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At the Bedside

Red Towels: Maximizing the Care of Patients Who Are Dying

Edmund G. Howe

In this issue of *The Journal of Clinical Ethics*, in "Last Hours of Life: Encouraging End-of-Life Conversations," Benjamin F. Stump, Craig M. Klugman, and Barbara Thornton report findings on what people said they most wanted in their last hours. Some of what they wanted wasn't surprising. Those surveyed particularly wanted to be with their family and loved ones, and wanted them to do well later. ("Families and loved ones" will be referred to as "families" for the remainder of this discussion.) People also wanted to be with their pets. Other wants were surprising, for instance, a particular aroma or being outside. An unexpected and even disturbing finding was that people may *not* want to be with careproviders, which may have significant implications for careproviders.

Based on these findings, how can careproviders help patients to the greatest extent possible during their last hours? Since patients' last hours may be profoundly affected by their prior experiences, how can careproviders best care for patients during the weeks and months prior to their death?

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The best approaches may not be as well known as they could be. For instance, during a meeting that I attended not long ago, a careprovider asked if anyone present knew of a local careprovider who was especially skilled in treating patients who were imminently dying, because he was seeing a patient who desperately needed this care. (Patients who are "imminently dying" will be referred to as "dying" throughout the remainder of this discussion.) More than 100 local careproviders were there, but not one knew a single careprovider who fit this bill.

Given this, I will discuss here what careproviders can best do for dying patients, beginning many months before their lives most likely will end. In this issue of *JCE,* Stump, Klugman, and Thornton provide a worksheet of important questions that careproviders can ask patients. As a supplement to this, I will add some other things that careproviders should know. I will not review much of what is well-known, such as the importance of listening to patients.[1] Rather, I will focus on less well-known interventions — for instance, that family members of patients who are dying at home from some kinds of head or neck cancers may want to buy red or black towels. On rare occasions patients may suddenly start "bleeding out" if their cancer involves their carotid artery and the skin of the neck. Dark-colored towels may reduce the horror that patients and their family members

experience, and buying towels to prepare for this possibility may at least help them feel more prepared.[2] This one example represents many others that are not common knowledge, and so I include it in the title of this article.

MEETING PATIENTS' NEEDS AS INDIVIDUALS

Careproviders should attend to patients' most urgent needs first, *as they are determined by the patients.* A common, most important example, and the one I will discuss as a paradigm, is relieving patients' pain — and ensuring that patients know their pain will be relieved.

Relieving Physical and Emotional Pain

When patients have physical pain, careproviders should know the best current approaches to safely give them optimal relief, for example: how to give the fastest pain relief possible; how to give *different* pain meds, because one may be successful when another isn't; and how to relieve side-effects such as constipation, which may be persistent.[3] If careproviders lack this expertise, they should refer their patients or consult. Patients may have excruciating emotional pain, and how to best treat that is more ethically controversial. Standard treatments such as antidepressants and anti-anxiety meds may be most helpful, but even these meds may not substantially reduce the greatest source of pain: the anguish that one is dying.

When patients have profound and unremitting physical *or* psychological pain, regardless of the source, they may benefit greatly from knowing in advance that if their pain stays as bad or gets worse, their careprovider will do *whatever is necessary* to make it bearable.[4] Patients may be afraid to ask whether their careprovider will do this and feel "petrified" that their careprovider will abandon them. Careproviders who will provide relief when needed should take the initiative to tell patients this. In extreme cases, it might mean giving patients adequate sedation, at least temporarily.[5]

It may be possible to heavily sedate patients for only a short time, such as a few days, and then see if they continue to request the same level of relief. Some patients may change their minds. One fear careproviders may have is if they take the initiative to make such a promise to patients in advance, it may be seen as suggesting the option, and, as a result, the suggestion may become a self-fulfilling prophecy. Patients could, for example, from the first time their careprovider mentions this level of relief, want it, and then they may never have the opportunity to have positive experiences such as finding meaning and joy in their last days, as otherwise might be possible and more beneficial for them. This could happen. Conversely, taking this initiative might have a paradoxical effect: it may *decrease* the likelihood of patients' ending their lives. Patients' anguish, physical or emotional, may decrease when they know that they *could* have relief should they need it. Patients may experience relief because they can see this light, at least, at the end of the tunnel.

A related controversial question is whether careproviders should try to relieve incompetent patients' pain in the same way. Compassion and justice might "argue" that careproviders should give incompetent patients equivalent relief. Readers who want to consider a case in which careproviders gave an incompetent patient such relief may review several articles published in a previous issue of *JCE*.[6] Incompetent patients may be much less able to find meaning that helps them compensate for the pain they have in their lives. Current practice may favor giving only competent patients a greater degree of pain relief; it might be, however, that the "threshold" for giving incompetent patients adequate pain relief should be lower. They can't request pain relief; if, due to pain, the quality of incompetent patients' lives is wholly negative, it is open to question (if they could express themselves) whether they would want to stay alive under these conditions.

Optimal Interventions

Careproviders should attend to patients' physical and emotional pain, and they should also ask patients about their other needs — things that are very important to them but are less obvious to others. Careproviders might then ask themselves whether a patient is in denial about dying, and, if this seems to be the case, the degree to which this should be respected. When patients aren't in denial, careproviders can concentrate on giving them the information

they need, doing it in a way that allows patients to retain hope. If patients are given too much information or are given it too early, it may break through their denial and harm them.

When patients do not want information because they are denying they are dying, they may indicate this explicitly or suggest it with nonverbal behavior, such as avoiding the topic or showing great anxiety during discussions about it. Careproviders may believe that they should always confront denial, or at least try to nudge patients so that they increasingly accept the reality that they are dying, over time. Careproviders have good reasons for wanting to nudge. Without denial, patients can try to get their affairs in order and, more importantly, be able to find meaning and even joy with loved ones during the time they still have together. Patients can also participate in and make medical decisions. When patients can participate, it is much easier for careproviders. Such increased ease cannot, however, be used as grounds for careproviders to break through a patient's denial.

Instead, careproviders should know that patients and families may be unable to overcome their denial at any given point in time. One careprovider who works extensively with dying patients reports that, with one patient, he was "reduced to" either supporting her denial or "alienating her completely."[7] Some patients may do better if their careproviders do not confront their denial,[8] because they need to accept dying at their own pace — if at all. This possibility is suggested by a recent study conducted in Japan. All of the patients in the study were inpatients on the same ward and were dying of liver cancer, but their careproviders didn't tell them they were dying. The patients accepted death at a pace that was acceptable to them. The authors claim that although there was no control group, based on the responses of equivalent patients who had been told they were dying, the patients who were not told died much more peacefully.[9] A wish to remain in denial may vary by culture. Patients from some cultures will want all information to be given to their families.[10]

Still, careproviders should be careful not to stereotype patients on the basis of their culture. They should not presume that patients share the beliefs attributed to a majority in their culture. Next-door neighbors may have radically different beliefs. I recall a patient's wife who shouted out to him with each breath to fight on so that he could get well, even as he died. This was her way to be with him as he died. Perhaps it was his way as well. I have seen her many times since and she has done well.

Careproviders should generally *not* try to break through denial, since it most likely will be futile and may make the denial worse.[11] When possible, careproviders should ask patients in advance what they would want. They might ask, "*If* you were dying, whom would you want me to tell?" If patients say that they don't know what they want, or say that they wouldn't want to know, careproviders can ask whether they would want to discuss "just the pros and cons" of knowing or not knowing another time, possibly later. Careproviders can say that the patients might be better able to decide at a later time, when (if ever) they might want to know more.[12]

This uses an approach called motivational interviewing, which presupposes that people change mostly in stages, and that careproviders can most help a patient by responding only to the stage that the patient is in. Some patients who are dying may believe that the gains of not knowing surpass those of knowing. The goal is not to oppose this position, but rather to reframe it or even side with it, "so that it becomes the patient who is the one arguing for change."[13] Asking a patient whether she or he would want to discuss the pros and cons of knowing may support the patient's denial, rather than cause the patient to feel pressured. This should enhance the likelihood that the patient will give up denial, if she or he can. If a patient doesn't want to discuss the pros and cons, careproviders might say, "We can always discuss the pros and cons together later. But if we do it later, it could be more difficult. Then we may know more about your illness, and we may lose the opportunity for you to decide, in advance, that you do not want to know that you have an illness that could end your life. But even considering this may be too stressful. Should we go on to discuss other things?"

It might seem that this tack might increase patients' stress, leading to increased denial. In this instance it may be ethically warranted for careproviders to take that risk. When patients

are rapidly dying, it may be preferable not to even ask if they want to discuss the pros and cons, as it might cause patients to feel more fearful, and make it more unlikely that they can accept that they are dying.[14]

The risk that patients will respond negatively may be reduced by acknowledging the responses they might have before they speak. Ngo-Metzger, Legedza, and Phillips offer a superb example when they discuss how careproviders should decide whether to counsel patients directly: on the one hand, if careproviders directly counsel when patients prefer nondirective counseling, patients can see this as "a lack of collaboration"; on the other hand, if careproviders are nondirective when patients would prefer them to be directive, patients may "lose confidence" in their careprovider.[15] The authors suggest that careproviders ask patients whether they want only to be given options, or to know what the careprovider thinks they should do. The authors recognize a particularly subtle reality, that careproviders risk unduly harming patients if they give only one of the options explicitly, rather than both, even though the meaning of only giving one option is just the same.

Patients may prefer receiving bad news to receiving no news, because even bad news may be less painful than uncertainty. Consequently, careproviders who see dying patients should ask patients repeatedly whether they want more information. Ideally careproviders might say that there are no dumb questions, but rather only questions that patients don't ask.[16] Patients may need additional encouragement to ask the questions that are most important to them. Careproviders should go beyond this and anticipate what patients might want to know; they might want to know, for example, the most likely clinical course, and — but only if they say they want to know — the worst outcomes they could expect.[17] Patients with certain kinds of cancer may, for example, be more likely to have a rapid downhill course; those with heart and lung disease may die abruptly or wax and wane for some time; those with dementia may go more steadily downhill.[18]

Patients with chronic obstructive pulmonary disease (COPD) are a good example of a group who may want to know how they will probably die — or, rather, how they will not die, due to their careproviders' interventions.[19] Their concerns may be greater than that of other patients, because they may fear (rightfully) that they may die with feelings of suffocation. Giving dying patients the information they desire respects their autonomy to the utmost degree. It may also help them decide what they want to do to make their remaining time most meaningful.[20]

This is crucially important when patients have little time. Some careproviders say that when patients want this information, they should be told, even that they have only "minutes to hours," although it must always be acknowledged that exceptions are possible in either direction.[21] Often patients find it very meaningful to tell their families how much they love them, to express their gratitude to them, to ask for forgiveness, and to give forgiveness in return.[22] Many find it meaningful to recall with their families the times they have shared, and sometimes to say their last goodbyes.

Some patients and families will not share in these ways for various reasons; for instance, it may not even occur to them to try. Or they may be afraid it would cause too much pain for them or family members. Careproviders can help patients and families by taking the initiative to say that when patients are dying, many patients and families find this kind of sharing deeply meaningful and emotionally rewarding.

When careproviders share the likely course of an illness with patients — for example, how much time they have left — they should also acknowledge their uncertainty.[23] This respects and benefits patients because it increases their knowledge, and such uncertainty may provide a needed source of hope for some patients. Careproviders may want to meet this need, although it may be essentially irrational. Careproviders can also acknowledge the frustration that *they* feel as a result of this uncertainty.[24] This may model for patients how they can share painful feelings, and it may help them to feel less alone.

Are there limits to how far careproviders should go in anticipating information that patients might want to know? A test example might be careproviders who tell patients on a respirator that they may have a "window of opportunity" during which they may be able to die suddenly, rather than taking a longer time. That is, in some circumstances a patient can't breathe

without assistance because of damage to the brain. Brain function may improve over time, so the patient might die if the careprovider discontinues the respirator *early on*, but the patient might not die if the respirator is discontinued later. If the patient — and, thus, the careprovider — waits too long to decide, the brain may recover enough that if the respirator is withdrawn, the patient will be able to breathe without assistance, and if the patient still wishes to die, he or she may only be able to die in another way, such as by not taking food and water.

Should careproviders tell patients who may be in this situation that they may have only a limited time during which they could die quickly by discontinuing the respirator? Some careproviders may believe that they should never give patients this much information. Their rationale may be somewhat like the concern discussed earlier, that informing patients about temporary sedation could result in this becoming a self-fulfilling prophecy. Even if this should happen, however, it may still be ethically preferable for careproviders to share such information, because it enhances patients' autonomy. Having greater autonomy is particularly important here, because the stakes are as high as they can possibly be — life or death.

This may provide emotional benefit for some patients. They may feel that they have greater control, and this is a time, surely, that patients most need this. Finally, this is an intervention that careproviders can do early on, before patients are dying, that may profoundly affect patients' experience of dying later. Why? Because patients may know, rather than hope, that their careprovider will provide what they need in the future. Patients will trust their careprovider, and this itself may give patients great relief.

People often need, or at least want to continue to have, hope, even when their reasons for hope are almost completely irrational. Patients who know that they are dying may greatly need and want information, but receiving this information may quash their hopes. What should careproviders do? Some careproviders who specialize in working with dying patients urge patients to try to adopt new hopes for different outcomes, other than continued survival. An example is the hope to die in a way that will enable family members to remember them well. This may be preferable by far for patients, because such hope is based in reality. There is a great deal of evidence that people *can* find new reasons for hope. Parents who have children who are born with the most profound special needs must give up their old hopes and replace them with hopes that are new; they must find what some refer to as "a new normal" life. Many are able to do this. Many find a life that is as rich or richer than usual, finding meaning and joy in sharing their lives with their children. People who are dying, or who are with people who are dying, can find "a new normal" life that is rich. A paradigmatic example is patients who have Alzheimer's disease. Abigail Thomas, the wife of a man who has Alzheimer's disease, writes, "Rich and I sit together, we hold hands . . . that's all the communication we need."[25]

Sometimes it isn't possible for patients to find meaning or to experience hope in a different "new normal," possibly because time is too limited time, or because it seems as though time is too limited. Careproviders have no choice but to tailor the care they provide to the needs of each patient. It may be possible to let patients retain some hope while still telling them the truth. Ngo-Metzger, Legedza, and Phillips suggest several possibilities. Careproviders may suggest that patients hope for the best while expecting the worst. Careproviders can discuss much of what patients will experience and what patients might want their careprovider to do in the "worst-case scenario," while at the same time not "taking away" the "possibility of the best-case scenario."[26] Another approach suggested is "sequential treatment." In this approach, careproviders support patients, but also discuss what the next step will be *if* the initial treatment isn't successful. This approach sets "practical parameters and allows discussion of alternatives if the initial treatment is unsuccessful."[27] They also suggest that careproviders can refer patients to a Phase 1 clinical protocol; indeed, some believe that careproviders have an ethical duty to make patients aware of such research opportunities when they are available.

There are other options. Careproviders may be able to tell patients truthfully that while statistically they are likely to die soon, there may be exceptions. They can also tell patients truthfully when there is no medically certain reason

that they can't recover. I think of a patient whose liver failed, and then his kidneys. Each day his lab values got worse, and all of his doctors believed that he would die, except me. No one knew why his organ systems were failing or why they continued to do worse. I didn't know that the patient would do better, but, on the basis of medical uncertainty, I did know that his dying wasn't inevitable. I told him that, and with his permission also told his wife. Days later when I arrived on the ward and checked the lab reports from the previous evening, I couldn't believe my eyes: the lab results weren't worse, in fact they got better, and so did the patient. It's noteworthy how the patient and his wife responded when I indicated that I had some hope. Their relationship totally changed. He had been silent and forlorn; she, irrational and demanding. Their relationship was emotionless and distant, but with some hope, he could smile, as could she. Their relationship became virtually ceaselessly intimate and, indeed, overtly passionate.[28]

Patients may respond differently. They may feel rage. They may "expend their waning energies," as one careprovider put it, "lashing out at the Grim Reaper."[29] If this happens, careproviders shouldn't imply that somehow patients should die a "better" death. They should validate patients' feelings and be present so they don't feel so alone.[30] To confirm that such feelings are valid may have a paradoxical effect: patients may feel more positive because they feel validated and because they feel less alone.

I recall a patient who had been caring for his wife constantly since she was bedridden. He developed cancer and knew he would be the first to die. "I planned to continue to care for her, and for her to die first!" he shouted from his hospital bed. He convinced his best friend to bring to him a knife, but it was spotted before he could use it. I said, "All you wanted, you lost. I can't imagine how devastating this is." He responded wordlessly, indicating, "Yes, this is life." But he didn't try to take his life again.

Some careproviders might ask whether there are any limits — are there some times that careproviders should *not* validate how patients feel? I know of none, but I believe in expressing that there always may be some ground for hope, even when it can't be seen. For example, in even the worst-case scenario of patients who want temporary sedation, the patients may, on waking up, for unknown reason, feel better. The reason this happens, I might say to patients, may remain unknown, not only to me, but to them.

Helping Patients Who Aren't Dying

Careproviders can take these initiatives with patients who aren't dying, but who may have a limited amount of time to interact meaningfully with their family members. One example is patients with progressive dementia, whose illness will rob them of their capacity for cognition. Once they lose this capacity they may live on for several years. Further, they may not live on like Abigail Thomas and her husband, mentioned above. Patients with dementia may become much worse, and for them and their families it may be equivalent to death.

I think of a woman whose husband had Alzheimer's. He lived at a nursing home, and when she went to enjoy a concert with him, he sat with one arm around her on one side, and one arm around his "new girlfriend" on the other. He apparently still had a warm feeling toward his wife of 52 years, although probably undefined, but otherwise he had no idea who she was. Thus, careproviders should ask patients as early as possible if they want to discuss things with their loved ones while they still can. If patients don't want to do this, careproviders can ask whether they want to discuss even just the pros and cons, as described above. Also, as above, careproviders can point out that it might be more difficult to discuss the same issues later, that they know this might be very stressful, and so it might be too much to discuss, ever.

For patients who have Alzheimer's disease, such discussions will not be more difficult later because they will be near death; they will be more difficult later because the patients will be less likely to understand or respond. I had a patient who had very advanced Alzheimer's. I asked her if she wanted me to try to help her reconnect with her son, whom she hadn't seen in decades. She said "yes," so I did. When she saw him, she recognized him and they were able to talk. Soon after this meeting, she lost the capacity to recognize loved ones and the capacity to talk. There is no way for us to know how important meeting her son was for her, but from what happened after they finished talking that

afternoon, it might be inferred. The patient's husband had driven her to where we all met in his pickup truck. I had come in my own car, but the patient didn't seem to realize that. After she had finished talking with her son, as she and her husband were leaving, she walked to the back of the truck and climbed up over the rear bumper into the open truck bed. "She's never done *that* before," her husband remarked. She seemed to want to express her gratitude to me by giving me the seat by her husband, in front.

HELPING PATIENTS BE WITH FAMILY

The best thing careproviders can do to help dying patients is probably to help them be with family and to help maximize their time together. Careproviders can help in many ways; for example, they can help family stay with patients in their hospital rooms. Ideally, careproviders may be able to help patients and family find a room where they can be together without the usual hospital noise, turmoil, and interruptions.

It may seem implausible, but with careproviders' support (and perhaps "a little pressure"), wards may allow this and other exceptions. Ann Berger, a nurse and internist who specializes in palliative care at the National Institutes of Health, for instance, helped a dying patient have her small dog with her in the ICU.[31] Some may believe that patients' feelings for their pets shouldn't be given the same respect and effort as feelings for family members. But, in general, patients should be allowed to define their own needs. Berger reports that arrangements were made for one patient to speak regularly with her dog over the phone. The dog would bark in response to hearing her voice![32] A question this raises is whether dying patients should have visits from young children.[33] This may be open to different views, based on what is or isn't best for the children. If the child's best interest isn't affected, this may be a situation in which wards may be willing to make an exception.

One very important intervention that careproviders can provide is to help estranged families reunite, as noted above. Here is the approach I have used. When I talk with patients, I listen for any ambivalence they have regarding family members they no longer see. If I hear this I make an offer: "It sounds as though you had *some* positive things together. I find that many patients gain greatly from being able to reunite with family members, even when they haven't seen each other for years. I would like to tell you how I do this. Is this okay?" If they say it is okay, I tell them that I contact the family member and say why I'm calling. I tell patients that, as their doctor, I will call their family member and ask for help, because that person can do something that I can't. I will ask the family member to come on the phone and talk with the patient and me, or come to be with us in person, even if for a minute. If the person wants to hang up or leave, even after only a minute, this is fine. I would feel only great appreciation. There would be one hitch: since I would be so grateful, I would want to insist on being able to end the phone call or meeting myself, if I thought that the family member was being harmed or even at risk of being harmed. I say that I am concerned that old patterns of behavior might repeat themselves, and I would want to be able to end the discussion, rather than allow any risk of harm. This has never yet been unsuccessful.

Should patients ever *not* reunite and forgive? Opinions differ. Years ago, Cornelia Wilbur, a psychiatrist, shared with me an argument against reuniting and forgiving. Wilbur treated a well-known patient called Sybil, who had multiple personalities, and whose life and therapy were depicted in a book and in films.[34] Sybil's mother did horrible things to her when she was a child. Wilbur asked me if I were treating Sybil whether my goal would be to try to help her to forgive her mother. I said yes; Wilbur said no. It would be bad for Sybil to forgive her mother, Wilbur explained, because her mother had done her such harm. The only "healthy" emotional response for Sybil, Wilbur maintained, would be for Sybil to sever ties completely and neither see nor forgive such a parent, forever. But I'm not sure that I can agree.

Maximizing Communication

If family members can be present, patients often find it very meaningful to share together what it means to each person that the patient will die. Some patients may deny that they are dying, but may know that they are dying and not want to tell their family. Hospital wards can establish practices to ensure that family mem-

bers know that if a patient is dying, he or she can choose to keep this information confidential.[35] Patients may realize that it is more likely that family members may suspect that they are dying, even if the patients don't tell them. Patients and family members may not want to share their feelings with each other openly. This may be for any number of reasons, such as being afraid it would be too painful. Careproviders may help by taking the initiative to tell patients and their families that, despite their concerns, most patients and families greatly benefit from such discussions. One careprovider who specializes in this area tells patients and their families about this in a way that may allow them to maintain hope. He says, "Are there things you would want to say . . . just in case?"[36] When families do this, they are thankful later, because "They have made allowance in their calculations for their loved one's demise. . . ."[37]

Careproviders should prepare patients that they might have negative interactions with family, to reduce the chance of harm. Family may respond in negative ways to physical changes in dying patients. We often see ourselves not as we are but as we imagine others see us, and as patients become increasingly ill, they may become particularly vulnerable to this. They may regress emotionally as they feel more helpless and become more dependent on how others see them, as small children do. When patients undergo changes such as losing hair, some family members may shrink back and respond in negative ways, even if they try not to. Or family may respond to what patients do or say; as one careprovider notes, patients say "fearful things and wear . . . pained expressions that make their loved ones uncomfortable."[38] Changes may be profound, as when patients have cancer of the face or neck.[39] Family members may no longer want to go out with them to dinner, and the patients may feel guilty about it.[40]

Careproviders should try to anticipate such outcomes when they can and discuss them with patients before they occur, so patients can be better prepared. Patients may find such experiences traumatic because they want their families to remember them in a positive way. Many dying patients focus on leaving their family the best memories of them they can, and as a result, may not want to others to see them, even people they love. They worry that being seen in a discrepant and debilitated state may affect how their family will remember them. For instance, when I was younger, my mental image of my father was as a grandfather to my two older children, with a bright twinkle in his eyes, pushing them on swings from the front, pushing them by their feet. Swinging toward him, their feet would push into him, smack into his belly. To the children's great delight, he would make a show of falling over backward, his white hair flying. Later he had a stroke and died after three months in a persistent vegetative state. Now my memory of him is not of his twinkling eyes, but of his eyes staring vacantly into space.

Careproviders should support patients who wish to be remembered well, even when it causes them to avoid those dearest to them. Careproviders should try to discuss this possibility with patients and family members ahead of time. Dying patients who refuse to see family members will probably need support from their careproviders, because the pressure from their families to see them may become very great.

Helping Families Afterwards

As Stump, Klugman, and Thornton report, dying patients' greatest concern often is not for themselves but for their family. Careproviders can help in various ways, from asking a patient if he or she would want to consider family members' emotional and financial needs when discussing advance directives, to telling a patient how they will try to help the patient's family before and after the patient dies. Careproviders rightfully focus on the care of the patient, but families may also feel devastated. Before a patient dies, careproviders can tell family members what they can probably expect.[41] This may include physical changes in the patient and the negative responses that family members may have despite their best efforts. In this way careproviders can help patients and families deal with feelings such as shame and guilt. Careproviders can also anticipate and recommend practical measures such as buying red or black towels for patients with head or neck cancer, mentioned above.

If a patient is dying at home, it is important for families to have a number they can call to get help 24 hours a day.[42] Families tend to fear

sudden medical "disasters" that they don't know how to handle, and having a number can quell their fears, whether or not it's ever used. After the patient dies, careproviders can help families by giving them sound information regarding the process of bereavement.

Many people incorrectly believe, for example, that there is only one "right way" to grieve, and that if family members don't cry or at least grieve painfully in an obvious way, they didn't care. Ideally, careproviders can tell patients and family members together that there is no right way to grieve, and that if they don't grieve, they may be fortunate because that involves less pain, and it may indicate that they have especially good emotional health.[43] Careproviders should strongly consider calling the family after a patient dies to inquire how they are doing, to go to a patient's funeral (when possible), and to even write the family a note on the anniversary of the patient's death.[44] In considering any of these interventions, careproviders should consider that, to the family, they *and they alone* shared, and continue to be, a precious and unique part of their past. When careproviders decide they would like to do any of these things, it will benefit the patient to tell him or her about it as early as possible. The beneficial effect may be disproportionately great.

CAREPROVIDERS

For many, the worst aspect of dying is the fear of dying alone. Dying patients may benefit from doing these four things: saying "I love you," expressing thanks, forgiving, and asking for forgiveness. Obviously all of these are interpersonal. When patients don't have family members who are present, their careprovider may be all that they have. Stump, Klugman, and Thornton indicate that dying patients may *not* want a careprovider by their deathbed; it may be not because careproviders *can't* be immensely meaningful to patients at this time; it may be simply because they currently are *not*.

Ernest Becker, in his Pulitzer Prize winning book *The Denial of Death*, suggests that although people greatly fear death, one way to reduce this fear is to place childlike faith in another.[45] Such faith is largely irrational, since others can't forestall or prevent death — still, the effect of this faith, like religious faith, can be immense. Patients become more dependent and tend to regress when they become fatally ill, and become more like they were as children; thus careproviders should try to help patients, particularly when they have no one else, if they can.

Helping Patients as Much as Possible

There are guidelines that can help careproviders to maximize the time they can have with a patient, as brief as their time together may be. When careproviders come to see a patient, they should sit down as far from the door as they can. They should turn off their cell phone or beeper or leave them with someone outside the room who will answer it for them. They should listen attentively to the patient and, unless there is a cultural or psychological contraindication, communicate that they are fully attentive by looking the patient in the eye. Careproviders may feel nervous if they don't know what to say; they may fear that to talk about everyday things, such as sports or art, may risk trivializing that the patient is dying. They may fear that if they take the initiative to talk with the patient about death, it may be an unwanted downer.

I recall laughing together with a patient for hours, even though we both knew that he would soon die. I felt anxious because we were laughing, and I feared that I was being phony. But feeling either that one may be too light, on one hand, or too heavy on the other, may be right. St. Augustine wrote that he made jokes with his friend as his friend died, and his friend "shrunk back" as though St. Augustine was his "enemy."[46] But asking dying patients about their feelings may be the last thing that they want to hear. For example, one patient told his psychologist, "Barry, cut the psychological crap."[47]

Many dying patients delight in laughing and interacting with others as though they aren't dying, maybe because it is distracting and gives needed relief. Such interactions create moments when patients are just people, rather than people who are dying. Actress Gilda Radner, who died of ovarian cancer, describes how careproviders came to her home and gave her chemotherapy: "They called it 'the chemo party'. . . . Those nurses would make me laugh, or they'd dance around the bed and entertain me. . . . The chemo parties were like the scene in *Cinderella* when

the little birds and mice come to wake up Cinderella in the morning. One minute you think her life's so bad, but then she has all these little friends. That's what I felt like."[48]

When careproviders feel they have to choose between trivializing dying on the one hand, and being too serious on the other, I suggest they share their dilemma with the patient and ask the patient what she or he prefers. It might cause the patient some pain, but it avoids hiding or trying to repress feelings, and engages the patient as an equal. Asking helps a patient to say what she or he wants. As Callahan and Kelley note, "Don't push. Let the dying control the breadth and depth of the conversation." They add: "If you don't know what to say, don't say anything. . . . Sometimes the best response is simply to touch. . . . Touching gives the very important message, 'I'm with you'."[49]

Dealing with Feelings

What should be done in response to exceptionally strong or even overwhelming feelings, for example, wanting to cry? You should.[50] This may be more meaningful to a patient than anything else that a careprovider does. On the other hand, careproviders may be especially vulnerable to denying feelings and then acting them out. Careproviders have power and mixed responsibilities, and so may be prone to becoming exceptionally rigid. For instance, they may force an unnecessary "stand-off" between themselves and patients or families about whether patients should have cardiopulmonary resuscitation (CPR). Patients or families may change their view and accept a do-not-resuscitate (DNR) order if given more time. When careproviders feel unusually moved to oppose patients and families, they should make a habit to check their own views with others. They should do this routinely to help ensure that the position they take makes as much sense to them as it first seems, or that they are not "acting out" in response to exceptional pain and grief they feel due to a patient's dying.

Patients and families have exceptionally strong emotions in these circumstances, and may make requests that are not rationally based. Ambulance drivers report, for instance, that some families want them to perform CPR even hours after a patient has died. Some comply. They perform CPR to meet families' requests, although they may think this might be ethically wrong, since it would be like doing a "slow code." But some report that doing CPR, even if only for a few (token) minutes, almost miraculously gives some families immediate and profound emotional relief. It is as if they required ambulance personnel to make an attempt for them to have emotional closure.

CONCLUSION

Because the extent to which careproviders can cure is always limited, I have described some lesser known initiatives that careproviders may be able to use to help dying patients and their families.

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Features

Rethinking the Ethical Framework for Surrogate Decision Making: A Qualitative Study of Physicians

Alexia M. Torke, Mary Simmerling, Mark Siegler, Danit Kaya, and G. Caleb Alexander

INTRODUCTION

When patients lack decision-making capacity, physicians work together with surrogates to make decisions for patients. Standard bioethical approaches to surrogate decision making have relied on the principles of respect for autonomy and beneficence to navigate these difficult clinical situations.[1] This standard approach encourages decision makers to determine what patients would have wanted by using advance directives or substituted judgment. When decision makers do not know patients' wishes, they turn to the principle of beneficence, which aims to promote and protect patients' interests. Usually, surrogates are persons patients have previously chosen through a durable power of attorney document, or else they are patients' legal next-of-kin.

Such an approach to surrogate decision making has been advocated by the courts in cases beginning with Karen Ann Quinlan, in which the New Jersey Supreme Court argued that patients should not lose their right to refuse medical therapy because they can no longer speak for themselves.[2] In such cases, surrogates could speak for patients, basing decisions on knowledge of patients' wishes and their own assessment of patients' interests. The courts have also generally advocated that decisions be based on patients' prior wishes,[3] but allow states to set their own evidentiary standards to evaluate the certainty of patients' preferences.[4] This general approach is also supported by the federal Patient Self-Determination Act[5] and by state laws that include statutory documents for advance directives that allow patients to specify both their wishes for care and their preferred

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surrogate.[6] Professional guidelines also direct decision makers to rely on patients' wishes and best interest.[7]

In recent years, there has been increasing criticism of these autonomy-based approaches to surrogate decision making.[8] Major objections include the fact that most patients do not have advanced directives.[9] Additionally, in empirical studies, surrogates are often inaccurate in predicting what patients would want in a given clinical scenario,[10] even after extensive discussion with the patient or completion of advance directives.[11] Finally, advance care planning requires that people make decisions about life situations that they have never experienced.[12] Empirical studies report that persons with chronic illness change their minds about medical treatment over time,[13] and we can never know what persons who lack decision-making capacity would decide if they were able to suddenly express preferences again.

