsifying information (fictionalizing or masking) without good reason.
- Authors must be cautious in seeking patients' consent, as some patients may feel used or manipulated at being the source of information in a case published by their careprovider.
- When it will not cause harm, authors should explain the use and function of actual cases with the patient (or parent, guardian, or surrogate) and obtain written informed consent from the patient (or representative) to publish details from the patient's life. These discussions should include eliciting the patient's preferences regarding how his or her personal information will be masked (if at all). A patient (or representative) who provides written consent should be allowed to review the case presentation before publication.
- Photographs must never be used without a patient's (or representative's) written informed consent.
- Authors who include a case presentation in a manuscript must include a statement, at the end of the article and before the end notes, that describes the extent to which the case has been masked or fictionalized, and whether written informed consent was obtained.
- Authors should include a copy of any written informed consent when their manuscripts are submitted for publication in the journal.
- The families of deceased patients have privacy rights. Authors should use the above points when fictionalizing, masking, or seeking permission to publish case information from a deceased patient's family members.

The Journal of Clinical Ethics has prepared worksheets and consent forms for authors to use in obtaining informed consent from patients, patients' representatives, and/or patients' families, which may be obtained from the editorial office using the contact information listed at the top of these instructions for authors.

Reviewers. Reviewers' identities are known to editorial staff, but are not revealed to authors without reviewers' permission. Unless reviewers give editorial staff permission to give an author their name, their identity will not be revealed to the author or to anyone else. Reviewers' comments may be sent to other reviewers of the same manuscript, and reviewers may be notified of the editor's decision regarding publication.

RESEARCH INVOLVING HUMAN SUBJECTS

When they report on research that involves human subjects, authors must indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human research. Authors may not use patients' names, initials, or hospital numbers, especially in illustrations, without the express written permission of these persons. See "Privacy: Patients and other third parties," above.

LETTERS TO THE EDITOR

Readers, authors, and others are invited to respond to articles and cases published in the journal as letters to the editor. The editorial staff reserves the right to make all decisions regarding materials that are included in the journal.

PEER-REVIEW PROCESS

The majority of articles published in *The Journal of Clinical Ethics* have been subjected to double-blinded peer review. That is, the manuscripts are reviewed by experts who agree to review materials for the journal without remuneration; some of the reviewers are members of the Editorial Board. Members of this Board receive a complimentary subscription to the journal but receive no other compensation.

"Double-blinded" means that the reviewers do not receive the names of the authors or their affiliations, and authors will not receive the names of reviewers, unless the reviewers give their explicit permission. The names of reviewers are not blinded to editorial staff. Manuscripts are assigned numbers, and their progress through the peer-review process is tracked using these numbers.

Some articles are invited by members of the Board of Editors, and, as a result, are not subject to the blinded peer-review process. They are reviewed by the Board of Editors.

The peer-review process typically takes six to eight weeks. At the end of this time, authors will receive notice regarding the status of their manuscript; typically, a decision will be one of the following:
- Accepted for publication as submitted.

- Accepted for publication pending minor revision by the author(s) as recommended by the reviewers.
- The reviewers have recommended major revision of the manuscript before it is considered for publication; the revised manuscript will reenter the review process after the major revision is completed; when possible, the original reviewers will review the revised manuscript.
- Not accepted for publication.

As stated above, the editorial staff may accept or reject manuscripts according to their suitability and the needs of the journal.

The editorial staff welcomes questions and comments, which may be addressed to Leslie LeBlanc, Executive Editor, at the address listed above.

REFERENCES

Citations to sources for direct quotations or facts that are not generally known or easily checked should be provided in end notes, in the format described in section 16.3 of *The Chicago Manual of Style*, 15th edition. *JCE* uses a modified version of the *Chicago* notes and bibliography system, in which the full citations are provided in end notes, but a bibliography is not included.

A brief description of this system follows. Authors should not use software functions to embed notes in the manuscript or to automatically number notes; instead, they should type the text of the notes at the end of the article, as regular text.

Note reference numbers in the text should be set as superior (superscript) numbers. In the notes, the note numbers should be full size and not superscripted. Authors should place note reference numbers in the text at the end of sentences, unless this would reduce clarity (for example, if there are two separate statements in a sentence that are supported by different sources).

Note reference numbers should be consecutive throughout the article, that is, the first note reference number is 1, the second is 2, and so on, with no number used more than once; that is, the same source may be listed several times; when it is, the author may use a shortened reference to the source (see note 3 below). When a statement is supported by more than one source, authors should include all of these sources in the same note, and separate the sources by a semicolon (see note 2 below). Authors should not list more than one note reference number at a single location in the text (that is, not [1,2] or [1-4]).

The full titles of journals should be used. If a source has more than four authors, only the name of the first author, followed by "et al.," should be listed (see note 2 below). Authors should be listed using their first and middle initials and last name. Examples of this system follow.

1. J.L. Smith, R.M. Miller, Jr., and W.C. Callahan, "Tracking the Virus in Africa: The Etiology of AIDS," Journal of AIDS Epidemiology 124, no. 6 (June 2006): 1147-59.

2. L. Greene and W.K. Nelson, "The Ethics of Care," in Principles of Nursing Science, vol. 2, ed. W.K. Nelson (Plano, Tex.: Nursing Administration Press, 2007): 122-4; T.M. McCall et al., "Cost-Effectiveness v. Total Patient Care: Who Wins?" Health Care Administration Quarterly 6, no. 2 (Summer 2007): 150-6.

3. See note 1 above, pp. 1127-8.

4. Ibid., 1148.

5. Greene and Nelson, "The Ethics of Care," see note 2 above.

Notes to tables and figures should be placed at the end of the table or figure and should be numbered independently from references in the general text and from other tables or figures. Tables and figures that are not the original work of the author must be acknowledged, and, when appropriate, authors must include written permission from the owner of that material to reproduce it in the journal. (See "Ethical issues: Permission to use the work of others," above.)

This statement draws upon materials developed by the International Committee of Medical Journal Editors, *www.icmje.org.*