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At the Bedside

Three Keys to Treating Inmates and their Application in Ethics Consultation

Edmund G. Howe and Chelsea Howe

In this issue of *The Journal of Clinical Ethics*, several authors discuss ethical problems relating to the treatment of inmates. One of the authors, Bernice S. Elger, emphasizes in "Medical Ethics in Correctional Healthcare: An International Comparison of Guidelines," that the treatment that inmates receive may depend largely on the resources society is willing to provide.

Beyond the question of resources, however, the all-important clinical question is, *how* can careproviders best help patients who are inmates? The answer is that, to a large degree, we don't know.[1] Given this, even when resources are available, careproviders may not know how to help.

In this introduction, therefore, we will discuss what are likely to be the three optimal approaches to help inmate-patients:

- Become as non-judgmental as possible,
- Become patients' allies to the greatest extent possible, and
- Treatment of inmate-patients should start wherever they happen to be "at."

While these approaches may sound standard, we propose them to stretch prison careproviders' usual boundaries. The approaches may pose ethical quandaries, but may be the only way careproviders can assist inmate-patients who otherwise might remain wholly "recalcitrant." This is because, as the cliché says, inmates may change only if they want to. The only way they may want to change is if their careprovider can establish a unique, perhaps even unprecedented, relationship with them.[2]

The second author of this introduction, Chelsea Howe, has been doing counseling in a women's prison, and kept a diary of the clinical problems that arose and the ethical problems they posed. We will use examples from the diaries to illustrate the three approaches presented. Although the approaches haven't been proven to be effective for this population of patients, the approaches have been subjected to empirical study in other contexts.

A threshold ethical question could be, why should we want to provide optimal care to inmates in the first place? For some, this question precedes all others. One answer may be that, ethically, inmates are worse-off than those at liberty. Rather than focus on this question, though, we will de-

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scribe instead why inmates do what they do — for two reasons. First, some careproviders may not be interested in providing optimal care unless they can see inmates as deserving an improved level of care. Second, even those careproviders who see inmates as deserving may have difficulty overcoming negative feelings toward inmates, especially inmates who commit heinous crimes; for example, it may be difficult not to feel contempt for them.

A better understanding of why inmates act as they do may help careproviders overcome negative feelings that can thwart their success in treating inmate-patients, and so this will be our first consideration. Second, we shall present three key approaches to treating inmate-patients. Third, we will consider how to use the same approaches in ethics consultation.

WHY HELP INMATES?

As above, some may wonder why we would want to improve the care given to those who commit heinous crimes. Perhaps understanding inmates better may make careproviders more open to providing optimal care to inmate-prisoners. To increase understanding, we will discuss three different types of inmate:

- Those who commit crimes impulsively,
- Those who commit ongoing crimes but have denial, and
- Those who may ruthlessly plan their crimes.

Clearly there are problems in categorizing inmates — as there would be for any person, in any way. All persons differ, sometimes substantially. Yet to answer the question of why we should treat inmates optimally, it may be that we must categorize inmates in one way or other to better understand them.

Inmates Who Lack Control

Some inmates commit crimes in part because they lose significant control. Often, inmates describe these times as moments in which it seemed that another part of their mind took control. One way that this can occur is that inmates experience dissociation, in which they go, as it were, on "automatic pilot," and thereafter remember nothing that occurred in this altered state. Dissociation occurs in most persons. An example is driving on a highway and passing several exits. We may not notice the exits we pass. Our mind may be off somewhere else; this is called "highway hypnosis." The most severe example of dissociation is what the public knows as "multiple personality." Multiple personality usually occurs in persons who have experienced severe trauma early in childhood. Those who have this disorder, even to a less serious degree, often have an angry "part of themselves" take over. Commonly, they don't remember what occurs.

Sybil is the masked name of a famous patient who had multiple personality.[3] She became well known when her life and successful psychotherapy were depicted in a book and films. Cornelia Wilbur was Sybil's psychiatrist. The first author had the opportunity to talk with Wilbur decades ago. She was interested in how many persons with dissociative disorders, like Sybil, due to this disorder commit violent crimes, but are arrested and convicted without anyone ever discerning that they have this disorder. Consequently, Wilbur obtained permission to examine inmates in prisons, and she found that what she had suspected was the case: many inmates did have dissociative disorders that had not been detected, and they didn't remember how their crimes had occurred. Her findings subsequently have been reaffirmed.[4] One investigator studied 145 serial killers in depth. He concluded that the inmates "often" came from "horrific backgrounds, where they were brutalized by one or both parents."[5]

Inmates may also have diminished control because they are influenced by alcohol and drugs. They may experience dissociated states and impulses that are less within their control. It may be generally "easier," in these instances, to blame the inmates for their crimes; they chose, after all, to use alcohol or drugs *initially*, before they were addicted or lost control. Still, the inmates may have urges to drink or retake drugs that are triggered by cues wholly outside their awareness. One expert on substance abuse states, "when treated patients of addiction return to their normal environments, families, neighborhoods, and sources of stress, they are likely to relapse due to conditional responses — their brains form links that immediately activate the reward system."[6] Fur-

ther, the environmental cues to relapse may be unimaginably strong. Cocaine, for example, may trigger feelings of pleasure 10 times the feelings of pleasure of having sex.[7]

Inmates Who Deny

A second wholly discrepant kind of crime involves inmates who don't imagine that what they do is wrong. This may be because they have rationalized away the wrongness of their behavior or because, from the outset, they had denial. An example of a person who may have done this is Gunter Grass, a writer who won the Nobel Prize. Grass served in the Nazi army during his youth. He has written since that he never imagined then that what he was doing was wrong. He regrets this now deeply. He depicts the process of denial he and others experienced, and we will use what he has written to illustrate how this may occur. Grass was a member of the Hitler Youth; he was a Young Nazi, he says, who believed in what he was asked to do with "untroubled unquestioning fervor."[8] Grass describes how his denial fell apart: "The image that was crystal clear. . . . [Then it turned] fuzzy around the edges."[9]

There were plenty of people like him, Grass writes, who wanted to belong among the "less guilty."[10] They told themselves, he reports, that they were only "obeying orders."[11] They related "mitigating circumstances that had blinded and misled them, feigning their own ignorance and vouching for one another's."[12] "How easily words came to me in the early sixties," he reports, "when I was oblivious enough to think I could give lie to the facts and pin clear-cut explanations on all sorts of absurdities."[13] He writes, "It was some time before I came gradually to understand and hesitantly to admit that I had unknowingly — or, more precisely, unwilling to know — taken part in a crime that did not diminish over the years and for which no statute of limitations would ever apply. . . . "[14]

Grass concludes: "Guilt and shame it engendered can be said, like hunger, to gnaw, gnaw ceaselessly. Hunger I suffered only for a time, but shame. . . ."[15]

Inmates Who Plan

The behavior of a third category of inmates may be still more troubling. These inmates may commit crimes as if they "have no heart." An example might be Richard Loeb, who, with Nathan Leopold, in 1924 notoriously killed a 14-year-old boy they kidnapped for ransom. Loeb seemed to feel no remorse. He said, "I enjoyed being looked at through the bars, because I was a famous criminal."[16] What sort of person is this?

An example of a person in this same category is a fictional character created by Edgar Allen Poe, in the short story "The Cask of Amontillado." The character seals another person in a tomb to exact revenge, and states, "I vowed revenge. . . . At *length* I would be avenged: but the very definiteness with which I was resolved precluded the idea of risk . . . my smile *now* was at the thought of his immolation."[17] How should we regard inmates who may have less control, who may deny, and who may knowingly act in ways that are unconscionable?

A character from a play by Pirandello may indicate a possible response. He has gone to a bordello, where he encounters his stepdaughter. He knows that his stepdaughter and her mother hold him in contempt. He says, "we are not wholly in that act, . . . therefore it would be abominably unjust to judge us by that act alone, to hold us suspended, hooked, in the pillory, our whole life long, as if our life were summed up in that act!"[18] This raises many relevant considerations. Even if we believe that some inmates are "evil," we may be unable to tell which inmates these are. Regardless of what one has done, he or she is still human. Some people believe that we are all prone to the same behaviors, but, by luck, we do not all engage in them — to the same degree.

"Luck" may contribute other effects: empirically, it is known that persons who have antisocial personalities and commit crimes statistically differ from the rest of the general population: they have different genes, an abusive or neglectful early childhood, or both.[19] Ethically, the principle of justice holds that persons shouldn't be treated unequally for what they can't help. They shouldn't be penalized accordingly because they "drew bad cards" in this regard.

THREE KEYS TO TREATING INMATES

What might enable careproviders to break through an inmate-patient's pattern of repeated criminal behavior, and help the inmate want to

change? We would suggest that perhaps the only way is to establish a unique and even unprecedented inmate/careprovider relationship. There are, we believe, three keys to doing this.

Preparing to be Optimally Spontaneous

Dan Stern, an eminent psychiatric researcher, has done "micro-analyses" of filmed interactions of mothers and their infants.[20] On the basis of these studies he has reached a startling conclusion: he suggests that when many psychiatric patients get well, it may be due not to the therapy psychotherapists used, but to how the psychotherapists responded spontaneously during moments they were caught off-guard. Therapists tend to assume that how patients respond is primarily a function of what their therapists *consciously* choose to do. Stern claims that it may be just the opposite: his observations of parents and infants made him familiar with the "constant derailing and repairing in dyadic interactions." For certain stretches, he says, "interaction, rupture and repair constitute the main activity of mother and baby."

Likewise, there are empathic "mishaps," he reports, "every minute," in even the best of therapeutic interactions, and the majority of them are quickly repaired by one or both partners. *These* moments can lead to "sudden dramatic therapeutic changes."[21] He gives as examples of a patient saying something funny and the therapist breaking into "explosive laughter," or of a therapist going to a movie and then finding him- or herself just behind a patient in line.[22] Stern calls this process of spontaneous interaction a "shared feeling voyage."[23] The participants create, Stern says, "a shared private world . . . their *relationship is changed . . .* there has been a *discontinuous leap* . . . it is co-created by both partners and lived originally by both."[24] "This delicate choreography goes on mostly outside of consciousness."[25] Further, Stern writes, ". . . I view the intersubjective exchange within the dyad as going on all the time, every . . . minute . . . I see it as *a basic motivation* . . . for the treatment."[26]

How might careproviders use this in their work in prisons, and what sort of ethical boundaries would it push? An example reported by the second author (CH) may be useful. One of the strongest rules in all prisons — as in all in-patient psychiatric settings — is that therapists shouldn't physically embrace patients. CH had been working with one inmate intensely for some time. The patient had been denied parole, but CH thought she knew her well enough, especially on the basis of what she'd heard from other patients. CH appealed on the inmate's behalf. This initiative illustrates the kind of unconditional regard and commitment we will discuss below. The inmate was given parole on the basis of this appeal. When the inmate saw CH, she spontaneously moved to give CH a hug. CH hugged the inmate back, although she fretted whether she should have violated this rule.

If CH hadn't hugged back, the inmate would not have felt the same way about her, and may have continued to feel worse over time. The inmate, however, did well. What is worth highlighting is that, in addition to the other positive effects of careproviders showing such spontaneous warmth, the effects of *not* showing warmth may be incredibly harmful to patients in the long run. For example, the first author (EH) worked with a parent who had an infant with very extensive special needs. The infant's mother was referred to a genetic counselor. The first thing this counselor said was, "Why didn't you ever get genetic counseling?" The mother remains bitter and hasn't forgiven the counselor to this day. A second negative example will be presented when discussing ethics consultation, below.

CH's response to the inmate's hug seems exactly the kind of spontaneous response that Stern had in mind. Stern sees this as critical to therapists' success. The problem for careproviders, of course, even if they agree with Stern, is that spontaneous responses can't be planned. What, then, can be done? We can try to maximize the likelihood of responding optimally, but how? We would suggest that careproviders try to assess themselves, and if necessary change, so that when spontaneous moments happen, they can respond as positively as possible. For instance, they can try to assess the degree to which they consciously may feel contempt for an inmate, based on what the inmate has done. This may enable them to change.

Change *is* possible. Careproviders should not avoid trying to change simply because they think they can't. The following example may be convincing and compelling. Fear is one of the most

difficult feelings to change and overcome, particularly when it is realistically based. Some people fear horses, because they can kick and bite, and they are big. A man known as the "horse whisperer" has had unusually great success in calming horses when others can't. He relates that when he first worked with horses he felt fear. Yet he willed himself to not feel fear, and was abe;e to overcome it. He states, "I . . . realized the fear blocked our communication . . . we lost our sense of partnership and didn't communicate anything constructive to one another."[27] It is equally important to change negative emotions to avoid being caught off-guard when acting as ethics consultants, as will be discussed below.

Putting Inmate-Patients First

Stern's idea is that many patients — including inmates — may be moved to change when they observe that careproviders genuinely care for them, as revealed in such off-guard, spontaneous moments. For decades it has been empirically known that the relationship between patients and psychotherapists makes the most difference, not the type of psychotherapy used. We also know that persons must feel sufficiently motivated to actually change.