While it is possible that physicians may share some of these objections to the standard legal and bioethical guidelines for surrogate decision making, it is not known to what extent physicians adhere to an autonomy-based approach in clinical practice. A few empirical studies have presented physicians with hypothetical scenarios regarding end-of-life care and suggest that physicians often override advance directives or prior preferences when making surrogate decisions.[14] In addition to patients' wishes, physicians consider legal issues and the needs of patients' family members in their decisions.[15] However, these hypothetical scenarios are unable to capture the interpersonal and emotional aspects of decision making that may also be important in the clinical setting.[16]

To study how physicians make surrogate decisions in clinical practice, we interviewed physicians within a month of their having made a major medical decision for an adult in-patient who lacked decision-making capacity. Interviews were analyzed to explore how physicians justified the decisions they made for their patients. We reasoned that our qualitative methods would be particularly helpful in allowing us to identify the concerns of physicians without imposing a particular decision-making model.

METHODS

Study Design and Population

We conducted semi-structured, in-depth interviews with physicians from an academic medical center in a large Midwestern city. Subjects were recruited from a complete list of house staff and attending physicians in the medicine, geriatrics, and intensive care unit services at this hospital. After a physician had been on service for at least two weeks, but no later than one week after the end of the rotation, we contacted the physician to request participation in an audiotaped interview about experiences with surrogate decision making. Physicians on the service lists were contacted sequentially until approximately five interviews had been completed during each month. The study was approved by the hospital's institutional review board and each physician provided written informed consent.

Data Collection

Interviews were conducted by one investigator (AMT) using a semi-structured interview guide (see table 1). For each section, physicians were asked an open-ended question about an aspect of surrogate decision making followed by optional prompts. Prompts were included in the interview guide to assure a consistent approach to questioning. However, the interviewer could ask additional questions for clarification or expand on a given topic as appropriate.

Physicians were asked about patients they had cared for within the past month who lacked decision-making capacity and required a major decision about life-sustaining therapy (such as a change in code status) or long-term disposition (such as nursing home placement) that involved discussion with surrogates. The interview explored physicians' approaches to their patients and their knowledge and understanding of bioethical guidelines for surrogate decision making. Interviews were audiotaped and transcribed verbatim. Selected audiotapes were reviewed for accuracy.

Data Analysis

After the completion of approximately every five interviews, transcripts were read by two

investigators (AMT and GCA) to identify major themes that required further exploration in subsequent interviews. This iterative process, in which data are reviewed multiple times as interviews are conducted and as new themes emerge, is a standard practice in qualitative methodology[17] and allowed us to refine and test our ideas at each step of data collection. At each meeting, we also determined whether new themes were continuing to emerge with each additional interview. Interviews continued until no new themes were identified in subsequent interviews.[18]

At the conclusion of the interview process, each interview was read and independently coded by two investigators (AMT and MCS) using principles of grounded theory, a systematic process of developing new theory through a careful examination of raw data.[19] Using these methods, segments of text in each interview (sentences or paragraphs) were identified by topic and labeled. The labels, or codes, were then organized into categories reflecting major themes. The interview text and codes were entered into Atlas.ti (Scientific Software, Berlin), a qualitative data analysis program that allows the organization of interview data. The two coders met regularly to review emerging codes and themes. Disagreements were resolved by consensus. For the current analysis, we selected all codes that addressed the physicians' reasoning about decisions for patients who lacked decision-making capacity.

Qualitative research involves several steps to ensure "credibility," a term that is conceptually similar to "validity" in quantitative studies.[20] In this study, we took the following steps to ensure credibility: independent coding of all data by more than one investigator; familiarity with all interviews by three researchers; analysis from two disciplinary perspectives (a doctorate-level philosopher, MCS and two practic-

Table 1. Interview Guide

1. **Decision-making situations**
   In the past month, can you think of one or more situations in which you had to make a clinical decision for a patient, and the patient could not participate in the decision-making process?
2. **Target interventions**
   In any of these cases, did you discuss any decisions about whether to forgo medical therapy, discuss code status, or discuss whether life-sustaining therapy was appropriate for the patient?
3. **General information**
   The most recent decision you identified was _____. Tell me about the decision.
4. **Decision-making capacity**
   How did you decide that the patient could not make this decision?
5. **Assistance with decision making**
   Who or what was helpful to you in making the decision?
6. **Communication**
   Tell me about any discussions with the family or surrogate decision makers and other staff during (patient's) time in the hospital.
7. **Outcomes of the decision**
   Regarding this decision, where did things stand when your ward/ICU month ended?
8. **Conflict**
   Was there conflict between you and anyone else regarding the decision? Describe the conflict.
9 **Ethical standards for surrogate decision making**
   You have described a real-life decision-making situation. Now I want to ask you about decision making in general. When a patient lacks decision-making capacity, what are the ethical standards physicians should use when they are making medical decisions?
   What are the ethical standards for deciding *who* should make the decision?
   What does the *law* say about how doctors should make surrogate decisions?
   What does the *law* say about who should make the decisions?

ing physicians with bioethics training, AMT and GCA); and an interview process that continued until saturation of a theme was reached. Finally, we reviewed our data and our theme structure with a group of physicians who practice in the in-patient setting to assess validity of our findings and conclusions.

RESULTS

Subjects

A total of 21 physicians were interviewed, of 33 physicians initially approached (see table 2 for the subjects' characteristics). The other 12 physicians refused or could not arrange an interview within two weeks after the end of the target month due to scheduling difficulties.

Of 21 interviewed physicians, 20 had made a major medical decision within the past month for at least one patient who lacked decision-making capacity. These 20 physicians were asked to provide an in-depth description of their most recent such a patient. From these descriptions, we identified three major themes regarding decision making:

Table 2. Subjects' Characteristics (*N* = 21)

Characteristic	*n*
Gender	
Female	8
Male	13
Status	
Intern	6
Resident	8
Fellow	1
Attending	6
Race	
African-American	1
White	15
Asian	5
Religion	
Protestant	2
Catholic	6
Jewish	4
Muslim	4
Other	5

1. Patient-centered ethical guidelines (patients' wishes and best interest),
2. Surrogate-centered ethical guidelines (surrogates' wishes and surrogates' interests), and
3. Issues of knowledge and authority (of the physician and surrogate) (see table 3).

In addition, we found physicians often concurrently relied on multiple decision-making factors for a given decision and/or sought to balance competing clinical and ethical principles.

Patient-Centered Guidelines

Physicians often appealed to patient-centered ethical guides for decision making, including patients' interests and patients' wishes.

Patients' wishes. Some physicians regarded patients' wishes as the most important consideration. One said, "Number one, your goal is to make decisions that you think the patient wants." Others balanced patients' wishes against other considerations, such as best interest. Physicians often recounted conversations in which surrogates or other family recalled specific statements by patients about preferences for care. In other cases, surrogates relied on a general understanding of patients' values or preferences. Although physicians sometimes inquired about living wills, none of the patients described in these interviews had one.

Some physicians encouraged family members to consider patients' prior wishes and to place them ahead of other considerations. One physician described his approach to a family meeting, "I always think its important that it's not a decision that the family member or the surrogate is making for themselves but it is a decision that they are making for someone else, based upon their best knowledge of what that person would want."

In some cases, patients who lacked decision-making capacity because of psychosis or mild dementia were still able to express their own preferences. In such cases, physicians expressed conflict about overriding patients' stated wishes, even while acknowledging that these patients lacked the capacity to make informed choices.

Patients' interests. Physicians often used the precise term "best interest" to describe this as-

Table 3. Major Themes, Codes, and Quotations

Themes	Codes	Examples of Quotations
Patient-centered ethical guidelines		
Patients' wishes	Respect for autonomy Advance directives Substituted judgment Patients' preferences	I always think it's important to get at that it's not a decision that the family member or the surrogate is making for themselves but it is a decision that they are making for someone else, based upon their best knowledge of what that person would want. …the niece then said, "I spoke with her three days ago, and I know that she was coherent because she was saying things that only she would have said... I asked her if she would want a colostomy and she said no." So it was actually a very good conversation because the niece felt very confident about what the patient would have wanted. (The patient) made it clear that what she really valued was her functional status and that without it she wouldn't really want to be around.
Patients' interests	Best interest Quality of life Pain and suffering Risks Benefits	Treating everything that the patient had, aggressively, would probably not be in the best interest of the patient. Survival at one year was very minimal, let alone the next six months. You know with risks of aspiration, rebleeding, inability to anticoagulate …it was mutually agreed upon that what would be in his best interest was a palliative approach. To subject them to invasive tests and invasive procedures are, is this really going to benefit their quality of life?
Surrogate-centered ethical guidelines		
Surrogates' wishes	Surrogates' wishes Belief and religion	We talked about what (the daughter's) goals were, and she wanted (her mother) to be home, she didn't want her to be in a nursing home, which was great that we established that right away. And then… what she wanted was for her to be comfortable. Yet her daughter was extremely religious and…felt that God would make her heart stop beating when the time was ready and so she didn't want hospice care and so I think it was sort of a struggle to get her even to agree to a DNR/DNI type of status.
Surrogates' interests	Emotions Family burden	I think when it came down to the question of should he stay in the hospital or should he be allowed to go home…the feeling of the patient's daughters and his wife were that it would be too hard emotionally for them to take care of him and let him lapse, you know, let him pass at home.
Knowledge and Authority		
Physicians	Clinical judgment Physicians' judgment Appropriate care Futility	Having good clinical sense was probably the most helpful thing. I do try to guide (the family) toward one thing. I don't think I'm unbiased when I suggest one thing or another.

(continued next page)

pect of decision making. In addition, physicians often appealed to related concepts such as quality of life, and pain and suffering (see table 3).

Sometimes physicians offered their own assessment of patients' interests and relied on this to guide family members. As one physician said, "When I feel strongly that the patient's quality of life is really poor then I do feel that it is appropriate for the physician to try and guide the family member towards a decision."

In other cases, physicians relied on surrogates' assessments of patients' interests as they made decisions about therapy. In many cases, there was general agreement on what was in patients' interests.

Although physicians varied in whether they relied on their own assessment of best interest or surrogates' assessments, they often did not acknowledge this distinction. On one occasion, a physician commented on the agreement between her assessment and that of the surrogate, stating, "In that instance, I think the best thing for the patient was also the thing that the daughter thought was best."

Surrogate-Centered Guidelines

In addition to patient-centered factors, physicians often referred directly to the wishes and interests of surrogates.

Surrogates' wishes. Physicians often contacted family members to ascertain surrogates' own preferences for care. In these cases, physicians did not explore the reasoning behind surrogates' preferences or ask them to reason based on patients' interests or wishes, but rather the physicians accepted the surrogates' preferences for care at face value. In such cases, surrogates' wishes were generally respected as a key element of decision making.

In one example, an attending physician described her advice to her resident and intern regarding a decision to perform an endoscopy to diagnose a suspected gastrointestinal bleed, "I recommended that they discuss this with the family. . . . And if the family said oh, we really want you to go and look and make sure it isn't a bleeding ulcer, then we would go ahead and do it." In this case, the family refused the intervention on behalf of the patient. The medical

Table 3. Continued from previous page

Themes	Codes	Examples of Quotations
Surrogates	Appropriate surrogate Legal next-of-kin Surrogates' motivations Surrogates' knowledge and understanding	If there is no spouse involved then we try to find the next closest family members. So if there's children we involve them. If there's no children we start going to siblings or whoever seems to be the next in line. The first thing is to try to identify someone that the patient would want to make decisions for them. Some of her motivations were probably a little bit self-serving to…do all this for her mother, if she wanted her mother to be around to be with her, et cetera. But still… I think she did care for her mother….she wanted to do well by her mother.
Multiple Principles		But at the same time…you want to have hopefully discussed these issues and do what that individual would want, what's best for them. In the end, you have to do what the family wants, because if you don't do what the family wants, then there's a huge conference and then everyone leaves unhappy…I wish that what I think is best for the patient was able to trump what the family wants.

team did not inquire further about the basis for the surrogate's decision.

At times surrogates explicitly based their decisions on their own values or religious beliefs. Physicians expressed discomfort with this, especially when surrogates' decisions were in conflict with physicians' beliefs about appropriate care.

Surrogates' interests. Physicians were concerned with surrogates' well-being, including their emotions and experience of burden. However, physicians generally said that surrogates' needs were less important than patient-centered concerns: "I think family burden is an issue. I don't think it should govern what the final decision is, but I do think it should be addressed."

However, another physician described the in-hospital death of a patient who had expressed a previous desire to die at home. In this case, the patient's family members felt that they could not cope with caring for the patient (see table 3). This physician expressed discomfort with the decision, while acknowledging the complexity of balancing patients' and families' needs.

Knowledge and Authority

Physicians' authority. Physicians justified their own role in decision making based on two sources of authority: clinical knowledge and duty toward patients. Physicians who made complex surrogate decisions often appealed to clinical considerations to guide their decisions. These considerations included the individual physician's clinical judgment, providing care that was "appropriate" for the patient's medical condition, and meeting an external "standard of care."

Although such clinical decision making may implicitly be built on considerations of the patients' good (that is, on the principle of beneficence), physicians often justified choices that had an ethical dimension using only such clinical considerations. For example, a physician justified a decision to pursue palliative care based on his observation that ". . . clearly the prognosis was poor, and going further with treatment like, you know, trach and G-tube and these sorts of things, and likely ventilator dependence, was just futile . . . just inappropriate, just not right for the patient."

Another physician reviewed the process of making a difficult surrogate decision and concluded that "having good clinical sense was probably the most helpful thing."

Secondly, physicians expressed a belief that their sense of authority as a decision maker was based on their duty toward patients. In some cases, this duty included guiding the family members toward the correct decision: "If the patient can't make the decision then I discuss it with the family, I sometimes will push the family, to do what I think is best for the patient."

At other times physicians guided surrogates toward specific therapies based on surrogates' own preferences: "If you guys are really leaning toward comfort, and making pain control the goal here, then we should talk about code status and what we would do in the event that something would happen."

Surrogates' authority. Physicians attributed authority to surrogates based in part on surrogates' social and legal status as durable power of attorney or next-of-kin. Some physicians sought to identify the persons patients would have chosen as surrogates. However, physicians also appealed to the knowledge and motivations of surrogates as justifications for their authority. For example, physicians described surrogates' level of caring and concern for patients as they justified honoring surrogates' preferences for care (see table 3).

Balancing Multiple Principles

Physicians often considered several principles simultaneously and at times seemed to give each equal consideration. Some physicians clearly identified a single principle as most important. At other times they described how they resolved conflict among several competing decision-making factors or among individuals who were reasoning from different principles. Physicians struggled when the concerns of family members appeared to conflict with concerns centered on patients.

DISCUSSION

In this qualitative study of physicians' framework for surrogate decision making, we found that physicians' moral reasoning ex-

tended beyond the principles of patients' autonomy and beneficence that dominate most ethical discourse. First of all, physicians reported considering the wishes and needs of surrogates in addition to those of patients. Second, physicians expressed a sense of shared authority with surrogates. Physicians considered both clinical judgment and their duty toward patients as sources of their own authority in decision making. However, we found that ethical and clinical reasoning were not separate processes, but were often combined in complex ways. These findings suggest that ethical models based entirely on patient-centered guidelines[21] do not adequately capture how physicians make surrogate decisions.

The Impact of Concerns Around Surrogates

We found preliminary evidence that although physicians are aware of the traditional, autonomy-based approaches to surrogate decision making, concerns regarding surrogates often affected decisions in the hospital setting. We propose that the interpersonal interactions between the physicians and surrogates, as well as the practical considerations around the role of family members in providing care make surrogates' concerns much more salient in the clinical setting than they are in theoretical models. For example, the wishes of a caring family member may be given great authority in actual clinical decision making, regardless of whether the surrogate provides a justification that is based on a particular ethical principle.

The most vexing clinical cases for physicians may involve direct conflict between the wishes and needs of family members and those of patients. In our study, physicians were ambivalent about honoring the requests of family members in such cases but recognized practical constraints. For example, a family who was unwilling to take a patient home could not be forced to do so, even though the patient had previously expressed a wish to die at home. Some physicians described how they coped with such conflict, and some expressed acceptance of differences and recognition of the validity of the family's point of view even if it conflicted with their own.

Shared Decision-Making Authority

Although most of the ethical literature has focused on the nature of the surrogates' authority as decision makers,[22] physicians in this study described a sense of shared authority. They respected surrogates' authority based on legal standards, through durable power of attorney documents or through guidelines for assigning authority to the next-of-kin. However, physicians often considered the motivations of the surrogates when justifying their role as decision makers. Physicians often made comments about the level of care provided by surrogates or about surrogates' goodwill toward patients. This information was used to justify giving surrogates greater leeway in decision making. Although it is rare to disqualify surrogates in the clinical setting, surrogates may have more of an impact on decision making if they are judged by the physician to have goodwill toward the patient.

Physicians also exerted authority in surrogates' decisions. Physicians often expressed a belief that they should guide the family toward a clinical decision, based either on patients' preferences, surrogates' goals, or even on physicians' own assessment of best interest. The amount of authority physicians ought to exert in surrogate decision making is still a matter of debate among bioethicists.[23] Regarding the patient-physician relationship,[24] several authors have argued that physicians' duties to patients include advice and guidance. In cases when patients cannot make decisions, physicians may have a similar obligation to guide surrogates in their decision making.

Physicians' own sense of decision-making authority derived from two sources: their clinical knowledge and their duties to patients. However, clinical and ethical reasoning were often combined or overlapped in complex ways. In some cases, physicians justified surrogates' decisions entirely in clinical terms without reference to ethical concerns or moral values. We recognize that clinical standards may be implicitly based on ethical principles, such as beneficence. However, in these cases, physicians' level of reasoning did not include consideration of ethical concepts that may have impacted their decisions in important ways. More commonly, physicians' reasoning combined clinical con-

cerns about diagnosis and prognosis with ethical concerns about best interest and individuals' preferences.

Although clinical medicine and bioethics may often be regarded as separate disciplines, they require a similar approach: the application of general principles and rules to unique individual circumstances. This "practical reasoning," or *phroenesis,* was first described by Aristotle in regard to the practice of ethics. Such a practice requires knowledge of both the discipline and also of how rules of the discipline apply to an individual case. Clinical medicine is an example of this type of thinking.[25] In this study, we found that physicians often combined elements of clinical and ethical reasoning as they made complex choices for patients. Physicians considered how concepts such as patients' preferences or best interests apply to particular patients. Simultaneously, physicians considered issues of diagnosis, clinical status, and prognosis in making decisions. The application of practical wisdom was an important similarity in clinical and ethical reasoning in patient care.

We also found evidence that physicians sometimes drew upon both clinical and ethical knowledge without making clear distinctions between them. In some cases, physicians answered questions that had an ethical dimension through appeals to clinical knowledge, with the tacit assumption that clinical findings could guide them to make the "right" choice for patients. We conclude that there are important similarities between the "practical reasoning" of ethical and clinical decision making, but that physicians may not be able to identify whether their basis for decision making arises from the discipline of biomedical science or ethics.

This study has several limitations. Because it involved interviews with physicians in a single medical center, findings may not generalize to other healthcare settings. Additionally, there may be differences in the culture of a medicine service compared to other specialties. This study explored physicians' own explanations for their decision making. It may be the case that individuals have incomplete insight into the true underlying factors that motivate their own behavior. However, the field of applied biomedical ethics rests upon the assumption that examining the moral principles that underlie clinical decisions is a valuable enterprise that can improve the quality of patient care. Finally, this qualitative study identified decision-making factors important to physicians, but could not quantify the relative importance of each factor or determine how frequently each consideration affected decision making.

CONCLUSIONS

We conclude that although physicians who are engaged in surrogate decision making often rely on the traditional, patient-centered ethical principles of respect for autonomy and best interest, they also consider the surrogates' interests and wishes. Physicians' sense of authority in surrogate decision making came from both their clinical knowledge and their own duties toward patients. Physicians respected surrogates' authority based on the law and the nature of their relationship with patients, but also based on surrogates' good intentions toward patients. These findings suggest that physicians' decision-making framework was broader and more complex than previously thought, and may rely on factors that have been ignored in traditional ethical models. In order to be useful for practicing physicians, future guidelines for surrogate decision making should take account of actual clinical practices, and should be expanded to explicitly address these additional considerations.

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Deciding in the Best Interest of Clients with Dementia: The Experience of Public Guardians

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INTRODUCTION

Dementia, a syndrome characterized by multiple cognitive impairments, adult onset, and normal alertness, is a major public health problem affecting an estimated 4.5 million elders in the United States.[1] Dementia is usually progressive and results in severe disability. Most individuals with advanced dementia lack the capacity to make important decisions and must rely on a surrogate decision maker. While most elders either expect or plan for a loved one or trusted friend to serve as a surrogate decision maker if needed, some gradually or suddenly reach the point of incapacity without having such a person. In the absence of an advance directive or legally eligible surrogate decision maker, a public guardian may be appointed.

We did not find any previous studies that detail the process by which court-appointed guardians in the U.S. make medical and end-of-life (EOL) care decisions on behalf of clients with dementia. The available empirical literature on public guardians' involvement in medical and EOL care decision making on behalf of clients with dementia reports on: the infrastructure in place for the appointment of guardians;[2] quantitative data regarding activities in which public guardians in one state engage on behalf of their clients;[3] and the prevalence of public guardians as a subset of surrogate decision makers for incompetent, frail elders.[4]

The U.S. court system has developed two legal standards rooted in the ethical principle of respect for persons: substituted judgment and best interest.[5] The substituted-judgment standard relies on the notion that individuals who are knowledgeable about a patient's preferences should be able to make judgments similar to those the patient would have made in the same circumstances, if the patient were competent.[6] A second standard, the best-interest standard,

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is utilized when no one is available or is considered capable of making a decision in the manner the court would consider an appropriate substitute for the patient's own judgment.[7]

The Maryland Health Care Decisions Act (HCDA), passed in 1993,[8] created a legal framework to facilitate decisions made by physicians in cooperation with surrogate decision makers, including public guardians, regarding medical and EOL care decisions on behalf of incompetent adults. Of particular relevance to this project, the HCDA counsels that "any person authorized to make health care decisions for another . . . shall base those decisions on the wishes of the patient, and, if the wishes of the patient are unknown or not clear, on the patient's best interest."

In the state of Maryland, local administrators for the Maryland Department of Aging (MDA) are appointed by the court to serve as the "Public Guardians" for clients age 65 and older who reside in their local jurisdictions. There are 24 such jurisdictions in Maryland: 23 counties and the City of Baltimore. Because it would be impossible for the local MDA administrator to provide for all of the clients in his or her jurisdiction, case managers are given the responsibility for addressing the daily healthcare needs of the clients.

An in-depth interview study was conducted to explore the decision-making process utilized by case managers who make medical and EOL care decisions for decisionally incapacitated elders with dementia (referred to subsequently as "clients with dementia") in three local jurisdictions in Maryland.

METHODS

Sample

A convenience sample of all 13 case managers working in one of the three local jurisdictions was eligible for the study; 13 case managers were asked to participate.

Data Collection

Interview guide: A draft interview guide was developed based on our understanding of the Maryland public guardianship program through conversations with state officials responsible for the program. To provide background and context for the data to be collected from the case manager and to refine the interview guide to be used, we conducted key informant interviews with administrators of the statewide public guardianship program, a staff member of the Attorney General of Maryland, two judges familiar with the implementation of the HCDA, and a physician contracted by the state to be available for medical consult to all case managers. Topics in the final interview guide included:

- The public guardian appointment process,
- Involvement in routine medical decisions,
- Making EOL care decisions,
- Interactions with healthcare professionals,
- Attitudes about relevant current state law and guidelines.

The project was approved by the institutional review board (IRB) of the Johns Hopkins Medical Institutions.

Recruitment: All case managers affiliated with the MDA from three local jurisdictions who had clients with dementia in their caseload were invited to participate. A letter from the secretary of the MDA was sent to the local administrators notifying them of the project. Contact information for eligible case managers was obtained from the MDA. A second letter was sent from the primary investigator (PI) of the project to each case manager. The letter provided a phone number for additional information and a postcard that case managers could return to indicate their willingness to be interviewed. All case managers who indicated an interest in participation were interviewed. One eligible case manager who did not call or return a postcard was not contacted.

A total of 17 interviews were conducted, five with key informants who were familiar with the public guardianship program and 12 with case managers and case manager supervisors. Interviews were conducted from October 2002 to September 2003. The average interview lasted approximately 60 minutes (range, 45 to 90 minutes).

Analysis

All interviews were conducted in person, audiotaped, transcribed verbatim, and verified against the audiotape.[9] Our analytic goal was to obtain informational redundancy on key themes.

Transcript data were coded and segmented with the aid of N6 qualitative data software.[10] Major themes were further analyzed and sub-themes identified.[11] A table that included major themes and sub-themes related to the content of this manuscript was prepared. A consensus was reached regarding minor adjustments to the categorization of some data. Interpretations of the data were verified by re-immersion in the data.[12]

FINDINGS

Demographics

The majority of the case managers interviewed (n = 12) were female (83 percent) and African-American (75 percent). All but one case manager had a degree in social work. Case managers reported responsibility for an average of 35 (range, 25 to 50) clients with dementia. The case managers interviewed had spent nine years on average in their current position (range, one to 16 years). The findings reported here focus on what case managers considered when making medical and EOL care decisions on behalf of clients with dementia and will be organized around two issues: (1) how case managers determine what is in the best interest of their client, and (2) barriers to maximizing the client's best interest.

Best Interest, in Context

As discussed below, all case managers had strikingly similar views about what the meaning of the phrase "best interests" in the context of medical and EOL care decision making.

Medical Decision Making

Once appointed, case managers are involved in making all routine medical decisions for their clients. They report that they act in the best interest of their clients by assuring that their quality of life is maximized and that they consider the clients' prognosis, medical history, baseline functional level, and current condition. Case managers also report weighing both the immediate and long-term risks and benefits of a given procedure or intervention and agree with the recommendation when the immediate and long-term benefits outweigh the immediate and long-term risks. This list of considerations reflects the language from Maryland's HCDA.[13] In fact, most case managers report that making medical decisions is routine and relatively straightforward; that is, they find it relatively easy to determine the balance of risks and benefits. "Almost from the outset, is this really working towards that person's overall well-being or not and if it is, then it should be done and if it isn't, it shouldn't be done" (case manager 2).

The process by which case managers recounted making medical decisions was similar across respondents. Case managers reported that they gathered information from the attending physician and/or from other physicians involved in the case, reviewed material (for example, text books, internet databases) on the given condition or intervention, and discussed the decision with their supervisor and/or colleagues. They spent more time reviewing information and consulting with others when they were faced with a new condition or a unique set of circumstances. Decisions became difficult, however, when risks and benefits were closely balanced. One case manager noted that in such situations it was especially helpful to have been able to glean information about the client's preferences from the client and the client's family members and friends during the process of appointing a guardian. Other case managers noted that they took particularly hard questions to court and had a judge weigh in on the decision and were comforted by this option.

End-of-Life Care Decision Making

In the context of EOL care decision making, case managers agreed that acting in the best interest of their client meant making decisions that minimized pain and suffering. One case manager quoted a judge who articulated the goal of EOL care decision making as "passing from this life to the next with the greatest degree of comfort" (case manager 5). Case managers attempted to anticipate the outcome of particular diagnostic procedures that may have resulted only in additional pain and suffering. That is, they considered making medical EOL care decisions to be points on a spectrum, with the difference between the two contexts being the point at which a case manager believes that any further interventions would be, using the language of

the HCDA, medically ineffective. One case manager noted that EOL care decisions begin "essentially when it becomes clear that an individual's systems, his crucial systems to live, have or [are] in the process of shutting down. . . . In essence, in spite of all of the means for what you can avail to the individual, life as they know it or as we know it has pretty much passed them by" (case manager 2).

That is, the reference point for decisions changes when the case manager concludes that no additional medical intervention will improve the client's quality of life, but that intervention can be made to minimize pain and suffering. This concept was articulated by another case manager who referred to a case she had had prior to the passage of the HCDA. She and all of the medical professionals involved in the case believed that the client, who had terminal cancer that had metastasized to her chest, should have a do-not-resuscitate (DNR) order. The judge denied the DNR. The case manager knew that if CPR were performed, "every bone in her chest [was] going to go through to her heart and it is going to be excruciatingly painful for her" (case manager 11). The case manager added that since the HCDA has been in place such a scenario has not been repeated.

Most case managers discussed DNR orders when they were asked to describe their experiences with EOL care decision making. Requests for DNR orders were usually initiated by the attending physician, but it was then up to the case manager to decide whether a DNR order was in the client's best interest. Case managers reported that they generally agreed with any considered request for a DNR, and they reported that they followed the procedures outlined in the HCDA once a physician requested a DNR. Two physicians must state that cardiopulmonary resuscitation (CPR) or other lifesaving procedures would be "medically ineffective" and that the client was in an "end-stage condition," was in a "persistent vegetative state," or had a "terminal condition."[14] The case manager must provide the court with a memo describing the facts of the case and the justification for the DNR. Case managers from all three jurisdictions reported that DNR requests were routinely approved by the courts.

Barriers to Making Decisions in the Client's Best Interest

In the context of medical and EOL care decision making, case managers identified physicians as barriers to acting in a way that they believed to be in the best interest of their clients. Case managers generally referred to any recommended action that they believed was not in the best interest of their client as "overtreatment" or "undertreatment." In general, the case managers in this study sample were more likely to report examples of physicians' recommendations that they believed would result in overtreatment for their client, rather than in undertreatment.

Overtreatment

A number of case managers reported encounters with physicians who appeared to make recommendations for diagnostic procedures based on a belief that every patient of a certain age should have a particular procedure (for example, every patient ought to have a colonoscopy at age 50), but case managers reported that they generally did not consent to a diagnostic procedure unless there was intent to change the client's current plan of care based on the results of the procedure. This was especially true if the diagnostic procedure was an invasive one. One case manager noted, "For example, if the overall plan for Joe is not to perform surgery if a colonoscopy would determine a tumor, then one would be hard pressed to justify the colonoscopy with medical practice as well as legal practice" (case manager 2).

Almost every case manager reported having the experience of challenging a physician's recommendation for the placement of a feeding tube. When a feeding tube was recommended, case managers first reviewed the medical history to determine if less invasive alternatives had already been pursued. Many of the case managers reported that they believed physicians in nursing homes often recommended the placement of feeding tubes out of convenience, and recounted specific cases in which less-invasive options, such as observed feeding, encouraged feeding, food consistency change, or appetite enhancement medications, were not pursued prior to the feeding tube request.

Undertreatment

With the exception of one instance in which a case manager found herself advocating for a colostomy against the recommendation of a physician who was satisfied with prescribing several daily enemas for her client (case manager 12), case managers rarely described physicians who avoided aggressive medical treatment when caring for elders with dementia. Case managers did report occasionally encountering "ageist" attitudes from physicians, in the context of EOL care decision making, and stated that they were unlikely to consent to DNR orders in response to physicians' requests that were driven by what they believed to be an "ageist" attitude that all elders with dementia should have a DNR. Case managers also voiced their dissatisfaction with institutions that believed all residents should have a DNR.

One case manager reported a case in which a client's stated preferences created an obstacle to acting in what she believed to be in the client's best interest. This client, despite her dementia, clearly articulated her discomfort with a physician's recommendation, believed by the case manager to be in the client's best interest, to have a diagnostic exam for cervical cancer (case manager 7). The case manager found the client's statement so powerful that she refused the procedure on behalf of the client. Another case manager noted that if she believed that her client's request to refuse a procedure was "solid," she would take the request to the court.