Another useful concept may seem self-evident: careproviders who want to help patients change should do whatever they can to demonstrate that they are genuinely committed to the patient, and like a parent, not place conditions on this commitment. Even when an inmate has committed a horrendous crime, a parent still might say, "I continue to love you absolutely and will continue to do whatever I can do for you." The impact of this kind of commitment, especially when an inmate feels wholly alone, may be staggering. The inmate is accepted despite the crime, and because of this no longer feels alone.

The data here supporting the importance of persons having another ally is beyond question. If people have just one person who stands by them, they feel incomparably better. The first author felt this as a child when he had done something wrong. He felt alone. Another child he knew then said to all their friends, "I know that he didn't mean it." EH remembers this, still, with heartfelt appreciation, more than half a century later.

The effect of forming a unique relationship with an inmate-patient is suggested by a new approach to therapy for chronic depression. James P. McCollough, Jr., the person who founded this therapy writes,

> Treating the chronically depressed adult — dislodging the refractory cognitive-emotional and behavioral armor that is the disorder — is analogous to breaking through a granite wall using a 10-pound sledgehammer. One hits the wall repeatedly in the same area with little or no effect until, almost imperceptibly, a slight hairline crack appears. Under continuous pounding, the crack gradually enlarges until, finally, the wall breaks and crumbles.[28]

This statement could apply just as well to "recalcitrant" inmates. Since symptoms of depression may include decreased tolerance to frustration and increased impulsivity, it may be that this treatment for chronic depression is what many inmates need and require. McCollough continues: "I know of no other therapy program recommending that clinicians become personally involved with their patients."[29] Therapists who use this approach, he adds, have "a unique opportunity to teach them what it is like to interact with a decent and caring human being."[30] How might careproviders go about doing this? One example is as telling as it is astounding. At the most recent meeting of the American Psychiatric Association in May 2008, a psychiatrist described what he did in his office with one patient, to try to get through to the patient — he literally stood on his head.[31]

Have any of us ever heard of anyone who would do this? More importantly, how can this be applied in a prison setting? An example from the second author may help. She was with an inmate and a prison staff member. The staff member spoke to her about the inmate in the third person, as if the inmate wasn't there. (This, as we all should know, is demeaning, but is nonetheless common. Careproviders commonly do this when they have patients with Alzheimer's disease. They talk to these patients' loved ones, who often bring them, as if the patients aren't there.) CH interrupted the staff person, and told him the inmate's name. This may seem to be a small matter, but, to an inmate, maybe it's not. To an inmate, it may be disproportionately important for a careprovider to "stand up" for her or him. This is especially the case when the careprovider is willing to pay a price on the inmate's behalf. CH did pay a price,

as the staff member, then and forever after, wasn't pleased. But the inmate, of course, knew this.

Starting Wherever the Inmate-Patient Is

The last intervention is equally as valid in other contexts, including ethics consultation. It may all too often be missed. Careproviders may be too quick to confront patients who see things differently than they do. Careproviders should instead start from wherever these patients are "at." This is particularly important with inmates because often inmates have denied or rationalized away what they have done. An example from the experience of the first author is a serial murderer who told him, "But I was a leader in the Boy Scouts." It may be exceptionally hard for many careproviders to initially validate and support such views, but it is essential; it may be the only way careproviders can connect with their patients.

Regarding making connections, Leston Havens and Nassir Ghaemi write, on manic patients (who, for biological reasons, are known for having fixed, grandiose views):

> First, one must meet the patient. This involves empathic connection. There needs to be a meeting on common existential ground. In this work, the therapist must struggle to avoid theorizing or judging, but rather should seek simply to think, feel, and experience what is happening as the patient is thinking, feeling and experiencing it. The second step, *after connecting with the patient*, is to help the patient put perspective on his/her experiences.[32]

Careproviders who treat inmates must find some way to confirm the patients' positive view of themselves or of what they have done. An example from the second author may illustrate this. CH was seeing a patient who had multiple personality, which, as we have suggested, may not be uncommon within prison populations. CH was introducing the inmate to one of the prison staff. Although the inmate was an adult, she was at that time in an altered state, like a young child. She was wholly dependent on CH, and feeling scared. CH sensed that if she introduced the inmate to the staff member in a formal way, it would increase the child-like personality's fear. Consequently, CH "bit the bullet" and told the staff member the inmate was her "friend." This was not classically professional, and CH could have been criticized for calling this inmate — or any inmate — her friend. But the inmate, in this child-like state, only beamed.

ETHICS CONSULTATION

The three approaches described are also exceptionally effective in ethics consultation. Patients may feel like outsiders in healthcare settings, and, like inmates, lack power, relative to others on whom they are wholly dependant.

Being Spontaneous

As previously discussed, careproviders can't will themselves to always be spontaneous. But they *can* prepare themselves for unanticipated encounters by assessing themselves to discern whether they can accept patients as they are, regardless of what patients want. When this is the case, (hopefully) only positive spontaneous responses will "emerge" in unguarded moments. A common example is when patients request an intervention that careproviders may see as futile. If careproviders do not anticipate and assess their feelings about this, they may respond in a way that profoundly affects patients and their loved ones in a negative way, as in the following case, from the experience of the first author.

A patient was in a coma, and it would have been reasonable, at that time, to withdraw *or* maintain his life-sustaining treatment. The patient hadn't indicated at all what he would have wanted. The applicable law required that the patient's closest relative make a decision on behalf of the patient. If there was more than one relative who was this close — in this case, the patient had two daughters — they all must agree on a decision, or the decision would be made by the hospital ethics committee. This patient had two daughters with equal decision-making authority. Very unfortunately, the daughters totally disagreed on what their father would have wanted. Worse, over time, neither was willing to budge an inch.

After some time had passed, they met with a new attending physician, who said, on hearing of their differing views, that it didn't much matter to him, because he was unwilling to withhold treatment, and would only be willing to agree to

a DNR order. He said this adamantly, responding spontaneously with what he felt. The sisters responded: instantly, they became wholly united. They were like a married couple who argue until someone calls the police, and then present a united front. The sisters demanded that the attending withhold all further treatments, and, in time, with their insistence, he did.

Helping Patients Not Feel Alone

When careproviders are spontaneous, put patients' interests first even when it "hurts," and start from wherever patients are at, they can foster a unique and even inspiring patient/careprovider relationship. Patients, as all persons, can do better when they have an ally. Careproviders who work in prisons, like the second author, may be the only ally that some inmates will have. In hospitals, patients may have their loved ones, and if ethics consultants can help patients have a loved one as an ally, it may be preferable to trying to take on that role themselves.

This is illustrated in the following case from the experience of EH: a patient increasingly insisted on staying at home, even though his health was deteriorating due to a progressive but treatable medical condition. The patient's wife tried repeatedly — and ever more fervently — to persuade and then cajole him to leave the house to see his doctor and get the care he needed. Finally, the wife called the patient's doctor, and the doctor called for an ethics consultation. The ethics consultant saw the need to take strong action, which might cause the patient to be seen — against his wishes — and receive treatment. At that point, the treatment was not yet lifesaving.

The ethics consultant told the patient's wife that rather than confront her husband and continue to alienate him, she should be his ally and be by his side. The ethics consultant suggested to the patient's careprovider that he should take on the role of "the enforcer," which the careprovider was willing to do. Thus, the careprovider called the patient and told him that he was, after all, the patient's physician and could not simply sit idle, knowing that if he did, his patient might die. The careprovider said that he could, if necessary, insist the patient come in to see him. The patient's wife was relieved (and actually ecstatic). She'd been married to her husband for 38 years, and taking on the role of confronter, persuader, and enforcer had been devastating to their relationship. With this change, she became her husband's ally. Paradoxically, after the patient's wife indicated that she would support her husband in whatever he wanted to do, the patient, feeling her support, softened and became willing to go in to see his doctor — which he did, without actual coercion.

In general, to apply this same approach further, ethics consultants might encourage patients (or, when a patient cannot speak for him- or herself, patients' loved ones) to bring another person whom they know and trust with them to an ethics consult, especially when they may face a larger group in an ethics committee meeting. When patients or loved ones can't bring an ally, ethics consultants should attempt to fill this role. Consultants might help to establish such a bond through the use of humor. The humor must not be insensitive to the seriousness of the situation in any way. Perhaps this bonding could be conveyed by just a soft smile.

Starting Where Patients Are At

When patients request a treatment that careproviders consider futile, ethics consultants may do best by first allying themselves with the patient's interests. An example from the experience of EH is that of a patient who had cancer and had had three trials of chemotherapy, all of which had failed. Even so, the patient still wanted to "try." The staff members, to a person, felt that "it was time for the patient and his wife to accept that it was time for him to die." The patient wanted, however, to try "anything," and the more the staff opposed him, the more he and his wife dug in. The ethics consultant was called in. Although he agreed with the staff, he believed it would be optimal to start from where this couple was at, and so he took an initiative on their behalf.

He sought out and found an expert who did research on this very type of cancer. The doctor said that he would be willing to give the patient an experimental drug, but that it might have several undesirable side-effects, and that it had only about one chance in 100 of significantly prolonging the patient's life. The staff criticized the ethics consultant for taking this initiative, but the patient and his wife considered the consultant the

finest ally they ever had. Finally, though, the patient decided to decline the treatment. He said that having had the ethics consultant as a partner is what had enabled him to feel strong enough to be able to make this decision.

In a similar kind of case, parents wanted their child's careproviders to give the child an herbal alternative treatment although he had brain death. The comments of Arthur Applbaum and colleagues, who wrote up the case, are radical and illuminating; they state, "If another course of treatment is necessary to assure the patient that every effort has been made, it would be reasonable to agree, even though the extra effort is on strict biological criteria one step beyond reasonable."[33] They add, "it would be decent to acquiesce; …it is both insulting and unnecessary for medical authorities or institutions to insist that [parents of a child who meets brain death criteria] are mistaken; and . . . a sensitive physician ought to be able to find a decent interval between shock and denial."[34]

These views, much like CH's approaches, push the margins of conventional care. It may be, for some patients and parents — as well as for inmates — pushing the boundaries may sometimes not only be reasonable, but, as Applbaum and colleagues suggest, *minimally decent.*

CONCLUSION

Some inmates have done terrible things. In some cases, they have done these things because they were dissociating, used alcohol or drugs, or had denial. They may also be unconscionably ruthless, and this may be, in part, due to genetic and/or environmental contributions. Careproviders who know of these possibilities may help inmates-patients want to change. Knowing these things may help careproviders overcome feelings of horror at what the inmates have done, so that they can more effectively treat inmates. Acquiring the capacity to not be judgmental may be absolutely necessary when careproviders hope to establish a unique and possibly unprecedented relationship with inmates. Such relationships may be the only possible means to move inmates to want to change.

We have described three approaches that may be particularly effective: spontaneity; standing up for inmates and putting their interests above all else; and starting where inmates are at. The last may be hardest, because it may require careproviders to overtly support attitudes and rationalizations they abhor. The murderer Richard Loeb, mentioned above, may provide an example of what we mean. During his trial, Loeb said he had no mental illness, and clearly knew right from wrong. This may have increased the risk he would receive the death penalty. A careprovider who wanted to start where inmates are at could use his or her imagination and might take the initiative to note Loeb's honesty, or perhaps his courage and his strength in making that statement.

These approaches may help careproviders who want to push the boundaries of what they will do for their patients who are the hardest to reach.

NOTES

1. Although no treatment has proved effective, this does not mean that no treatment will ever be found. S.C. Yudofsky, *Fatal Flaws* (Washington, D.C.: American Psychiatric Publishing, 2005), 206.

2. It may be, for example, that in response to the feeling of being trusted, people, including recalcitrant inmates, have a sudden surge of oxytocin that enhances their capacity to relate, despite previously acquired negative cognitions that have — and would, in other cases — normally oppose this. P.J. Zak, "The Neurobiology of Trust," *Scientific American* 298, no. 6 (June 2008): 88-92.

3. F.R. Schrieber, *Sybil* (New York: Warner Books, 1973); *Sybil,* Lorimar Productions, 1976; *Sybil,* Norman Stephens Productions, 2007.

4. "The heterogeneous dissociative disorders are often hidden and unrecognized. . . ." K. McDonald, "Dissociative Disorders Unclear? Think 'Rainbows from Pain Blows'," *Current Psychiatry* 7, no. 5 (2008): 73-85, p. 73, citing B. Foote et al., "Prevalence of Dissociative Disorders in Psychiatric Outpatients," *American Journal of Psychiatry* 16 (2004): 2271-6.

5. Michael Stone also found that approximately one-fourth of these 145 serial killers had had head injuries and periods of unconsciousness. J. Arehart-Treichel, "Multiple Factors at Root of Antisocial Behavior," *Psychiatric News* 45, no. 15 (1 August 2008): 4-18, p. 18. See, e.g., also J.B. Kotch et al., "Importance of Early Neglect for Childhood Aggression," *Pediatrics* 121 (2008): 725-31.

6. G.N. Pachas, "Understanding Drug Addiction and Substance Abuse," *Psychiatry Report* 2, no. 1 (Spring 2008): 5-19, 8.

7. Ibid., 7, citing G. Di Chiara and A. Imperato, "Drugs Abused by Humans Preferentially Increase Synaptic Dopamine Concentrations in the Mesolimbic System," *Proceedings of the National Academy of Sciences USA* 85 (1988): 5274-8.

8. G. Grass, *Peeling the Onion* (New York: Harcourt, 2007), 36.

9. Ibid., 91.

10. Ibid.

11. Ibid.

12. Ibid.

13. Ibid., 132.

14. Ibid., 28.

15. Ibid., 96.

16. S. Baatz, *For the Thrill of It/Leopold, Loeb and the Murder that Shocked Chicago* (New York: Harcourt, 2008), 140-1. Quoted from the notes of W.A. White (Loeb, National Archives in Washington DC, fol. 6, Trial transcript, fols. 1295-6, 1534-5).

17. E.A. Poe, "The Cask of Amontillado," in *Tales of Edgar Allan Poe* (New York: Pennyroyal Press, 1991), 51-9, 51. Even this murderer may have felt a pang of guilt: "My heart felt sick. It was the dampness of the catacombs," (p. 59).

18. L. Pirandello, *Six Characters in Search of an Author*, trans. E. Bentley (New York: Signet, 1998), 57.

19. W. Bernet et al., "Bad Nature, Bad Nurture, and Testimony Regarding MAOA and SLC6A4," *Journal of Forensic Science* 52, no. 6 (November 2007): 1362-71, 1365.

20. D.N. Stern, *The Present Moment in Psychotherapy and Everyday Life* (New York: W.W. Norton, 2004), 157.

21. Ibid., 165.

22. Ibid., 166-7.

23. Ibid., 172.

24. Ibid., 172-3.

25. Ibid., 179.

26. Ibid., 185.

27. P. Wood, *Secrets of the People Whisperer* (New York: MJF Books, 2005), at 21.

28. J.P. McCullough, Jr., *Treatment for Chronic Depression* (New York: Guilford Press, 2000), 8.

29. Ibid., 17.

30. Ibid.

31. The psychiatrist was Eric Lavender, speaking with J.P. McCullough, Jr., during a presentation, "Treating the Chronically Depressed Patient Using the Cognitive-Behavioral Analysis System of Psychotherapy," at the American Psychiatric Association Annual Meeting, Washington, D.C., 5 May 2008.

32. L.L. Havens and S.N. Ghaemi, "Existential Despair and Bipolar Disorder," *American Journal of Psychotherapy* 59, no. 2 (2005): 137-47, 138.

33. A.J. Applbaum et al., "A Family's Request for Complimentary Medicine After Brain Death," *Journal of the American Medical Association* 299, no. 18 (14 May 2008): 2188-93, 2189.

34. Ibid., 2191-2.

Errata

The second half of notes 24 and note 25 were deleted from A.M. Torke, Mary Simmerling, M. Siegler, D. Kaya, and G.C. Alexander, "Rethinking the Ethical Framework for Surrogate Decision Making: A Qualitative Study of Physicians," *The Journal of Clinical Ethics* 19, no. 2 (Summer 2008): 110-9. The journal apologizes for the error. The complete text of the notes follow.

24. R.M. Veatch, "Models for ethical medicine in a revolutionary age. What physician-patient roles foster the most ethical relationship?" *Hastings Center Report* 2, no. 3 (June 1972): 5-7; M. Siegler, "Critical illness: the limits of autonomy," *Hastings Center Report* 7, no. 5 (October 1977): 12-5; J.F. Childress and M. Siegler, "Metaphors and models of doctor-patient relationships: their implications for autonomy," *Theoretical Medicine* 5, no. 1 (February 1984): 17-30; E.J. Emanuel and L.L. Emanuel, "Four models of the physician-patient relationship," *Journal of the American Medical Association* 267, no. 16 (1992): 2221-6; J. Balint and W. Shelton, "Regaining the initiative. Forging a new model of the patient-physician relationship," *Journal of the American Medical Association* 275, no. 11 (1996): 887-91; T.E. Quill and H. Brody, "Physician recommendations and patient autonomy: finding a balance between physician power and patient choice," *Annals of Internal Medicine* 125, no. 9 (1996): 763-9.

25. K. Montgomery, *How Doctors Think: Clinical Judgment and the Practice of Medicine* (New York: Oxford University Press, 2006).

Features

A Qualitative Report of Dual Palliative Care/Ethics Consultations: Intersecting Dilemmas and Paradigmatic Cases

Julie W. Childers, Richard Demme, Jane Greenlaw, Deborah A. King, and Timothy Quill

INTRODUCTION

Palliative care consultation services in acute hospitals have been rapidly emerging over the last 10 years. Recent surveys estimate that 25 percent of all hospitals have palliative care consultation services, with substantially higher percentages in academic medical centers and Veterans Affairs hospitals.[1] In comparison, all hospitals are required by the Joint Commission on Accreditation of Healthcare Organizations to provide some kind of ethics consultations, and 60 to 70 percent of American hospitals now have ethics committees.[2] The functions of the two services are often seen as separate, with palliative care (PC) addressing the domains of symptom management and clarifying goals of care in severely ill patients, whereas ethics consultants assist with conflict resolution and medicolegal questions. However, because much of the conflict revolves around end-of-life issues, there may be significant overlap between the cases referred to these independent services.

Palliative care is provided in a variety of settings: hospitals, hospices, nursing homes, outpatient offices, and patients' homes. PC assistance is most often sought for management of difficult-to-treat pain and other symptoms,[3] but a significant minority also help with goal-setting and with difficult medical decision making, provide support to patients and family members, and link patients with services as they become more severely ill and are moving toward the end of life.[4]

In contrast, the American Medical Association defines the functions of an ethics consultation as education, facilitation of discussion, and conflict resolution among patient, family, and staff.[5] Previous efforts to characterize ethics consultations have identified a number of common

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issues. One case series found that questions of withholding or withdrawing treatment and communication issues predominated.[6] Other reviews have identified questions about patients' autonomy and conflict resolution,[7] and issues of medical futility, communication, and family conflict.[8]

Ethics and palliative care overlap: both are called upon to do interpersonal work among patients, families, and clinicians treating them, and to assist with difficult decision making. Increases in consultation rates in both fields have paralleled the growing number and complexity of medical choices available to severely ill patients, as well as enhanced regard for patients' autonomous decision making. They both help identify decision makers, set goals of care, and make medical decisions when patients are unable to do so.

This review of cases that received both palliative care and ethics consultations identifies a subset of particularly challenging cases for both families and clinicians. We use qualitative analytic techniques to identify clinical issues that led to the dual consultations, and then describe five paradigmatic cases to explore the roles that palliative care and ethics consultation services assumed and how they attempted to resolve these difficult questions.

METHODS

Setting and Consultation Services

The University of Rochester Medical Center (URMC) is a 750-bed academic tertiary-care hospital in upstate New York. An ethics consultation service has been in existence since 1991, providing an average of three consults per month during the study period. Ethics consultations can be requested by patients, their families, or anyone on the hospital staff. Ethics consultations are conducted by one of three consultants (one nurse/lawyer and two physicians) and are discussed at a consultation meeting held weekly. The URMC palliative care consult service was established in November of 2001, providing an average of 26 inpatient consultations per month over the study period. Consultations must be requested by the patient's primary attending physician. Patients are initially evaluated by a nurse practitioner or a resident, and subsequently by an attending physician. All palliative care consultations are discussed at a weekly multidisciplinary team meeting.

Design

Initial consultation notes from all cases at URMC that had both palliative care and ethics consultations requested within 30 days during the same admission were included. The cases took place during a three and one-half year period from January 2002 to July 2005. Altogether, 47 cases fit these criteria.

Data Collection

A structured, comprehensive PC intake form is routinely completed during the initial patient assessment on all patients seen in PC consultation (this form available from the authors upon request). This includes a wide range of demographic information about patients, as well as data about their medical problems and medications, ratings of pain and other symptoms, advance care planning, performance status, capacity for decision making, family dynamics, and eventual PC assessment and recommendations. The initial form is completed by a nurse practitioner, resident, fellow, or medical student, and the final assessment and recommendations are completed by the attending physician. A much briefer follow-up form summarizing patients' outcomes is then completed weekly by the palliative care nurse practitioner until a patient is discharged, dies, or the team signs off the case. The ethics consultation provides an unstructured, narrative note completed by the consulting faculty member, often after consultation with other members of the ethics team. When follow-up ethics notes were available in the central ethics office, they too were included in the review.

Data Analysis

Initial ethics and palliative care consultation notes on each patient were reviewed simultaneously by each author, who independently categorized the main questions that led to each consultation. The group then discussed the categories and developed a list of the main issues and treatments in question by consensus.

After the analysis was completed, five cases were chosen by group consensus as paradigmatic examples of dual consultation cases. For each of these cases, an author (JC) who was not personally involved in any of the consultations reviewed the medical charts in depth and interviewed consulting clinicians for first-person accounts of the

interpersonal dynamics and the roles of the consulting services. Each member of the group then reviewed the cases until consensus was reached on the main issues involved in each.

Research Ethics

The data analysis from the palliative care and ethics intake processes was approved and exempted by the University of Rochester Institutional Review Board. All cases described here have been disguised to protect patient confidentiality, while preserving fundamental characteristics of interest to the study.

RESULTS

We identified 47 dual consultations over the 42-month period, representing 37 percent of the total ethics consultations during that period (126) and 4.3 percent of the total palliative care consultations (1,092). In these 47 cases, 70 of the patients died in the index hospitalization. Table 1 summarizes the demographic characteristics of patients who received dual consultations during the study period.

Table 2 lists the main diagnoses associated with the dual consultations. Most of these patients had very advanced disease with a poor prognosis or a life-threatening, acute event or injury, also with a poor prognosis. Table 3 concerns the life-sustaining treatments at issue in the consults. Not surprisingly, whether or not to provide (or continue) cardiopulmonary resuscitation (CPR), ventilatory support, and/or feeding tubes, which are among the most common life-sustaining treatments considered in acute hospitals, head the list.

CLINICAL QUESTIONS

We identified four clinical questions around which conflict or questions centered. The most frequent clinical context was a patient with a severe, probably terminal illness in which the burdens of treatment appeared (usually to the clinical staff but not to the patient/family) to outweigh the benefits. Most of these 43 cases involved uncertainty about how to proceed in this setting of what the staff considered "near futility." Less-frequently encountered clinical issues were related to patients' capacity to make decisions (13 cases), discharge planning (seven cases), and guardianship or proxy determination (seven cases). Many cases posed several of the above dilemmas at once (see table 4).

Another lens through which we viewed the cases was the type of interpersonal work required of the consultation teams. A frequent role of the

Table 1. Ethics and Palliative Care Populations Compared to the Dual Consultation Group, January 2002 - July 2005

Characteristic	Ethics	Palliative Care	Combined
Gender (%)			
Female	54%	52%	51%
Race (%)			
Caucasian	62%	80%	66%
African-American	29%	14%	25%
Hispanic	6%	2%	6%
Other	3%	3%	2%
Age (years)			
Range	0-103	0-105	0-103
Median	61.5	65	67
Died in index hospitalization (%)	44%	44%	70%
Average consults per month	3	31	1
Total consults over the 42-month study period	126	1,308	47

Table 2. Main Diagnosis of Patients Who Received Both Ethics and Palliative Care Consults 2002 - 2005

Main Diagnosis	*n*	%
Cancer	11	23.4
Multisystem failure	8	17.0
Trauma	8	17.0
Neurological	4	8.5
Congenital malformations/ prematurity	3	6.4
Dementia	3	6.4
Cardiac	2	4.3
COPD	2	4.3
ESLD	2	4.3
Sepsis	2	4.3
AIDS	1	2.1
ESRD	1	2.1

consultants was that of conflict mediator, although in nine cases (19 percent) no mediation was required, as the consultations focused more on decision-making support for families and/or medicolegal assistance (many consultations were complex and had more than one focus for interpersonal work).

Table 3. Main Treatment(s) in Question Given to Patients Who Received Both Ethics and Palliative Care Consults 2002 - 2005

Treatment	*n*	%
CPR	18	38.3
Artificial ventilation	16	34.0
PEG	15	31.9
Dialysis	7	14.9
Tracheostomy	6	12.8
Surgery	3	6.4
Transfusion	3	6.4
Antibiotics/other medications	2	4.3
Chemotherapy	2	4.3
Transplantation	2	4.3
BIVAD	1	2.1
Sedation	1	2.1

Table 4. Main Issues and Questions Involved in Consultations Cases that Had Both Palliative Care and Ethics Consultations (*N* = 47)

Main Issue/Question	*n*	%
Clinincal context		
Terminal Illness (limited utility of treatment)	43	91.4
Medicolegal	13	27.7
Discharge planning	7	14.9
Question about decision maker		
Capacity	13	27.7
Guardianship/proxy	7	14.9
Decision-making support needed	16	34.0
Mediation of conflict between		
Family and staff	30	69.7
Family and other family	17	36.2
Staff and staff	8	17.0
No mediation of conflict necessary	9	19.1

PARADIGMATIC CASES

We now present five paradigmatic cases to illustrate how this dual consultation process worked in practice. Most cases involved multiple concurrent clinical issues. For example, there might be interpersonal conflict both around treatment with high-perceived burdens and low-perceived benefits, and simultaneous disagreement about who was the proper surrogate decision maker. Through these cases, we illustrate in more detail how ethics and PC consultants collaborated with each other, and the differing agendas of the medical teams in consulting the two services.