Only one case manager reported refusing consent for a physician's recommendation that she believed would result in the undertreatment of her client with dementia, and therefore was contrary to his best interest. In this case, the guardian reported that her client with dementia disagreed with a physician's recommendation that he have a DNR order in his chart. The client had suffered a stroke and was unable to speak, but the case manager reported that the client responded affirmatively to her direct question as to whether he would like the doctors to "do everything in their realm possibly to keep you alive" (case manager 10). In contrast to decisions described by other guardians that relied on the best-interest standard, this guardian acted in a way that she believed to be responsive to a direct request from her client (neither substituted judgment nor best interest). It is relevant to note that this case manager was relatively new to the job and stated she was overwhelmed by the thought of making life and death decisions. A number of case managers reported that they began their careers with a similar attitude, but became more comfortable with making decisions to withhold treatment. Specifically, a number of case managers reported that one of the signs of their maturity as case managers was their willingness to challenge physicians' recommendations.

SUMMARY

We conducted an in-depth interview study of public guardians in three local jurisdictions in the state of Maryland to explore the decision-making process utilized by court-appointed public guardians making medical and EOL care decisions on behalf of their clients with dementia. Overall, public guardians appeared to make their decisions in the context of relevant ethical principles and relevant case law and state statute, and the basis upon which they made informed decisions was dependent on their training and experience. The stated goal of public guardians is to make decisions that they believe are in the best interest of their clients. In the case of a healthcare decision, their goal is to maximize quality of life; and in the case of an EOL care decision, their goal is to minimize pain and suffering.

In general, public guardians gathered information in order to identify previous preferences of their now-incapacitated clients, so that they could develop a preference profile to assist both an initial decision on whether an individual ought to have a court-appointed public guardian, and with healthcare and EOL decisions once an appointment was made. When guardians were unable to develop a preference profile for a particular client, they relied on past decisions in similar situations.

Healthcare and EOL decisions were most often triggered by a recommendation by the client's healthcare provider. Once a decision-point was identified, the public guardian considered the risks and benefits of the proposed

intervention in light of the client's current condition. At times the guardians reviewed informational resources such as textbooks and the internet. In addition, most guardians sought advice from a medical consultant who is available to all public guardians in Maryland. Some guardians sought the advice of this medical consultant only when faced with more complex decisions.

Guardians challenged physicians' recommendations when they believed the physicians were recommending an intervention that was not in the best interest of the client — that is, they advocated against either overtreatment or undertreatment. Ultimately, guardians took particularly difficult issues to the court and obtained a judge's opinion.

DISCUSSION

We believe these results serve as a starting point for local and statewide discussions regarding how decisions are being made for older adults who lack decisional capacity and whether there are ways in which the approach to decision making ought to be clarified. These data may be particularly helpful to guardians and physicians who are new to the context of medical and EOL care decisions on behalf of clients with dementia. Whether this model of decision making can be generalized to decisions made by private guardians and/or on behalf of younger incapacitated adults ought to be tested.

For public guardians, the difficulty of making consequential health and EOL care decisions seems to decline with experience. For a particular family member, making healthcare and EOL decisions on behalf of a spouse, parent, or sibling with dementia may be a unique experience. Public guardians learn from their experience and become more confident in their knowledge and abilities as they mature in their professional role. Ways to take advantage of the experience of veteran public guardians to facilitate decisions made by family members ought to be considered.

One limitation of this study was our inability to observe and document decisions being made in real time. We relied on descriptions and stories told by the public guardians. In addition, we did not review the medical charts of any of the clients with dementia discussed by the public guardians to explore whether their reporting of a case was accurate. Future studies can test the applicability of the approach to medical or EOL decision making described in this report to real-time decision making about individual patients. Additional research could also be conducted to verify these results among public guardians appointed in other Maryland jurisdictions, as well as explore this phenomenon in states with similar and different policy approaches to decision making on behalf of incapacitated clients. Future research in this area is essential as the U.S. aging population grows and the number of patients with dementia who will rely on strangers to make decisions increases.

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13. "(1) The effect of the treatment on the physical, emotional and cognitive functions of the individual; (2) The degree of physical pain or discomfort caused to the individual by the treatment, or the withholding or withdrawal of the treatment; (3) The degree to which the individual's medical condition, the treatment, or the withholding or withdrawal of treatment result in a severe and continuing impairment of the dignity of the individual by subjecting the individual to a condition of extreme humiliation and dependency; (4) The effect of the treatment on the life expectancy of the individual; (5) The prognosis of the individual for recovery, with and without the treatment; (6) The risks, side effects, and benefits of the treatment or the withholding or withdrawal of the treatment; and (7) The religious beliefs and basic values of the individual receiving treatment, to the extent these may assist the decision maker in determining best interest." (Annotated Code of Maryland 2001d)

14. See note 8 above, § 5-601:(i)(o)(q).

A Forced Choice: The Value of Requiring Advance Directives

Elmer D. Abbo and Angelo E. Volandes

INTRODUCTION

Interest in advance directives has re-emerged in light of the tragic case of Terri Schiavo.[1] The conflict among Schiavo's family highlighted the unresolved problem of making medical decisions for incompetent patients who do not leave an advance directive, either a living will or healthcare proxy.[2] Without objective evidence of an incompetent individual's wishes, any surrogate — whether it be spouse or parent, child or sibling, physician or judge — is left to construct those wishes in the abstract. Inevitably, often surrogates will make decisions that are inconsistent with the patient's preferences,[3] and conflict in end-of-life decision making will remain a ubiquitous problem.[4]

Ironically, the calls for increased use of advance directives come at a time when living wills, although not necessarily healthcare proxies, are increasingly criticized for lack of effectiveness.[5] In addition, advance directives have failed to be widely adopted despite more than 25 years of advocacy inspired by the similarly tragic cases of Karen Quinlan and Nancy Cruzan, whose deaths even led to the implementation of the Patient Self-Determination Act, a federal law requiring hospitals who care for Medicare and Medicaid patients to provide information about advance directives to their patients. Thus, we are not optimistic that the case of Terri Schiavo will do much to solve the continuing problem of decision making for incompetent patients. Although we certainly favor the use of advance directives, we believe advance directives must be improved through systematic changes in their use. It is time we start requiring them.

We will argue that insurance and care provider institutions should be allowed to require patients to declare an advance directive. The directives we favor would give patients the option to limit *or pursue* life-sustaining interventions in common death trajectories as well as name a healthcare proxy. Federal and state laws that currently prohibit such practices should be changed. We believe requiring patients to express their preferences in advance directives will promote better end-of-life decisions, decisions that not only prevent conflict but are more

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likely to be consistent with patients' preferences than our current troublesome approach.

A FORCED CHOICE

The goal in end-of-life care should always be to provide care that is consistent with the wishes of the patient. Unfortunately, end-of-life care is often at odds with what patients would have wanted.[6] Since death is ubiquitous and periods of incapacity prior to death are common, it is shortsighted not to establish routinely the goals of care for patients. Requiring individuals with decision-making capacity to complete an advance directive — a forced choice — would largely resolve the open question of how to decide for incompetent patients, while at the same time respecting and promoting patients' autonomy.[7]

As implied by the term "choice," individuals, when completing the advance directive, should be presented with the opportunity to declare their preferences for either a life-prolonging or a comfort-oriented approach. Unlike traditional living wills, the directives we envision would do more than merely allow patients to limit the use of life-sustaining interventions. In addition, an individual could complete a living will, a healthcare proxy, or a combined form. While including an instructional, or living will, component would provide some substantive guidance regarding an individual's values, all individuals would, at a minimum, be required to complete a healthcare proxy. However, unlike most current statutory proxy requirements, any proxy would be required to provide his or her assent and to confirm that he or she has discussed end-of-life wishes with the patient.

Since individuals can still pursue a preference for either life-sustaining interventions or limiting interventions, such an approach is only minimally paternalistic.[8] No particular type of care or vision of a good death is being forced on anyone. More importantly, any small infringement of individual rights that occurs as a result of requiring a declaration of preferences before the time of illness is justified by the preservation of those same rights at the critical time of incapacity.

An ideal opportunity to require completion of an advance directive would be at the time of initiation of healthcare insurance, whether provided privately or publicly, or the initiation of care with a healthcare provider or system. Completing an advance directive would be required within a reasonable time period, perhaps three to six months from initiation. This time would allow for thoughtful consideration and consultation with loved ones and medical providers. To improve the reliability of the advance directives, individuals must be sufficiently informed. Written or multimedia educational information, which clearly explains the full range of patients' options and provides examples to help individuals understand how advance directives are used in various contexts, would be sufficient for many people.[9] Others who require additional information and counseling would have sufficient time to meet with their physician or confer with a provider skilled in advance care planning.[10] Since willingness to accept life-sustaining interventions is known to decline over time as disability increases,[11] individuals would be asked to update their advance directive on a regular basis, most likely annually, and could alter their advance directive at any time.

Although most people actually welcome the opportunity to discuss end-of-life preferences,[12] some policy makers may object to forcing all patients to complete an advance directive. One reason often cited is that members of minority groups have tended to distrust advance directives in the past.[13] However, many minority patients do accept palliative care approaches.[14] In addition, some studies suggest that the differences in the use of advance directives across ethnic groups are modifiable and such differences may not exist for some communities.[15] In addition, previous advance directives have generally only been written to limit care, which has led patients who prefer life-prolonging approaches to distrust advance directives. Since with our approach individuals would be free to pursue all options, we believe trust may even be *increased* as people gain familiarity over time with the way these advance directives actually work.

We recognize that there may be some individuals who are uncomfortable confronting these issues formally. We suspect this will be a small number of people, but regardless, life inevitably presents uncomfortable questions that

we must confront. There is evidence that many individuals who are uncomfortable discussing these issues still prefer limiting life-sustaining interventions in some situations.[16] These preferences are unlikely to be met, however, unless they are known. Societal policies should not shelter people from reality, particularly when the reality of death and dying has profound effects that extend beyond the individual, affecting not only the individual's family but also the community as a whole.

The idea of requiring advance directives of individuals has been discussed previously.[17] However, our approach is unique. For example, we do not advocate for legislation that would require all individuals to complete an advance directive simply by virtue of being a member of society or require all healthcare insurance and provider institutions to obtain advance directives for their insureds and patients. Rather, we favor an approach in which institutions can freely choose to pursue a forced-choice policy for their clients or patients.

Our approach places the choice to require advance directives in the private sphere, which presents several distinct advantages. First, it avoids free speech and privacy concerns that are inevitably raised when dealing with governmental actors mandating advance directives.[18] And although these legal hurdles may be overcome,[19] completely avoiding them will reduce political concerns, which, as will be discussed below, are not insignificant.

Second, and more importantly, with our approach institutions can more freely develop advance care planning mechanisms that fit the needs of their patients or clientele. Thus, only if requiring advance directives routinely of individuals is found to be effective, useful, and worthwhile will this practice become the standard of care. Even if our institutionally based forced-choice approach is shown to be effective, it is highly conceivable that forced-choice approaches and traditional approaches would coexist in the same marketplace. Therefore, by leveraging the market accountability of insurance companies and healthcare providers to insureds and patients, individual choice is at least to some degree retained.

A mandated approach, such as that used in the Patient Self-Determination Act, is less likely to be sensitive to the costs and benefits encountered in developing and administering such a policy. In fact, it has been argued that the financial costs incurred by the Patient Self-Determination Act have been wasteful.[20] Indeed, they have been. Requiring the simple distribution of information about advance directives without the expectation of having patients execute an advance directive was shortsighted. The better reason to invest resources in advance directives is to actually obtain information about patients' preferences, not simply to inform them of their rights. However, a mandated approach is not easily abandoned if indeed the policy of requiring advance directives of patients, like the policy of mandatory hospital-provided information about advance directives in the Patient Self-Determination Act, is not found to be useful.[21]

LEGAL, ETHICAL, AND POLITICAL ISSUES IN IMPLEMENTING A FORCED CHOICE

Unfortunately, there is no place in the United States where an institutionally based forced-choice policy could be implemented today because insurers and providers have been forbidden from pursuing such strategies by state and federal statutory limitations on the use of advance directives: 48 states and the District of Columbia prohibit insurance companies from requiring advance directives of their insureds; 33 states prohibit providers from requiring advance directives.[22] In addition, the Patient Self-Determination Act prohibits conditioning care on the execution of an advance directive.

We presume these prohibitions exist to protect individuals from being forced to accept unwanted limits on treatment, limits that may appeal to third parties because of the cost-savings they may represent. If individuals were required to execute advance directives and many patients chose options that limited care, it is possible that these directives would subsequently lead to greater withholding and withdrawing of costly life-sustaining interventions and result in cost-savings. In fact, early proponents of advance directives hoped that they would lead to savings by reducing marginally beneficial care at the end of life.[23] Taking this assumption for granted, it is possible to imagine insurers offering an insurance premium discount to those

individuals who complete an advance directive that limits life-sustaining interventions.

We acknowledge that such an approach is ethically controversial because it may be seen as coercive for individuals of modest means, as it provides these individuals limited alternatives. Although the degree of savings may not be substantial,[24] if the savings were large enough, one might predict that health insurers and hospitals that cater to patients of low income would be more likely to embrace a forced-choice policy in order to avoid marginally beneficial but costly care, thus disproportionately compelling low income patients to complete an advance directive. Indeed, similar concerns were raised in negotiations over the Patient Self-Determination Act even after initial attempts to mandate advance directives were abandoned.[25]

However, a forced-choice policy cannot be seen as discriminatory against the poor if it is implemented as we suggest. The advance directive would present both options of limiting and pursuing life-sustaining interventions. If a forced choice actually saves resources and lowers premiums, the poor will benefit the most from improved affordability of insurance and thus increased access, while still retaining choice at the individual level. Indeed, the forced-choice policy that we embrace creates a mechanism by which an individual's preferences for end-of-life care can be more clearly known no matter his or her preference. A forced choice is still a choice.

Nevertheless, one may still be worried about price discrimination against those who indicate their preference for greater access to life-sustaining interventions. Differential pricing signals important differences in insurance products to consumers. However, if price discrimination in this area is considered ethically unsound, it is possible to avoid this problem while still requiring a declaration of preferences. In this scenario, any savings that may accrue would benefit all individuals in the insurance pool as a whole rather than benefit only particular individuals. In fact, 26 states have passed laws forbidding insurers from using advance directives in underwriting.[26]

It should be noted that depending on the presence of a statutory anti-underwriting provision and its expansiveness, it may currently be legal in some jurisdictions for institutions to offer financial incentives to complete an advance directive, since a financial incentive that is not tied to a patient's premium has no effect on underwriting. Although financial incentives without institutional obligation to complete one may still raise the same ethical concerns, particularly if the incentive is only offered for completing an advance directive that limits life-sustaining interventions, such use of financial incentives today should be seen as ethical. No one is made worse-off than before by offering financial incentives. Individuals are only better-off because a new option of some financial value is now being offered. If the individual is uninterested in completing any advance directive, the individual simply need not participate. Of course, as in the case of price discrimination in the setting of a forced choice, regulations could be developed to assuage any ethical concerns that financial incentives will only be triggered for completing an advance directive and not for its content.

Daniel Callahan has argued that requiring advance directives is unethical because the inevitable tying of advance directives to monetary concerns corrupts the trust underlying the doctor-patient relationship.[27] Financial considerations are an inescapable aspect of seeking healthcare today, and yet the doctor-patient relationship survives. We do not think that doctor-patient relationships are so fragile that they are likely to be undermined should individuals be asked about their care preferences as a result of initiating an insurance or patient relationship. In fact, for many individuals trust may be strengthened, because they may not only benefit immediately financially, but may have greater confidence that their future preferences for care will be honored.

Although we would welcome the use of financial incentives for advance directives as well as statutory changes, when necessary, to allow financial incentives to be more readily available, we prefer our forced-choice approach because it promises greater participation in the use of advance directives. Therefore, we advocate for changes in federal and state legislation that would allow insurers or providers to require advance directives of their patients at the level and discretion of the institution.

We do recognize that there would be significant political opposition to such legislative changes. The legislation leading to the Patient Self-Determination Act initially embraced a mandatory approach that was abandoned on account of political pressure.[28] Given the inherent political responsiveness of the Centers for Medicare and Medicaid,[29] government institutions are unlikely to initiate a forced-choice policy, particularly given the sensitive nature of end-of-life care. Ironically, Medicare likely has the most to gain from successful implementation of such a policy, if indeed such a policy results in substantial cost-savings. The elderly, who are covered by Medicare, have higher end-of-life costs than younger patients do.[30] It is well known that approximately one-quarter of Medicare spending occurs in the last year of life, 70 percent of which occurs in the last six months.[31]

Our approach actually presents an opportunity for such political opposition to be minimized. We believe institutionally required advance directives are more politically palatable than legislatively mandated universal advance directives because, under our approach, the introduction of required advance directives would likely be gradual, not universal, and more sensitive to market demands and individual preferences. Indeed, our approach presents a constructive middle ground on which greater political consensus regarding the requiring of advance directives may be built. If private insurers and providers can successfully implement the policy and demonstrate that it is both ethical and effective, then political opposition will likely recede, and the practice may eventually be embraced by governmental institutions.

Thus, it is time to lift the ban on preventing insurers and providers from requiring advance directives of individuals. At the very least, federal legislation granting waivers of current prohibitions to a small number of willing insurers or large health systems, to test institutionally required advance directives, would be a valuable exploratory step. Any congressional action allowing or exploring the requiring of advance directives by insurers and providers would be a far more useful federal intervention aimed at improving future end-of-life care than the actions taken by Congress in the life of Terri Schiavo.

IS REQUIRING ADVANCE DIRECTIVES WORTH THE EFFORT?

A Second-Best Reality

Some may question our approach, given the ambiguity of living wills and the suggested inefficacy of advance directives generally.[32] But the reality is that the alternatives are worse. Whereas there is no appetite to return to the days of unbridled paternalism in medicine, upholding patients' autonomy through surrogate decision making is often little more than surrogate autonomy. Surrogates present particular challenges to implementing the end-of-life wishes of a loved one,[33] the least of which is that sometimes no surrogate is available.[34] More importantly, surrogate decision making is especially prone to bias and error in executing patients' wishes.[35] In addition, surrogates are less likely to withdraw care for a relative than they would be for themselves,[36] which is why we question the conventional wisdom that discounts living wills in favor of healthcare proxies.[37] Since healthcare proxies simply name the surrogate decision maker rather than rely on state default rules of surrogacy, proxies can minimize conflict but they do not necessarily increase fidelity to patients' wishes.[38] Even if proxies do discuss end-of-life wishes with the patient, surrogates themselves prefer that patients express their wishes not just orally, but in writing.[39] And more than 80 percent of patients and recently bereaved family members reported that they believed that having preferences in writing was important.[40]

Of course, some may question the autonomy paradigm that underpins the logic justifying both surrogacy and advance directives. Rebecca Dresser has been one of the most ardent advocates of embracing an objective best-interests standard. She argues that precedent autonomy is flawed. That is, since individuals cannot accurately predict future preferences for a hypothetical life state, such preferences should not bind our future selves.[41] Rather, she argues that decisions should be based on what the community, including but not limited to the family's preferences, determines to be in the patient's best interests.[42]

A full discussion of the merits of the best-interests standard is beyond the scope of this

article, but, ultimately, we construct our approach on traditional precepts regarding the autonomy of patients because best-interests standards have not been able to establish consensus on normative ideals. The national debate that took place surrounding the case of Terri Schiavo only serves to remind us that we remain far from developing normative end-of-life care standards as a society.[43] And even if the autonomy of patients is a second-best alternative, the fact remains that patients' autonomy serves as the foundation of modern medical ethics and health law. Ironically, pursuit of a forced-choice strategy may eventually lead us to a best-interests standard, in that more universal agreement on normative standards may evolve when we increasingly learn about individuals' attitudes about life-sustaining interventions in a more global fashion.

Since we as a society have accepted a framework built around the autonomy of patients, we have an obligation to embrace policies that actually promote the provision of care in alignment with individuals' preferences. Given that surrogacy is failing us, requiring advance directives offers much promise, even though past empirical research has failed to demonstrate the effectiveness of advance directives. A careful review of the history of and research regarding advance directives, suggests that there is room for continued optimism regarding the potential efficacy of advance directives. It is important to note that past research that utilized hypothetical scenarios or voluntary advance directives has told us little about how institutionally required advance directives would affect care.[44] This past research simply does not apply to this policy. The policy we suggest has never been tested, nor can it be tested without a change in the law. However, past research is useful in suggesting how future advance directives must move beyond the recognized problems of the past.

Drafting Applicable Advance Directives

Advance directive statutes evolved in the midst of skepticism and concern about the withdrawal of care. Thus, they were intentionally drafted narrowly to apply to cases of terminal illness, in which death was thought to be inevitable, or to the rare case of suspended life in which recovery was not possible, such as a persistent vegetative state. This terminology makes intuitive sense, but is misleading. It implies that the disease has progressed to a point where recovery is unlikely despite continued treatment. But for the physician who carries the primary responsibility of interpreting an advance directive, the language of terminal illness is a term of art used with great caution.

Whereas a doctor may be willing to predict that recovery is unlikely, stating that a patient is "terminal" requires a greater confidence that in practice is generally lacking. Judging an illness to be terminal before the fact is difficult. Physicians, aware that they are poor prognosticators of death,[45] describe a disease as terminal only when the natural history of the underlying disease process is uniformly known to lead to death. The paradigmatic case of terminal illness is metastatic cancer, but cancer only accounts for 22 percent of elderly deaths. The majority of elderly deaths occur in the setting of an acute and sudden illness or from an acute decompensation in the setting of a chronic illness or frailty. In fact, a condition of frailty precedes the deaths of almost half of all patients age 65 and older and 20 percent of those age 85 and older.[46] Furthermore, 27 percent of elderly patients who die have at least some degree of dementia, a figure that will likely increase.[47] These deaths are the result of a critical illness that is not readily described as terminal until the time of death, or very close to it.[48] In the mind of a physician, the potential for the reversibility of the acute component, even if unlikely, disqualifies an illness from being described as terminal.

This framing effect of terminality may help to explain the negative results of the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT).[49] SUPPORT, the largest study of end-of-life care involving more than 9,000 patients across the U.S., attempted to study end-of-life care and to develop an intervention to improve end-of-life decision making. Although the study included patients with advanced medical illness, half of whom died within six months, the use of a nurse-based communication intervention to provide physicians with information regarding pa-

tients' preferences, as reported by the patient or surrogate, made no difference in the type of care that patients received.

One possible reason physicians in the study did not implement end-of-life preferences, even when these were known, was a belief that preferences to withhold life-sustaining interventions should not be acted upon until patients are terminal, since a perception of terminal illness has been the standard paradigm on which polices promoting the withholding and withdrawing of life-sustaining therapy have traditionally been based. A qualitative substudy of SUPPORT patients provided further evidence of this terminality problem, as it particularly relates to advance directives. Physicians generally did not view an advance directive limiting life-sustaining interventions as applicable until the patient was seen as "absolutely hopelessly ill" or "actively dying."[50] Other studies on the use of advance directives in SUPPORT also failed to demonstrate any effects on the type of care received or the costs of care provided.[51] However, most of the directives utilized in the study were simply healthcare proxies, which, as we previously noted, have limited value when not combined with an instructional component.

Earlier proponents of advance directives have recognized this terminality problem and have attempted various solutions. A second generation of advance directives has attempted to refocus care decisions regarding unwanted medical interventions and utilized a bidirectional approach, allowing individuals to limit or prolong care that we favor.[52] A third generation focused on incorporating patients' values.[53] However, neither approach improved surrogate accuracy in hypothetical scenarios nor has either been widely utilized in practice.[54]

It is worth noting some useful developments in advance directives as formulated by the Uniform Health-Care Decisions Act (UHCDA), a model for advance directive legislation.[55] Similar to past efforts, the UHCDA relies on traditional operational language, such as irreversibility, permanent unconsciousness, and burdens outweighing the benefits. However, the UHCDA combines a proxy with an instructional living will component and is bidirectional. It also separately addresses artificial hydration and nutrition, which many individuals value differently from other life-sustaining interventions. Although the model act has been explicitly adopted by six states and has likely influenced many other states that have incorporated some of these features, the value of the UHCDA remains unclear, and we suspect it is limited due to its reliance on traditional terminality language.

Future advance directives need to be uncoupled from a perceived requirement of terminality or irreversibility to be able to respond to common death trajectories, such as multisystem organ failure, congestive heart failure, chronic obstructive pulmonary disease, and advanced dementia. In order to become more widely applicable across a wide range of death trajectories, advance directives should focus on two key preferences that are widely shared by many patients. First, patients share an overwhelming desire for a chance at recovery.[56] However, patients commonly do not desire indefinite life-sustaining therapies. Most patients only want a reasonable trial of life-sustaining therapy attempted before care is withheld or withdrawn.[57] Thus, advance directives should specifically address whether a patient would like a reasonable trial of life-sustaining interventions in critical illness for an attempt at recovery, versus life-sustaining interventions administered indefinitely to prolong life as long as possible. The requirement for terminality or irreversibility is simply too rigorous and too narrowly construes patients' intentions, and it should be abandoned.

The other critical preference that advance directives should address is the preference for care in severe, irreversible neurologic compromise. The desire to avoid a life dependent on machines and not to be a "vegetable" is a well-known preference that is poorly articulated in current advance directives.[58] Most patients do not want life-sustaining therapy continued if recovery results in severe neurologic compromise.[59] And most patients would withhold life-sustaining interventions in the setting of advanced dementia, frequently including artificial hydration and nutrition and dialysis.[60] Although physicians prefer a more specific advance directive when making decisions, the specificity must also be useful.[61] Rather than simply focusing on terminal illness, an advance directive

should contain sufficient specificity to apply to the most common death trajectories without the complexity of previous intervention-specific advance directives. We believe that an advance directive should address preferences for a reasonable but limited trial of life-sustaining interventions in critical illness. An advance directive should also assess preferences regarding the use of life-sustaining interventions in advanced dementia, separately addressing the use of artificial hydration and nutrition and dialysis. We believe that such well-tailored advance directives will positively and meaningfully affect care by conveying an individual's intended goals of care in these death trajectories and addressing important values about acceptable health states currently not well articulated in today's advance directives.[62] We suspect these values can be more easily applied in common end-of-life health states by physicians in practice than preferences in traditional advance directives.

Of course, there remain legitimate questions regarding the accuracy, validity, and the effect of advance directives. Perhaps communication in advance care planning is inadequate to elicit patients' preferences, choice in end-of-life care is a fiction, or advance directives are simply insufficient to capture patients' preferences reliably or in a manner that may affect care.[63] We cannot hope to settle such deep skeptical worries here. Indeed, only time and experience can reveal whether our approach to advance directives avoids these problems. However, we think a trial of our policy is worth it, given the alternatives. Of course, we agree there is need for more and better communication about advance care planning between providers, patients, and family members. However, in a world in which surrogates remain unreliable and an objective consensus on what is in patients' best interests is lacking, we remain optimistic that advance directives remain a vital mechanism to improve decision making at the end of life.

Ambiguity, Accountability, and Accessibility

Even when an advance directive does not provide definitive guidance, limited objective information can still be helpful to both physicians and surrogates in assisting end-of-life decision making. Often what is at issue in end-of-life decision making is whether a patient would accept *any* withholding or withdrawal of life-sustaining interventions. As a patient's status deteriorates, surrogates may cling to the hope provided by prolonging life as long as possible and claim that patients would not be one to give up fighting. Thus, the presence of an advance directive that limits the use of life-sustaining interventions presents an opposing and more objective view of a patient's true preferences. Such evidence converts the decision to withhold or withdraw life-sustaining interventions from a philosophical one to a practical one about medical appropriateness.

Advance directives should be interpreted flexibly. Many patients desire flexibility in the interpretation of their living will, generally deferring to surrogates.[64] Physicians as well may not always execute an advance directive literally.[65] To some extent, this variability on the part of physicians is desired precisely because physicians play a leading role in determining medical appropriateness. Regardless, strict interpretation of a living will is not necessarily critical to its effective function in many end-of-life scenarios. For example, physicians are more likely to accept withholding and withdrawal of life-sustaining interventions when patients are suffering from dementia or recovery is unlikely, particularly when patients are receiving mechanical ventilation or dialysis.[66] Thus, physicians are likely to accept withholding and withdrawal of interventions in the common death trajectories with which we often struggle.

Acknowledging that living wills will never be universally strictly interpreted and placing this responsibility primarily in the hands of physicians does create a potential opportunity for abuse by physicians. However, a forced-choice policy actually creates greater accountability and may help to mitigate this inevitable weakness of advance directives. One major barrier to the use of advance directives has been the non-availability of an advance directive at the time it becomes relevant. In SUPPORT, less than 10 percent of the patients in the study who had advance directives had their advance directive placed into the medical record.[67] In another study, only about 25 percent of patients had their advance directive documented in the medical record, although, once documented, the directives did appear to influence care.[68] A

forced-choice policy would likely lead to an improvement in the accessibility of advance directives. In fact, it is likely that a legal obligation based in malpractice law to have documents accessible would follow from any institutional policy to require them. Insurers would make sure the information would be readily available to providers, and providers would develop internal systems of documentation to allow easy access to advance directives. The ongoing development of electronic medical record systems makes this technical barrier increasingly possible to overcome.

With greater accessibility to living wills comes increased accountability to follow their instructions, by both providers and surrogates. Systems could be developed to monitor and enforce compliance with the advance directive, including a mechanism by which one may seek to escape the plain terms of a directive. We suspect that such a system would actively involve an institution's ethics committee, but such forecasts are beyond the scope of this discussion.

Greater accessibility to advance directives through a forced-choice policy also responds to the growing problem of discontinuity of care in our healthcare system. Discontinuity of care places increased importance on the objective documentation of patients' preferences. A lack of continuity in care can severely undermine general efforts at advance care planning in which discussions about end-of-life wishes take place, but an advance directive is not formally completed. When such discussions transpire without the presence of potential surrogates, as they often do, surrogates may not find documentation by providers alone compelling enough to overcome their own understandably conflicted views, particularly when the provider who documented the prior conversation is not an active member of the care team at the time of illness.

Discontinuity of care has progressed in the last decade as in-patient medicine has been redefined with the rapid growth of hospitalists.[69] Advance directives may not have been as necessary in the past when most hospitalized patients were cared for by their primary care physicians, but now, in some markets, more than 50 percent of patients are cared for by hospitalists.[70] In one study, advance directives did not have any effect on the accuracy of decision making by surrogate family members or primary care physicians, but did improve the accuracy of emergency room and critical care physicians.[71] Like these types of hospital-based physicians, hospitalists tend not to have pre-existing relationships with patients and are likely to benefit from an advance directive in improving end-of-life decision making.

The Role of Advance Directives in the Evolving Paradigm of Palliative Care

Advance directives evolved in response to an era of paternalism by physicians that valued the prolongation of life above other goals. The language and legal authority of advance directives evolved directly from common law rights to refuse unwanted bodily invasion and treatment.[72] Thus, advance directives were created to protect patients from the medical profession. However, as the medical profession tolerates, and in many cases promotes palliative approaches to care, the role of advance directives has shifted. Advance directives serve less to protect patients from physicians who are unwilling to allow their patients to die than from family members who are unwilling to accept the inevitable.

We have witnessed dramatic changes in medical orthodoxy regarding palliative care in the last decade. Partly as a result of the disappointing findings of SUPPORT, many individuals within the ethics and palliative care community have successfully worked to transform medicine. Palliative approaches to patients with advanced complex disease have not just become acceptable alternatives, but are quickly becoming the mainstream professional paradigm.[73] Accepting death by withholding and withdrawing life-sustaining interventions has become more common. In one study, approximately half of the patients who received mechanical ventilation who later died had the ventilator withdrawn in anticipation of death.[74]

Further evidence of this change in medical orthodoxy can be seen in the types of cases presenting to hospital ethics committees. In the past, physicians went to ethics committees to obtain approval to withdraw care after a family's request. But today, ethicists increasingly note that requests for an ethics consultation are

being made to manage conflict when surrogates insist on pursuing marginally beneficial care for patients with advanced complex illness who are dying. At Beth Israel Deaconess Medical Center in Boston, Lachlan Forrow, MD, the director of the ethics service, estimated that in the last 15 years 80 percent of the ethics cases were right-to-die cases, whereas now 80 percent involve families pushing for care that is perceived to be inappropriate by the medical staff.[75]

Palliative medicine and ethics consultation have evolved in large part as ways to manage this common end-of-life scenario. But given our current reliance on surrogate decision making, these approaches often resolve conflicts only by validating the right of the surrogate to speak for the patient. Physicians in these situations could invoke futility, but the concept of futility is problematic, generates greater distrust and conflict, and should be avoided.[76] Thus, without an advance directive, physicians must defer to the flawed decisions of surrogates.

Surrogate decision making is frequently complicated by the clinical reality of multiple surrogates, who are generally members of the same family.[77] In such cases disagreement amongst individual family members is not uncommon. Despite legal hierarchies to identify a primary surrogate, families commonly attempt to attain consensus or, if that is not possible, to minimize conflict. However, attempts to minimize conflict amongst surrogates may increase the likelihood that life-sustaining interventions are continued inappropriately. Advance directives, as we envision here, could be very useful in resolving such cases of family disagreement and prevent these cases from entering the courts.[78] Such advance directives would not simply insert a legal certainty into an area of uncertainty, but would provide valuable objective evidence that would help both physicians and surrogates steer a course based on the best understanding of the patient's preferences. Of course, dialogue and shared decision making will, and should, continue to be a prominent aspect of end-of-life decision making,[79] but advance directives can serve as an appropriate foundation from which such conversations begin. Advance directives are, indeed, most useful when used as the basis of such open discussions with surrogates.[80]

Today's physician may be more accepting of palliative approaches, but authority to withhold or withdraw life-sustaining therapies must still be obtained, generally from a surrogate. By loosening the operational language of the advance directive beyond terminal illness as we suggest, advance directives may more readily apply and subsequently influence physicians in their discussions with surrogates. Physicians may become more comfortable framing decisions for surrogates with direct recommendations to withhold or withdraw life-sustaining interventions when patients stated such preferences in an advance directive and when such action is medically appropriate.[81] Physicians must be confident in knowing patients would not want to receive continued life-sustaining interventions prior to withdrawing care. In fact, a physicians' belief that care is undesired is a stronger predictor for withdrawing care than a physician's prognosis of survival or future neurological function.[82] And such recommendations may be received with greater trust when accompanied by an advance directive, rather than a recommendation made solely on the basis of the physician's medical opinion.

Thus, an advance directive may serve as permission for surrogates to let go. In those cases when a surrogate does not agree with such recommendations, despite an advance directive, or conflict remains amongst surrogates, an applicable, well-tailored advance directive may give sufficient confidence to the medical team to proceed with a unilateral withdrawal of care. Even when such cases go to court, advance directives can play a critical role in resolving end-of-life legal disputes.[83]

In light of the increasing willingness of physicians to embrace palliative approaches, we need better ways for those patients who want palliative care to get it. Through institutional requirements of advance directives, their greater availability offers much hope to address the continuing disconnect between the kind of care at the end of life that patients want and the care they actually receive.

CONCLUSION

It is time we start requiring patients to complete advance directives. Legal prohibitions

against such an approach should be modified to allow insurers or providers to require advance directives of their patients. Requiring advance directives has the potential to improve the fidelity of the provision of end-of-life care to patient's preferences as well as build consensus and resolve conflict in end-of-life decision making. In light of the increasing willingness of physicians to embrace palliative approaches, we need better mechanisms for all patients to realize their own desires for palliative care. Through institutional requirements of advance directives, systematic use of advance directives can serve a valuable role in actually allowing patients to realize their final wishes.

DISCLAIMER

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Organ Donation

KidneyMatch.com: The Ethics of Solicited Organ Donations

Richard H. Dees and Eric A. Singer

In June 2008, nearly 80,000 people in the United States were waiting for organs to save them from kidney failure or an indefinite future on dialysis.[1] The growing demand for renal transplantation has pushed the median wait time for a donated cadaveric organ to over three years, although waits of five to seven years are not uncommon in major metropolitan areas.[2] The number of patients on the waiting list for kidney transplantation has increased by approximately 10 percent annually, yet the number of donors has increased by only 4 percent each year.[3] There simply are not enough organs to go around. Since organs from cadaveric donors are increasingly difficult to find, patients are urged to try to find a live donor who is willing to give up one of his or her kidneys for the sake of the patient. Now, in fact, more kidney transplants use live organ donors than cadaveric ones.[4] Indeed, since live donations have a higher success rate than cadaveric donations, such efforts benefit the patient in more ways than one. The most obvious source of live organs has always been the patient's family — parents, adult children, siblings, cousins — especially when exact tissue matching was necessary. But newer antirejection medications make an exact match less necessary, and so donations have been approved from spouses and from close friends who have an emotional, but not biological, connection to the patient. As time has passed, the definition of a "friend" has gradually been expanded to include co-workers and fellow church members, even if the actual connection between the patient and the donor is tenuous.

If these recruitment efforts fail, the next obvious step is for patients to seek donations from unrelated donors through whatever means are available. In a computer-savvy world, many have turned to the internet to plead their cases in the hope that some altruistic stranger will come forward and offer to donate one of her or his organs. Not surprisingly, several services, most notably *MatchingDonors.com,* have emerged to facilitate the interaction between patients and donors. For a fee of $295 (which can be waived for economic hardship), *Matching Donors.com* allows patients to tell their stories and post pictures to make their case. About 250 patients have profiles posted to the website at any given time. Potential donors can register for free, and over 5,000 people have done so. To date, *MatchingDonors.com* claims, the service has facilitated 78 renal transplants at more than 20 different hospitals, with about another 40 in

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the works.[5] Only seven of the hospitals have refused.[6]

Until 2006, the American Society of Transplant Surgeons publicly resisted efforts to expand donations through the internet. The society acknowledged that genuine friendships may develop over the internet and that such friendships may provide the emotional tie that is generally required for donations, but they wanted to confine such donations to "pre-existing" relationships. The society was "strongly opposed to the solicitation of organs by recipients or their agents. . . . We believe that such solicitation and directed donation will undermine the trust and fairness on which the system of organ transplantation depends."[7]

Now, however, the society claims, "In so far as these solicited directed donors will add an additional scarce resource, there are ethical grounds to proceed with these types of transplants as long as the motivation is based in altruism and there are well defined safeguards regarding informed consent. . . ."[8]

The United Network for Organ Sharing (UNOS), which oversees organ transplants in the United States, has no official policy on such donations. Its past president, Francis Delmonico, MD, has argued, "I don't think we can legislate or regulate how people get to know each other. Once that occurs and someone decides they want to save another person, I don't think we ought to stop that as long as they are medically suitable, are not violating the law, and are fully informed."[9]

The decision to transplant is left to each hospital. But very few hospitals have an official policy on whether to accept such donations. We argue here that hospitals should be reluctant to accept such donations, but not that they should categorically refuse them. A better approach would be to try to offer a more systematic promotion of kidney donations, including altruistic donations from unrelated, living individuals to those most in need, based roughly on the current UNOS ranking criteria.

THE CASE FOR SOLICITATIONS

The most compelling argument for allowing solicited organ transplants is that the kidneys obtained from altruistic donors are organs that would not otherwise be donated. If so, then some people benefit from the donation and none are harmed.[10] Consider everyone who is or might be affected by the donation: the recipient, the rest of the transplant waiting list, the donor, and everyone else. Obviously, the person receiving the organ from an altruistic donor benefits from it. Everyone below that person on the transplant list benefits because the recipient is no longer on the list and so they are all moved up the list, and so each of these people becomes somewhat more likely to receive an organ.[11] No one above the person on the transplant list is harmed because the kidney would not otherwise be available, and so it neither improves nor decreases their odds of receiving an organ. The donor is not harmed, the argument claims, as long as he or she understands and accepts the risk freely and gives meaningful informed consent to the procedure. No one else is harmed, simply because no one else is affected, one way or the other, by the donation. Thus, proponents claim, the new situation is better than the old in a straightforward way: some people benefit and none are made worse-off. Surely, the argument concludes, an act from which some people benefit and none are harmed is morally permissible.

Before we accept this argument, however, we should examine it in more detail. The argument depends crucially on three claims, which will be examined in detail: (1) the organs solicited through the internet would not otherwise be available to any of the patients on the list, (2) the donors are not harmed by giving up their kidneys, and (3) no one else is harmed by the transaction.

POTENTIAL HARM TO OTHERS

The claim (1) that those higher on the list are not harmed by the donation rests on the assumption that the solicited organ would not be available to them. This claim is true only if the sole reason that people donate is in response to the particular personal stories they find on a website and that they would refuse to donate to anyone else. However, we can imagine that the kinds of stories told on *MatchingDonors.com* might motivate some people to donate an organ altruistically to whomever needs it most. If suitably channeled, their desire to donate might lead

them to give a kidney to, say, the official waiting list maintained by UNOS, a list that carefully weighs the many factors that determine who can best use a given organ at a given time. For that reason, some have argued that we should counsel potential donors about how their gift might benefit the next person on the waiting list, rather than the individual who solicited their organ.[12]

We can even imagine a public awareness campaign — much like that used for blood donations — that would extol the virtues of giving to the UNOS list and thereby increase the number of donors. Indeed, on independent grounds, such a program is certainly worthwhile.

However, even if such a campaign were effective, some people would still want to give their organs only to the specific person whose particular story moved them, and they might then be unwilling to donate to anyone else. So, whatever the independent merits of a public awareness campaign, we should accept the claim that in some cases, the donor would not allow her or his organ to be used by anyone else. In these cases, those above the patient on the UNOS list are not harmed.

THE LIMITS OF AUTONOMY

The claim (2) that donors themselves are not harmed when they freely consent to give an organ may also seem uncontroversial, but in fact, donors *are* harmed: an organ donation is a major operation that injures donors, and it requires significant recovery time and involves serious risks. To claim that donors are not harmed, we must argue that the injury and the health risks associated with donation are outweighed by the benefits that donors receive by helping recipients, by being altruistic in general, and by exercising their autonomy. Blood donations, which have virtually no risk, raise little concern. Similarly, bone-marrow donations, which have relatively little risk in themselves and carry little long-term risk, also raise few concerns. Because the risk of kidney donation is higher — both because the surgery itself carries some risk and, more importantly, because it carries long-term risks apart from the operation itself — the issues are more complex. At this point, however, as long as the donors themselves are the only one affected, autonomy usually trumps. We typically allow people to weigh these factors for themselves and then decide what is best based on their own values and judgments. After all, we allow people to bungee jump off high bridges, despite the very real risks, for nothing more than the thrill of it; generally, donors themselves can decide what risks they are willing to take for what benefits. So, for kidney donations, it would seem, we should allow potential donors to make these judgments for themselves, provided that the act of donation is not medically contraindicated.

Yet there are limits to autonomy: we obviously don't allow live heart donations, even from parents to children — although we revere people who are willing to sacrifice their lives so that others may live. Carl Elliott argues that it may be morally acceptable, or even praiseworthy, for a person to be willing to make such a sacrifice, but that doctors, who must treat their patients equally, cannot morally accept such donations.[13] We are willing to accept a certain amount of paternalism here. We think individuals should not take on too much risk, even if they understand it and are willing to accept it, and they certainly should not expect others to aid them when they do take exorbitant risks.[14]

Kidney transplants fall in between these kinds of cases: the risks to donors are significant, but not prohibitive. Hemorrhage; injury to adjacent organs such as the bowel, liver, or spleen; infection; and the need for additional surgery are all possible complications of undergoing a donor nephrectomy (either open or via laparoscopic technique).[15] Post-operative hospitalization is usually short (several days) and donors are able to return to their normal activities without restrictions within four to six weeks. But in the long term the donor is at risk for the development of hypertension, renal insufficiency, and even renal failure, that would require hemodialysis or renal transplantation.[16] Most institutions have determined that the risk of kidney donation is significant enough that they are reluctant to allow individuals to take the risk unless they would benefit from the donation because they have a real stake in the well-being of the recipient. So we think it an acceptable risk for family members and for close friends, both of whom have an emotional stake

in the life of the recipient. Of course, even more distant friends and members of a church community may have some emotional ties to the patient. But casual acquaintances and anonymous members of large churches don't meet this criterion, and so if we take this requirement seriously, we may have to exclude some donations that have been previously allowed.

Adopting such a policy would, of course, encourage some people to game the system by inventing stories of previous relationships. Indeed, we may acquiesce to donations from casual acquaintances, not because we think they are morally innocent, but because the harm to the donor is not too great and the costs of weeding out inappropriate donors is too high. Similarly, we could conclude that policing internet relationships would simply be too difficult, and we would rather not encourage deceit. However, the two cases differ in one morally crucial aspect: even distant friends and church members share a community with the patient, and contributing to that community has direct benefits to the donor. Moreover, the fact that we acquiesce to dubious donations because we think it too costly to police them does not imply that we should not attempt to discourage them when we can and to bar them when the evidence that there is no real relationship is obvious. Nevertheless, precisely because the risks are well known and relatively modest, the case for prohibiting internet solicitations on the grounds that it will harm the donor is weak.

INSTITUTIONAL HARMS: UNDERMINING THE SYSTEM

The claim (3) that no one outside the waiting lists is harmed by solicited donations is only obviously true if we assume harms occur only if we can identify particular persons who are harmed. But harms need not be assignable to particular people. Think, for example, of what we might call "institutional harms." An institutional harm can occur in at least one of two ways: (a) when a practice undermines an institution that benefits people in general, even if the practice directly harms no specific person; or (b) when an institution harms a group of people even if no particular person can claim that she or he was hurt by it. Either way, the existence of institutional harms undercuts the claim that the only outsiders who could be affected by the donation are those on the waiting list. Of course, this abstract point does nothing to show that internet solicitations do in fact cause institutional harms, but they might do so in at least three ways: (a) by undermining the whole transplant allocation system, (b) by unfairly promoting the interests of some groups at the expense of others, or (c) by leading to the commodification of organs that would itself be morally suspect.

The most straightforward institutional harm that we might think solicitations cause is (a) that they would sabotage the whole UNOS mechanism. The perception that the transplant rankings could be circumvented by the rich and the savvy undermines the general sense that the system is fair. A widespread belief that the system is unfair, that people "like me" are unlikely to benefit by it, and that it works against them would lead to a broad distrust of the system, which would undermine efforts to increase donations of both cadaveric and live organs.[17] Insofar as people think that internet solicitations allow some people — those who have the education and the resources to use the internet effectively — to manipulate the system, then people lose faith in the system as a whole. Such a result might not affect anyone currently on the list, one way or the other, because its full effects would only be seen several years from now. But it would obviously impose great cost on people who will need organs in the future. The question, then, is how likely is it that internet solicitations would lead to a general disillusionment with the transplant system? Any answer is speculative, but since few people understand how the organ distribution system currently works, the probability that a change in the rules would lead to a drop in donations seems low. Such a possibility does not, then, constitute a strong objection to the internet solicitations.

INSTITUTIONAL HARMS: FAVORING THE SAVVY

A second, related way that organ solicitations could cause an institutional harm is (b) by unfairly promoting the interests of some over

others. As Douglas Hanto argues, "Directed donation ties donation to the emotional appeal, public relations skills, photogenicity and financial resources of the patient, family and others involved in the campaign. It assumes that the person soliciting for the organ is ethically special because of some characteristic that allows an exemption from criteria that apply to everyone else."[18] Kidneys are distributed to those who are the most media savvy, to those who are most telegenic, and to those who can tell the most heart-wrenching story — not to those in the greatest need.[19] Of course, much of life works this way, from job interviews to political candidacies. Too often, jobs do not go to the best qualified or to the persons who need them most, but to the persons who can present themselves the best. Still, we often think the basics of life should not be based on such criteria. As an analogy, think of a system of assistance for the poor that is run completely on charity as opposed to one based on state welfare. Such a system may provide an unreliable source of support for the poor, and it could often be short of money at exactly the times when people need it the most. But, even more importantly, such a system might humiliate the poor by forcing them to beg to survive, and it might favor those who can grovel in the right way rather than those with the greatest claim. Indeed, the logical extreme of such a system is a feudal world in which every person is dependent on his social superiors for the basics of life.[20] In the same way, a system of organ distribution that unduly favors those who plead their case the best becomes geared to favor one type of recipient for morally and medically irrelevant factors. Such a system would harm those who cannot plead their case well and deny them organs, and it would even harm those who can make such please by forcing them to act in a way they may find humiliating.

In both the welfare and the organ cases, the *donors* prefer a system in which they have the power to judge whether the recipients are "worthy" of their donation, in which they can expect to receive direct gratitude from the recipient, and in which they can see the results of their beneficence. While these motivations are not inherently immoral, they may contain a morally dubious desire to control the process, if not the other person. Such a system gives power to the donors, a power whose use may undercut the altruism of their act. The creation of that power is perhaps unavoidable; the gift relationship that is created between the donor and the recipient in both cases is bound to be complex. In the case of organ donations, the complexities are even worse, because the need is so great and the duties of gratitude and reciprocation that are created can never be fully discharged.[21] For that reason, such gifts from relatives and friends can be overwhelming, even oppressive.[22] For just that reason, many *recipients* would prefer to receive an organ from a stranger, from whom they can escape and to whom they would feel less responsibility if complications arise.[23] But of course these motivations *are* morally suspect: recipients will feel less guilty if they lose their new organ through their own negligence than if it had come from a friend or relative. So, both the donors and the recipients may prefer a system that encourages internet solicitations of organs. But the fact that both the donors and the recipients would consent to this arrangement does not make it just. Indeed, any time one party in a transaction is desperate, he or she may agree to unjust terms. Think, for example, of labor contracts in desperately poor countries; if the alternatives are bad enough, many people would even consent to become slaves.

We solve the problems created by private charity by creating a welfare system in which people have rights to basic goods, and we then set up a social mechanism that taxes some to support others to insure that society can protect that right. Such a solution is not, of course, feasible for organ donations. We cannot "tax" anyone to provide the organs necessary to support a right to needed organs without dramatically undermining the autonomy we value so highly. The procurement of organs, then, will always require us to cultivate donors, and so donors or their surrogates will always have much power in any system we devise. But only if we were to accept the principle that what donors want is always what is most important are we forced to the conclusion that they are entitled to control the whole process. By the same logic, we should accept the conclusion that if what the donors want is money, then they should be allowed to negotiate whatever the market will bear.[24] The principle that the donor

should be allowed to control the process, then, may lead to a free market in organs and the full commodification of organs. If we reject that principle, then we should set up a system that is more fair to all potential recipients.

INSTITUTIONAL HARMS: THE COMMODIFICATION OF ORGANS

A third potential source of institutional harms lies in (c) an indirect path to the commodification of organs. Think, as an example, of the institutional harms of slavery. Even if slaves were treated humanely, we think the very act of being owned by another person is degrading — even if some might choose it to save themselves from a desperate financial plight or from death. Even free Blacks in the nineteenth century were harmed by the institution, because the very existence of Black slavery legitimated the view that Blacks were inherently inferior. We do not regard a ban on slavery as unwarranted paternalism; we regard it as a way of protecting the most vulnerable and of maintaining the basic dignity of all humans. People simply are not commodities that can be bought and sold.

Similarly, the existence of prostitution, we can argue, harms all women by making sexuality a commodity. Even if it were true that prostitutes entered their profession voluntarily and continued to practice it because they viewed it as their best option for employment, the practice itself would demean all women. Sexuality should be something that can be bought and sold, rather than an expression of mutual self-giving and intimacy.[25] Our sexuality, we could argue, is connected closely to our identities; it is deeply a part of who we are and of how we express ourselves in our most intimate relations with others. Because sexuality is such an intimate part of ourselves, selling it alienates us from ourselves in a way that selling our labor as a doctor or an accountant does not. Prostitution creates a way of viewing all women as people whose core identities can be bought, sold, and traded, and it creates an option for people the very existence of which makes their lives worse. Prostitution thereby dehumanizes women.

In both slavery and prostitution, the institution itself undermines human dignity in the way it treats people, even when the parties agree to participate. Both also affect even those who do not directly participate in them by categorizing some people as potential commodities.

For our purposes, the question is whether solicited donation would cause harm in a similar manner. The most plausible argument that solicited donation would cause harm is that allowing it would commodify organs and lead to a market in organs. If organs do become commodified, we might then come to regard our bodies as sources of revenue, and thereby think of human bodies in ways that are disrespectful to them. Our bodies might be seen as potential sources of income, rather than as, say, temples of our souls. Like the selling of bodies for sex or trafficking in persons, the option of selling organs may be one that we do not want to exist even as a possibility. Just as prostitutes' bodies might be seen as "sex toys," human bodies might come to be seen as organ storage facilities. Like prostitution, the option of sale only has attractions for people who are desperate, and, for that reason, harvesting their organs would be exploitative. The objection, then, is that the ban on selling organs is an important measure for respecting human dignity and for protecting the most vulnerable in our society.

Some could argue that we already treat organs in precisely this way. People in the U.S. sell, for example, their sperm and their eggs, and elsewhere, people routinely sell their blood — though blood sales have long been seen as a poor way to generate the necessary blood supplies.[26] Yet blood, sperm, and eggs are different from kidneys in ways that are morally significant. The first two are replaceable, and, while eggs are not replaceable, most women have many more than they could possibly use in their lifetime. So they are not giving up any part of their bodies that are vital to their well-being when they give them away or sell them. (Bone marrow is replaceable too, but there is not — yet — a market in bone marrow.) But even in these cases, many people think the practice of selling them unseemly. In the case of a kidney, the stakes are considerably higher, and so something more important is being made into a commodity. Countries like India already support a lively market for kidneys — although the results are rather unpromising.[27] Indeed, the effects of markets for organs in poorer countries have al-

ready led the poorest to regard their organs simply as another means to pay off debts and to fear — legitimately — the theft of their organs.[28]

The key question then is whether allowing organ solicitations will in fact lead us to think of organs as commodities. Consider two different analogies for kidney donations. First, kidney donations are like other charitable donations, which donors can direct as they please.[29] Donors' kidneys are their own, and they can give them to whom they see fit. This model treats kidneys as a piece of property. When I own property, I can use it in any way I want, as long as I do not directly harm others. I can give it away if I like; I can even destroy it altogether if I wish. If I own a piece of property, I can use it to buy a new Mercedes, I can give it to the symphony or to my cousin, or I can give it to people who are in desperate need of it. Some of those choices may be morally better than others, but all of them are morally permissible. Using this model for kidney donations, barring medical considerations, I can give my kidney to whomever I wish. I do not need anyone else's permission, I do not need to know the recipient ahead of time, and I can choose the object of my generosity in any way I deem appropriate. But treating kidneys as property does commodify them. If we treat something as property, the presumption is that we can dispose of it as we like. If, then, we treat kidneys as property, we have no reason to prevent people from giving away their organs on the internet. But we also have no reason to prohibit people from selling them: like any piece of property, we can give it away or sell it, and no one can prevent us from selling what others would prefer that we give away. Of course, many now accept exactly this conclusion and argue explicitly for an open market in organs.[30] Importantly, this argument does not invoke a slippery slope: we are not sliding from one result to a closely related result. Instead, the principle we are using treats organs as property, and because we treat organs as property, that same principle implies that we can sell them as well as give them away.

Of course, property rights do have limits: generally, we cannot use our property to harm others, and society may impose some restrictions, such as environmental regulations or historical protections, on how we use our property. But only a great social good can override the presumption that we can do what we wish with our property. If, then, we assume that selling organs is wrong, then we must believe that we have good reason not to treat kidneys simply as pieces of property, as mere commodities. If we think that important body parts must be treated as something more than commodities, then we must feel that individuals should not decide how to dispose of their organs on their own; society must play an essential role in the process.

As a different model, think of the way we treat children. My children are "mine" in some sense, and I could give them away, but not in any way that I choose. Here society has an interest in the welfare of the child, and so I can only give a child away in a manner that suits that social interest. For that reason, society plays a more significant and more direct role in the process of giving away a child. Traditionally, we can "direct" our donations in very limited ways to very close relatives, but even then society has some role in deciding whether that adoption is appropriate. In this model of kidney donations, we could accept donations from anyone who wished to give, and we could then direct them to the place where they would do the most good. This model does not treat kidneys as mere property; instead, they are seen as a good over which society should exert significant control. Like children, kidneys belong to particular people, and the wishes of those people should have considerable weight in determining where the donation should go. Of course, kidneys are not children — most importantly because kidneys, as such, do not have independent interests that we must consider. Moreover, even for children, this model is breaking down: birth mothers often pick and choose adoptive parents and, more strikingly, women are paid to bear children and to give up their parental rights to particular people. Yet by thinking of kidneys as part of a broader social good, we take them out of the realm of commerce, and we would thereby better ensure that donors are treated with the dignity they deserve, both by themselves and by others.

If we think of organs as a community resource, then we should regard the supply of organs as a community project in much the same

way we regard the blood supply. In the past, blood banks paid people for blood, and patients were often expected to find their own blood donors, but now, even with the shortages that occur, we think the community should respond.

How exactly society should respond is a problem to which we can only offer a few suggestions here. Since as a society we have already invested UNOS with the power to determine the best recipient for a donation, it makes sense to delegate this task to UNOS, but the important point is to set up some mechanism for review. Because its interests are directed to society as a whole, this agency would probably want to direct organs to the persons most in need. For that reason, some have suggested that a person should legitimately be able to direct a donation only to their close friends and relatives; all other donations would go to the official organ waiting list.[31] But even if we think of organs as a community resource, we need not, in principle, impose such a stringent requirement. Just as state agencies have a role in all adoptions, an entity like UNOS could approve on a case-by-case basis the desire of some donors to give to particular people. But, given the larger social mission involved here, we think some effort should be made to steer donors to recipients who might need their organs more than those who advertise on *MatchingDonors.com.* But we need not reject solicited donations altogether. We just need to insist on a social mechanism to monitor them and perhaps to channel them to where they can do what society deems to be the most good. By doing so, we avoid the institutional harms caused by the commodification of organs, and, by attempting to direct donations to the UNOS list as much as possible, we ameliorate the injustices that are caused by the fact that some people's stories may seem more compelling.

With its completely hands-off attitude toward solicited donations, UNOS is in danger of allowing society to lose a vital role in maintaining the standards of donation. By deferring to hospitals to decide for themselves which donations are acceptable,[32] it leaves the system to sink to the lowest common denominator. If, instead, UNOS directed a national altruistic donor registry, it could do much to ensure that the process is as fair and as dignified as possible. By setting up its own website and public information campaign to put a face on the need for donations and by encouraging those who came forward to consider donating to those highest on the list, the program as a whole might be able to maintain the ban on the selling of organs and yet provide hope for everyone on the waiting list.

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NOTES

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3. G. Remuzzi et al., "Long-Term Outcome of Renal Transplantation from Older Donors," *New England Journal of Medicine* 354 (2006): 343-52.

4. See note 1 above.

5. *www.MatchingDonors.com*, accessed 9 June 2008.

6. We have been able to verify that 10 hospitals have performed these surgeries and that one has refused, and we have no reason to doubt claims by *MatchingDonors.com.*

7. American Society of Transplant Surgeons, "Statement on Solicitation of Donor Organs, January 20, 2005."

8. American Society of Transplant Surgeons, "Statement on Directed Donation and Solicitation of Organs, October 23, 2006."

9. Quoted in R. Stein, "Search for Transplant Organs Becomes a Web Free-For-All," *Washington Post*, September 23, 2005, p. A1.

10. See, for example, C. Robertson, "Who is Really Harmed Anyway? The Problem of Soliciting Designated Organ Donations," *American Journal of Bioethics* 5 no. 4 (2005): 16-7.

11. L.F. Ross notes that some forms of complicated donations can hurt people on the list — when, for example, someone donates to the next suitable person on the list to gain preference for a cadaveric organ for their intended recipient. But those complications do not affect the argument here. See "The Ethical Limitations in Living Donor Transplantations," *Kennedy Institute of Ethics Journal* 16 (2006): 151-72.

12. D. Steinberg, "The Allocation of Organ Donations by Altruistic Strangers," *Annals of Internal Medicine* 145 (2006): 197-203.

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14. In research contexts, we use a similar standard. The risks of certain experiments are simply too high to allow persons to bear them, even if they are willing to do so. For a discussion, see for example, B.A. Brody, *The Ethics of Biomedical Research* (New York: Oxford University Press, 1998), chaps. 2, 6.

15. R. El-Galley et al., "Donor Nephrectomy: A Comparison of Techniques and Results of Open, Hand Assisted and Full Laparoscopic Nephrectomy," *Journal of Urology* 171 (2004): 40-3 and A. Breda et al., "Complications of Laparoscopic Living Donor Nephrectomy and Their Management: The UCLA Experience," *Urology* 69 (2007): 49-52.

16. I. Fehrman-Ekholm, "Living Donor Kidney Transplantation," *Transplantation Proceedings* 38 (2006): 2637-41.

17. The 2005 statement of the ASTS had this view. See note 7 above.

18. D. Hanto in Harvard Medical School Ethics Forum, "Soliciting Organs on the Internet," *Lahey Clinic Medical Ethics* (Fall 2005): 5-8.

19. What counts as the greatest need in this context is not, of course, a simple matter. It depends not only on who is most likely to die without a kidney, but also on who can survive the best and the longest with a kidney, who has been waiting the longest, and other factors that the UNOS system tries to capture.

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21. G. Meilaender, "Gifts of the Body," *New Atlantis* 13 (2006): 25-35.

22. See N. Scheper-Huges, "The Tyranny of the Gift: Sacrificial Violence in Living Donor Transplants," *American Journal of Transplantation* 7 (2007): 507-11.

23. So Martin Zandt reports, based on an informal survey of his patients at the University of Rochester Medical Center.

24. This principle does not even allow the more nuanced view of Michael Gill and Robert Sade, who argue that we should allow donors to accept money, but not allow recipients to buy them. If the donors are allowed to control the process, then they should be able to get whatever money they like. See M. Gill and R. Sade, "Paying for Kidneys: The Case against Prohibition," *Kennedy Institute of Ethics Journal* 12 (2002): 17-45.

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29. See D. Brock in Harvard Medical School Ethics Forum, "Soliciting Organs on the Internet," *Lahey Clinic Medical Ethics* (Fall 2005): 7-8. Also see P. Ford and T. Nicoletti, "My Organs, My Choice," *American Journal of Bioethics* 5 no. 4 (2005): 30-1.

30. See, for example, R. Epstein, "Remarks to the President's Council on Bioethics, April 20, 2006," *bioethics.gov/transcripts/april06/session2.html* and B. Hippen, "The Case for Kidney Markets," *New Atlantis* 14 (2006): 47-61.

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Special Section: End-of-Life Conversations

Last Hours of Life: Encouraging End-of-Life Conversations

Benjamin F. Stump, Craig M. Klugman, and Barbara Thornton

In a culture rooted in a medical ethos of saving life, beginning a conversation on how a person wants to die can be challenging. Research such as the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT) describe the difficulties in encouraging people to make plans for their end-of-life care by completing such documents as advance directives. SUPPORT reported that the needs and preferences of dying individuals were not being addressed in an effective and adequate manner.[1] Beyond such studies, anyone who has given talks, led seminars, or provided clinical conversations with individuals knows the resistance involved in furthering such conversations.