Case 1

Conflict between family and staff about treatment with high burden and low benefit in the setting of terminal illness. A common reason for calling either consultation was when the expectations of the patient or surrogate clashed with that of the attending or floor team. Frequently, the medical team recommended limiting or withdrawing treatment while the family disagreed. The case below is a typical example, but it also illustrates how the two services were used by the medical staff to address the same issue. In this case, when palliative care "failed" to achieve the desired objective, ethics was consulted.

Mr. S was a 67-year-old man who had had multiple myeloma for several years and had relapsed several times after chemotherapy and a bone-marrow transplant. He had briefly been referred to hospice, but changed his mind and opted for salvage chemotherapy, completed by the time of his admission. He was admitted to the hospital for shoulder pain and shortness of breath and was found to have bacteremia and renal failure, as well as a demand-mediated myocardial infarction. When admitted to the hematology/oncology unit, he had a do-not-resuscitate (DNR) order. Dr. Z, the attending hematologist, initially consulted PC for both symptom management and goals of care (with the hope of setting further limits on treatment). The patient's mental status waxed and waned; some discussions were conducted with him, whereas at other times family members were needed to make decisions. Initially, there was little conflict about the goals of care — the plan was to change back to hospice status. The patient was to continue antibiotics and transfusions as long as

they contributed to a quality of life he found acceptable, after which they too would be stopped. An initial palliative care note read:

Spoke with patient's wife — she is looking into hospice options, has spoken with [social worker]. . . . Wife interested in knowing "how long" — likely days-weeks rather then weeks-months. She is accepting of diagnosis.

However, a few days later, a new hematology attending physician, Dr. X, took over the service and wanted to stop the antibiotics. A social worker described the change of direction:

A meeting at 5:30 occurred. Two of their children expressed concern with the discontinuation of antibiotics if we were to switch to hospice. They still concur with their father's decision about DNR, but do not believe that he would wish to discontinue antibiotics. . . . Emotionally Mrs. S appears to have come to terms with the circumstances. She understands that we are gradually moving closer to the end of his life. The children have a more difficult struggle with this than she does, but they are becoming more aware of the changes. . . . I do not believe that they will come to a realization that hospice is the right mode of care for Mr. S.

At that time, the patient's wife told the team she was feeling "pressured" to accept hospice and she wanted her husband to have continued antibiotic treatment. A week later, with the patient's condition clearly deteriorating despite continued antibiotics, a conflict between the attending oncologist and the family was growing. Palliative care continued to meet with the family, but shortly thereafter, Dr. X called an ethics consultation. The ethics consultant met with the attending, the patient and family, and the palliative care consultant. The ethics consultant's note read in part:

Unclear if patient has full capacity, but is able to give assent to current treatment and wife reports she and her 3 children want to continue antibiotics and possible transfusions. Dr. X clearly feels that further aggressive diagnostic or therapeutic trials are unwarranted. Patient family reports they wish continued supportive care. . . . Dr. X does not have to provide medical care which will have no further benefit (e.g., chemotherapy while pancytopenia exists). It is possible that continued antibiotics could extend Mr. S's life for a brief period, and he remains somewhat interactive with his family. It is possible that PRBC transfusion may decrease symptoms of fatigue and dyspnea, so may be included in a palliative regimen.

In this case, an attending physician first consulted PC with the expectation that they would facilitate transition to hospice care. However, when conflict developed between the family and a new attending physician, PC consultants supported the family's wish that antibiotics and transfusions be continued if they contributed to his quality of life. An ethics consultation was requested to convince the family otherwise. The conflict that the ethics team then had to mediate had expanded to include the oncologist and the palliative care consultants as well as the family and patient. The ethics consultant supported the approach outlined by the PC team and family, and helped the attending understand the underlying principles of this decision. A week later, Mr. S's condition declined further. One night, he became alert enough to express a preference for a purely comfort-oriented approach, and made that transition before he died soon thereafter.

Case 2

Absence of a suitable decision maker to represent the patient. This case involved a difficult medicolegal issue around choosing an appropriate surrogate decision maker for a patient who had never had capacity. There was little or no conflict between any of the parties involved. Here, palliative care and ethics consultants had roles that were well demarcated into the respective domains of symptom management and the navigation of the legal system.

Mr. G was a 55-year-old man who had been institutionalized since childhood for profound mental retardation who was found to have large B-cell lymphoma. Potential treatment included chemotherapy, but his behavior was difficult to manage, and he could not sit still for the infusions that would be required. Mr. G had no identified family members or established guardian. Treatment with chemotherapy had a reasonable chance of providing a remission for the patient; there was a consensus that treatment directed at his cancer was in his best interests. The head nurse on the oncology unit was the one who called for the ethics consultation, with the agreement of the treatment team. The initial ethics note addresses the issues of guardianship:

1. It appears the treatment goal is not under dispute here. It is in Mr. G's best interest to receive timely chemotherapy.

2. As long as the situation is urgent according to medical opinion of attendings, hospital policy would permit going ahead with treatment. This would cover all necessary treatment-related procedures to accomplish the goal of administering the chemotherapy safely.

3. There is clear need for a stable, surrogate decision-making process that is legal, readily available, and flexible since the chemotherapy course will be several months, and there will be many unforeseen eventualities that cannot be pinned down in a document ahead of time. I would recommend pursuing legal guardianship.

The next day, the palliative care team was consulted for help managing the practical aspects of Mr. G's care such as how to control his behavior enough so that he could receive the treatment directed at his cancer. The palliative care consultant eventually recommended intubation and sedation as the only way that Mr. G could receive treatment safely, and held a multidisciplinary meeting to discuss how this would be carried out. The PC note read:

I will not reiterate the ethical issues previously addressed by Dr. K. I think that successful administration of chemotherapy will require at least a state of conscious sedation. Given the nursing team's observation of aspiration on Seroquel (which did not control agitation) I think he'll need to be sedated and intubated for the week of follow-up care after chemotherapy. This is clearly a very aggressive plan but without it we can predict an agonizing death for this patient which will require terminal sedation to achieve comfort.

Mr. G's course was not as simple or effective as predicted. He received chemotherapy but then developed respiratory failure and sepsis. The guardianship process recommended by the ethics consultant had to be completed before a subsequent decision could be made to pursue a comfort care approach (a complex logistical process that takes several weeks to months). Two months later, Mr. G died in the intensive care unit (ICU) after having received aggressive treatment.

In this case, ethics and PC were consulted on separate questions. PC assisted with palliation of agitation and planning for controlling behavior and symptoms during chemotherapy, while ethics was consulted with regard to legal and ethical issues about making complex decisions in patients with mental retardation. Once plans for guardianship and chemotherapy with intubation and sedation for this patient were in place, his further care and the process for establishment of a guardian were managed by the primary team. Both palliative care and ethics weighed in later in his course when decisions about treatment withdrawal had to be considered.

Case 3

Conflict between medical staff and family around plans for discharge and then around benefits and burden of treatment. In many cases, central issues changed over time. This case initially involved a family's wish to take a hard-to-manage patient home, and the staff's belief that the plan was both unrealistic and unsafe. The central issue later evolved into conflict between the family and the medical staff around the use of heavy sedation to control behavior.

Mr. E was an 81-year-old retired farmer admitted to the psychiatric floor for agitation and aggression; he had a history of depression and vascular dementia, stroke, and a seizure disorder. He lived at home with his wife; both required 24-hour care. Professional caretakers provided care and supervision during the week, but the patient's two daughters provided care on the weekends. There had been two mental health arrests in the prior weeks for violent behavior toward his wife and talk of suicide. After Mr. E had been in the hospital for two months, palliative care was initially called for assistance. Although the initial consult question was framed as assistance in managing the patient's depression, it became clear that the true question of the attending psychiatrist was whether Mr. E's dementia qualified him for discharge to hospice. The consultant wrote:

Depressed, fluctuating course, refuses to eat and intermittently agitated and combative. States at times wants to die. Currently wants to go home. Family very stressed and are themselves suffering to have him suffer so much.

However, Mr. E was still independent in his daily activities and showed no sign of dying within six months, and the palliative care consultant's assessment was Dementia — mild/moderate. At present, does not meet hospice criteria. Later palliative care notes mentioned that although Mr. E's visits with his daughters were difficult and his wife rarely visited, Mr. E was interactive with his grandson, and they appeared to enjoy each other's

company. The role of the palliative care consultant became helping the daughters cope with their guilt about their inability to take him home, and assistance with managing his verbally and physically abusive behavior. The PC and the psychiatric attending service worked together to manage the patient's agitated depression; ultimately, the patient received electroconvulsive therapy.

However, nearly a month later, Mr. E was still in the hospital because of difficulty finding a suitable placement for him given his difficult behavioral problems, and the daughters were again in conflict. One daughter requested heavy sedation for her father, who remained confused and at times agitated despite multiple medication trials. The attending physician felt this would be inappropriate, equating it with euthanasia, and the palliative care team felt that Mr. E's symptoms were not severe or intractable enough to warrant heavy sedation. The daughter then independently initiated an ethics consultation. The ethics consultant had a lengthy family meeting with the patient's four children, and wrote in the chart:

> Discussed palliative sedation — family does not want patient to continue to suffer. He has had violent agitation at times. Discussed patient is sometimes distressed, but not having physical pain, and not imminently dying, so does not meet general criteria for when terminal sedation might be considered. Discussed — spiritual suffering — might benefit from increased chaplain/priest involvement.

Thereafter the ethics consultant assumed the role that palliative care held previously, as a mediator in the internal conflict between family members and with the attending physician. The patient was not heavily sedated, and ultimately was transferred to a behavioral unit in another city.

In this case, PC and ethics were consulted sequentially at separate times in attempts to deal with a worsening clinical and interpersonal situation. Initially, PC helped the family come to grips with the fact that the patient could not return home, and then helped manage his agitation while alternative plans for placement were developed. Later, the possibility of heavy sedation was brought up by one daughter who was having particular difficulty dealing with her father's behavior. The issue was framed as concern about the patient's suffering, but the family's distress also prompted the request. Although PC redirected the case toward symptom management and an appropriate disposition, the conflict continued to escalate as the patient's hospital stay lengthened. When a request for heavy sedation was "turned down" by palliative care, the family requested an ethics consultation and made the same request. The ethics consultation was able to support the PC team's recommendations and help find a solution to the patient's discharge plans.

Case 4

Decision making when a patient's capacity was uncertain. Another common setting for dual consultations occurred when there was difficulty with the decision-making process due to uncertainty regarding the patient's mental capacity. In some instances, surrogates had difficulty making decisions; in others there was no suitable surrogate decision maker or guardian. Case 2 above (Mr. G) is an example of a guardianship case.

Mrs. P was an 83-year-old woman who had been in an assisted living facility, admitted to the hospital with decreased responsiveness. She had a meningioma, which was worsening and causing increasingly debilitating symptoms. She was found to be severely thyrotoxic and needed a biopsy to rule out thyroid cancer. With her limited overall prognosis, it was uncertain if she would benefit from or want treatment for a thyroid cancer. When she was more capable of making decisions, she had been allowing her potentially curable meningioma to progress naturally without treatment, but at this point, it was unclear whether Mrs. P had full decision-making capacity. For the past several months at the nursing home, she had sometimes been confused, but at other times she was able to answer yes or no questions and to make simple decisions for herself. Her ability to speak English was also limited. Several messages were left for the patient's son, who replied that he did not want to participate in her care.

An ethics consultation was called first to explore treatment and consent issues. The initial note summarized the issues in question:

> Several ethical issues are evident. First, she has no advance directive, proxy, or POA [power of attorney], and has not stated to her PMD [primary MD] or to [the nursing home] staff any requests for end-of-life care. She also has no DNR order at [the nursing home] or in the hospital. Second, it is not certain how to address her thyroid crisis. A medically invasive proce-

dure (biopsy) is required to rule out cancer. The biopsy alone is risky; it can send her into a fatal thyroid storm. . . . According to [the nursing home], Mrs. P has limited capacity: she was able to make simple decisions for herself with "yes/no" answers. She can probably consent to medical procedures that are simple, low-risk, and high-benefit. It is unlikely, however, that she was able to make major decisions regarding her medical care, such as brain surgery or other high-risk procedures even before this hospitalization. In these situations, a high decisional capacity is desired to ensure a complete understanding of risks and benefits.

The consultant concluded by recommending guardianship and medical treatment of thyrotoxicosis until a decision for or against thyroid biopsy could be made by the guardian. Two days later, the patient's mental status continued to decline and a two-physician DNR was signed based on the lack of utility of cardiopulmonary resuscitation, as well as her past statements and decisions about treatment of her meningioma. The attending physician requested a PC consultation to help with symptom management. Their recommendations included morphine drip, scopolamine patch, and Ativan around the clock. Based on Mrs. P's poor prognosis, high level of suffering, and prior statements, the consultant recommended:

Consider change to comfort approach only — i.e., discontinue decadron, tube feeds, antibiotics, nasal trumpet, etc. As 2 physician DNR has been invoked, would consider extension to 2 physician consensus to provide medically appropriate care (as recommended above).

In this case, ethics was involved first to assist in identifying a suitable surrogate decision maker. The guardianship process was initiated, and the ethics consultant also recommended medical treatment of Mrs. P's thyrotoxicosis, hoping that her decision-making ability would return with treatment. Palliative care was involved in a different phase of the case; its role was assisting with symptom management, but also to maximize the patient's mental capacity, and to also assist with medical decision making in the absence of a surrogate decision maker. PC supported the ethics opinion that a DNR decision could be made in the interim without a surrogate, while awaiting the conclusion of the guardianship process based on the patient's prior wishes and the lack of utility of CPR in her current condition.

Case 5

Decision-making support. There were 16 dual consultation cases that involved families who needed varying degrees of support or help in clarifying values to make decisions on behalf of a family member who had become incapacitated. These cases fell on a continuum: in some cases, the family was noted to be "vacillating" (frustrating the staff by changing their decisions or refusing to make a decision); in others, there was disagreement within a family about the proper way to proceed; and in still others, as in the case below, the family needed time and support before it could make difficult medical decisions.

JB was a full-term, eight-week-old infant born with several serious cardiac and other anomalies. She was admitted to the tertiary care hospital for surgery, but after two weeks it became clear that she was not a candidate for repair of her defects. JB's mother and extended family were overwhelmed by these new developments. While JB's grandmother expressed a willingness to allow treatment to be stopped, JB's 23-year-old single mother was at times angry with the staff, at other times tearful, and required repeated explanations of the situation. One physician noted that she seemed "uninformed and ill-prepared," despite multiple meetings. Clinicians in the neonatal intensive care unit called an ethics consultation to help the family understand the situation. At this meeting with the ethics team, JB's family seemed to understand that the infant could not survive for long, but, according to the chart note:

They did express the belief that stopping or withholding interventions would feel to them like deciding JB should die. They were encouraged to review with Dr. S the entire list of interventions currently being provided, and, for each one, to understand its purpose and whether it contributes to JB's comfort.

The mother was not ready to agree to a DNR order or to any other limitation on treatment. After continued discussions, the ethics consultant suggested that palliative care become involved. The palliative care clinician then also began discussions with the mother and the rest of the family. Her note read in part:

Lengthy discussion re: JB's current health status, discussed chest compressions as they would be associated with JB's eventual decline. [The mother] stated: "I know JB is terminal. I am

not ready to do a DNR — I just want to be able to hold her if that happens."

In this case, both palliative care and ethics consultants served as added supports to the family, helping them follow the recommendations of the team to avoid putting the infant through medically futile CPR that would not bring her back, would only add to her suffering, and would take her out of the mother's arms at the very end of her life. A few days later, the family had received enough support to be able to make the decision, and JB died without receiving a futile attempt at cardiopulmonary resuscitation.

Here, not only did the infant's mother and other family members need support, but the clinical team needed help dealing with the patient's mother, who often took her anger and grief out on them, as well as dealing with their own grief over the loss of a child. This case illustrates how palliative care and ethics can work jointly. With overlapping roles, the two services can provide the assistance needed to help family members to understand a medically devastating situation and to provide support to family members and clinical staff when a decision is not easily reached.

LIMITATIONS OF THIS REPORT

Initial palliative care and ethics consultation notes were analyzed retrospectively for this report, and no additional information was gathered from the medical staff or the chart except for the five cases presented in more depth. There are significant limitations to this approach. First, the consultation notes from the ethics service in particular did not use a template, and varied considerably in their depth and detail. Although both services provide consultations independent from one another, they both reside in the same administrative center, and this might introduce bias and minimize conflict between consultants. The main descriptive analysis was limited mainly to a review of initial consultation notes, which may not have fully reflected some of the more sensitive issues that might have emerged with a more extensive chart review or interview of additional consultants or family members. Staff-staff conflict is probably underrepresented in this regard, as it was likely played down in the official chart notes. In addition, some members of our research group were themselves involved in the cases as ethics (JG and RD) or palliative care (TQ) consultants. They may have been able to provide a better sense of where the conflicts lay, but their personal biases might have influenced the description and analysis. This bias is minimized by the fact that the author who performed the chart reviews, conducted the interviews, and selected the cases and quotations from chart notes (JC) was not personally involved in any of them.

A more objective in-depth study would include longitudinal review by an independent rater of all cases from time of consult to disposition, augmented by interviews with staff and patients or families about their perceptions of conflict and reasons for consulting the two services.

IMPLICATIONS

In these cases, both palliative care and ethics services were called to manage often-overlapping domains of concern affecting patients, families, and medical staff. By far, the dominant concern involved questions about offering or continuing treatments with high burden and low benefit in the context of advanced terminal illness. The usual conflict was patient/family desire to continue aggressive treatment, and medical staff who thought it was more appropriate to withhold or withdraw. In more than 80 percent of the cases, some kind of conflict mediation was involved, most commonly between family and staff, but also within families and sometimes among different elements of the medical staff. The distribution of clinical issues involved in dual consultations parallels previously identified studies of ethics consultations that have found that end-of-life considerations, communication issues, and conflict resolution predominate.

If these dual consultation cases often deal with issues that usually are managed by either consultant service alone, why use both services? Some of the illustrative cases above show how the clinicians and even families may consult the two services in sequence, at times because they are not satisfied with the resolution provided by the first consultation (as in cases 2 and 3). In other cases, the addition of a second consultation may provide additional assistance in a clinical situation that is escalating in difficulty. The additional consultation service could provide another level

of support and expertise in handling conflict. This is shown in the case of the infant JB (Case 5), in which the palliative care and ethics consultants were called because of the emotional and medical complexity of the case to help support and assist both family and staff. In cases when roles overlap, PC and ethics teams functioned best when there was clear communication and collaboration between the two services.

On other issues the palliative care and ethics consultants had distinct roles. Assisting with symptom management and/or addressing practical clinical issues around treatment withdrawal most sharply defined palliative care's distinct role. In contrast, the ethics team was exclusively involved with requests to assist with obtaining guardianship for someone who clearly did not have capacity or when other medicolegal questions were at issue. These disparate roles played out most clearly in Case 2, where ethics was called to establish a legal guardian and palliative care was involved to help with the logistics of managing symptoms and the behavioral challenges the patient faced in receiving chemotherapy.

Since conflict of one kind or another was central in more than 80 percent of these cases, the role of the dual consulting teams was often to try to resolve this conflict and help medical decision making move forward. Many times, the themes identified within a given consultation overlapped and were multidimensional. These consultations were complex and frequently did not yield a simple or straightforward resolution. These overlapping consultations have raised questions for further research. Applying ethnographic interviewing techniques with patients, families, and staff going through these dual processes in real time, or perhaps focus groups with patients or families and medical caregivers after the fact may help tease apart the multilayered factors that contribute to the complexity of these cases. The importance of such future research is underlined by the challenging nature of these cases for all involved, as well as the relative lack of knowledge about the dual consultation processes.

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Dignity Matters: Advance Care Planning for People Experiencing Homelessness

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INTRODUCTION

Despite efforts to elucidate good end-of-life (EOL) care in the U.S., there are many aspects that remain poorly understood. The needs of those whose daily lives are tenuous, and for whom the end of life is most uncertain, are rarely addressed. Homeless people have the highest mortality rates in developed nations and often die prematurely.[1] Yet their concerns have generally been ignored, as most research on end-of-life care has focused on concerns of the White middle class.[2] Homeless people have been found to be very willing to describe their preferences and concerns, and they wish to have a voice in what the future might bring in the event of serious illness or death.[3] They have considered how life might end because they frequently witness death on the streets. Many of these deaths occur suddenly or violently. A unique concern for people who are homeless is dying anonymously and without memorialization.[4]

Moller found similar concerns when he recorded the stories of urban poor dying people. From these stories he concluded that neglect in dying can reflect neglect in life. "Perhaps the crowning indignity of a life lived in poverty about which no one cares is death died in poverty while the culture smiles indifferently."[5] A sense of disempowerment, fear of disrespect, and continued marginalization often pervade thoughts about death.[6] Indignity is a part of daily life on the streets and raises fear of even greater indignity as homeless people look at the prospect of death. Although "death with dignity" has become a slogan for end-

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of-life care, the meaning for a given individual remains nebulous.

Unique Concerns of Homeless People

Previous research has reported that homeless people share many concerns with others about end-of-life care, including a desire for treatment of pain and concerns about being tethered to machines.[7] These studies also found unique concerns based on experiences on the street and in healthcare systems. For example, homeless people have described fears of undertreatment or lack of respect in response to the stigma of being homeless. In addition, distance or alienation from families raised specific concerns about whether, in the case of serious illness or death, their bodies would be recognized or their lives and deaths acknowledged. They also described concerns related to both locating loved ones in case of serious illness or death as well as concerns about people they would *not* want contacted.[8]

In response to these findings, an investigational meeting was convened to specify and prioritize interventions to address the end-of-life concerns of homeless people. Participants included relevant stakeholders such as homeless individuals, shelter providers and street caseworkers, hospice providers and experts in end-of-life care, and representatives from state health departments and medical examiner's offices. Five participants were homeless — two women and three men (age range 38 to 67 years); three Native American, one African-Americans, and one White.

After a review of end-of-life concerns of homeless persons identified in previous research, these constituents were assigned to small groups that were asked to identify and prioritize possible interventions to address end-of-life concerns. They described barriers to end-of-life care that were both systemic and structural and then suggested interventions to address them. Participants suggested that relationships between homeless people and healthcare providers could be enhanced by setting aside assumptions, being honest, and investing time in building trust. Each small group supported opportunities to create advance directives as a primary effort to support improved end-of-life care. They also indicated that standard living wills do not address the unique concerns of homeless people or the indignities they may encounter in healthcare and social service systems. In addition, they suggested creating various forms of identification (cards, bracelets, and so forth) and documenting contact numbers or the existence of living wills.

Because many of these concerns described indignities encountered in healthcare situations as well as the ultimate indignity of unacknowledged death, the investigators sought a way to address dignity concerns in the context of advance care planning. Chochinov and colleagues have developed a model to conserve dignity as a way to concretely address dignity-related concerns.[9]

A Care Model that Conserves Dignity and the Development of an Advance Directive

Chochinov and colleagues conducted research with people who were dying in order to explicate the meaning of dignity at the end of life.[10] Participants in their study described concerns related to the effects of terminal illness in terms of level of independence and control of their medical symptoms. Dignity-specific themes included:

1. Generativity: the sense that one's life has stood for something
2. Continuity of self: a sense that one's essence is intact despite advancing illness
3. Role preservation: a sense of identification with previously held roles
4. Maintenance of pride: ability to retain positive self-regard
5. Hopefulness: ability to maintain a sense of meaning or purpose
6. Concerns regarding the aftermath of death: worries or fears about the challenges or burdens that one's death may impose on others
7. Tenor of care: the attitude and manner with which others interact with the patient that may or may not promote dignity.[11]

These authors used these empirically derived themes to develop *dignity therapy,* an approach that invited imminently dying people to identify their concerns, tell their stories, and describe how they would like to be remembered. The responses of terminally ill patients were recorded and shared with their loved ones. This opportunity to share thoughts about things that engendered pride and respected dignity was found to bolster a sense of meaning and purpose while reinforcing a contin-

ued sense of worth.[12] Patients who initially reported the most psychosocial despair seemed to especially benefit from dignity therapy. These participants experienced an increased sense of purpose as they approached death, even when their pain wasn't well controlled.[13] Addressing dignity in this manner within hospice and palliative care programs can assuage the spiritual and emotional suffering that may be associated with the dying process.

Because many of the themes generated in Chochinov's model are similar to themes reported in previous empirical work exploring concerns about EOL care among homeless persons, a novel advance care planning process was designed to honor end-of-life care preferences by building in themes from Chochinov's model along with recommendations from empirical work with homeless people.[14]

The format expanded on the recommended language for legal sufficiency of advance directives in Minnesota state statutes. The standard Minnesota advance directive includes contact information for proxies, one's preferences regarding treatment and organ donation, and one's preferences regarding the disposal of one's body. Questions were added that captured the unique concerns of homeless persons, such as physical features (for example, tattoos) that might help with identifying one's body, preferences for disposition of one's body after death, and the designation of people who should and should *not* be notified in the case of serious illness or death. Questions concerning dignity were adapted from Chochinov and colleagues' domains and were incorporated into the process of completing the advance directive (see table 1 for specific questions).