In an attempt to improve the quality and the facility of having end-of-life care conversations, beginning in 1996 the Nevada Center for Ethics & Health Policy (NCEHP) developed "Last Hours of Life." This brief worksheet enables healthcare providers, individuals, and even groups to have a rich and informed conversation about end-of-life issues. The worksheet gives a person a contemplative space to address death and dying issues in a nonthreatening manner that permits introspection and thoughtful response. The completed tool also can provide a launch pad for discussions between an individual and careproviders, family and friends, as well as for seminars on end-of-life issues. This article discusses our analysis of the results of the first "Last Hours of Life" worksheet (1996), and how the investigation of more than 466 participants' answers led us to develop a new and improved version that follows from an "emic" perspective — that is, the new version was derived from the participants' categorizations, rather than from a schema imposed from outside. The new version appears as an appendix at the end of this article.

BACKGROUND

The first phase of SUPPORT identified failures within the medical community to recog-

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nize dying patients' needs, especially in relation to aggressive treatment (such as cardiopulmonary resuscitation) and pain control.[2] The study reported that communication, or lack thereof, between healthcare providers and patients was largely to blame for these failures.[3] The second phase of SUPPORT was designed to address the problems in patient-provider communication and the understanding of patients' preferences during the dying process.[4] The interventions used in Phase II of SUPPORT included providing physicians with information regarding rates of survival and quality of life following cardiopulmonary resuscitation. Additionally, specially trained nursing staff facilitated increased communication between physicians, patients, and families of patients to increase awareness of patients' preferences and needs, specifically through pain control and advance care planning. Unfortunately, the interventions designed to increase the quality of the end of patients' lives did not yield successful results.[5] A follow-up study conducted 10 years later found that the state of end-of-life care and research was little changed and that work reevaluating the use of advance directives was still occurring.[6]

Recent trends in research and literature relating to death and dying place significant emphasis on determinants that affect the quality of the dying experience.[7] The dying process has a profound and powerful effect on the individuals who are experiencing death and the people who bear witness to those deaths. Investigations into the preferences expressed by the dying and individuals involved in the dying process have identified three dominant themes: (1) spirituality, meaning, and emotional well-being; (2) pain and physical suffering; and (3) adequate communication between patients, healthcare providers, and patients' family members.

Spirituality, Meaning, and Emotional Well-Being

Spirituality, the search for life's meaning, and emotional well-being are integral components of the dying process.[8] The concept of spirituality is not confined to a traditional and common association with organized religion.[9] While organized religion remains a definite component of the spiritual experience for some, others find spiritual satisfaction through prayer, meditation, and social interaction. Christina M. Puchalski identified spirituality as having a profound effect upon the dying by providing patients with hope and a sense of meaning that allows a comfortable transcendence. Puchalski contended that the experience is dependent upon the values and beliefs of each individual. Spirituality has been found to have particular importance for those who are directly confronted with death and who are in search of life's purpose.[10] Assisting patients to address spiritual concerns allows an easier transition or transcendence from life to the experience following life.[11]

Craig D. Blinderman and Nathan I. Cherny described meaning as it relates to patients' desire to raise a family, have faith in God, and hold personal spiritual beliefs.[12] Identifying the aspects that provide a sense of meaning to one's life is up to the individual. Adequate preparation for death and the attainment of a sense of completion and meaning in one's life are dominant forces that can add to patients' satisfaction with the dying experience.[13]

The dying process can be characterized as emotionally demanding and stressful. Attending to the spiritual needs of individuals who are at the end of life has been associated with reduced stress and anxiety.[14] Douglas K. Miller and colleagues reported that the inclusion of interventions such as support groups that address the psycho-socio-spiritual needs of patients with life-threatening illnesses reduced the incidence of depression, feelings of meaninglessness, and anxiety in the group of patients who received the intervention.[15]

Pain and Physical Suffering

Concerns regarding pain and other forms of physical suffering are well documented in the end-of-life literature.[16] James Hallenbeck reported on a study in which 310 critically ill patients identified the desire to be free of pain and suffering as their first and foremost concern regarding the end of life.[17] The inadequate management of pain and other symptoms frequently have been found to be among the failures of modern medicine.[18]

Pain and other physical symptoms have been attributed to a decreased quality of life at the end of life for a number of reasons: inad-

equate pain management in the in-patient hospital setting causes moderate to severe pain for patients within the last few weeks of life.[19] Studies report that 30 to 80 percent of patients living in nursing home facilities receive inadequate pain management.[20] In the case of nursing homes, Sandra H. Johnson identified three dominant reasons for poor pain management: (1) the existence of regulations that seek to avoid the overuse of pharmaceuticals, (2) healthcare providers and family members tend to underestimate the patient's level of pain, and (3) patients inaccurately report their level of pain to avoid being a burden to others. Johnson reported that pain and suffering can negatively influence patients' "thought, self-awareness, emotional engagement, and social relationships [so] that it can rob the individual of the experience of being human."[21] The breadth of distress, aside from physical discomfort, that pain and suffering have upon patients indicates the importance of appropriate pain management.

Communication

Inadequate communication has been identified as a dominant barrier to the provision of high quality end-of-life care.[22] Although SUPPORT failed to identify effective interventions that would increase the quality of life as death approaches, it accentuated the importance of communication between healthcare providers, patients, and the families of patients during the dying process. [23]

As Jeanie S. Kayser-Jones noted, "Health care provider-patient relationships (i.e., interactions) are critically important when providing care to people who are dying."[24] The provider-patient relationship, like many others, is dependent upon the adequacy of communication between all of the parties involved, including the provider, patient, and family.

METHODS

As part of a series of statewide seminars and lectures on advance care planning, speakers from NCEHP administered the "Last Hours of Life" worksheet. This instrument was designed to stimulate conversations on end-of-life issues and not as a research survey. Worksheet questions mixed open-ended and pre-coded answers and provided room for answers/comments from the participant's own frame of reference. Additionally, the worksheet requested the participants' age, gender, occupation, and income level. Although the seminars were offered across Nevada, participation was not dependent upon residency in Nevada. Many participants were from Western states including California and Oregon. The seminars and lectures targeted healthcare professionals, but many attendees were students and retirees. The worksheets were completed anonymously by workshop participants who voluntarily attended end-of-life seminars and lectures conducted between 1996 and 2003.

Seminars would begin by having the attendees complete the worksheet and then sharing their answers with others in small groups. Later, the participants could share select answers with others at the seminar. After several hundred worksheets were collected, two of the authors (Thornton and Klugman) realized that they had a rich source of data about people's desires during their final hours of life. Therefore, we sought and received approval from the University of Nevada, Reno Social-Behavioral Institutional Review Board to analyze these worksheets.

A thematic codebook was developed for the open-ended questions based on topics that appeared in a large number of the worksheets. After the thematic codes were created and tested, all of the worksheets were coded. To increase inter-rater reliability, two coders reviewed each worksheet. When coding results differed, the raters negotiated the appropriate coding. The coded results and responses to closed-ended questions were entered into Microsoft Excel XP. Due to the overall goal of the project and the ways in which data were collected, analysis was restricted to descriptive information. A frequency analysis was conducted and results were also presented in percentages. A free response answer was considered statistically significant if it comprised at least 5 percent of all of the responses to a particular question.

RESULTS

A total of 466 people completed the 1996 "Last Hours of Life" instrument. The ages of the

respondents ranged from 18 to 94, with a mean age of 45.06 and a median age of 46.0. Regarding the gender of respondents, 375 were female and 91 were male. Of the 466 respondents, 40 were physicians, 135 were nurses, and 291 were other health professionals, students, retirees, and others (see table 1). The majority (50 to 91.3 percent, depending on the question) of written responses to the instrument were provided by less than 5 percent of all of the subjects.

The first question was, "What would you like to have happen during the last hours of your life?" The total number of responses provided by all 466 of the participants was 1,250. Participants provided 63 different responses that fell into two recurring themes. The first theme (799 responses) was related to the state of the participant's mind and body at the end of life. Many people said that they wanted pets (19), friends and family (387), and music (67) present at the deathbed. The second theme (341 responses) concerned the respondent's desired physical state at the time of death, such as freedom from pain (86) and a sense of peace for patient and family (152). The remaining 110 comments (in more than 11 categories) were placed in a miscellaneous group that included notions such as wanting a quick death (23), being comforted and pain-free (33), and having religious needs fulfilled (43).

Question 2 ("What do you fear most about dying?") offered five possible responses (pain, fear of the unknown, suffering, things left undone, and seeing family and friends grieve), to stimulate thought in each participant. Question 2 also offered space for participants to identify individual answers that were not provided in the five above-mentioned options. The total number of responses provided by all 466 of the participants was 934. Participants identified 33 different responses to Question 2 ("What do you fear most about dying?"). Three common themes were identified. The first theme (318 responses) related to fears of mental, emotional, or spiritual suffering, such as fear of the unknown (119) and leaving things undone (156). The second theme (215 responses) expressed fear for the suffering of others who would bear witness to the end of life. The final theme (331 responses) addressed fear of pain or other physical suffering at the end of life. The remaining responses (70 responses over 12 categories) comprised a miscellaneous category, including concerns about leaving people behind (22) and having no fears of dying (14). No single response in the miscellaneous category had statistical significance.

Table 1. Professions of Respondents

Profession	*n*
Nurse	135
Social worker	80
Student	77
Physician	40
Clergy	26
Administration	22
Teacher	15
Healthcare (other)	9
Home caregiver	9
Pharmacist	6
Mental health	6
Respiratory therapist	6
Retired	6
Volunteer	5
Attorney	3
Coroner	2
Dental hygenist	2
Ombudsman	2
Sales	2
Server	2
Technical	2
Author	1
Baker	1
Communications	1
Geologist	1
Juvenile Services	1
No answer	1
Public guardian	1
Researcher	1
Self-employed	1

Question 3 ("Who would you like to have with you during those last hours of life?") offered six selections (spouse, healthcare providers, children, spiritual advisor, friends, and animals), to stimulate thought in each participant. Question 3 also offered space for participants to identify individual answers that were not provided by the six above-mentioned options. The total number of responses provided by all 466 of the participants was 1,466. Question 3 elicited a total of 14 different responses. The first of three dominant themes in response to Question 3 was "family or friends" (1,073 responses). The second theme identified a desire to have a spiritual advisor present during the final hours of life (144 responses). Finally, a small portion of the participants desired healthcare providers to be present at the end

of life (49 responses). The remaining 200 responses (over six categories) to Question 3 comprised a miscellaneous category. The only statistically significant response in this third category was wanting animals present (174).

Question 4 ("Do you want to be told you are dying?") included "yes" or "no" answer options with space for an explanation as to why or why not. "Yes" was chosen by 439 subjects, "no" by 17, and 10 chose "uncertain." All 466 respondents provided a total of 606 responses; 31 different responses were provided in the comments section of Question 4. Three dominant themes were identified after examining the responses to the "why or why not" section. The first of the three themes (275 responses) related to a desire to make the remainder of the time left in this world count. A number of the responses under this theme identified tasks that the participants would undertake if they were informed that they were going to die. The second theme (101 responses) identified participants' desires to gain a sense of closure and peace prior to death. The final theme (115 responses) identified the desire of participants to spend the remainder of their time alive with family and friends and to repair damaged relationships. These 115 responses fell into 15 categories that were not individually statistically significant.

Question 5 ("Do you believe in life after death?") included "yes" or "no" answer options, with additional space for personal comments. In this question, 355 subjects answered "yes," 73 said "no," and 38 were "uncertain." All 466 participants provided a total of 125 responses; 23 different responses were provided in the open-ended section of Question 5. The first of the three themes identified in the open-ended section of Question 5 related to religious beliefs and spirituality (77 responses). The second theme was comments identifying uncertainty about an afterlife (16 responses). The remaining 32 responses in eight categories did not provide any statistically significant themes or categories.

Question 6 ("Where would you like to die?") offered three selections (hospital, hospice, and home), to stimulate thought in each participant. Question 6 also offered space for participants to identify individual answers that were not provided by the three above-mentioned options. All 466 participants provided a total of 607 responses. The first theme (398 responses) identified participants' desires to die in a familiar setting, such as dying at home (382). The second theme (116 responses) related to a desire to die in a healthcare setting. The remaining 93 responses (more than 17 categories) were not statistically significant except for the desire to die outdoors (37 responses).

DISCUSSION

Results from the present project identified several issues in relation to end-of-life concerns and discussions. Most important, the wide variety of responses to the open-ended questions pointed out the inadequacies in the worksheet that was originally developed in 1996. A response that appears in a free-response section, but not in the listed choices, represents a lost opportunity. Unless a person thought of an idea on his or her own to write in, he or she would not be prompted to consider that notion. For example, the listed options did not include a choice for smells. Unless a person thought of this idea on his or her own, smells may never even be considered. The lesson is that one should be wary of trying to impose "etic" categories — that is, categories that are imposed from outside a subject's experience, such as by a researcher — regarding dying. Thus the 1996 worksheet is flawed, as it tried to impose just such a schema. A richer conversation would be possible by creating a worksheet that draws on an emic categorization, such as could be developed from this data.

Many of the common themes in response to the worksheet coincided with results from previous research. Spirituality, the search for life's meaning, and emotional well-being have been identified as important concerns at the end of life.[25] Responses pertaining to spirituality, meaning, and emotional well-being were dominant themes in this worksheet. Additionally, in response to Question 6, two participants said that they wanted to die in a monastery or other religious building, and four participants said they wanted to die where God wanted them to die. Clearly, spirituality, meaning, and emotional well-being must be addressed to increase the quality of the end-of-life experience.

Previous research has also noted pain and physical suffering as important concerns relating to the end of life.[26] In the present project, 35.44 percent of the responses to Question 2 ("What do you fear most about dying?") were related to experiencing pain and other physical ailments at the end of life.

The researchers did not expect to find that so few participants would want a healthcare provider by their deathbed. Likewise, we did not expect the large numbers of respondents who wanted a pet present at the end of life. These findings suggest that individuals do not fall neatly into categories, but rather are unique in their wishes. Thus, there is a need for more flexibility in death planning, such as programs like hospice that enable people to die at home, and for more bending of hospital rules that do not allow animals on the wards.

Communication and issues related to shared decision making during the end of life comprised the third dominant area of concern.[27] In the current analysis, aside from one participant who expressed a fear of not being able to communicate, there were not any responses on the worksheet that related to these issues. The authors believe that the results do not indicate a lack of concern, but, rather, a failure of the worksheet to directly address communication and shared decision making. The nature of the information gathered highlights two important factors relating to communication during advance care planning: (1) tools, such as the worksheet used in this project, should be used to guide and stimulate conversation and thought during discussions relating to the end of life; and (2) the breadth and variability of answers provided by the participants in the end-of-life seminars and lectures necessitates addressing needs and desires in relation to the end of life on an individual basis.

The first factor is related to the importance of using tools, such as the "Last Hours of Life" worksheet, to stimulate and guide conversation on the end of life. The worksheet was helpful in provoking thought and facilitating conversation when identifying participants' needs and preferences. Shirley S. Travis and colleagues identified the difficulty of initiating conversation between patients and their families during discussions about the end of life.[28] We suggest that using these tools can increase the ease of initiating discussion. Providing questions and examples of concerns of people experiencing the death and dying process could help facilitate conversation about an individual's personal needs and desires.

The second factor was identified from the breadth and variance in responses to the open-ended portions of the worksheet. With the exception of Question 3, the majority of the participants' open-ended responses were provided by less than 5 percent of the participants. This lack of free responses indicates a need to increase the prepared choices, as most people did not partake in the free-writing sections. Also, this lack suggests a need for facilitators to encourage participants to write in the free-response areas. The breadth of answers in the free-response sections highlights the need to address each person's needs and desires in relation to the end of life on an individual basis and to improve the quality of life for people who are dying. Using tools to guide and stimulate conversation between individuals and their families provides an opportunity to identify an individual's unique preferences — other than medical treatment choices — rather than assuming that people want preconceived, etic notions of a "good death."

In addition to facilitating communication on end-of-life issues, the results from the worksheet indicate the importance of describing the setting in which one wants to die. As Jan Selliken Bernard and Miriam Schneider note in *The True Work of Dying: A Practical and Compassionate Guide to Easing the Dying Process,*

> It is through creating a safe place that the process of letting go is eased. The preparation for these life-changing events is critical. The quality of a person's death experience is directly related to the preparation of a home environment — no matter whether it is in a hospital, nursing home, adult foster facility, hospice house, or a family home. The physical space is not what creates a "home"; it is the people that create it.[29]

A number of participants identified the desire to listen to music, hear birds singing, have windows open, and to have light at the end of

life. Descriptive comments discussing the setting in which participants wanted to die comprised 64.82 percent of the responses to Question 1. As identified by Bernard and Schneider, adapting the setting of death to fit with the desires of the dying can increase the quality of life at the end of life.[30] The need for an instrument that uses an emic perspective from those thinking about their death is evident.

An Emic Worksheet

NCEHP realized that our data strongly supported the development of a new worksheet tool based on our analyzed results from the 466 previous participants. The result of that effort is the 2008 "Last Hours of Life" worksheet (see the appendix at the end of this article). This worksheet comes out of the emic concepts and categorization created by the participants rather than from an etic schema imposed from outside.

The revised worksheet is made up of eight questions, including one identifying the participant's use of advance directives. The open-ended nature of the questions on the original worksheet yielded a broad range of results that now allows participants to individualize their responses. The authors believe this to be the most important aspect of the original worksheet. Room is also provided on the revised worksheet for open-ended responses or comments on each of the questions. New directions also promote the completion of free responses. Additionally, the use of prearranged answers may have assisted in the facilitation of thought during the use of the original worksheet as well as encouraged completion by people who were reticent to write free responses. All of the revised questions contain expanded prearranged responses that not only serve as possible answers to questions, but may also serve as examples that will stimulate thought, allowing for more complete open-ended responses. The prearranged answers included in the revised worksheet are composed predominantly of common responses and themes identified in analysis of information from the original sheet.

Previous research and literature have devoted little attention to specific details concerning the setting of one's death. A worksheet that prompts individuals to explore their hopes, fears, and preferences may help the individuals, loved ones, and careproviders to create a setting that will improve the dying process and be more attuned to patients' wants and needs. The common themes in response to Question 1 of the original worksheet ("What would you like to have happen during the last hours of your life?"), including statements describing the scene of one's death and the desired state of mind and body at the time of death, were broken down into two separate questions to allow more careful examination of both components.

The original worksheet identified who the participants wanted to have present during the last hours of life, but did not identify the capacity in which those present would serve. A large portion of the literature on the end of life has devoted attention to decision-making power. The revised worksheet addresses who the dying individual would want to take part in making decisions concerning the end of his or her life. Finally, many of the responses to the original worksheet identified concerns over leaving things undone or not completing tasks. The final question on the revised worksheet pays specific attention to the tasks the dying individual would want to complete prior to death.

The setting in which one will spend the final moments of life should be designed based upon the individual's needs and desires, and not limited to settings that have been found to be statistically significant in the general population. Statistical significance alone cannot aid us in assisting patients who are at the end of life. The present project establishes the importance of addressing end-of-life preferences on an individual basis and also demonstrates the usefulness of a worksheet to stimulate conversation outside the medical setting, as well as to identify individuals' needs, values, and preferences on a basic level. The identification of elements that affect the end-of-life experience is essential in improving the quality of the last hours of an individual's life experience. This worksheet is an attempt to do just that.

ACKNOWLEDGMENT

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Appendix: 2008 Last Hours of Life Worksheet

Instructions and Suggestions on Using the End-of-Life Discussion Worksheet

This worksheet will present 8 different questions and topics for discussion. A number of possible answers and comments have been provided under each question of topic. Please select as many answers as you want.

Space has also been provided at the end of each question or topic for your individual answers. We encourage you to write down any response you want. You can also use this space for writing comments and concerns you have about your answers. Because each person has unique ideas for his or her last hours, we suggest that you write down your thoughts in your own words in the spaces provided.

This worksheet is meant to help guide a conversation with others. Close friends and family are good choices of people to include. You are encouraged to discuss your responses and concerns with others in order to help them understand your needs and preferences towards the end-of-life. Be sure to write down the names of the people involved in this discussion on the front page. You may also want to write down their relationship to you.

Lastly, you should revisit your responses and keep them up to date. If your values, preferences, or needs change after completing this worksheet, make sure your new values, preferences, or needs are known. Keeping this worksheet in a place where it will be safe but is easily accessible is suggested. Be sure your family or friends know where to find it in case of emergency.

With whom are you completing and discussing this worksheet: _____

Date: _____

Do you have an advance directive?

___ Yes
___ No
If you answered "yes" please indicate what type of advance directive you have:
___ Living will/directive to physician
___ Healthcare proxy: who is
___ Do-not-resuscitate order (DNR)
___ Out-of-hospital DNR
___ Other/comments _____

(continued next page)

Where would you like to die?

___ My home
___ A relative's home
___ In a church
___ Outside/in nature
___ Hospital
___ Hospice
___ Nursing home
___ Other/comments _____

Describe the setting in which you would like to die:

___ Alone
___ Surrounded by friends
___ With music playing
___ Surrounded by flowers
___ Surrounded by photographs
___ In a warm place
___ In a quiet place
___ Surrounded by family
___ Surrounded by friends
___ In a well-lit room
___ Surrounded by pleasant smells
___ Surrounded by my favorite art
___ In my bed
___ In nature
___ Other/comments _____

Describe the state of mind you would like to be in at the time of your death:

___ Calm
___ Free of stress
___ Satisfied
___ Accepting of death
___ Happy
___ Independent
___ Other/comments _____

Who would you like to have with you when you die?

___ Nobody, I want to be alone
___ Parents
___ Other relatives
___ Spiritual advisor
___ Doctors
___ Spouse/partner
___ Children
___ Close friends
___ Nurses
___ Pets
___ Other/comments _____

Who do you want to make decision about your healthcare and death?

___ Myself
___ Parents
___ Other relatives
___ Spiritual advisor
___ Doctor
___ Spouse/partner
___ Children
___ Close friend
___ Nurses
___ Other/comments _____

What do you fear most about death?

___ Pain/physical suffering
___ Things being left undone
___ Being a financial burden
___ Losing my mind
___ Leaving family and friends
___ Being forgotten
___ Leaving problems unresolved
___ Leaving before mending relationships with friends
___ I have no fears
___ Fear of the unknown
___ Watching family grieve
___ Being cold
___ Losing my independence
___ Losing my dignity
___ Not going to heaven
___ Leaving before mending relationships with family
___ Leaving before mending my relationship with God
___ Other/comments _____

Describe tasks you would like to accomplish before you die:

___ Tell my family and friends I love them
___ Prepare myself
___ Mend relationships
___ Gain a sense of closure
___ Spend time in my favorite place
___ Try a new hobby
___ Try new food
___ Travel
___ Prepare my friends and family
___ Say good-bye to family and friends
___ Become religious
___ Gain peace of mind
___ Get my finances in order
___ Help plan my funeral
___ Tell my story
___ Other/comments _____

Spiritual Issues as an Essential Element of Quality Palliative Care: A Commentary

Christina M. Puchalski

"Last Hours of Life: Encouraging End-of-Life Conversations" by Stump, Klugman, and Thornton provides an excellent analysis of the critical domains of quality end-of-life care.[1] Their solid study demonstrates the evidence needed to ensure that all dimensions of patients' lives are included: the spiritual and psychosocial, as well as the physical. The Nevada Center for Ethics and Health Policy (NCEHP) should also be credited for its foresight and leadership in adopting the new worksheet for addressing important issues for end-of-life care.

Hospice and palliative care recognize the importance of the spiritual dimension in the care of dying patients. When Cicely Saunders started St. Christopher's Hospice in London, she listed one of the goals to be the relief of "total pain," including the physical, emotional, social, economic, and the spiritual.[2] The basic tenets of this field are rooted in patient-centered care: attention to all these dimensions of a patient — physical, emotional, social, and spiritual.

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Spirituality, broadly defined as that which gives meaning and purpose to life, is often a central issue for patients at the end of life and for those dealing with chronic illness.[3] Every individual has to make a decision as to whether one's life has meaning and value.[4] As people face their dying, that search for meaning becomes more intense, thus their main task might be answering the fundamental question of what is their *ultimate* meaning and purpose in life. Throughout life, all people find meaningful activities and relationships. Impending death forces one to move deeper within, to a meaning that can withstand loss and even death. This is a profound journey that patients often describe as leading to indescribable joy and intensity, as they find a meaning that transcends the physical. Numerous surveys indicate that people turn to spiritual and/or religious beliefs in times of stress, serious illness, loss, and dying.[5] It is not uncommon for people to question their life choices and their relationships, including their relationship with God.

The spiritual issues that people face include hopelessness, despair, guilt, shame, anger, and abandonment by God or others. These issues can provoke deep suffering, which can result from people feeling alienated from themselves, others, God, or from their ultimate source of meaning. If these deep questions are not attended to,

suffering may result, as people struggle with despair or hopelessness. Spirituality helps one to find meaning in the midst of suffering and to accept life's difficulties.

In more recent years, the National Consensus Project for Quality Palliative Care (NCP) identified spiritual care as one of eight domains in its report, *Clinical Practice Guidelines for Quality Palliative Care*.[6] The NCP recommendations for spiritual care emphasize regular and ongoing assessment of and response to patients' spiritual and existential issues and concerns. The NCP emphasizes the use of a spiritual assessment to identify the religious or spiritual preferences, beliefs, rituals, and practices of patients and their family members. The *Clinical Practice Guidelines* also recognize the need for inclusion of pastoral care in the interdisciplinary care team. The *Clinical Practice Guidelines* have been adopted by the National Quality Forum (NQF), one of the leading national forces for quality in healthcare.

The American College of Physicians, in a consensus conference on physicians' role in end-of-life care, determined that physicians have an ethical obligation to attend to all dimensions of a seriously ill or dying patient — patients' psychosocial and spiritual suffering, as well as physical suffering.[7]

Addressing spirituality in healthcare is especially important when a patient is dealing with a serious illness. The *ICN Code of Ethics for Nurses* states, "The nurse promotes an environment in which the human rights, values, customs, and spiritual beliefs of the individual, family, and community are respected."[8] The "Code of Ethics of the National Association of Social Workers" declares, "social workers should obtain education about and seek to understand the nature of social diversity and oppression with respect to . . . religion.[9] Sulmasy has written of medicine as a moral enterprise, and that it is morally imperative that healthcare professionals attend to patients' spiritual needs and issues.[10]

Numerous studies report that spiritual issues are paramount in the care of seriously ill and dying patients. Spiritual and religious beliefs affect how people cope with serious illness and life stresses; spirituality and religion can improve coping,[11] improve quality of life,[12] will to live,[13] and provide social support.[14] Spirituality and religion have been associated with decreased depression in patients.[15] Spiritual beliefs affect healthcare decision making.[16]

Yet in spite of the history of the biopsychosocial-spiritual model of care in palliative care, professional ethical mandates to address spiritual concerns, and research supporting its importance, patients' spiritual needs often are not addressed. In a recent study, Balboni and colleagues reported that 75 percent of terminally ill cancer patients said that spiritual issues were not addressed by their healthcare professionals.[17]

This suggests that healthcare professionals and family members need practical tools to address the spiritual issues that patients and their family members face. The article by Stump and colleagues provides an excellent tool based on the biopsychosocial-spiritual model of care. It helps clinicians and patients identify the spiritual, physical, and psychosocial issues patients face at the end of life. This tool identifies critical questions that will enable patients and their family members to reflect on important questions related to dying. It helps healthcare professionals create an environment of trust and willingness and to hear from the patient or family whatever concerns they may have, including the spiritual and psychosocial ones.

The worksheet can be used as indicated in the article, in end-of-life situations. But it also has broader applications. It can be used in clinical education programs with healthcare professional students to explore issues around death and dying. It can be used across all phases of life, as patients and clinicians discuss advance care planning in the clinical setting. It can be used in any situation in which one begins to approach the critical questions that will ultimately face all of us: Who am I? or Who will I be in the face of my active dying? What is the ultimate meaning and purpose of my life?

NOTES

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3. C.M. Puchalski, E. Dorff, and Y. Hendi, "Spirituality, religion, and healing in palliative Care," *Clinics in Geriatric Medicine* 20, no. 4 (November 2004): 689-714; A.B. Astrow, C.M. Puchalski, and D.P. Sulmasy, "Religion, spirituality, and health care: Social, ethical, and practical considerations," *American Journal of Medicine* 110, no. 4 (March 2001): 283-7; D.P. Sulmasy, "A Biopsychosocial-Spiritual Model for the Care of Patients at the End of Life," *Gerontologist* 42, spec. no. 3 (October 2002): 24-33.

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13. S. Cotton et al., "Spirituality and Religion in Patients with HIV/AIDS," *Journal of General Internal Medicine* 21, supp. 5 (December 2006): S5-13.

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End-of-Life Care: Conversations and Opportunities

Margaret M. Mahon

INTRODUCTION

Any discussion about end-of-life care is likely to address several points. Most people would agree that end-of-life conversations should occur, but there is likely to be divergence regarding *who* should convene and be involved in such discussions. The next question might address what should be the topic of the conversation. In this issue of *JCE*, Stump, Klugman, and Thornton chose to focus on the time immediately preceding death, asking how a patient wants to die. An expansion of the question and the context may result in even greater opportunities to improve how people live with, and die from, many diseases.

EVOLUTION OF END-OF-LIFE CARE

Healthcare providers' discomfort in caring for patients and families at the end of life is relatively new, resulting in large part from advances in healthcare technologies. This change of attitude began in the second half of the twentieth century.

At the end of the nineteenth and beginning of the twentieth centuries, people died differently than they do now. The paucity of means to forestall death meant that options for patients and families around the time of death were limited. The standard of care at that time was to create a calming environment, and to use those medicines that were available to manage symptoms.[1]

In 1900 life expectancy was shorter; causes of death were more likely to be from acute illness, infection, trauma, and childbirth. Gender disparity was actually less than it is today (women were likely to live just two years longer than men).[2] The time between diagnosis and death was estimated in days in 1900, as opposed to years in 2000. In 1900, the median age of death in the United States was 58 years; only 87.6 percent of infants survived the first year of life.[3] In 1900, the life expectancy of Whites was 14.6 years longer than Blacks (see table 1).[4]

Most importantly, though, in 1900 clinical tools to forestall death were far fewer than today, whereas, in the twenty-first century, it is presumed that death can be delayed. Myriad interventions (medications, surgery, radiation, or other technological interventions) have changed the implications of certain diagnoses. Treat-

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ments might allow cure, but more often modern medicine promotes longer life, albeit with disability.

As a result, often the slightest chance of cure limits discussion about other likely or inevitable outcomes. Patients, families, and providers may focus on cure as the only option. This singular vision extends beyond the healthcare environment. The Race for the Cure or the Armstrong Foundation's "Live Strong" campaign have made significant inroads towards cures by increasing funding for research and knowledge about diseases. The emphasis on cure or survivorship, though, can leave others for whom cure is not possible with a notion of failure. ("The patient failed a trial of [X medication or therapy]." "She lost her battle with the disease.") If death or the absence of cure is seen as a failure, a reluctance to engage in conversations about the end of life is understandable.

COMMUNICATION: TIMING AND RESPONSIBILITIES

Providers often believe that not only are patients unwilling to discuss the end stage of their lives, but further, providers worry that an introduction of the topic sends the message that "We've done everything we can; there's nothing else we can do," and engenders fear that the patient is being abandoned by the physician. Stump and colleagues suggested that discussions about end-of-life care in group situations (presumably similar to the sessions they conducted), or in clinical encounters, are likely to be met with resistance.

Perhaps the question, "How do you want to die?" isn't the discussion patients want to have about the end of their lives. Perhaps patients and families are more focused, not on the minutes immediately preceding death, but on how they will live the days, weeks, months, or years they have left.

Even if a patient is aware of his or her impending death (as the vast majority are), the patient is unlikely to initiate the discussion.[5] In fact, most patients *do* want to discuss end-of-life issues with their physicians, although they expect that the physician will initiate the discussion.[6]

Opportunities for conversations with patients and families about the end of life are common in certain specialties. Heart disease, cancer, cerebrovascular disease or respiratory illnesses, diabetes, Alzheimer's, and kidney diseases are most often chronic, their trajectories predictable. Providers caring for people with these diseases can make specific predictions about prognosis, timing, and quality of life.

Structuring the Discussion

Conversations about the end of life may be roughly dichotomized to two situations: in the context (proximal reality) of illness, and with-

Table 1. Causes of Death in the United States, 1900 and 2004

Rank	Causes of Death, 1900	Causes of Death, 2004
1	Pneumonia and influenza	Heart disease
2	Tuberculosis	Malignant neoplasm
3	Diarrhea, enteritis, and ulceration of the intestine	Cerebrovascular disease
4	Heart disease	Chronic lower respiratory disease
5	"Intracranial lesions of vascular origin"	Accidents (unintentional injuries)
6	Nephritis	Diabetes mellitus
7	All accidents	Alzheimer's disease
8	Cancer and other malignant tumors	Influenza and pneumonia
9	"Senility"	Nephritis, nephritic syndrome, and nephrosis
10	Diphtheria	Septicemia

Data extracted from M.P. Heron, "Deaths: Leading Causes for 2004," *National Vital Statistics Reports* 56, no. 5 (2007) and E. Arias, "United States Life Tables, 2003," *National Vital Statistics Reports* 54, no. 14 (2007

out the context (no immediacy or proximal reality) of illness. While the context changes the urgency of one's responses, broadly construed, the questions that should be asked do not change.

In their new version of the tool, Stump and colleagues ask whether the respondent has an advance directive. This is an important question, although there are several challenges. Patients and families may not know what the term means. Even if the patient has designated, for example, a durable power of attorney for healthcare (DPA-HC), too often there are disconnects. The respondent may not realize that a DPA-HC is one component of an advance directive. Additionally, the person who is designated may not know of the designation, may be unable to complete the duties (for example, the sister with Alzheimer's, the brother who has been out of touch for 20 years), or may have no idea of the patient's preferences.

Thus, conversations about end-of-life care should address the two dimensions that are a part of most advance directives: "If you are unable or choose not to participate in decision making, who should represent your wishes?" and "What factors should we consider in making decisions about your care?" Stump and colleagues described their tool as a vehicle for conversations with healthcare providers or within families. That is certainly important. Another tool for guiding these discussions is Five Wishes (*http://www.agingwithdignity.org/5wishes.html*).

The other questions in these conversations should be disease-specific. Good decisions can be made only with an understanding of the facts and of what realistic options are. It is incumbent on healthcare providers first and foremost to ensure that the patient understands the current state of the disease. Based on that, options for treatment (including symptom management) are constructed. These first two rely on the expertise of the healthcare team, most often the physicians. Autonomous decisions can be made (and thus respected) only in the context of knowledge of the biology of the disease.

Asking patients, or especially families, about specific treatments, though, is likely to engender discomfort. Before focusing on a specific decision, it can be extremely helpful to focus on the goals of care. What are the overall goals for this patient at this time? What is the goal of this treatment? "If this treatment does not accomplish that goal, then we can and should stop it."

The Proximity of Death

The proximity of death does narrow the focus of conversations. The focus should still be on physiologic realities, on goals, and on the patient's wishes.

Stump and colleagues found that respondents' concerns about their final hours of living had to do with their environment, their loved ones, and their personal well-being. Thankfully, all of these things can be addressed. With the exception of symptom management, initially addressing these questions within hours of death limits the likelihood of accomplishing the goals of patient or family, so the discussion should be held earlier, both within families and with providers.

In an attempt to increase communication between provider and patient, providers may have relinquished some responsibilities. Under the guise of sharing control due to considerations of patient and family autonomy, providers have failed to consider how the facts of a patient's illness frame the clinical options for a specific clinical situation. Instead, we ask the amorphous question, "What do you want us to do?" Very few patients or families have the clinical expertise to provide informed input to that specific way of delineating options for decision making.

Another difference between the early twentieth century and the twenty-first is that death is now most likely to occur away from home. As a result, there can be a poignant awkwardness that surrounds the patient's bedside as death approaches. Whereas in prior centuries, families were likely to abide with the dying person, to sit at the bedside, to be present, many families have no experience being with someone whose death will be soon (though a majority of Stump and colleagues' respondents wanted to die at home, consistent with prior research).

Again, there are opportunities. Saying to family members, "Six months from now, I don't want you to have any 'what ifs . . . ?' or 'I wish I

hads. . . .' Although this is a very sad time, it's a chance for you to tell him what you want to make sure he knows," gives them ideas, and perhaps even permission. We sometimes even have to model how to sit with, to talk to the person who is dying. Asking family members about who should be present, about what environment the patient would want, or if they see something that providers have missed, validates the value of the family members' presence and their more intimate knowledge of the person who is dying.

Stump and colleagues were surprised that "so few participants would want a healthcare provider by their deathbed." The job of providers is to provide an environment and symptom management that allows the person who is dying to be with those who have been a part of their living, not necessarily of their dying.

CONCLUSION

To provide care at the end of life remains a challenge. How could it be otherwise, when those most involved with it on a regular basis are often reluctant to discuss it? Healthcare providers have a responsibility to be good at it. Physicians must be involved, but they do not have to be alone. There are frequently differences between health team members' perceptions of the adequacy and completeness of the decision-making process.[7] An interdisciplinary team will provide complementary skills and knowledge.

The clinical situation is similar to other situations in which one party is ethically opposed to being involved. The reluctant participant is not forced to be involved. The responsibility does not end there, though. If one provider is unwilling to address the implications of serious illness, then someone who does it well must be brought in. This may mean a consultation with a palliative care team or an ethics consultation service. Neither of these options allows the primary provider to withdraw. Rather, consultations can allow the building of a team that will result in better patient care. Involvement of a palliative care team is likely to increase a patient's understanding of the disease and its implications.[8]

Healthcare providers who are involved in the care of patients with potentially life-threatening diseases should be prepared to discuss difficult issues across the course of each patient's illness. These conversations must be (1) specific, (2) structured by the provider, (3) amenable to input from the patient, and (4) most importantly, based on *this patient's condition.*

Asking how a person wants to die gives important consideration about people's concerns about the end of life. These data can provide important reminders about what should be addressed. Even absent these data, though, healthcare providers have a responsibility to manage symptoms aggressively, and to address physical and other issues at the end of life.

NOTES

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3. E. Arias, "United States Life Tables, 2003," *National Vital Statistics Reports* 54, no. 14 (2007), *http://www.cdc.gov/nchs/data/nvsr/nvsr54/nvsr54_14.pdf*, accessed 25 June 2008.

4. Ibid.

5. L.M. Ramondetta et al., "Approaches for end-of-life care in the field of gynecologic oncology: An exploratory study," *International Journal of Gynecological Cancer* 14 (2004): 580-8.

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8. B. Jack et al., "Hospital based palliative care teams improve the insight of cancer patients into their disease," *Palliative Medicine* 18 (2004): 46-52.

Commentary on "Last Hours of Life: Encouraging End-of-Life Conversations"

Craig D. Blinderman

In this issue of *JCE,* Stump and colleagues present a novel tool, the "Last Hours of Life" worksheet, to address inadequate communication between healthcare providers and patients at the end of life. Their tool is based on a revised (*emic*) version of a 1996 worksheet completed by participants who attended seminars and lectures targeting healthcare professionals. The project identifies several themes important to individuals at the end of life: good pain and symptom management, attendance to spiritual and existential concerns, and preferences regarding where and how they would like to die. The worksheet allows the documentation of advance directives and preferences. The authors postulate that using such a worksheet may help facilitate communication at the end of life so that providers may better identify patients' needs, values, and preferences. The result of such a process would presumably help improve the quality of life in patients' "last hours."

The authors attempt to tackle a formidable challenge, namely, how to honor individuals' preferences and values at the end of life. While the worksheet may be helpful in stressing the importance of exploring several issues when patients consider their own death, there are several limitations that should give us pause before we consider the worksheet's clinical usefulness. First, the revised worksheet is based on responses from a healthy population of mostly healthcare professionals. The bias seems obvious — healthcare professionals likely have their own conceptions of "a good death," and this would certainly impact their own preferences. While such input from healthcare professionals is valuable, for example in guiding policy decisions or developing research questions, the themes that emerge and their stated preferences may not be generalizable. Indeed, it would be worthwhile to investigate this tool in a terminally ill population — to evaluate its feasibility (not too burdensome or harmful) and utility (elucidates the concerns of dying patients).

If such a tool is to address the disparity in patients' preferences and outcomes at the end of life as described in SUPPORT, we should evaluate whether such a communication tool can affect things like: days spent in the intensive care unit during the last six months of life, do not resuscitate/do not intubate orders, referrals to hospice or palliative care and place of death. There is some evidence that end-of-life discussions may result in increased patient understanding of illness severity, fewer invasive procedures, and lower rates of ICU admission at the end of life.[1] Nevertheless, it may be the case that "prognostic awareness," at least with respect to oncology patients, plays a greater role in reducing these unnecessarily burdensome treatments at the end of life. The hypothesis that improved communication around death and dying, facilitated by a worksheet, improves quality of life in a meaningful way would also need to be demonstrated in a future study.

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Although it would be important to evaluate if this worksheet is clinically useful to care providers, I am skeptical that such a tool would be effective, given the complex psychological adjustments employed by terminally ill patients. Efforts by earnest clinicians who hope to explore patients' end-of-life preferences using the worksheet may be undermined by not recognizing terminally ill patients' various coping styles, which complicate such conversations. Weissman described how patients may acknowledge their inevitable death and yet maintain a sense of hope and concurrent disbelief that they will die.[2] Maladaptive denial, which is marked by a rigid belief that one is not seriously ill, is another coping style. Both of these coping patterns would likely constrain the utility of such a communication tool. The impact of other psychosocial factors, such as psychiatric disorders, developmental stage, family dysfunction, and financial stressors, should be addressed for effective communication at the end of life.[3] In my experience working with patients with advanced illness, well-developed communication skills are required to effectively discuss preferences and concerns at the end of life; a static assessment tool will not suffice.

Finally, there is an inherent philosophical limitation to virtually any type of advance care planning. While this worksheet is not an advance directive *per se*, it serves a similar role in documenting patients' preferences for the future. The concern is that, in general, we make systematic errors in predicting our future desires. What we believe we prefer in a pre-morbid, healthy state is likely to be inaccurate compared to what we would choose when actually faced with a life-threatening illness. Research corroborates this.[4] Thus, as one critic of advance directives points out, if we are not aware of this difficulty when we consider what we would desire in a future hypothetical scenario, we undermine the principle of autonomy we are attempting to protect.[5] Beyond this philosophical objection, there seems to be a practical issue at stake, since seriously ill patients often change preferences over time.[6] Given the complex medical, psychological, and social factors at play at the end of life, it is not uncommon that what was once seen as desirable for a patient and family, for example, dying at home with loved ones, can become an unwelcome option as patients approach death.

The authors have constructed an interesting tool that is meant to encourage conversations around death and dying. Presently, there is insufficient evidence to recommend its use among providers caring for the terminally ill. My sense is that a semi-structured interview with open questions tailored to the unique psychological make-up of the patient is a clinically more effective and compassionate strategy. However, this worksheet may be an effective way for patients to facilitate a dialogue between family, friends, and their healthcare agents about end-of-life wishes. Indeed, such a worksheet would be invaluable to proxy decision makers struggling with making end-of-life decisions for an incapacitated patient. Similar to advance directives, there are limitations in how one might use preferences about death and dying to make important clinical decisions. Nonetheless, this worksheet may improve the chances of discussing our values and beliefs about death and dying, an opportunity we often circumvent.

NOTES

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5. C.J. Ryan, "Betting your life: an argument against certain advance directives," *Journal of Medical Ethics* 22 (1996): 95-9.

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Law

Legal Trends in Bioethics

Sigrid Fry-Revere, Sheeba Koshy, Greyson C. Ruback, Rex L. Wessel, and Nathaniel B. Revere

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 *Sigrid@ethical-solutions.org.*

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 guarantees of separation of church and state and individual rights in the U.S. Constitution 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, while others do not.

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 the federal and state constitutions from violation by legislative and executive 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. So, in bioethics cases, courts often have to deal with preventing governments, either through legislation or through 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 when confronted with divisive issues.

An understanding of these inherent tensions between legislative and judicial action and the various individual interests that are balanced by

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the courts makes it easier to understand legal trends in bioethics.

It is also important when considering trends to watch how far bills that are introduced advance even if they do not pass. For example, a bill that is introduced and quickly moves through several committees and is voted on by one chamber but not the other before the legislative session ends has a better chance of passing if reintroduced at the next session than a bill that was introduced but was never even voted on in committee. If a bill is listed as having died or failed, that means it was voted down either in committee or by one of the legislative chambers. The success of such a bill is not likely even if it is reintroduced in the following legislative session unless there is an election that sufficiently changes the composition of the legislature or some other intervening event rejuvenates the bill's chances. If the session ends without a bill being voted on by both chambers, it has failed; but it has a better chance if it is reintroduced in a later session than if it is voted down. A bill that is reintroduced also probably has a better chance than a bill that is never even voted on in committee. The reason that some bills are listed as having died due to the end of the session, while other bills are still listed as active, is that some states have one-year legislative session cycles and other states have two-year cycles.

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 (*).

Subject headings are not listed alphabetically. Sections are listed in descending order with those subjects with the most activity or the most significant activity listed first. It is important to note that the order of subject headings can vary from one issue of "Legal Trends" to the next depending on what subjects have the most legal activity in any given quarter.

INTRODUCTION TO "LEGAL TRENDS IN BIOETHICS" SUMMER 2008

The most significant development this quarter reflects the changing approach the U.S. is taking towards accountability in the manufacturing of drugs and other medical goods. A shift in the balance of power between the federal government and the states is evident in Congress's ever-growing allocation of responsibility to the U.S. Food and Drug Administration (FDA). But it is not so clear the states and the Supreme Court are ready to put more responsibility in the hands of the federal government. The deference the Court showed Congress in *Riegel, et ux. v. Medtronic, Inc.,* reported below, was clearly not as evident in *Warner-Lambert v. Kent*, also reported below. These cases may indicate that the Court is going to draw some lines. The Court is closely divided on the issue of federal preemption of state action, and it will be important to watch how the Court decides. In *Riegel*, preemption was directly written into the Medical Device Amendments of 1976 (21 U.S.C. § 360k(a)) and dealt with the state trying to impose a stricter liability standard than imposed by federal law. *Warner-Lambert* was more of a general preemption case, in which the issue was the state's right to look into enforcement of a federal law rather than holding companies to a stricter standard than what is expected at the federal level.

Other topics in which trends are changing involve healthcare coverage and organ procurement. In most states, ambitious attempts to provide healthcare for more citizens are being thwarted by fiscal realists. And despite some remaining optimism, a sense of desperation is starting to creep into the types of measures that states (and other countries) are willing to consider, given the ever-growing organ shortage and the questionable measures some physicians have resorted to, to provide organs for their transplant patients.

FDA

Behind the scenes of this quarter's updates on the FDA is a struggle over who will control regulatory actions against pharmaceutical and medical device companies. The decision in *Warner-Lambert v. Kent*, reported below, shows that the U.S. Supreme Court is conflicted. From a constitutional perspective, this is a states' rights issue and the Court has split its two decisions. *Riegel* decided in favor of federal preemption and *Warner-Lambert* decided against. It will be important to watch how the Court rules later this year in *Wyeth v. Levine*, another preemption case currently before the Court.

At issue in these preemptions cases is the very important constitutional issue of states' rights, but also the degree to which pharmaceutical and device manufacturers can rely on federal action or non-action as a defense against litigation. Simply

put, *Riegel* made it clear that states cannot impose more-stringent liability rules on manufacturers than the federal government does (at least not if a federal statute expressly prohibits them from doing so), but *Warner-Lambert* dealt with a duplication of enforcement efforts.

If only the FDA can decide when FDA rules are violated, the burden of protecting consumers and litigating violations rests solely with the federal government. In short, state tort laws and private litigation at the state level with respect to FDA-regulated products becomes moot. Individuals could no longer ask state courts to look into the facts surrounding an FDA-regulated product's approval or regulation to see if there was wrongdoing on the part of manufacturers. It would become the sole responsibility of the federal government to do FDA-related fact-finding. Manufacturers would be relieved of the considerable burden of having to worry, not only about how the FDA enforces its regulations, but also about how each individual state decides to help the FDA enforce its regulations.

This type of federal preemption of state drug and medical device laws would clearly be advantageous for manufacturers, but whether it would be good for society as a whole is less certain. It is expensive for companies to guard against possible litigation at so many different fronts. It could be argued that the funds expended on defending state lawsuits would be better spent on testing and developing new products and that state fact-finding demands on the FDA pose an unnecessary burden on the already overburdened agency. But, on the other hand, it can be argued that it is prudent to have more rather than fewer industry watchdogs and that it is better for individuals to have several avenues for righting possible wrongs.

Can the FDA do it all? Everyone agrees that the agency is overburdened, so wouldn't it be an even greater burden to expect the FDA to investigate and litigate every potential case of manufacturers' misconduct on its own, rather than taking the time to provide state courts with the documentation they need to do the investigations themselves? Understandably the FDA prefers not to have state courts determining whether a manufacturer managed to defraud the FDA, but what about the individuals who are hurt when the FDA doesn't meet its responsibilities? While somewhat messy in execution, duplication of enforcement efforts at the state level creates more incentives for manufacturers to assure compliance and more avenues for individuals to secure redress when regulations are broken. A vital part of the states' rights issue has nothing to do with the rights of states *per se,* but with the right of the people to have someone watching the watchdog.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. On 20 February 2008, the Supreme Court upheld a Second Circuit decision that a state tort law that required that a device be safer than what was approved by the FDA would interfere with the FDA's regulatory scheme, and that more-stringent liability state requirements were preempted by the specific language of the federal Medical Device Amendments of 1976 (21 U.S.C. § 360k(a)). The case involved an angioplasty procedure in which a catheter balloon reportedly burst, causing complications for the patient. *Charles R. Riegel, et ux v. Medtronic, Inc.,* 552 U.S. ____ (2008), decision available at *http://www.scotusblog.com/wp/wp-content/uploads/2008/02/06-179.pdf.*

On 3 March 2008, in the case of *Warner-Lambert v. Kent*, the United States Supreme Court upheld, in a four-to-four decision (Chief Justice Roberts recused himself from the case due to stock ownership), an October 2006 ruling by the U.S. Court of Appeals for the Second Circuit that declined to preempt a 1995 Michigan law that protects drug companies from products liability claims, absent cases involving "fraud-on-the-FDA." Warner-Lambert sought a decision affirming that the federal Food, Drug and Cosmetic Act preempts the Michigan law, following the precedent set in the 2001 decision of *Buckman Co. v. Plaintiffs' Legal Comm*. 531 U.S. 341 (2001). Among other things, plaintiffs argued that the lower court's ruling would "interfere with the FDA's ability to perform its critical functions, which is precisely what [the Supreme Court] sought to avoid in *Buckman*." The issue was not whether fraud-on-the-FDA is a sufficient criteria for liability, but whether a state court could make a determination that fraud took place, even if the federal government had never made such a determination itself. *Warner-Lambert v. Kent*, 552 U.S. ____ (2008), decision available at *http://www.supremecourtus.gov/opinions/07pdf/06-1498.pdf*.

The *Warner-Lambert* decision sets the scene for another U.S. Supreme Court drug industry

preemption case expected to be heard later this year, *Wyeth v. Levine*, which concerns preemption of state tort claims that impose a liability based on FDA-approved labeling. *Wyeth v. Levine*, U.S. Supreme Ct. Docket No. 06-1249 (certiorari granted 5 February 2008).

District of Columbia. On 4 March 2008, the United States District Court for the District of Columbia dismissed a suit brought by numerous nonprofit organizations seeking to vacate the FDA's supplemental New Drug Application (sNDA) pertaining to Duramed's Plan B, an emergency contraceptive tablet. The new application maintains Plan B's prescription status for women younger than 18, but allows the drug to be made available to women 18 years or older over the counter (OTC), that is, without a prescription. Plaintiffs in the case, including the Family Research Council, Safe Drugs For Women, the Association of American Physicians and Surgeons, and Concerned Women for America, argued, among other things, that the sNDA was in violation of the Food, Drug and Cosmetic Act because of its age-based restrictions. Plaintiffs also argued that by allowing simultaneous marketing under both prescription and OTC regulation, the FDA effectively created a "third class" of drugs not permitted under the Food, Drug and Cosmetic Act. The case was dismissed because the court determined that plaintiffs had not exhausted available administrative remedies and lacked legal standing because they had no "sufficient personal stake in the outcome." K. Karst, "District Court Dismisses PLAN B Case Against FDA Based on Lack of Standing and Failure to Exhaust Administrative Remedies," *FDA Law Blog: Hyman, Phelps & McNamara, P.C.*, 10 March 2008, *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/03/district-court.html,* accessed 7 May 2008.

Wisconsin. On 29 February 2008, the United States District Court for the Eastern District of Wisconsin dismissed a suit seeking judgment against three manufacturers of prescription polyethylene glycol 3350 (PEG-3350), a laxative. The suit was brought by Schering-Plough Healthcare Products, Inc., makers of Miralax, another PEG product that had recently switched from prescription to OTC, and sought judgment against the defendants for violating the Food, Drug and Cosmetics Act, which prohibits marketing of the same drug as prescription and OTC simultaneously. Further, Schering claimed that the manufacturers' labeling containing the statements "prescription only" and "Rx only" was "literally false," which Schering asserted established liability under the Lanham Act. Defendants argued successfully that the FDA had not definitively ruled on how the Food, Drug and Cosmetic Act should be interpreted under such circumstances, and that in this case statements pertaining to one particular product does not apply to all products of that type in general. J. Ellison, "Wisconsin Court Adds to Precedent Holding that the FDC Act Cannot Be Privately Enforced," *FDA Law Blog: Hyman, Phelps & McNamara, P.C.*, 9 March 2008, *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2008/03/wisconsin-court.html,* accessed 7 May 2008.

Recent Developments in Law and Regulation
January - March 2008

*The FDA issued new draft guidelines that allow pharmaceutical and medical device companies to send physicians studies on "off-label uses," that is, non-FDA approved uses, of medications. Physicians can prescribe medications and medical devices for off-label uses, but the FDA currently prohibits the marketing of drugs and medical devices for unapproved purposes. Under the draft FDA guidelines, companies can send physicians unabridged reprints of studies on off-label uses of medications that have been published in peer-reviewed medical journals as long as the studies are not significantly influenced by a company's financial support of the studies in question. The guidelines were open for comment until 21 April 2008. Stanford University Medical Center, "Guidance for Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices," Draft Guidance FDA-2008-D-0053, *http://www.fda.govOHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl. pdf.*

California. A number of local government bodies in California are mounting opposition to the FDA's decades-old policy barring men who have sex with men from donating blood. Read more about this under the HIV section below.

TRUST / ACCOUNTABILITY

Some topics previously included in this section are now under a new heading, "FDA," so please also review that section for issues involving government oversight and patient trust directly

related to FDA regulatory actions. Regulatory actions with relevance to bioethics issues by government entities other than the FDA at both the federal and state level are reported here. Also reported here are civil actions that often parallel regulatory actions taken by government. Civil suits are filed because, while regulatory actions can result in fines and regulatory relief, they do not result in damages or reparations. For plaintiffs to receive damage awards, they must seek relief in a civil suit.

In addition to continuing battles over wrongdoing both in the private and public sectors, there are two positive events that do not, strictly speaking, fit under any heading in an article on legal trends included here, because it is easy to forget how important the sharing of information is to accountability, particularly in medicine. On 25 March 2008 a not-for-profit group, iHealth Alliance, announced its plans to implement a 2006 FDA guideline regarding notifying physicians about changes to labels, warnings, and recalls by e-mail instead of regular post. The group says that the site and e-mail system are a necessary step because previously physicians' offices had a hard time distinguishing mailings about significant updates from "junk mail" from pharmaceutical companies. The service will be offered at no cost to doctors, but pharmaceutical companies will be required to pay to receive updates about their products distributed via the e-mail service. iHealth also has plans for a website to allow doctors to comment on the label updates, and iHealth Alliance will collect and forward those comments to the FDA. Kaiser Family Foundation, "Not-for-Profit Group To Launch Web Site To Notify Physicians of Medication Label Changes, Warnings, Recalls," *Kaiser Daily Health Policy Report*, 25 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=51130*, accessed 8 May 2008.

And second, on 3 March 2008 a group of doctors and lawyers working with a local hospital launched a pilot mediation project with the goal of keeping malpractice disputes out of court. The group started planning the program at the advice of the Pennsylvania State Supreme Court, who in 2005 recommended considering alternatives to court battles when doctors threatened to leave the state in response to rising costs of malpractice insurance. The developers of the program noticed that many lawsuits were being filed simply so that patients or their families could find out exactly what had gone wrong, so they set up the program in two parts. First, people with grievances are brought together with hospital doctors and nurses, who listen to the complaints and attempt to explain what happened clearly as possible. If they are not happy after the first part, they move to mediation, where a trained mediator works with both sides to try and get them to agree on a solution. S. Burling, "Doctor-lawyer project tackles malpractice," *Philadelphia Inquirer*, 3 March 2008, *http://www.philly.com/philly/business/breaking/20080303_Doctor-lawyer_ project_tackles_malpractice.html*, accessed 19 June 2008.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. A spokesman for the U.S. attorney's office in Newark announced on 21 March 2008 that the ongoing investigation into kickback payments in the form of consulting fees from manufacturers of orthopedic devices to doctors was shifting focus, and would now be looking into the conduct of individual surgeons. The reason for the shift is that the government reached settlements last year with the five manufacturers under investigation. The terms of each individual settlement vary, but all companies agreed to stricter scrutiny of their compensation of surgeons for consulting services in exchange for the government dropping its criminal cases related to the alleged kickbacks. The companies were ordered to employ special monitors who are paid as much as $985 per hour plus a monthly retainer to oversee all payments made to doctors. It is sadly ironic that the U.S. attorney supervising the investigation appointed his former boss to the most lucrative of those positions. B. Feder, "New Focus of Inquiry Into Bribes: Doctors," *New York Times*, 22 March 2008, *http://www.nytimes.com/2008/03/22/business/22device.html*, accessed 18 June 2008.

Alaska. On 26 March 2008, the State of Alaska settled with drugmaker Eli Lilly for $15 million in a lawsuit seeking damages for expenses incurred by the state when it paid for the treatment of Medicaid patients who developed diabetes while taking the schizophrenia drug Zyprexa. Alaska originally sought damages in the hundreds of millions but settled for less. Eli Lilly admitted to no wrongdoing in the settlement. A. Berenson, "Alaska Suit Against Lilly is Settled," *New York Times*, 27 March 2008, *http://www.nytimes.com/2008/03/27/business/27zyprexa.html?_r=1&scp= 2&sq=eli+lilly &st=nyt&oref=slogin*, accessed 4 May 2008.

Currently 16 other states have disclosed similar claims against Lilly, but none of them are likely

to reach trial before the Supreme Court rules on preemption in the *Wythe* case, which could potentially rule out such state claims altogether. These states are **Arkansas, California, Connecticut, Florida, Illinois, Louisiana, Mississippi, Montana, New Mexico, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Utah, Vermont, and West Virginia**, *http://www.psych search.net/lawsuits.html*, accessed 20 June 2008.

Mississippi. The Mississippi Supreme Court announced on 3 March 2008 that it will consider a request from a panel of the fifth U.S. Circuit Court of Appeals to clarify when the clock starts running towards the statute of limitations in certain malpractice cases. Specifically they are asking for clarification on cases "where the alleged negligence is either the administration of a drug by a physician or the physician's failure to disclose about the risks of a drug, and experts disagree as to whether the drug caused the plaintiff's injuries." The request stems from a 2006 holding that gave plaintiffs two years to file suit after diagnosed with a condition. Associated Press, "Miss. Supreme Court to consider clarifying medical malpractice limits," *Picayune Item*, 4 March 2008, *http://www.picayuneitem.com/local/local_story_064125214.html*, accessed 19 June 2008.

Pennsylvania. On 14 March 2008 the Court of Common Pleas of Philadelphia County ruled in *Clark v. Pfizer, Inc.* that drug manufacturers who fraudulently promote off-label uses of their drugs may be liable for the costs to purchasers of generic versions of their drugs. The court found that, "Under Pennsylvania law, a defendant may be liable for misrepresentation to foreseeable plaintiffs even without any direct relations between the parties." The ruling on manufacturer Pfizer's motion for summary judgment means that the class action lawsuit on behalf of people who purchased the drug Neurontin or its generic equivalent, Gabapentin, will be allowed to advance to trial. *Clark v. Pfizer Inc.*, Pa. C. No. 040601819. Opinion available at *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/clark_v_pfizer_opinion_2008.pdf*, accessed 5 May 2008.

Virginia. The Virginia Supreme Court ruled on 29 February 2008 that physicians working for charitable foundations are not immune from malpractice liability under the state's charitable immunity laws. Three malpractice suits against doctors working for the University of Virginia Health Services Foundation were consolidated for this case. Each of the doctors claimed they should not be liable since they were working for a not-for-profit foundation. The court held that charitable immunity protects only groups organized and operated for charitable purposes. Although the Health Services Foundation was organized for charitable purposes, the court found that it was in fact operating much like a business, regularly ending up with a profit that it paid to its physicians as bonuses, and therefore the physicians were not immune from tort liability. *University of Virginia Health Services Foundation v. Morris*, ___Va. ___(Va. S. Ct. 2008), No. 070214, 29 February 2008. Opinion available at *http://www.courts.state.va.us/opinions/opnscvwp/1070214.pdf*.

Recent Developments in Law and Regulation
January - March 2008

***Federal**. There has been no action on a bill introduced in the Senate on 6 September 2007 that would require drug, medical devices, and biologics manufacturers with at least $100 million in annual revenue to disclose, every quarter, gifts or payments that they make to physicians exceeding $25 in value. The legislation would require the Secretary of the U.S. Department of Health and Human Services (DHHS) to create a website and post payment information. Penalties would range up to $100,000 per violation. Companies would be required to disclose any payment or benefit made "directly, indirectly, through an agent, subsidiary or other third party," which might include payments by universities and by companies that set up conferences for influential physicians with drug or medical device manufacturer funding. Funding of continuing medical education would also need to be disclosed. No-cost drug samples and financing for clinical trials would not have to be disclosed under the bill. The legislation was read twice and referred to the Committee on Finance. S. 2029, 110th Cong. (1st Sess. 2007).

***New Jersey**. There has been no action on a bill originally introduced on 14 May 2007 that would require doctors to inform patients of gifts of more than $25 accepted from pharmaceutical firms in the last year. S. 2660, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

Interesting Developments in Other Countries
January - March 2008

Britain. The pharmaceutical company Reckitt Benckiser is accused of cheating the National

Health Service. Internal memos were leaked by a whistle blower within the company that describe a secret plan to manipulate regulators and doctors to prevent a generic version of a highly successful indigestion drug, Gaviscon, from coming on the market and undercutting Reckitt's existing NHS contracts. The NHS estimates that generic versions of the drug would have saved them as much as 40 million pounds (around 78 million U.S. dollars), but a generic version of the drug has never been developed, even though Gaviscon has been out of patent for 10 years. Reckitt's accusers say that the leaked memos reveal that this is due to deliberate manipulation of the patent process by Reckitt, via a method known as evergreening, wherein a company will repeatedly file for revised patents on their existing products that extend their period of patent protection from competition. D. Leigh, "Company Accused of Cheating NHS," *Guardian*, 7 March 2008, *http://www.guardian.co.uk/society/2008/mar/07/health.nhs*, accessed 19 June 2008.