This article describes the results of a content analysis of advance directives completed by homeless persons during a pilot study conducted at a drop-in center in St. Paul, Minnesota. The advance directive was developed as a tool for this pilot, which tested whether homeless people would complete advance directives under two conditions: (1) a "minimal intervention" that included education about end-of-life issues and dissemination of the advance directive form for self-completion, and (2) a "guided intervention" that included education and an opportunity to complete the advance directive in a one-on-one session with an investigator (doctor, nurse, or counselor) who assisted completion of the advance directive.[15] The current study describes the content of the advance directives completed by homeless people who participated in the guided intervention arm.

METHODS

After approval by the University of Minnesota's Institutional Review Board, a convenience sample of 59 subjects was recruited at a homeless drop-in shelter. Volunteers were randomized into two intervention arms: minimal intervention and guided intervention. Compensation was provided to all participants for their study participation (for example, completion of pre-intervention survey tools), but was not linked to returning for follow up or for completing an advance directive.

The 29 individuals assigned to the guided intervention group were invited to return on subsequent days to meet with an investigator to complete the advance directive. On return, an investigator met privately with the subject to answer questions about end-of-life care and to assist in documenting the subject's preferences on a legally signed and witnessed advance directive, using the tool developed for this study. Depending on an individual participant's preference, either the participant or the investigator actually wrote the responses on the living will form as well as the participant's responses to the questions regarding dignity. In either case, the participant reviewed the written responses on completion.

After this review, the form was witnessed by two people (investigators or shelter staff). The intervention averaged 30 minutes per subject; none lasted more than 45 minutes. Participants were offered copies of the form to keep or send to their designated agent and others of their choice. Investigators retained a copy of completed advance directives in order to assess the utility of each question and for qualitative content analysis. The results section below describes responses of participants who elected to participate in the guided intervention.

ANALYSES

The number of participants who responded to each question in the advance directive was tal-

lied as a measure of the utility of the item. No quantitative analyses were planned because of the small number of respondents. All responses to each question on the advance directive were recorded verbatim on a master tally sheet by study number of the participant to maintain anonymity. The results section includes verbatim responses of participants in response to individual questions. Responses to open-ended questions that specifically related to maintenance of pride (#2B in table 1) were collated and independently coded by two investigators. After analysis, two themes were identified to describe the content, and items were re-coded until full agreement on the items included in each theme was attained.

TABLE 1. Dignity Questions Included in the Advance Care Planning Process

I. Concerns related to illness
  A. Current illnesses/health challenges that concern me
  B. Symptoms of greatest concern
    1. Physical distress
    2. Psychological distress
      a. Things I worry about related to death
      b. Concerns I have about being recognized in case of emergency or death
      c. Relationships that cause me concern or worry
      d. Possible actions that would relieve any of the above concerns
  C. Concerns about level of independence
    1. Worries or concerns I have about my ability to think, communicate, or act

II. Concerns related to dignity
  A. Continuity of self
    1. Roles or relationships which are important to me
    2. Person(s) I want to make medical decisions in case I am unable to make them (primary decision makers)
  B. Maintenance of pride
    1. I am proud of these things
    2. I want to be remembered as a person who . . .
    3. People who care for me could do the following to respect my dignity
  C. Finding spiritual comfort
    1. After death, what should happen to my body
      a. Burial (where)
      b. Cremation and ashes put where
      c. A memorial service (where/by whom)
      d. Other
    2. My concerns related to religion of spirituality are:
      a. Who should be notified for assistance with these needs (name, address, phone, or other contact information)
      b. Who could be helpful in making arrangements/ notifying others (name, address, phone, or other contact information)
  D. Other values that should influence my care in the event of serious injury or death

Note: Each prompt was presented as an open-ended statement with blanks for responses. Adapted from H.M. Chochinov, "Dignity Therapy: A Novel Psychotherapeutic Intervention for Patients Near the End of Life," *Journal of Clinical Oncology* 23 (2005): 5520-5.

RESULTS

Of a possible 29 participants, 17 who were offered guided intervention returned to the drop-in center to meet with an investigator to complete an advance directive with assistance. Of these 17 participants, 14 were men, 11 were Black, four were non-Hispanic White, and two were Native American. In terms of education, six had finished at least some college, six were high school graduates, one had not finished high school, and four did not answer the education question. Religious affiliation included: four Baptist, three Roman Catholic, six Christian (three specifying nondenominational), one Jehovah's Witness, one Jew, one non-response, and one "none." Of the 17 respondents, 12 were veterans. Over the last year, two people had lived exclusively on the streets, while others had moved among a variety of settings including homeless shelters, hotels, apartments, and rehabilitation facilities. Descriptions below include participants' responses to individual items in the advance directive. Frequencies of response to each question are included with content analysis as a description of the utility of the question.

Identification and Body Disposition

When asked about "things that would help healthcare staff to recognize you in case of emergency or death," 13 respondents described scars from surgeries or injuries and/or tattoos. Examples of responses included:

- Check the I.D. he always carries
- None
- "C-section scar — bikini cut"
- USMC tattoo on right shoulder.

Three left the query blank. Several respondents described both scars and tattoos.

In response to the query regarding "wishes regarding care of my body when I die," eight participants indicated burial and six designated a specific site. Three indicated that they would want to be cremated. Six people indicated that a specified friend or relative could decide what should happen to their body. Four responses added written caveats describing a wish for the lowest cost option to avoid financially burdening relatives, for example, "Burial if financially independent, cremation if dependent. . . ."

Appointment of Primary Decision Maker and Notification of Others

Of 17 participants, 16 identified a specific person to be a primary decision maker for them in the event of serious injury, illness, or death. Six appointed family members (mother, brother, sister, or a combination of these relatives). One of the appointed proxies was from a health plan; two were staff at the drop-in shelter. Eight participants supplied names and contact information, but a relationship was not identified. Five people also identified other people, including friends, a sister, a stepmother, an aunt and brothers, a brother and mother, in addition to decision makers who should be notified in the event of serious injury or death. Three wrote "no one" and nine respondents did not answer the question. Two identified individuals by name who should *not* be notified and another wrote, "Don't notify family."

Stated Wishes for Treatment

In response to the query, "what I would want for my healthcare if I am seriously ill or dying and unable to decide for myself," eight people indicated that they would want all measures taken and one indicated that (s)he would want all measures with the exception of a blood transfusion. Six participants indicated that they would prefer limited treatment, with specifications: "Yes, no Quinlan situation," "if brain dead, no treatment," and "don't keep me alive for a long time." Two participants indicated a desire for no treatment. One person did not answer this question.

Dignity-Specific Concerns

In response to a query regarding "current illness/health challenges that concern me," 13 of 17 people described specific illnesses about which they were concerned. Individual responses included:

- Heart disease and open-heart surgery
- Schizophrenia and multiple broken bones
- Dizziness and bronchitis
- Mental illness and gastritis
- Schizophrenia, depression, affective disorder
- Anxiety, two bad knees, lower bad back
- Bottoms of feet turn yellow, back and hip pain secondary to work injury, hearing voices over the airwaves
- Throat cancer, chronic obstructive pulmonary disease, posttraumatic stress disorder (PTSD)
- Dental: "always bad teeth"
- High blood pressure, hepatitis C
- Bipolar and schizophrenic tendencies
- Hernia, allergies that bother eyes all year long
- High blood pressure and concern about developing multiple sclerosis.

Four had no current illness-related concerns.

Related to "symptoms of greatest concern," 11 people indicated concern about *physical distress* related to their illnesses. Six described specific pain, one reported allergies, one reported sleep apnea, and one reported high blood pressure. One person indicated "none" and four did not answer the question.

Only two responses indicated concern about *level of independence,* one indicated depression while another was concerned about the possibility of a "manic episode."

Concerns about *psychological distress* included:

- Worrying about four children
- Fear of the unknown, depression, schizophrenia, bipolar disorder, and PTSD
- Boredom due to inability to work
- Concern about being off medication
- Worries or concerns about being homeless (reported by three persons)
- Concern about lack of insurance: "treatment is based on insurance — not on need as a human being."

Participants' response*s* regarding "things I worry about related to death" included:

- Family not being notified
- Leaving a wife and children behind
- Being a burden to family

- Lack of resources to cover burial costs (family or friends would be responsible)
- Being alone
- One person indicated that he/she didn't want to die: "felt like giving up in the past, but not now."

Five respondents indicated that they had no death-related worries.

Responses to a query regarding "relationships that cause me concern or worry" included:
- Spouse
- Brother who is an alcoholic
- "Relationship with self"
- Not keeping in touch with family
- With nearly adult kids — "sometimes don't get along with my daughter"
- Not spending quality time with family — would like to be more self-sufficient
- "Just interpersonal"
- "What relationships? Everyone wants one and I won't get into one. I am alone . . . but planning to stay and not go home to 'meth'."

Seven respondents wrote "none."

Only three people had suggestions in response to a query regarding "possible actions that would relieve any of my concerns":
- Get work or housing and to notify sister about proxy appointment
- Continue to think positively
- Completing a living will.

Three people indicated "none," and others did not answer the question.

Maintaining Pride

There were 18 responses to a query regarding what "I am most proud of" (see #2B in table 1) that were grouped into two themes: (1) accomplishments and (2) elements of character. Accomplishments described activities that made a contribution including:
- Taking care of oneself
- Ability to work
- Returning to or completing college
- Completing alcoholism treatment
- Taking care of one's health by seeing a doctor regularly
- Serving in the military
- Special skills like building a house or speed skating.

Only one person's source of pride was his/her family. Character items were personal attributes that created a sense of pride including:
- Honesty,
- Compassion and understanding,
- Holding high morals, for example, "I am a good guy, helpful to other people."

Indications of how one *would like to be remembered* were invariably about dimensions of character, with the exception of one person who would hope to be remembered as "a congressman or alderman . . . who created programs for homeless persons." Elements of character included:
- Liking and enjoying life
- Being optimistic in the face of adversity
- Happy
- Helpful
- Believing in God
- Being open-minded
- Able to function in spite of struggling with addiction
- Having a "good spirit."

One person stated, "I lived life to the fullest, loved all people, and was always a helper and listener." Another wrote, "Fair, open-minded, believe in God. Honest, reliable, and unselfish. I know myself and am not ashamed."

Responses addressing *how providers could respect dignity* reflected basic concerns:
- "Treat me like I treat others"
- "Try the best to keep me alert and tell me who I am if I am confused"
- "Don't judge a book by its cover, but from within" and "accepting me for who I am and not telling me what to do."

Additional responses included telling the truth and respecting privacy.

Responses regarding *spiritual comfort* primarily related to specifying post-death plans including burial, cremation, or memorial services. One person indicated that calling clergy would be helpful. Another indicated, "I know who my maker is." Seven people indicated that they would want a memorial service and designated a place. Some

gave specific instructions about services and pallbearers. One indicated, "Yes, sing a song . . . 'He keeps his eye on the sparrow' so I know he is watching me."

A unique answer was from a person who wanted his ashes poured into a fishing spot on the Mississippi River. He told the investigator that there was a place under the bridge where he had been fishing since he moved to the state, and indicated that the catfish knew him. He directed that his ashes be taken to the river by the fishing spot so that the catfish could provide "a free trip to [his hometown]."

DISCUSSION

This pilot project built on prior research into end-of-life care concerns among homeless people and the results of a working group focused on the development of interventions to improve such care. The process resulted in development of a unique advance care planning process specifically designed for homeless individuals. The first and possibly most significant finding was that homeless people not only said they would like to complete advance directives, but actually came at a specified time to complete an advance directive with assistance. The high number of people who returned for voluntary, uncompensated guided intervention demonstrates a high level of interest in advance care planning in this population.

Appointment of a healthcare agent or proxy occurred in almost every advance care planning process. In addition, more than half of the participants named additional individuals whom they wished to be notified. Homeless individuals may not be in contact with their relatives, so it is often not obvious who should be notified when they become sick, or die. Some participants solved this problem by naming homeless shelter staff as healthcare agents, while one specifically stated that family should *not* be notified. Without such an advance directive, notifying family members would likely be the first response of careproviders. Earlier research reported that homeless individuals expressed a concern regarding unacknowledged and unmemorialized death; when homeless people are able to appoint a healthcare agent or another to notify, this concern is addressed.[16] Thus, the advance directive in this population takes on a relatively important role in understanding and potentially honoring patients' preferences. Stated priorities for end-of-life care and post-death care can provide direction for shelter staff, healthcare, or morgue personnel to perform actions that would respect the person's wishes even in the event that no proxy is identified in the form.

In terms of dignity-related concerns, homeless people shared many concerns with hospice patients. They reported few concerns about level of independence and more concern about psychological than physical distress. This distress frequently related to severed relationships or concern about imposing a burden on survivors. Dignity-related questions elicited responses that suggested options for individualized end-of-life and post-death care. For instance, even a proxy who has known someone from childhood would be unlikely to know that a trip down the river with the catfish, or a particular funeral song, would be a source of solace. Participants' thoughtful responses gave voice to the level of anticipation and concern about illness and death that is a part of everyday life for people without a home. Respondents were not hesitant to describe illness-related concerns, things for which they would like to be remembered, or what kind of treatment would respect their dignity.