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

Not specific to this quarter of "Legal Trends in Bioethics," but nevertheless worth mentioning, is the fact that victories for either side in the abortion debate seem in general to be small and fleeting. Over time the battlegrounds shift slightly, but the issues themselves are never resolved. For example, 30 years ago protest buffer zones were frequently in the news, and in this quarter's reports there is just such a case again in the news (see *Brown v. Pittsburgh* below). Also seemingly continuously in the news are cases over parental notification (see entries for Arizona and California below) and funding battles (see Vitter Amendment below). Arguments over the appropriateness of in-vitro fertilization have developed into arguments over more recent medical advancements such as stem-cell research, and more recent informed consent debates have moved from simple verbal or written information to battles over mandating ultrasounds. While undoubtedly everyone would like to see these issues resolved, one of the beauties of our legal system is that it provides avenues for the most deep-seated disagreements to be argued and debated peacefully. "Peacefully" here doesn't necessarily mean tactfully or without bitterness, acrimony, and occasionally even violence. Yet, the fact that these issues have not resulted in systematic government censorship or mass riots is proof that the system is working.

Judicial Cases and Regulatory Actions January - March 2008

***Federal.** U.S. District Court for Western Pennsylvania upheld on 22 February 2008 a Pittsburgh ordinance that creates a buffer zone between protesters and healthcare facilities, including abortion clinics. *Brown v. Pittsburgh* (Western PA District Court No. 2:06-CV-00393-NBF, 22 February 2008). Opinion available at *http://www.womenslawproject.org/Briefs/Bufferzon_opinion.pdf*.

***Kansas.** On 25 January 2008 a grand jury convened to investigate whether George Tiller, MD, broke a state law concerning late-term abortions ordered that Dr. Tiller provide the medical records of patients who sought late-term abortions between 1 July 2003 and 18 January 2008. Dr. Tiller refused to turn over the records, in part because he wanted to protect his patients' privacy. On 5 February 2008 the state supreme court ordered a stay on the issuing of any more grand jury subpoenas for Dr. Tiller's records and scheduled oral arguments for 8 April 2008. *George R. Tiller, MD, et al. v. Hon. Michael Corrigan, et al.* (Kas. Sup. Ct. No. 99,951).

Recent Developments in Law and Regulation January - March 2008

Federal. The Vitter Amendment, a part of the Indian Health Care Improvement Act reauthorization bill, was approved by the Senate on 26 February 2008. The amendment prevents the Indian Health Service from paying for abortion except in the case of rape, incest against a minor, or to save the life of a mother. C. Horton, "Bills limiting abortion move through state, federal processes," *Alaska Journal of Commerce*, 16 March 2008, *http://www.alaskajournal.com/stories/031608/hom_20080316003.shtml*, accessed 19 June 2008.

Arizona. Two bills passed the legislature in the week of 28 March 2008. The first, HB 2263, changes the parental notification laws, making it more difficult for minors to obtain a judicial bypass. The second, HB 2769, is a state ban on partial birth abortion, allowing doctors who perform the procedure to be prosecuted on both a state and federal level. Feminist Wire, "Arizona Legislature Passes Anti-Choice Bills," *Feminist Wire*, 28 March 2008, *http://www.msmagazine.com/news/uswirestory. asp?ID=10907*, accessed 19 June 2008.

California. For the third time in three years, anti-abortion advocates are trying to get enough signatures to place an initiative on the November 2008 ballot that would require parental notification and a 48-hour waiting period before a woman may obtain an abortion. Under the current initiative if a doctor performs an abortion on a dependant minor without parental approval, the doctor would be subject to a fine. M. Tafoya, "Parental Notification Effort in California," *Reproductive Health Reality Check*, 21 April 2008, *http://www.rhrealitycheck.org/blog/2008/04/21/parental-notification-amendment-may-face-california-voters*, accessed 20 June 2008.

Florida. A state senate bill that would require all women to undergo ultrasound testing prior to obtaining an abortion failed. The bill was presented as an extension of the theory of informed consent under which doctors are required to fully inform patients prior to allowing them to make a medically related decision. S.B. 2400, 2008 Reg. Sess. (Fla. 2008).

***Hawaii**. There has been no action on two bills that were held over from the 2007 legislative session that would allow all forms of stem-cell research. If no new action is taken, the bills will die at the end of the 2008 session. H.B. 364, H.B. 1261, 24th Leg., Reg. Sess. (Haw. 2007).

Kansas. On 21 April 2008, the governor vetoed an anti-abortion bill, stating that it was in violation of both the Kansas and the U.S. Constitutions. The measure encouraged litigation against providers of late-term abortions. It would have allowed patients, their spouses, or family members to sue abortion providers if they believed the provider was in violation of restrictions against late-term abortions. It also allowed the same parties to go to court to stop a late-term abortion if they believed it would be illegal. S.B. 389, 82nd Leg., Reg. Sess. (Kan. 2008).

***Michigan**. The state senate passed a bill that would ban "partial-birth" abortions. The legislation includes an exception in the event that the procedure is necessary to save the life of the mother. Violation is a felony and subjects anyone found guilty to up to two years imprisonment and a fine not to exceed $50,000. The bill is currently under consideration in the state house. SB 776, 94th Leg., Reg. Sess. (Mich. 2007).

Missouri. A bill is stalled in the state senate that would modify the informed consent requirement for an abortion by adding new requirements to be fulfilled at least 24 hours prior to obtaining an abortion. Specifically, the bill would require that the woman be presented with printed materials and videos detailing the risks of an abortion, the physiological characteristics of an unborn child, provide an opportunity to view an active ultrasound of the unborn child, and offer to let the woman hear the heartbeat of her fetus. The bill also creates the crime of knowingly coercing a woman to seek or obtain an abortion. S.B. 1058, 94th Gen. Assem., 2nd Reg. Sess. (Mo. 2008).

Nebraska. On 25 March 2008, the governor signed into law a bill that represents a compromise on the controversial issue of stem-cell research. The law prohibits the use of state money or facilities for creating or destroying embryos for stem-cell research using the therapeutic cloning technique. However, it also allows for the continuance of research using federally sanctioned stem-cell lines. The law also mandates the creation of an advisory committee that would award matching grants of up to $500,000 for research on non-embryonic stem-cell research. L.B. 606, 100th Leg. Sess. (Ne. 2008).

***Ohio**. Two similar bills are moving their way through various committees in the state legislature. Originally introduced in the state house on 18 September 2007 and the state senate on 4 October 2007, they would require abortion providers to provide a patient with an opportunity, at no extra cost, to view an ultrasound of the fetus before the abortion can take place. Both bills are currently in the state senate's Health, Human Affairs and Aging Committee. H.B. 314, S.B. 230, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

Pennsylvania. A bill that provides for an umbilical cord blood bank and requires healthcare practitioners to give pregnant patients information regarding umbilical cord donation passed the state senate on 31 March 2008. The bill passed the state house on 17 July 2007 and now goes to the governor for approval. H.B. 874, 191st Gen. Assem., Reg. Sess. (Pa. 2007).

South Carolina. On 14 May 2008, the governor signed into law a bill that would require a woman to be informed that she has a right to view an ultrasound image of her fetus. The law also requires signed documentation of the doctor's offer and the woman's decision whether or not to view the ultrasound. No ultrasound may be performed sooner than 60 minutes prior to the commencement of the abortion procedure. H.B. 3355, 117th Gen. Assem., 2nd Reg. Sess. (S.C. 2008).

***South Dakota**. On 17 March 2008, the gover-

nor signed into law a bill that would require abortion facilities to offer sonograms to pregnant women and document the offer and the woman's decision whether or not to view the ultrasound. The woman must attest with her signature to having made an informed decision. S.B. 88, 82nd Leg. Sess. (S.D. 2008).

Tennessee. A bill has been held over to the summer session that would require informed consent and a 24-hour waiting period prior to obtaining an abortion. SB 3512, 105th Gen. Assem., Reg. Sess. (Tenn. 2008).

***Wisconsin**. A bill died which would have required physicians who perform abortions to take certain steps if a woman seeking an abortion seems to have been coerced into having the abortion or seems to be in danger of being harmed if she declines to have the abortion. S.B. 218, 1007 Reg. Sess. (Wis. 2007).

Interesting Developments in Other Countries

***United Kingdom**. The Human Fertilisation and Embryology Bill was introduced in the House of Lords on 17 January 2008. The bill would amend the Human Fertilisation and Embryology Act of 1990 by changing the legal definition of parenthood in cases involving assisted reproduction and provides for regulation of procedures that combine several human embryos. It has progressed through the first sitting of the report stage, with a second scheduled for 21 January 2008. Amendment proposals seeking changes to current abortion law are expected to be introduced. The bill in its most recent incarnation would allow researchers to create inter-species hybrids by injecting human DNA into a hollowed-out animal egg cell. The resulting embryo would be 99.9 percent human and 0.1 percent animal. Supporters argue that this process will allow scientists to make a large number of human embryos to allow for adequate research into the cures for many diseases. House of Lords: HL 2007/08 6. The entire text of the bill is at *http://www.publications.parliament.uk/pa/ld200708/ldbills/006/08006.i-iv.html.*

HEALTHCARE COVERAGE

The entries in this quarter reflect the sobering realization that it is one thing to wish the government could provide more healthcare coverage for its citizens, and quite another to find a way to pay for it.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. On 24 March 2008, the U.S. Supreme Court declined to consider a challenge of a recent ruling by the Equal Employment Opportunity Commission, as brought by AARP (formerly the American Association of Retired Citizens). The AARP has argued that the ruling, which allows employers to reduce benefits for Medicare-eligible retirees, amounts to age discrimination, as employers are now able to create two different sets of retirees, and offer substantially different benefits to each group. Kaiser Family Foundation, "U.S. Supreme Court Allows Employers To Continue Reducing Health Care Benefits for Medicare-eligible Retirees," *Kaiser Daily Health Policy Report*, 25 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51121*, accessed 16 May 2008.

*There have been no new developments in a suit filed by the Medicare Rights Center in the U.S. District Court for the Southern District of New York on 26 November 2007. The plaintiff argues that the DHHS should not deny coverage for "off-label" use of prescriptions. The plaintiff was using a fertility drug as a cancer treatment and Medicare refused to pay for the treatment because the drug was not approved as a cancer treatment. Such "off-label" use is common in the medical profession and is based on clinicians' experience, published guidelines, and research findings in medical journals. *Layzer v. Leavitt*, *NY12525-#412881-v13-JL_SDNY_complaint_11_26_07.Doc.* A copy of the complaint is available at *http://www.medicarerights.org/off_label_complaint_ Nov 2007.pdf*.

***California**. There have been no further developments in the appeal of a Second District Court of Appeals for the State of California ruling on 4 December 2007 that canceling individual health insurance policies for omissions or mistakes on applications after claims are submitted is prohibited under state law. The court also held that insurers cannot cancel a member's policy if they do not attach a copy of the application to the policy. The case is on appeal to the state supreme court. *Ticconi v. Blue Shield of California* (Ca. S. Ct. No. S162434). Opinion available at *http://www.courtinfo.ca.gov/opinions/documents/B190427B.pdf*.

Illinois. A suit was filed in the Seventh Circuit Court of Sangamon County, Illinois, on 4 De-

cember 2007 by the Illinois Coalition for Jobs, Growth and Prosperity. Plaintiffs challenge the constitutionality of the governor's emergency ordered expansion of the state's FamilyCare program. The first court hearing is scheduled for 11 March 2008. *Gidwitz, et al. v. Maram*, No. 2007 MR ____. Complaint available at *http://www. jobscoalition. org/1054848_1.pdf*.

***Nebraska**. There are no new developments in a lawsuit filed in the Lancaster County District Court on behalf of Sandra Cartwright, alleging that state employees living in predominately African-American areas are offered inferior health insurance coverage. J. Funk, "Lawsuit: State discriminated against blacks with insurance choice," *Lincoln Journal-Star*, 5 November 2007, *http:// www.journalstar.com/articles/2007/11/05/news/ nebraska/doc472e5be 94739f900866308.txt*, accessed 4 February 2008.

Recent Developments in Law and Regulation January - March 2008

Federal. The Indian Health Care Improvement Act reauthorization passed the Senate on 26 February 2008, by an 83 to 10 vote. The bill provides $35 billion to the Indian Health Service to allow for expanded healthcare for almost two million participating American Indians. The bill also seeks to promote increased participation of American Indians in healthcare professions, the expansion and modernization of reservation healthcare services, including additional funding for cancer and diabetes screening and mental health programs, and easier and more complete tribal access to Medicare and Medicaid. S. 1200, 110th Cong., 2nd Reg. Sess. (2008).

The Healthy Americans Act, first introduced in the Senate in January 2008, was referred to the Committee on Finance on 24 April 2008. The bill would create incentives for private health insurers to provide coverage directly to individuals, while employer contributions would be shifted to wages, and eventually a health insurance contribution to the federal government. S. 334, 110th Cong., 2nd Reg. Sess. (2008).

*There has been no action on a bill 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. On 9 July 2007, the bill was referred to the Subcommittee on Health, Employment, Labor, and Pensions, where it is still pending. H.R. 1841, 110th Leg., 1st Reg. Sess. (2007).

Alabama. The governor's proposed 2009 fiscal budget has drawn criticism from state health officials. According to the Alabama Department of Public Health, the governor's $1.95 billion budget would not cover several important programs, including Alabama's AIDS Drug Assistance Program, the Alabama Home and Community-Based Waiver Program, the state's Breast and Cervical Cancer Early Detection Program, and Alabama's SCHIP program, known as All Kids, which officials claim would need to freeze enrollment unless additional funds were provided. State health officials also have warned that these funding cuts will result in reductions of federal matching funds made available for Alabama's healthcare programs. Kaiser Family Foundation, "Highlights Recent Budget Developments," *Kaiser Daily Health Policy Report*, 21 March 2008, *http://www.kaiser network.org/daily_reports/rep_index.cfm?hint =3&DR_ID= 51095*, accessed 16 May 2008.

***Alaska**. A universal healthcare proposal was sent to the finance committee. The bill, originally introduced on 10 September 2007, called the Mandatory Universal Health Care Act, would require all state residents to obtain health coverage, with the state subsidizing plans for low-income residents. It would create a healthcare board that determines which medical services are covered under the subsidized program and would certify private coverage plans that meet state requirements. The board would also oversee the state and federal government jointly funded Alaska Health Fund, as well as contributions from employers and employees. A sliding-scale voucher system would be funded by the tax revenues collected to pay for the program. Residents would be able to use the vouchers to obtain coverage from the Alaska Health Care Clearinghouse, a "marketplace" for various certified policies. S.B. 160, 24th Leg., Spec. Sess. (Alaska 2007).

***California**. There has been no action on a bill originally introduced in the state Assembly on 11 September 2007 that proposes a plan that would increase tobacco taxes to increase state revenues and, as a separate measure, mandate health insurance. Families for whom insurance costs amounted to more than 6.5 percent of annual family income would receive subsidies to pay for insurance. AB 1X, 2007-2008 Leg. 2d Ext. Sess. (Cal. 2007).

Illinois. On 26 February 2008, the Joint Committee on Administrative Rules rejected the governor's emergency ordered expansion of the state's FamilyCare program for the second time. The order would have expanded eligibility for the FamilyCare program from families with up to $38,202 in annual income to families with as much as $82,600 annual income. A similar order was overturned in November 2007 over questions of where the money would come from to finance the expansion and because the program was expanded without legislative approval. A suit has also been filed by the Illinois Coalition for Jobs, Growth and Prosperity challenging the constitutionality of both orders, and the first hearings were scheduled for 11 March 2008. Kaiser Family Foundation, "Illinois Legislative Committee Rejects Gov. Blagojevich's FamilyCare Expansion," *Kaiser Daily Health Policy Report*, 28 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50671*, accessed 15 May 2008.

Iowa. Iowa's Health Care Reform bill passed the Senate Human Resources Committee on 6 March 2008 and was sent to the full senate for consideration. Introduced on 6 March 2008, the bill would mandate health coverage for nearly all Iowa children by 2011, and expand HAWK-I, the state's State Children's Health Insurance Program (SCHIP), to provide coverage for children from low-income families. Additionally, the bill includes regulations to mandate "quality measure" reporting by the state's hospitals and physicians, and would provide incentives for the adoption of electronic health records. H.F. 2539, 82nd Gen. Assem., 2nd Sess. (Iowa 2008).

***Maryland.** The state house approved a $31.2 billion 2009 fiscal budget by a 105 to 34 vote on 20 March 2008. Included in the house version of the budget are appropriations of $15.1 million to provide expanded access for oral health services, and an additional $10 million to provide subsidies to small businesses for healthcare procurement. Kaiser Family Foundation, "Highlights Recent Budget Developments," *Kaiser Daily Health Policy Report*, 21 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID= 51095*, accessed 16 May 2008.

Minnesota. On 27 March 2008, the state senate approved a proposed healthcare system overhaul that would, among other things, provide for expanded coverage for 47,000 additional residents. The bill mandates the public accounting of fees charged by healthcare providers and demands the development of tools to allow consumers to easily compare the benefits and costs of competing plans. Under the proposals, the state would also begin monitoring childhood obesity and facilitate treatment of residents who have chronic conditions. Additionally, the plan would allow small businesses to obtain private health insurance with pre-tax dollars. Governor Tim Pawlenty has expressed concerns over the costs of the legislation, which the proposals plan to offset through projected long-term savings, and some Minnesota Democrats have voiced concerns over the far-reaching implications of the omnibus package. S.F. 3099, 85th Gen. Assem., Reg. Sess. (Minn. 2008).

Oregon. The Oregon Health Plan, which, due to budgetary restrictions has had closed enrollment since 2004, was reopened in February to fill 3,000 newly available slots. Faced with an overwhelming applicant pool, state officials began drawing names through a statewide lottery to fill the new openings. More than 90,000 of Oregon's estimated 600,000 uninsured residents had applied to the lottery within a month of the announcement of the opening. The current standard plan, which currently covers about 18,000 Oregonians, provides the insured access to general services, medications, and even limited dental and vision benefits, with premiums no higher than $20 a month. Kaiser Family Foundation, "Lottery To Fill Open Spots in Oregon Health Plan Draws 'Overwhelming Response'," *Kaiser Daily Health Policy Report*, 10 March 2008, *http://www.kaisernetwork.org/daily_reportsrep_index.cfm?hint=3&DR_ID=50864*, accessed 16 May 2008.

Tennessee. On 10 March 2008, the governor proposed new legislation to streamline the process of qualification for state home-based care coverage. The plan hopes to reduce overall healthcare spending, while simultaneously providing an expanded array of choices in providing elderly care throughout the state. Kaiser Family Foundation, "Tennessee Gov. Bredesen Proposes Home-Based Care Plan," *Kaiser Daily Health Policy Report*, 11 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50894*, accessed 15 May 2008.

VACCINES

Vaccines are marvels of medicine that save millions of lives every year, yet government policies have resulted in reducing rather than increasing the effectiveness of vaccine programs. The U.S. Supreme Court in *Jacobson v. Massachusetts,* 197

U.S. 11 (1905) upheld a state statute compelling smallpox vaccinations. Smallpox, the Court held, is highly contagious and extremely deadly and thus justified mandatory vaccination with no exception except for an individual's unique medical susceptibility. (A modern day example would be that vaccination not be required for someone who is immunosuppressed.) No other exemption made sense in the Court's mind because the more exemptions there are, the less effective an immunization program becomes.

Today in the U.S. the effectiveness of vaccination programs is undermined by the overzealous mandating of vaccines and a laissez-faire attitude toward the granting of exemptions. Most of the 41 vaccines for children that have been recommended by the U.S. Centers for Disease Control and Prevention — and consequently are required by the states — don't come anywhere near meeting the criteria set forth in *Jacobson* for justifying a mandate. When people learn that some vaccines are not as necessary as government officials suggest, understandably, even if erroneously, they question the necessity of other vaccines. Similarly, when legislators make exceptions to their mandates for less-critical vaccines, they open the door for people to demand exemptions from taking other vaccines.

Currently all of the U.S. states allow medical exceptions, but most of the states also allow religious and philosophical exemptions for all types of vaccines. To complicate matters, there are nearly 5,000 families who are currently suing the government for vaccine-related autism and other developmental disabilities allegedly caused by vaccines. Under such circumstances, government efforts to revitalize trust in vaccines face serious obstacles.

Recent Judicial Cases and Regulatory Actions January - March 2008

Federal. A U.S. federal judge ruled that the U.S. Department of Defense must consider exonerating two military pilots whose careers ended after they refused to take compulsory anthrax vaccine shots. The plaintiffs were two out of hundreds in the same situation. The military's mandatory inoculation program, which started in March 1998, continued for more than six years. Federal courts have since found the program illegal and in direct violation of an individual's right to informed consent. E. Grossman, "Judge advances anthrax vaccine refusal case," *Global Security Newswire,* 24 March 2008, *http://www.govexec.com/dailyfed/0308/032408gsn1.htm*, accessed 18 June 2008.

Recent Developments in Law and Regulation January - March 2008

***California**. There has been no action on a bill that would require all girls entering the sixth grade to receive the human papillomavirus (HPV) vaccine. The bill includes an opt-out provision. A.B. 16, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

***Michigan**. There has been no action on a bill that would require the Michigan Department of Health to "encourage" every school (both public and private) to provide information regarding the risks associated with HPV and the availability, effectiveness, and potential risks of immunization to students and parents. The legislation makes no reference to the age or grade level at which this information should be provided. H.B. 5171, 94th Leg., Reg. Sess. (Mich. 2007).

***Wisconsin**. A bill that would have required schools to provide parents with information about the HPV vaccine has died. The bill directed the Department of Public Instruction, in conjunction with the Department of Health and Family Services, to distribute information that includes the recommendations made by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. An identical bill that was being considered by the state assembly has also died. S.B. 252, A.B. 492, 2007 Reg. Sess. (Wis. 2007).

ORGAN AND TISSUE PROCUREMENT

Since the last issue of "Legal Trends in Bioethics," one more state, Michigan, has passed the Uniform Revised Anatomical Gift Act of 2006. That brings the number of states in which the act has passed up to 21 states (**Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Kansas, Michigan, Minnesota, Montana, Nevada, New Mexico, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, and Virginia**).

This quarter's entries on organ procurement indicate a mix of optimism and desperation when it comes to solving the organ shortage. New Jersey is implementing a high school organ donation education campaign and Wisconsin established a donor registry. Kansas is considering implementing tax credits for donors, and Israel is considering special benefits for donors. Britain is mandating donation with an opt-out only program; in Ire-

land organs were taken surreptitiously; in California a surgeon is accused of having rushed a patient's death to retrieve his organs.

Recent Judicial Cases and Regulatory Actions January - March 2008

California. On 19 March 2008 the Superior Court of San Luis Obispo ordered a transplant surgeon to trial on one count of felony dependent adult abuse, but dismissed two other felony charges against the surgeon relating to the improper administration of drugs to a dying patient. The defendant is accused of hastening the death of a man to harvest his organs. California law prohibits transplant surgeons from directing the treatment of potential donors until they have been declared dead. This action is the first of its kind in the U.S. *The People of California v. Hootan Roozrokh*, Case No. 405885.

Recent Developments in Law and Regulation January - March 2008

***Alaska**. There has been no action on a bill introduced 13 May 2007 to amend the state's anatomical gift act. S.B. 181, 25th Leg., Reg. Sess. (Alaska 2007).

***District of Columbia**. There has been no action on a bill introduced 9 January 2007 that would amend the state's anatomical gift act since it received a public hearing on 8 June 2007. D.C. Council, B17-58 (2007).

Georgia. A bill passed the state house Health and Human Services Committee on 26 March 2008 that allows organ procurement agencies to harvest organs without further permission from family members if the donor's intent is otherwise indicated, such as on a driver's license, state issued identification card, or living will. Overrides of the deceased's wishes by family members would only occur if the potential donor were under the age of 18. S.B. 405, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Kansas. A bill was discussed 30 January 2008 by the state house Taxation Committee that would offer living organ donors up to $10,000 in tax credit, applicable to travel and lodging expenses, as well as any lost wages from time off for surgery. The measure would apply to living donors only, and would cover liver, pancreas, kidney, intestine, lung, or bone marrow donations. Arkansas and Oklahoma already have similar measures, and Missouri is currently also considering a proposal. H.B. 2362, 82nd Leg., Reg. Sess. (Kan. 2008).

***Michigan.** A bill to amend the state's anatomical gift act was signed into law on 13 March 2008. The bill sets new criteria for individuals wishing to designate anatomical gifts and, among other things, makes the selling of body parts a felony. H.B. 4940, 94th Leg., Reg. Sess. (Mich. 2007).

***Missouri.** A bill introduced on 1 February 2007 to adopt the 2006 Uniform Anatomical Gift Act without changes died. S.B. 496, H.B. 723, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2007). But a bill was passed and sent to the governor that established a first-person donor consent registry for organs and tissues. S.B. 1139, 94th Gen. Assem., 1st Reg. Sess. (Mo. 2008).

***New Jersey**. A bill introduced on 9 January 2007 to amend the state's anatomical gift act died. A.B. 3909, 2007 Gen. Assem., Reg. Sess. (N.J. 2007).

A bill passed the state senate on 17 March 2008 that could make New Jersey the first state that would require anyone getting or renewing their driver's license to choose whether to register as an organ donor. The New Jersey Hero Act would also make mandatory teaching the importance of organ donation in high school health classes. S.B. 755, 211th Reg. Leg. Sess. (N.J. 2008).

***New York.** There has been no action on a bill introduced on 25 April 2007 to enact the Uniform Anatomical Gift Act. S.B. 5154, 230th Gen. Reg. Sess. (N.Y. 2007).

***Texas.** There has been no action on a bill introduced on 21 March 2007 to amend the state's anatomical gift act. The bill is currently under consideration in the state house. S.B. 1597, 80th Leg., Reg. Sess. (Tex. 2007).

***Washington.** A bill to amend the state's anatomical gift act was signed into law by the governor on 25 March 2008. H.B. 1637, 60th Leg., 2007 Reg. Sess. (Wash. 2007).

Wisconsin. Governor Doyle signed a bill on 19 March 2008 establishing a donor registration system that allows people to sign up at any time, not just when they renew their license. It also lowers the age of consent to 15, and grants healthcare agents elevated powers to grant consent (similar to the power of attorney) in cases when the donors' intentions are unclear. The law goes into effect within 90 days of the signing. Associated Press, "Bill expected to increase number of Wisconsin organ donors," *Journal Times*, 9 March 2008, *http://www.journaltimes.com/articles/2008/03/09/local_news/doc47d463e3853d9664857945.txt*, accessed 17 June 2008.

Interesting Developments in Other Countries

Israel. On 24 March 2008, the Israeli parliament passed a bill to combat the shortage of willing donors in Israel (only 4 percent of the population holds a donor card and there is a 60 percent refusal rate among relatives of the deceased). This legislation will allow doctors to remove organs from people who are brain dead, and encourages organ donation through a series of benefits for those who are alive and well. A living person who donates an organ receives the status of a chronic patient as well as having all participation fees for the medical procedure paid for. The state will also compensate them NIS 18,000 (or about $5,100). *http://www.guysen.com/articles.php?sid=6955*; *Ynet,* 25 March 2008, *http://www.ynetnews.com/articles/0,7340,L-3523461,00.html*, accessed 17 June 2008.

United Kingdom. Under a new system spearheaded by the Organ Donation Task Force, all British citizens will become organ donors unless they specifically object. This "opt out" system is supposedly backed by Prime Minister Gordon Brown. N. Dorman, "All Brits to be put on donor list," *People,* 30 March 2008, *http://www.people.co.uk/news/tm_headline=all-brits-to-be-put-on-donor-list&method=full&objectid=20367111&siteid=93463-name_ page.html,* accessed 17 June 2008.

Ireland. On 25 February 2008 a U.K. Freedom of Information Act inquiry revealed that a government inquiry in Ireland found "no malice or foul play" in a scandal in which the organs of deceased patients were harvested at several Irish hospitals without the consent of relatives. In some cases the organs were taken and the bodies were filled with sand so that relatives would not notice a difference in weight. While no wrongdoing was found, the inquiry report suggested that more than 2,000 families suffered needless grief and anguish due to doctors' failure to communicate openly and honestly with families at the time of their loved one's death. L. McDonald, "Children's Bodies Filled with Sand in Organ Scandal," *Redorbit News*, 26 February 2008, *http://www.redorbit.com/news/display/?id=1270877*, accessed 21 June 2008.

UNCONVENTIONAL TREATMENT

The authors do not mean to pass judgment on the merits of a form of treatment by calling it "unconventional." The term "unconventional" is meant to apply to treatments outside the mainstream; that is, those treatments that are not accepted or favored by the establishment. No assumption should be made that "acceptance by the mainstream" means a certain form of treatment (or non-treatment) is better. Nor does nonacceptance by the establishment, in and of itself, warrant banning a practice that some believe is beneficial.

In considering the cases and laws under discussion in this section, also look under the healthcare coverage and FDA sections for discussions of "off-label" uses for FDA-approved drugs.

One nongovernmental action worth noting is that the American College of Physicians (ACP) on 14 February 2008 issued a position paper endorsing the reclassification of marijuana and further study of its medicinal uses. The ACP "urges review of marijuana's status as a Schedule I controlled substance and its reclassification into a more appropriate schedule, given the scientific evidence regarding marijuana's safety and efficacy in some clinical conditions." The ACP also criticized the notion that marijuana is a "gateway" drug, stating, "marijuana has not been proven to be the cause or even the most serious predictor of serious drug abuse," although the paper notes that "gateway drug" concerns pertain only to nonmedical uses of the controversial plant. The position paper can be found in its entirety at *http://www.acponline.org/acp_news/medmarinews.htm*.

Recent Judicial Cases and Regulatory Actions January - March 2008

California. The state supreme court ruled on 24 January 2008 that employers can fire employees who test positive for marijuana even if they are using it in compliance with the state's Compassionate Use Act, which permits the medical use of marijuana if approved by a doctor. Gary Ross was fired by communications firm RagingWire after a routine drug test showed he had used marijuana. He sued, claiming that RagingWire had violated his rights under the state's Fair Employment and Housing Act by discriminating against him because of his disability by not making the reasonable accommodation of allowing him to use medical marijuana at home. RagingWire maintained that they could not be obligated to accommodate him, since it was illegal under federal law. The court agreed with RagingWire in a five to two decision, holding that "no state law could completely legalize marijuana for medical purposes because the drug remains illegal under federal law, even for medical users." *Ross v. RagingWire Tele-*

communications, CA S. Ct. No. S138130, 24 January 2008. Opinion available at *http://www.courtinfo.ca.gov/opinions/archive/S138130.PDF.*

Colorado. A couple whose medical marijuana plants were destroyed after being seized by local police filed a motion on 17 January 2008 in Larimer County District Court seeking compensation pursuant to a Colorado law that requires that plants seized in connection with the claimed use of medical marijuana shall not be destroyed while in the possession of state or local law enforcement. The motion requesting an estimate of the value of the plants from the U.S. Drug Enforcement Administration (DEA) puts the agency in an awkward position because it has long been criticized for inflating the value of seized marijuana to aid the prosecution of drug cases. L. Hernandez, "Couple Wants Police to Pay for Damaged Marijuana Plants," *ABC7 News*, 17 January 2008, *http://www.thedenverchannel.com/news/15076323/detail.html*, accessed 21 June 2008.

***Missouri**. The state supreme court heard oral arguments on 5 March 2008 in the Missouri Midwifery Supporters' appeal of a permanent injunction barring midwives from delivering infants without the supervision of a trained nurse or doctor. *Missouri St. Med. Health Assoc. v. State of Missouri and Missouri Midwives Assoc.* (Mo. SC88783, 6 September 2007).

Recent Developments in Law and Regulation January - March 2008

***Delaware.** A bill to allow freestanding birth centers to hire certified professional midwives may be permanently stalled. Under current law, all midwives working in a freestanding birth center, whether certified professional midwives or certified nurse midwives, must have a backup agreement with a physician who has hospital admitting privileges and would be available around-the-clock for consultation and referrals. A registered nurse with adult and infant resuscitation skills also must be present for each delivery. H.B. 106, 144th Gen. Assem., Reg. Sess. (Del. 2007).