Learning of homeless persons' deep level of concern about morbidity, premature mortality, and decisions they might confront as they approach the end of their lives should increase clinicians' empathy and ability to best provide care for this vulnerable population. The most difficult challenge a clinician may face would be to respect the wishes of those people who want no one notified. However, this is the situation in which an explicit expression of wishes is most important in guiding clinicians to make decisions that respect autonomy and dignity. Designated agencies or agencies that provide public burial services could be notified regarding preferences for after-death care. Responses to this pilot project suggest a strategy for enhancing advance directives that can have positive implications for homeless people and for clinicians who provide care for them.

Strengths and Limitations

In this study, physician and nurse investigators who had no prior relationship with the study

participants provided assistance with completion of written advance directives at the study site. It is unknown whether the expertise of the investigators in end-of-life issues, the ability to focus on advance care planning without the distraction from other clinical concerns, or the familiarity of the setting to the participants affected the rates of completion.

Responses to this intervention may not generalize to other homeless populations because of the limited number of participants and the fact that it was conducted in one site at one time period. However, many of the concerns identified by these participants reiterated themes from previous research.[17] Participants found the format understandable and the questions helpful for advance care planning. Investigators who worked with people in the guided intervention group were impressed with the sophistication and forethought shown in understanding of the relevant treatment options and consequences of various choices.

It was obvious that life circumstances, including the ubiquity of death in the streets, made concerns about what might happen in the event of serious illness or death an important issue that needed to be addressed. However, lack of longer term follow up precluded the possibility of assessing the impact of the advance care planning process when serious illness or death actually occurs. Although participants responded to the dignity-related questions, this intervention did not specifically ask them about whether the process enhanced their dignity.

Summary and Recommendations

Addressing the themes concerning dignity and asking questions about things like identification of one's body and one's wishes for postmortem care appear to have positive results for people who are homeless. This process can provide direction for healthcare providers and proxies who would make arrangements for cremation, burial, and memorial services. Inquiries regarding dignity invited unique responses that would not have been identified using standard advance directive formats. In future studies, it would be wise to address a larger population of homeless people and to formally measure a sense of dignity to verify whether participants perceive the process to be dignity-enhancing. A logical next step in the process would be to work with emergency systems and healthcare providers to ensure that advance directives are available in the medical record. Analysis of those records would answer the next important question about whether written directives actually influence the outcomes of end-of-life and post-death care.

Linking dignity items and after-death concerns to the process of creating an advance directive provided relevant information for end-of-life and postmortem care. Because the questions about dignity yielded such useful information, the authors plan to include these questions in the body of the advance directive in future explorations.

This project has demonstrated efficacy of a unique advance care planning process that included identifying the dignity concerns for people who are homeless. Other people who are disenfranchised face similar challenges and may benefit from this approach. Chochinov and colleagues report that most of the people who participated in dignity therapy research in palliative care settings in Canada and Australia said they were satisfied with their experience with the study.[18] Their successes, and the positive responses of these participants who are vulnerable but not imminently dying, suggest that it may be wise to assess in more settings whether dignity concerns will add value to the process of creating advance directives and end-of-life decision making.

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Using Family Members as Interpreters in the Clinical Setting

Anita Ho

In recent years, in response to growing immigrant populations and their frequently inferior care experience in the United States, many have argued that more resources should be devoted to hiring professional interpreters to help improve accessibility and quality of care.[1] Most proponents of such services have argued *against* using family members as interpreters.[2] This article challenges this common rejection of family interpreters as a suitable method to deliver information to limited-English-proficient (LEP) patients. Even though family interpreters may not have the same level of health literacy as professional interpreters, they may be able to facilitate understanding and informed decisions by serving as patients' cultural brokers and advocates. In considering the nature of patienthood, particularly within the context of foreign culture and unfamiliar ethos, this article argues that family involvement is often important to a patient's identity and can facilitate informed and autonomous decision making. While it is important to make professional interpreting available in cases when patients prefer or need such services, consideration of patients' cultural safety and larger decision-making contexts can help to explain why it may sometimes be more appropriate to respect a patient's wish to use family members to serve as interpreters than to impose professional services.[3]

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ARGUMENTS FOR PROVIDING PROFESSIONAL INTERPRETING SERVICES

According to the U.S. Bureau of Census, approximately 45 million residents speak a language other than English at home, with 19 million with LEP.[4] The healthcare situation of LEP patients is unfavorable compared to their English-speaking counterparts.[5] Many LEP patients who face communication barriers with their healthcare providers often defer needed medical care, have a higher risk of missing follow-up appointments or leaving the hospital against medical advice, have more trouble accessing or negotiating the system, or are less likely to have a regular healthcare provider.[6]

Language barriers also pose difficulties to obtaining valid consent.[7] In recent decades, autonomy has been considered a capstone value in Western bioethics.[8] The doctrine of informed consent, for example, demands that physicians provide patients relevant information regarding their conditions and medical options, so that patients can deliberate and decide according to their overall priorities and interests. When clinicians and pa-

tients speak different languages, professionals may have difficulty providing relevant, understandable, and meaningful information necessary for informed decisions and eliciting treatment preferences from their patients afterward. Without direct and effective communication, healthcare providers may also struggle to establish the necessary empathy and rapport to reassure, motivate, or support their patients.[9] LEP patients who are already vulnerable because of their health status and associated fears may be further disadvantaged if they cannot voice concerns or negotiate their priorities and care expectations with medical professionals.

As some have argued, healthcare is morally special because it can help sustain/restore normal functioning and reduce suffering.[10] Commitment to equal opportunity and respect for autonomy require that patients' healthcare access and decision-making processes are not compromised by morally arbitrary factors such as linguistic background. Professional interpreters, who have proficient knowledge and skills in the patient's primary language as well as mastery of medical terminology, can promote health literacy and bridge communication gaps between patients and clinicians, and thus help to fulfill the society's moral obligation to provide equal access to essential healthcare services. Since many interpreters also have cultural understanding of the patient's background, they can help interpret not only spoken words, but also attitudes, expressions, expectations, and emotional reactions.[11] Some have argued that when interpreters operate as collaborators and allies with clinicians, they can serve as cultural informants and teach clinicians about the patients' world. In addition, they can facilitate assessment of patients and promote effective planning and delivery of healthcare services.[12]

While there are important ethical reasons to ensure adequate health literacy of LEP patients, many who are concerned about equal access to quality care do not stop at arguing for improving access to professional interpreters. They often argue *against* allowing family members to interpret.

Four arguments are common. First, some worry that using family interpreters is clinically unsafe and may harm patients, since family members are generally unfamiliar with the medical context and vocabulary. Despite their good intentions, family interpreters may misinterpret key concepts, distort or omit messages about important symptoms and instructions, neglect questions regarding drug allergies or medical history, or intervene in the assessment or treatment process.[13] As one study cautions, errors made by *ad hoc* interpreters are more likely to have potential clinical consequences than those made by hospital interpreters,[14] perhaps partly because of these aforementioned errors. Reliance on untrained interpreters, including family members, may therefore lend a false sense of security that accurate communication is actually taking place.[15] This is particularly concerning in situations when family members appear to be biased or emotionally compromised due to high levels of stress. Unlike "neutral" professional interpreters, who are presumably objective and uninvolved intermediaries trained to systematically present clinical information, family members often bring with them their own attitudes, judgments, feelings, and/or distress that may negatively affect their interpretation and communication with the clinician and the patient.[16] This potential harm is not only a liability concern, but also an important ethical worry, since ineffective care that may result from poor interpretation may deny LEP patients' equal opportunity to access essential services.

Second, the suboptimal quality of family interpreting also raises autonomy concerns. Respect for patients' autonomy is generally considered the capstone value in Western bioethics, and the main justification for requiring clinicians to obtain informed consent for treatments. When family members are unable and/or unwilling to correctly interpret relevant information, patients' understandings of their situations, and thus their ability to deliberate according to their priorities or provide informed consent, may be compromised. People from some cultures and/or religious backgrounds consider it a taboo to discuss death and cancer directly, and it is not uncommon for family interpreters to refuse to directly interpret certain words to avoid these difficult subjects. However, despite their good intentions, these paternalistic actions may violate patients' rights to be informed of their situations and to make deliberative decisions according to their own values. Worse yet, in situations where the families may exhibit oppressive

characteristics or appear to be neglecting patients' preferences to get full information, suspicions may arise regarding the families' motives in shielding patients from certain medical information.

Third, the use of family interpreters may raise confidentiality and privacy concerns.[17] In the U.S., for example, professional interpreters are trained and obligated to abide by various ethical codes established by the National Council on Interpreting in Health Care (NCIHC) and the International Medical Interpreter Association, including confidentiality, impartiality, respect, and professionalism. Family interpreters, on the other hand, are generally unfamiliar with these ethical requirements. Some medical information may be sensitive or have significant implications, particularly surrounding mental health, sexual health, genetic issues, and end-of-life care. Family interpreters who have no professional training in such ethical issues may not know how to interpret and deliver such information in sensitive ways. Moreover, patients may not want their family members to hear the news before they themselves have had a chance to digest the information or consider various implications. They may want to retain control and determine if, when, and/or how they would like to inform their families of the situation. Some conditions are stigmatized in certain cultures, and direct disclosure to family interpreters during consultation may subject patients to embarrassment and emotional devastation.

This last point brings out the fourth concern regarding relying on family interpreters. Families in certain cultures have clearly defined structures and hierarchies, such that involving intimates to interpret may alter the power dynamics and create discomfort for all those involved.[18] Depending on the family structure, cultural background, and specific health conditions, some LEP patients may feel uneasy to have their intimates, particularly their children, to learn of their vulnerable situations, since that may disturb the established hierarchy within the family. At the same time, family involvement in clinical interpreting may also put additional burden on intimates who are already stressed out by the patient's condition. This is especially concerning in cases when the diagnoses are unexpected and/or grim, since it may be difficult for some family members to hear and translate about a loved one's critical illness and prognosis, and then assume their usual role within the family.[19] Given that many family interpreters are also caregivers, who may have additional familial and professional responsibilities, imposition of such emotionally exhausting tasks can further compromise their well-being.[20] Professional interpreters, who are usually impartial strangers to the family and the patient, can relieve all parties of such additional stress and may thus be a better resource for interpreting medical information.

WHY FAMILY INTERPRETERS CAN BE PREFERABLE IN SOME CONTEXTS

There are strong ethical and clinical reasons to support the provision of professional interpreters and for clinicians to ensure that LEP patients have equal access to quality care and a right to informed consent. However, it is unclear that the four common arguments presented justify a blanket rejection of family interpreting. Depending on the intimates' familiarity with the patient's condition and their overall dynamic, their involvement does not necessarily violate LEP patients' rights and well-being. Since familial relationships are often integral in preserving LEP patients' identity and promoting their agency in the clinical setting, family interpreters may sometimes even be preferable to professional interpreters who are unfamiliar with the patient's background and culture.

First, while it is important to ensure that patients' clinical safety is not compromised because of language barriers, it is unclear that the use of family interpreters would *necessarily* block patients' understanding, lead to suboptimal care, or harm patients' clinical interests. Professionals are generally suspicious of the ability of family members in conveying essential information to LEP patients, but it seems that such judgment should be made on a case-by-case basis, since family members may have varying abilities to interpret for their loved ones. In fact, even the aforementioned study that reports potential clinical consequences of errors made by *ad hoc* interpreters reports that there is *no statistically significant difference* between hospital and *ad hoc* interpreters in the *frequency* of errors; it appears instead that untrained interpreters, such as family members,

make far *fewer* fluency errors (that is, use of incorrect word, or one that does not exist in that language) than trained interpreters.[21] Another study reports that, even though physicians are often concerned about using family interpreters, most LEP patients are satisfied with and find comfort in the assistance of such intimates.[22] Before assuming an inability to interpret, clinicians should talk with the potential family interpreter to find out how familiar she or he is with the patient's medical history and current condition, his or her own comfort level with medical terminology, potential concerns about interpreting, and so on. Such conversations can give clinicians a glimpse into the potential interpreter's grasp of clinical vocabulary, relationship with the patient, and willingness to promote the patient's understanding.

Further empirical studies would help explore the reason for such discrepancy in data, how family members come to accrue knowledge of medical terminology, and the correlation between patients' satisfaction in family interpreters and the latters' interpreting skills. One possible explanation for divergent observations is that critics of family interpreting have not considered whether, or how, intimates can compensate for their lack of formal training in various ways. Many studies that looked at *ad hoc* interpreters did not distinguish between family members and other untrained interpreters. Family members who are familiar with a patient's medical, personal, and care history often have a larger medicalized vocabulary than clinicians realize,[23] since many family members may have accompanied the patient to medical appointments, discussed with healthcare professionals regarding their loved one's conditions, searched for information from other sources, and/or cared for the patient at home and in the hospital.