Michigan. The Board of State Canvassers approved petitions on 3 March 2008 to put the issue of legalizing marijuana for medical purposes before state lawmakers. The Michigan initiative would allow patients to grow and use small amounts of marijuana for relief from pain associated with several conditions, if recommended and approved by a doctor. If lawmakers don't approve the measure within 40 days, the proposal will be placed on the November ballot for voters to decide, which is the likely outcome, since the legislature has not acted on medical marijuana legislation that has been introduced in recent years. Five cities (Ann Arbor, Detroit, Ferndale, Flint, and Traverse City) have recently passed symbolic initiatives in favor of legalizing medical marijuana. Associated Press, "Medical Marijuana to go before lawmakers," *MLive Michigan News*, 4 March 2008, *http://www.mlive.com/news/index.ssf/2008/03/medical_marijuana_to_go_before.html*, accessed 19 June 2008.

Montana. The Montana Department of Corrections proposed new rules at a hearing on 3 January 2008 that would prohibit those on probation or parole from obtaining medical marijuana, which voters legalized in 2004. The new rules would also prohibit them from drinking alcohol or gambling. In Montana, sentencing judges can already ban convicts from such activities if there is a connection between the activity and their crime, but the agency states that the new rules would lead to a lower recidivism rate. Associated Press, "Ban Sought on Medical Marijuana for Parolees," *Washington Post,* 4 January 2008, *http://www.washingtonpost.com/wp-dyn/content/article/2008/01/03/AR2008010303669.html*, accessed 19 June 2008.

Interesting Developments in Other Countries

Austria. The United Nations-affiliated International Narcotics Control Board issued a press release on 8 February 2008 saying that computerized "vending machines" in medical marijuana dispensaries violate international drug control treaties, specifically citing the Single Convention on Narcotic Drugs of 1961. The press release called on the government of the U.S. to enforce its federal laws prohibiting marijuana use, and noted that research on the medical benefits of marijuana was inconclusive. There is nothing distinct about the machines that make them in violation any more than any other method of distributing marijuana. INCB Secretariat, "Marijuana Vending Machines in Los Angeles are Contrary to International Drug Control Treaties, says INCB," *United Nations Information Service*, 8 February 2008, *http://www.unis.unvienna.org/unis/pressrels/2008/unisnar1023.html*, accessed 21 June 2008.

Canada. A federal judge ruled on 10 January 2008 that patients who use medical marijuana will no longer have to rely on the government for their supplies. The ruling invalidated a provision of the

medical marijuana program that prohibited growers from supplying more than one patient. Previously, medical users were given the option of growing their own marijuana, buying it from the official government source, or buying it from another grower who was allowed to supply only one patient. A group of medical users sued, claiming that this scheme made the federal supplier the de-facto sole legal provider of marijuana, and that the one patient per grower rule was arbitrary. The judge sided with them, saying the restrictions were unconstitutional and caused "a major difficulty with access." Canadian Press, "Ruling Brings 'Great Remedy' for Medical Pot Users," *Edmonton Sun*, 10 January 2008, *http://www.edmontonsun.com/News/Canada/2008/01/10/4766737.html*, accessed 19 June 2008.

LIFE-AND-DEATH DECISIONS

Recent Judicial Cases and Regulatory Actions January - March 2008

***Montana**. There has been no further action in a suit originally filed in the Montana First Judicial District Court on 1 November 2007 seeking declaratory judgment and injunctive relief that would prohibit law enforcement officials from prosecuting physicians who assist mentally competent terminally ill patients by facilitating medication that allows patients to have a choice in ending their life. The suit makes reference to rights expressed in Montana's Constitution including rights to privacy, individual dignity, due process, equal protection under the law, and the "right to seek safety, health, and happiness in all lawful ways," and seeks to prove that charging any such physician with a crime is, therefore, unconstitutional. Plaintiffs hope the decision will clarify state law on the issue of a patient's right to choose how and when to die. *Baxter et al. v. Montana* (Mt. 1st Dist. DV 2007 787, 1 November 2007).

Recent Developments in Law and Regulation January - March 2008

***California**. The California Compassionate Choices Act will be reintroduced in early 2008. It failed due to lack of action during the last legislative session. On 18 September 2007, Compassion & Choices, a national end-of-life care advocacy organization, announced the launch of a new program designed to help terminally ill Californians access "hospice, pain treatment, information on aid in dying options and other excellent end-of-life care." AB 374 2007-2008 Leg., Reg. Sess. (Cal. 2008).

New Hampshire. A bill that would have required an original copy of any advanced directive, instead of a copy as allowed under current law, to be used by healthcare providers as an indication of a patient's wishes died in committee. H.B. 40 2007-2008 Leg., Reg. Sess. (Nh. 2008). Full text of the bill can be found at *http://www.gencourt.state.nh.us/legislation/2008/HB0040.html. www.legis.state.wi.us/2007/data/SB-151.pdf*.

Virginia. Governor Tim Kaine signed a bill into law on 4 March 2008 that sets up a state registry for living wills and advanced medical directives. H.B. 815, Gen. Assem., Reg. Sess. (Va. 2008).

Interesting Developments in Other Countries

Canada. The Court of the Queen's Bench of Manitoba, in *Golubchuk v. The Salvation Army Grace General Hospital et al.*, granted the plaintiff's request to continue an injunction prohibiting the hospital from disconnecting Samuel Golubchuk from the ventilator that is keeping him alive until the case has been heard by the court. Golubchuk's level of consciousness and cognitive function are in dispute, but the court also pointed out, "Contrary to the assertion of the defendants, it is not settled law that, in the event of disagreement between a physician and his patient as to withdrawal of life support, the physician has the final say." So both the facts and the law will be at issue in the forthcoming trial. *Golubchuk v. The Salvation Army Grace General Hospital et al.* 2008 MBQB 49. (The authors thank Pat Murphy, Clinical Ethicist at St. Boniface General Hospital in Winnipeg, Manitoba, for sending us this document.)

In March 2008, Jocelyn Downie, the Canada Research Chair in Health, Law and Policy from Dalhousie University, stated that new legislation was being drafted to legalize euthanasia. Francine Lalonde, the Bloc Québécois member of the Canadian House of Commons who in 2005 introduced bill C-407, a bill that would have legalized euthanasia and assisted suicide in Canada, stated in an interview in *Canada Press* that she intends to introduce new legislation to "relaunch the debate on assisted suicide." A test case has been drafted to combat this new legislation. A. Schadenberg, "Canadian MP About to Propose Assisted Suicide

Bill; Court Challenge Also in the Works," *LifeSite News.com,* 14 April 2008, *http://www.lifesitenews.com/ldn/2008/apr/08041404.html*, accessed 18 June 2008.

France. Chantal Sébire was found dead on 19 March 2008, two days after her request for "active euthanasia" was denied. Sébire suffered from esthesioneuroblastoma, an incurable cancer that attacked her nose and sinuses, leaving her disfigured, blind, unable to taste or smell, and in terrible pain. According to ABC News, the Dijon court ruled that "Sébire could not have a doctor help her die because it would breach medical ethics and French law, under which assisted suicide is a crime." D. Zaru, "Denial of active euthanasia in France sparks global debate," *Guilfordian*, 28 March 2008, *http://media.www.guilfordian.com/media/storage/paper281/news/2008/03/28/World/Denial.Of.Active.Euthanasia.In.France.Sparks.Global.Debate-3290412.shtml,* accessed 18 June 2008.

Netherlands. A March 2008 study published in the *British Medical Journal* found that terminal sedation may be being used by doctors as an alternative to euthanasia in some countries. The authors suggest this may be the case in the Netherlands, where the 2001 terminal sedation rate of 5.6 percent has risen to 8.2 percent in 2005. It is also unclear if these sedations were always in accordance with the patients' wishes. Of the sedated patients in this study, 9 percent had previously asked for euthanasia, suggesting that some of these sedations were to sidestep the legal issues involved in euthanasia. K. Kingsbury, "When Is Sedation Really Euthanasia?" *Time*, 21 March 2008, *http://www.time.com/time/health/article/0,8599,1724911,00.html*, accessed 18 June 2008.

THE RIGHT TO ACCESS AND CONTROL MEDICAL INFORMATION (INCLUDING MEDICAL TESTING, PRIVACY, AND DISCRIMINATION BASED ON TEST RESULTS)

Recent Developments in Law and Regulation January - March 2008

Federal. There has been no movement on a bill introduced by Senators John Kerry (D-Massachusetts) and John Ensign (R-Nevada) on 5 December 2007 that proposed appropriating Medicare funds as incentives for physicians to adopt e-prescribing technology. Medicare Electronic Medication and Safety Protection (E-MEDS) Act, S. 2408, 110th Cong., 1st Reg. Sess. (2008).

California. The California Pharmacy Board began consideration of an extension in the deadline for the implementation of an electronic drug-tracking system called for by the state legislature in 2004. The plan would extend the deadline from 1 January 2009 two additional years, for the first law of its kind in the nation to require an "electronic pedigree" that would enable pharmaceuticals to be tracked from production through sale. Pharmaceutical companies and wholesalers have expressed support for the legislation, but stress that more time is needed to refine the now costly and inefficient technology. Kaiser Family Foundation, "California Pharmacy Board To Consider Delaying Deadline for Electronic Drug Tracking System," *Kaiser Daily Health Policy Report*, 25 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51129*, accessed 10 May 2008.

Georgia. The state senate approved the Georgia Health Marketplace Act on 6 March 2008. The bill seeks to establish a web site that would provide consumers with a forum to easily access comparisons of deductibles, co-payments, benefits, and premiums for a wide variety of different plans; would allow purchases with pre-tax dollars; and would enable Georgians to set up personal health savings accounts. The bill also requires insurance providers to cover additional tests mandated by state law. S.B. 404, 149th Gen. Assem. Reg. Sess. (Ga. 2008).

Louisiana. The governor proposed a state budget for fiscal year 2009 that includes $18.6 million in funding for health information technology projects next year. The majority of the funding, $11.1 million, would be allocated to the Louisiana Rural Health Information Exchange to facilitate the acquisition of digital technologies for rural medical facilities. The budget proposes appropriating $4 million for continued development of the Louisiana Health Information Exchange, and $3.5 million as incentives to increase the use of interoperable electronic health record (EHR) software systems. Louisiana physicians who adopt and adequately implement such systems are eligible for annual Medicare bonuses of as much as $58,000 throughout the five-year pilot program. Kaiser Family Foundation, "Louisiana Initiatives Encourage Adoption of Health Information Technology," *Kaiser Daily Health Policy Report*, 12

March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ ID=50926*, accessed 10 May 2008.

New York. On 25 February 2008, New York City Mayor Michael Bloomberg announced the launch of a new $60 million electronic health record system. The EHR system, which draws half of its funding from state and federal governments, already has 200 physicians (with a combined total of 200,000 patients) committed to participate, and the city health commission hopes to increase those numbers to 1,000 and one million, respectively, by the end of the year. The system will store information including medical histories, lab results, and prescription information, and notify physicians to alert them about past-due prescriptions or treatments and provide information about current best practices. The city will provide licensing, low-cost tech support, and on-site training for all practices that have at least 30 percent uninsured or Medicaid patients. The health department will not be allowed access to the information of individual patients, but will be able to utilize general information on healthcare providers from the EHR system. Kaiser Family Foundation, "New York City Launches EHR System," *Kaiser Daily Health Policy Report*, 27 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50639*, accessed 10 May 2008.

Interesting Developments in the Private Sector

On 24 March 2008, Angie's List, an online consumer ratings site, launched an expansion that will allow its registered members to provide and access feedback concerning their healthcare experiences in 55 different categories, including dental, insurance provision, and hospital care. The members will be able to assign grades of A through F to each appropriate area, and access compilations of other members' feedback for the healthcare providers in their area. Criticism of the service has come from some medical professionals who worry that the complexities of medical care may be overlooked by consumers in favor of more easily rated characteristics such as staff courtesy or office appearance. Kaiser Family Foundation, "Web Site Launches New Service To Allow Members To Rate Health Care Experiences," *Kaiser Daily Health Policy Report*, 27 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=51200*, accessed 10 May 2008.

The iHealth Alliance, a not-for-profit subsidiary of Medem, announced plans to launch the Health Care Notification Network, a website designed to supplement current regular mail practices by notifying healthcare professionals of substantive label changes, warnings, and recalls through electronic media. The service will provide the information for free to participating physicians, but pharmaceutical companies will be charged for the service, which will not include any pharmaceutical marketing materials. Medem officials report that at least five major pharmaceutical companies have already requested contracts for the service, although no agreements have been finalized yet. Kaiser Family Foundation, "Not-for-Profit Group To Launch Web Site To Notify Physicians of Medication Label Changes, Warnings, Recalls," *Kaiser Daily Health Policy Report*, 25 March 2008, *http://www.kaisernetwork.org/daily_ reports/rep_index.cfm?hint=3&DR_ID=51130*, accessed 10 May 2008.

The Alliance for Health Reform sponsored a forum conducted over the last week of February 2008, where Patient Privacy Rights, and others, stressed their reluctance to support new healthcare IT legislation, such as S 1693 introduced by Senator Ted Kennedy (D-Massachusetts) last June. Privacy advocates have been wary of supporting any new legislation that does not include concrete language ensuring privacy safeguards. There has been no action on S 1693 since October 2007. Kaiser Family Foundation, "Forum Discusses Health IT Privacy Concerns," *Kaiser Daily Health Policy Report*, 6 March 2008, *http://www.kaiser network.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50806*, accessed 10 May 2008.

On 28 February 2008, Google announced the inauguration of Google Health, an expansion that will allow users to store personal health records online. The new site will compete in an emerging market that already includes similar internet-based applications from Microsoft and Revolution Health Group. Privacy concerns have been the main obstacle in attracting users, as some healthcare professionals worry that the federal medical privacy rule may not cover online records. Kaiser Family Foundation, "Google To Announce Web Site To Allow Storage of Personal Health Records Online," *Kaiser Daily Health Policy Report*, 28 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=50670*, accessed 10 May 2008.

HIV/AIDS

Recent Developments in Law and Regulation January - March 2008

Federal. A bill to reauthorize and improve upon the President's Emergency Plan for AIDS Relief (PEPFAR) was approved by the House Foreign Affairs Committee on 27 February 2008. The bill would allocate $50 billion to the program over the next five years, and seeks to replace the requirement that abstinence education programs account for at least one-third of each country's appropriation with a call for "balanced funding" for abstinence, fidelity, and condom programs relative to evidence gathered in each focus country. Additionally, the bill mandates that reports be made to Congress if abstinence and fidelity programs comprise less than 50 percent of spending on virus prevention programs. Unlike previous proposals for the renewal, the bill does not allow funds to be used for contraception or abortion services, and PEPFAR recipient nations must continue to oppose commercial sex work. The bill also seeks appropriation of $9 billion to fight tuberculosis and malaria, and to provide for food supplements and loans for people living with HIV. A Senate version of the reauthorization was introduced on 7 March 2008, and referred to the Committee on Foreign Relations. H.R. 5501, 110th Cong. 2nd Reg. Sess. (2008).

*There has been no recent action on a bill introduced in the House in September that would require inmates to undergo an HIV test upon entering and leaving prison. There would be an opt-out provision, unless it is determined that the inmate was exposed to a state-defined HIV risk, such as a pregnancy or a sexual encounter, while in prison. Additionally, the measure would require the Prisons Bureau to report to Congress its procedures for testing, treating, and preventing hepatitis and other sexually transmitted diseases, and those transmitted through intravenous-drug use. The Prisons Bureau would also be required to provide legislators with statistics on the results of the HIV tests. The bill has been read twice in the Senate and was referred to the Committee on the Judiciary. H.R 1943, 110th Cong. (1st Sess. 2007).

Alabama. The Alabama Department of Corrections is facing pressure to remove its prohibition barring HIV-positive inmates from participating in their work release program. Alabama is the only state with such a prohibition, which prison officials attribute to a 2004 settlement that established a series of healthcare requirements, including dietary needs and monitoring of antiretroviral treatments, that the corrections system is responsible for meeting. The Alabama work release programs allow participants to work during the day outside of corrections supervision, which prison officials worry would not meet their responsibilities under the settlement. Kaiser Family Foundation, "Alabama Advocates Urge Officials To Remove Work Release Restrictions for HIV-Positive Inmates," *Kaiser Daily HIV/AIDS Report*, 25 March 2008, *http://www.kaisernetwork.org/daily_ reports/rep_index.cfm? hint=1&DR_ID=51112*, accessed 6 May 2008.

California. On 26 February 2008 the Santa Clara County Board of Supervisors voted unanimously in support of a motion to oppose the decades-old FDA policy that prohibits homosexual men from donating blood. The measure also directs the board's federal lobbyists to work to retool the FDA policy, which the board maintains is excessive in light of recent advances in HIV screening of donated blood. Previously, many organizations, including the American Red Cross and the American Association of Blood Banks, have argued for the reduction of the ban to a moratorium within 12 months of homosexual activity. The board's vote comes in the wake of San Jose State University's decision to prohibit blood drives on campus, asserting that the FDA policy violates the school's antidiscrimination regulations. Kaiser Family Foundation, "California County Board of Supervisors Votes To Oppose FDA Policy Barring MSM From Donating Blood," *Kaiser Daily HIV/AIDS Report*, 28 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50653*, accessed 5 May 2008.

Illinois. On 4 March 2008, the state house rejected a bill that would overturn a state law requiring HIV-positive students to inform their school principal of their status. H.B. 4314, 95th Gen. Assem., Reg. Sess. (Ill. 2008).

New Jersey. Directors of the state's pilot needle-exchange programs are reporting low enrollment numbers for new programs created late last year. Some officials blame the low numbers on the absence of state funding, and fears from some injection-drug users that the program is a police sting operation. Recent estimates suggest that more than 40 percent of the state's 48,000 HIV cases were the result of intravenous-drug use. Despite the early struggles, program officials still as-

sert that the programs show promise. Kaiser Family Foundation, "Needle-Exchange Pilot Program in New Jersey is 'Struggling' To Enroll IDUs," *Kaiser Daily HIV/AIDS Report*, 26 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint= 1&DR_ID=50598*, accessed 5 May 2008.

New York. The governor is considering a plan that would mandate the enrollment of state Medicaid beneficiaries who are HIV positive in managed-care plans. The plan, still in its initial stages, has drawn scrutiny from Housing Works, an HIV/AIDS advocacy group, which worries that mandatory enrollment could prove to be a "large-scale disruption" of the current system, noting that the current HIV Special Needs Plans are only available in New York City, and cater to less than 5 percent of the state's 65,000 Medicaid beneficiaries living with HIV/AIDS. Kaiser Family Foundation, "New York Gov. Spitzer Considers Imposing Mandatory Managed Care Enrollment Among HIV-Positive Medicaid Beneficiaries," *Kaiser Daily HIV/AIDS Report*, 3 December 2007, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=49159*, accessed 29 January 2008.

Interesting Developments in Other Countries

International. On 25-26 February 2008, an international task force headed by the Joint United Nations Programme for HIV/AIDS (UNAIDS) and the Norwegian government met for the first time in Geneva to discuss HIV/AIDS-related issues. The task force issued calls to ease travel restrictions, which exist in some form in as many as 74 nations worldwide. The group is expected to hold another meeting at the U.N. General Assembly in June and at the Global Forum on Migration and Development in October. Kaiser Family Foundation, "Task Force Calls for Lifting of HIV/AIDS-Related Travel Restrictions," *Kaiser Daily HIV/AIDS Report*, 10 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50843*, accessed 6 May 2008.

Canada. A study released on 22 February 2008 by the British Columbia Centre for Excellence in HIV/AIDS claims that 40 percent of the 1,436 AIDS-related deaths in British Columbia, Canada, from 1997 to 2005 were of patients who never received antiretroviral treatments, despite the no-cost provision of antiretroviral medications. According to the study, the most common factors among the untreated included low-income, homelessness, mental illness, and drug use. The centre proposes a provincial government plan to establish outreach teams that would provide rapid-response testing and treatment to vulnerable populations. Kaiser Family Foundation, "40 percent of AIDS-Related Deaths in British Columbia Among People Who Never Received Treatment," *Kaiser Daily HIV/AIDS Report*, 27 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR _ID=50627*, accessed 5 May 2008.

On 25 February 2008, the British Columbia Centre for Disease Control initiated the Chee Mamuk Aboriginal HIV/STI Program in an attempt to stem the spread of HIV and other sexually transmitted diseases (STIs) among aboriginal communities in Prince George, British Columbia. The five-day program sought to link healthcare providers with HIV/AIDS and sexual health services within Prince George's aboriginal communities in hopes of creating a network of community-based solutions. According to plan managers, aboriginal people make up 5 percent of the provincial population, but as much as 15 percent of all new HIV cases in 2006. Kaiser Family Foundation, "Program Launched To Curb HIV Among Aboriginal Community," *Kaiser Daily HIV/AIDS Report*, 27 February 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=50627*, accessed 5 May 2008.

China. A Ministry of Health report released on 22 February 2008 outlines a 45 percent increase of reported HIV/AIDS cases from 2006 to 2007. Though the report did not include raw data, a government statement in November 2007 estimated the number of cases at 700,000. Health Ministry officials suggest the increasing numbers do not represent a major increase in infections, but more likely an increase in screenings. The report also outlined increases by 30 percent in hepatitis C cases, and 24 percent of syphilis infections during 2007. Kaiser Family Foundation, "Reported HIV/AIDS Cases in China Increase 45 percent From 2006 to 2007," *Kaiser Daily HIV/AIDS Report*, 26 February 2008, *http://www.kaiser network.orgdaily_reports/rep_index.cfm?hint=1&DR_ID=50595*, accessed 5 May 2008.

Malawi. On 4 March 2008, Malawi legislators began consideration of a bill that would create a registry of an estimated 30,000 traditional healers under the Ministry of Health. The legislation seeks to prohibit local healers from making claims that

they can cure HIV/AIDS by such methods as sex with albinos, or virgins. The bill also contains provisions that would prevent religious leaders from urging HIV-positive Malawians to forgo antiretroviral treatments in favor of prayer. Official estimates suggest that 14 percent of Malawi's 12 million residents live with HIV, with 100,000 new cases occurring every year. Kaiser Family Foundation, "Draft Legislation Seeks to Protect People in Malawi From Healers Claiming To Cure HIV/AIDS," *Kaiser Daily HIV/AIDS Report*, 5 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm? hint=1&DR_ID=50761*, accessed 5 May 2008.

United Kingdom. On 14 March 2008, the U.K.'s Crown Prosecution Service released new guidelines governing the prosecution of "intentionally or recklessly transmitting HIV" that limits prosecution to HIV-positive people who infect a series of partners, or who infect a partner during a period of high-risk activity. The statement outlines the need to show a "sustained course of conduct during which the defendant ignores current scientific advice regarding the need for and the use of safeguards." The guidelines also include "special measures" that cover the sensitive treatment of victims, which may include the accused, to lessen the possible traumatic situations. Kaiser Family Foundation, "U.K. Crown Prosecution Service Issues Guidelines To Clarify Law on Intentional, Reckless Transmission of HIV," *Kaiser Daily HIV/AIDS Report*, 18 March 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=51006*, accessed 6 May 2008. The full text of the guidelines is available at *http://www.cps.gov.uk/publications/prosecution/sti.html*.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

The cases in this section seem to indicate a confusion of conscience with convenience. There should be no dispute as long as companies make their policies clear to potential hirees and give customers notice by openly posting any possible unavailability of a product commonly supplied through similar merchants. Consider the following analogy. The owner of a restaurant should not be required by law to exempt a vegan waiter from serving steak. Nor would the restaurant owner be obliged to provide a vegan meal for a vegan customer when the owner has chosen not to have such a meal on the menu. No matter how hungry the vegan patron, the restaurant owner should not be forced by law to carry vegan meals on the menu, not even if this is the only restaurant in town. Admittedly the analogy isn't perfect, but the point is that a pharmacy employee who wants to be excused from selling certain drugs should work for a different pharmacy or be in a different line of business. A patron who wants access to a drug that is not available everywhere needs to be prepared to go to a place where that drug is available, much like the vegan can't expect every restaurant owner to have vegan meals on the menu.

Recent Judicial Cases and Regulatory Actions January - March 2008

***Federal.** The U.S. District Court for the District of Western Washington State is scheduled to hear arguments in October 2008 to review of a preliminary injunction handed down on 8 November 2007 to forestall the imposition of two recent regulations that would require pharmacists to sell emergency contraception and other controversial drugs, regardless of any moral or religious objections they may have. The injunction does require that inquiring customers be referred to an alternative nearby source. A lawsuit has been filed on behalf of several pharmacists seeking to overturn the law. *Stormans v. Selecky* (U.S. Dist. Ct. of Western Wa. No. C07-5374RBL 25 July 2007).

Illinois. On 18 March 2008, the Illinois Supreme Court heard arguments from a group of pharmacists who seek the nullification of a 2005 rule that mandates that all pharmacies provide emergency contraception when requested. The pharmacists' lawyers point to two state laws that they believe are violated by the ruling: one prohibits compelling healthcare decisions over moral objections, and one that protects citizens from religious interference. The state attorney general's office argues that the pharmacists lack standing, as they have not yet faced any repercussions. *Morr-Fitz v. Blagojevich* (Ill. Docket No. 104692, 18 March 2008).

Michigan. There have been no further developments in a case filed on 30 November 2007 by a Detroit-area pharmacist against Target Corporation, his former employer, alleging that his November 2006 firing over refusal to dispense emergency contraception violated the U.S. Civil Rights Act of 1964 by not accommodating his expressed

religious beliefs. *Bundy v. Target Corporation* (U.S. Dist. Court of Eastern Michigan No. 2:2007cv 15091, 30 November 2007).

Recent Developments in Law and Regulation January - March 2008

New York. A bill is still pending that was introduced on 2 February 2007 that would amend Section 6810 of the state's education law to prohibit pharmacists from refusing to dispense or refill a prescription based on philosophical, moral, or religious reasons. The bill was referred to the Committee on Higher Education on 9 January 2008. S.B. 2344, 2007 Gen. Assem., Reg. Sess.

MENTAL HEALTH

Recent Developments in Law and Regulation January - March 2008

Federal. On 6 March 2008, a bill was approved by the Senate Judiciary Committee that seeks to reauthorize and strengthen the Mentally Ill Offender Treatment and Crime Reduction Act, which established a grant program to provide for improvements in mental healthcare provided to inmates in correctional facilities. Among other changes, the reauthorization would increase funding from $50 million to $75 million from fiscal years 2009 to 2013. The bill was tailored to easily reconcile with HR 3992, which passed the House 23 January 2008. S.B. 2304, H.R. 3992, 110th Leg., Reg. Sess. (2008).

*The Paul Wellstone Mental Health and Addiction Equity Act of 2008 was passed in the House by a vote of 268 to 148 on 5 March 2008, and has been read twice in the Senate and placed under General Orders. Calendar No. 610. Originally introduced on 9 March 2007, the bill would require insurers to cover mental illness at the same level as they cover physical illness. The Senate passed a similar but less ambitious bill in September 2007, which is favored by officials in the Bush Administration, leading to a possible showdown in conference over the reconciliation of the different legislation. The Senate version is also favored by a majority of health insurance providers and employers, as they worry the House bill would drastically increase expenses, and feel the Senate version allows greater flexibility in determining coverage. The House version also includes prohibitions on "self-referrals" by physicians to specialty hospitals in which they share a "financial interest," and language that would prevent insurers and employers from discriminating against U.S. residents on the basis of genetic test results. H.R. 1424, S.B. 558, S.B. 358, 110th Leg., Reg. Sess. (2008).

The Amyotrophic Lateral Sclerosis (ALS) Registry Act is progressing through Congress. Originally introduced in the Senate on 14 May 2007, the bill would establish a national registry to collect and store data on ALS. The bill was placed on the Senate Legislative Calendar on 4 December 2007. A similar version of the bill passed the House in October. H.R. 2295, S.B. 1382, 110th Leg., Reg. Sess. (2007).

The Mental Health Improvements Act of 2007 is progressing through Congress. The bill, originally introduced on 15 October 2007 in the Senate, would provide for improved treatment of veterans with post-traumatic stress and/or substance abuse disorders. An identical bill was introduced in the House and referred to the House Veterans' Affairs Committee on 1 November 2007. H.R. 4053, S.B. 2162, 110th Leg., Reg. Sess. (2007).

The Medicare Mental Health Prescription Drug Access Act of 2007 is stalled in the Senate. Originally introduced on 17 October 2007, the bill was referred to the Committee on Finance where it is still under consideration. The bill would amend Title XVIII of the Social Security Act to include barbiturates and benzodiazepines as covered part D drugs. S.B. 2190, 110th Leg., Reg. Sess. (2007).

There is movement on a Down syndrome related bill. Originally introduced in the Senate on 17 July 2007, the bill would increase provision of scientifically sound information and support services to patients receiving a positive test diagnosis for Down syndrome or other prenatally and postnatally diagnosed conditions. S. 1810 and H.R. 3112, 110th Cong. (1st Sess. 2007).

NEW TECHNOLOGIES (NANOTECHNOLOGY, HYBRIDS, XENOTRANSPLANTATION, AND MORE)

Some new technology information can be found under the "Pre-Birth" subsection of "The Rights of Maturing Individuals and Their Parents" section, where legal developments in stem cell research are discussed. Also, some relevant entries can be found in the new "FDA" section.

Aetna Inc. and Cigna Corp., two major health insurance providers, announced an expansion of coverage to include internet-based doctor's visits. Aetna's actions expand on pilot programs that have been operating in **California, Florida, and Wash-**

ington with promising, yet limited, results. S. Burling, "Insurers look at virtual visits to doctor," *Philadelphia Inquirer,* 30 March 2008, *http://www.philly.com/philly/news/homepage/17133061.html*, accessed 6 May 2008.

Recent Developments in Law and Regulation January - March 2008

***Federal.** The U.S. Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society will discuss its draft proposal for the oversight of genetic testing at its February meeting. The report identifies "significant gaps in this oversight system that could lead to harms," and asserts that the FDA has not made clear how efforts to regulate genetic testing will function. The report comes as multiple companies are planning the release of direct-to-consumer genetic test kits, which have faced criticism over their cost, necessity, reliability, and privacy implications. Secretary's Advisory Committee on Genetics, Health, and Society, *U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS,* draft report, 5 November 2007. It is also worth noting that in November 2007, Navigenics Inc. announced the release of Health Compass, a $2,500 direct-to-consumer saliva-based whole-genome scan set for release in early 2008. Another company, 23andme of Mountain View, California, has announced plans for the release of a similar test later in 2008. R. Winslow, "Is There a Heart Attack in Your Future?" *Wall Street Journal*, 6 November 2007, D1.

Massachusetts. The governor's comprehensive life sciences industry bill continues its way through the state legislature. The bill, introduced in the summer of 2007, seeks to revitalize the life science industry within the commonwealth. The bill was set for public hearings on 17 December 2007, as well as 16 and 31 January 2008. H4234, 185th General Court, Reg. Sess. L. Wangsness, "Biotechnology incentives bill called unlikely to move in '07," *Boston Globe*, 20 November 2007.

MEDICAL ETHICS COMMITTEES AND INSTITUTIONAL REVIEW BOARDS

Recent Judicial Cases and Regulatory Actions January - March 2008

Colorado. Colorado Springs based Coast Independent Review board had its right to grant expedited approval revoked after allegations that Coast violated FDA regulations intended to protect patients in medical research. The allegations stem from an approval on 19 March 2008 of an advertisement for a California biotechnology firm seeking test subjects. The ad's language was found to be coercive and was submitted for review. The man who was appointed to review the ad approved it without any changes, even though he was not authorized to do so. Coast hopes to have the suspension lifted within a month. W. Heilman, "FDA disciplines local firm," *Gazette*, 14 April 2008, *http://www.gazette.com/articles/board_35273_article.html/coast_mcdaniel.html*, accessed 18 June 2008.

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