Even in cases when a family interpreter may lack extensive knowledge in medical terminology, she or he may still be able to explain complex issues to the patient in meaningful terms without using medical jargon. For example, in explaining the natural course of advanced leukemia to a patient, a family member may make reference to the patient's prior experience, or the situations of other relatives or acquaintances who had similar conditions to convey the message. While the family interpreter may not know or use specific medical terms, depending on the patient's medical history and other personal experience, such anecdotal explanations may suffice in facilitating the patient's understanding. In some cases, personalized explanation may be even more effective in conveying meaningful information than direct interpretation of complex and unfamiliar clinical terms. As some have pointed out, despite the promise of informed consent, even native-speaking patients often do not retain or understand a lot of the information presented to them.[24] There are thus reasons to challenge the assumption that the current practice of providing "objective" clinical data is necessarily the most effective method to promote understanding, and that the use of alternative methods to present the information will necessarily compromise patient comprehension.

Second, the possibility that family members can facilitate understanding in nontraditional ways can also address a concern about patients' autonomy. Recall that critics are worried that biased and emotionally involved family members may unduly edit information regarding grim news and thus undermine patients' autonomy. However, echoing Kaufert and Putsch,[25] I question the uncritical assumption that neutrality is possible and always necessary to promote patients' autonomy. While many differentiate between "objective" professionals and "biased" family members, it is important to note that clinicians of equivalent competence often have different instincts about how much information to disclose to their patients, which available clinical options should be offered, and how such information should be communicated. Depending on the clinicians' respective backgrounds, personalities, clinical experience, and communication styles, there can be significant variations even among professionals in terms of how and what to disclose — there can be many "versions" of the truth. Depending on the patient's situation, presenting an edited version of the overall situation to avoid a difficult subject does not necessarily confound the patient's understanding or violate his or her autonomy, as long as the communication channel is open and the patient is given meaningful opportunities to seek further information and/or clarification.[26] Depending on the patient's medical history, current condition, and family communication style, some-

times a patient may recognize what is happening to him or her by observing how the family interpreter communicates certain information, even if specific words (for example, "death") are never uttered.

We need to take the concern of medical paternalism seriously, which might allow professionals who have little knowledge of a patient's desires and backgrounds to withhold information for the patient's own good. Many clinicians are strangers to their LEP patients, and are unlikely to know for certain what may constitute a patient's best overall interest and preferences.[27] However, intimates are often in a different situation — many are familiar with the patient's goals and values, and how she or he processes medical and other important information. In some situations, family members may have even more knowledge regarding a patient's medical history than the clinician, since the patient may not have sought prior clinical help for the current condition, or the medical chart may not contain previous information from the patient's home country. For example, the spouse of a patient probably knows a lot about the patient's medical history, prior medical procedures, impact of such interventions, and so on. Such information can help the family member in delivering information to the patient in an understandable and relevant way.

While empirical studies are needed to confirm this hypothesis, it is possible that some family interpreters who omit information at the time of consultation will continue to provide clarification and further information for the patients when they return home. Incidentally, many patients indicate that the ability to help after the consultation is important to them.[28] While most studies focus on the information exchange at the consultation, it is important to note that this setting may not show the whole picture. For example, some family interpreters are also caretakers, who may consider it unnecessary to give the patient all the medication information right at the clinic or hospital, especially if they will receive printed instructions. Since some caregivers/interpreters will be helping the patient with medication and other forms of care, it may not be of utmost importance to give the patient all the specific and detailed information at the facility. The family interpreter may want to explain omitted information in private (for example, after the clinician has left the room) or once the patient has returned to a more familiar and comfortable setting, that is, his or her home.

Third, the fact that many family members typically have intimate knowledge of and involvement in LEP patients' medical and personal backgrounds also helps to address critics' worry of confidentiality. While many argue against using family members as interpreters on grounds of protecting patients' privacy and confidentiality, such arguments only require physicians to clearly explain the sensitivity of information and confidentiality implications, either through printed materials in the patient's first language, or by providing patients ready access to professional interpreters. Even though the requirement of confidentiality prohibits professionals from divulging information to others without the patient's consent, it does not preclude LEP patients from *voluntarily* giving their family members access to their medical information. Some LEP patients who have strong bonds with their intimates may consider the family their advocates or decision-making unit, and may consider privacy and confidentiality familial rather than individualist concepts, that is, they may be open with their family members regarding their situation but not with others outside of the family, including an interpreter. Sharing our most private information with our intimates and allowing them to take care of us can be part of what it means to be loved or to be part of the family.[29] In fact, some patients with stigmatizing conditions may particularly want to keep information within the family, especially if the cultural community in the new country is relatively small and the interpreter is also a member of the same community. These family members may also be the patient's caregiver or hold power of attorney, or have interpreted for the patient in other settings that involve personal information, such as financial matters. The confidentiality consideration should, therefore, be evaluated in reference to the patient's familial context and overall decision-making pattern.

This last point helps to address critics' fourth concern, that is, how involvement of family interpreters may affect the family's dynamic and intimates' well-being. Certainly, prior to the consultation, it would be helpful for a professional

interpreter to explain the process to ensure that patients and family members all understand various privacy and sensitivity implications, and that all parties voluntarily consent to the interpreting arrangement. But it is important not to pit patients against their families during this time of illness and stress. It is worth noting that many patients are not only concerned about their clinical well-being; they are also worried about how their situation may impact their families.[30] While it is important to consider how caregiving and interpreting duties may affect intimates' well-being, respect for autonomous agency also requires that we allow patients and their families to determine an acceptable level of involvement by themselves, based on their own assessment of their ability and boundaries. Many LEP patients from these cultures rely on family members to be their main support network and advisors, particularly in times of illness and crises. Family life often embraces a rich array of exchanges, and these intimates may not think of what they are doing for one another as giving help or sacrificing.[31] They may consider their care for each other as part of their collective responsibility and group self-definition.[32] Allowing adult patients and their consenting family members to deliberate with each other to determine the appropriate level of involvement provides all affected parties the opportunity to decide how they can promote each others' agency and autonomy. Some patients and their intimates may prefer to have family members rather than professionals interpret because they trust that their family members are in a special position to help make decisions that will promote all parties' overall interests.

CULTURAL SAFETY AS KEY TO UNDERSTANDING

Patients' trust and reliance on their family members in the clinical setting bring out one important consideration that is often neglected by critics of family interpreters, who seem to assume that clinical safety is mainly or even solely based on receiving detailed clinical data from neutral professionals. Certainly, opportunities to review relevant clinical information are important; but the larger context of information delivery and patient experience is also significant. I argue that clinical safety and ability to understand presented materials may partly depend on whether the patient feels *culturally safe.* While professional interpreters can help promote health literacy by using mutually intelligible terminology and vocabulary to decipher complex clinical data, the focus on providing "objective" clinical data does not capture other fundamental and systemic issues that continue to affect LEP patients' ability to comprehend and cope with their situation.

Cultural safety is not just about individual interactions — it is about the *environment* or the overall framework in which patients receive care. A culturally safe environment is one that facilitates and engages in respectful practices as well as delivers safe services, as defined by those who receive the care.[33] It acknowledges and respects that patients come from diverse backgrounds with varying needs and cultural references. Patients in a culturally safe environment feel empowered to voice their concerns without having to worry that their concerns or experience will be marginalized or dismissed as irrelevant, strange, or backward.

Various structural and institutional considerations can shed light on LEP patients' lack of cultural safety. Despite promises of patient-centered care and respect for autonomy, power structures continue to dominate relationships between clinicians and patients.[34] LEP patients in the clinical setting not only enter a different linguistic territory; they also face a highly controlled and bureaucratic culture that likely is in stark contrast with their prior care experience. While Western medicine offers promising clinical results, it sometimes alienates patients by inadvertently treating them as collections of symptoms or diseased body parts rather than as whole persons with rich personal stories, cultural histories, and relational frameworks. Advanced medical procedures are carried out in sterile settings, where patients are studied, tested, and prodded by unfamiliar instruments in mechanical and invasive ways. Their diets, diagnostic or check-up schedules, access to specialists, consultation time, and discharge plans are determined mostly by strangers, not out of patients' autonomous choices but primarily based on lab/bed availability, cost-benefit considerations, professionals' convenience, insurance coverage, and so on.[35] Given the increased provi-

sion of care by healthcare teams and division of labor, patients may have little contact with any particular provider, and they often experience no continuity of care. Specialized medicine causes patients to be attended by more clinicians than ever before, and care has ironically become increasingly impersonal and fragmented. Healthcare team members, especially in intensive care, are strangers at the bedside who usually only focus on their own specialized area. Even though many professionals are well meaning, they are often overworked and can only attend to patients in a very specific set of clinical circumstances. Contemporary medicine has inadvertently reduced many patients with full histories and relational identities to diseased body parts and medical jargon.

While it is important to note that such experience is not unique to LEP patients, it may be particularly disconcerting for those who are accustomed to holistic care methods. Many LEP patients have minimal formal education and/or little economic means, and may be unfamiliar with symptom-focused Western medicine, the hierarchical institutional medical system, complex payment and insurance schemes, and hospital diets.[36] It is therefore not surprising that many immigrant patients would first talk to their family and friends or are cared for by their intimates at home before considering professional help.[37] This may particularly be the case for immigrants who have low incomes and inadequate health insurance.

Professional interpreters who are familiar with a patient's linguistic and cultural histories can explain medical terms in culturally relevant ways and bridge communication gaps between clinicians and the patient. However, some LEP patients may have difficulty relating to interpreters who are of a different professional or socioeconomic background and with whom they have had minimal contact. Moreover, individual sensitivity and particular attempts by professional interpreters may still be inadequate in ensuring cultural safety and changing the overall care environment. Depending on the institutional cultural dynamic and a patient's care history and experience in the hierarchical medical structure, even a well-meaning professional interpreter may be perceived as yet another stranger or bureaucratic representative at the bedside. Most patients have had limited interaction with professional interpreters, some of whom only offer services over the phone. Also, since hospital or clinic-based interpreters are primarily accountable to the institution that employs them, some LEP patients may mistakenly perceive these professionals as the institution's gatekeepers, rather than as their advocates.

Putting aside the issue of power and control or dominance in this triadic (clinician-interpreter-patient) relationship,[38] the process of working with two professionals (simultaneously in an unfamiliar setting during a time of vulnerability) can be physically and emotionally exhausting. Since family involvement has sometimes been integral to patients' recovery and continued well-being, and family members may be able to continue to clarify and provide information after a consultation, intimates can serve as crucial cultural brokers and advocates for patients. They are constants in a plethora of health professionals, and can provide the much-needed reminder that patients are not merely collections of dysfunctional body parts or unfamiliar argot, but are moral agents who have full histories and important relationships. Since most professional interpreters do not usually have the opportunity to inquire into a patient's personal background or values, some LEP patients may take comfort in having medical information, particularly news that may have important implications on their functioning, capabilities, and mortality, come from a trusted and loving family member rather than a stranger.[39] Some LEP patients may have already been marginalized as "the other" in clinical and larger societal settings, so they may be more inclined to trust their family's judgment and resist medical domination or doctors' claim of beneficence.[40] In these cases, involvement of their intimates can be integral to maintain or restore their identity and cultural safety.

THE CASES OF CONTROLLING AND PROTECTIVE FAMILY INTERPRETERS

So far I have argued that family can be an important part of patients' identity and a valuable resource for LEP patients in the interpreting process. However, there are situations in which a patient may prefer to have a professional interpreter, but may appear to be pressured or inveigled into abiding by family members' wishes to take

over the process. LEP patients who come from societies that focus on hierarchical status and cooperative harmony may not verbalize their concerns,[41] particularly to strangers. In these cases, how should clinicians resolve such potential familial conflict?

While many professionals are well meaning, they only have limited contact with their patients and attend to them under a very specific set of clinical circumstances, and thus may be unfamiliar with a family's history and dynamics. Certainly, within their capacity, professionals need to carefully evaluate whether patients understand their right to use a professional interpreter, and whether their expressed desire to use a family interpreter in the consultation process truly represents their values. Attention to potential signs of neglect and abuse, such as a family's explicit and adamant refusal to consider a patient's well-being, or repeated attempts to override a patient's preference to involve a professional interpreter, can be helpful. However, professionals need to keep in mind that a patient's change of mind upon family influence may not be a reliable indicator of abuse or neglect. Given the realities of stress and vulnerability, many patients may prioritize familial harmony over having a professional interpreter deliver the information, especially if they generally trust their family interpreter's integrity and ability. Professionals who have little knowledge of a patient's familial background should generally trust the patient's expressed wishes and refrain from making premature assumptions that an LEP patient who accepts the family's wishes to interpret over the patient's initial desires are necessarily under undue pressure.

Some general strategies can help to support patients' interpreting preferences and deal with potential conflicts. For example, through printed materials in the patient's language and/or a professional interpreter, registration staff and/or clinicians can first explain to patients and families, preferably separately, their right to professional interpreters and the services these professionals offer. Such initial communication would allow LEP patients a chance to first meet the professional interpreter, learn how she or he can help communicate essential information and relieve pressure on the family, and discuss this with family members to determine if they would like to take advantage of such services. Patients who are concerned about family pressure and feel awkward about verbalizing such worries can indicate their preferences using a form (for example, check the appropriate box). Such conversations and tools can provide staff with an initial, albeit limited, glimpse of the family dynamic. If a patient chooses to use a family interpreter, the professional interpreter can facilitate the process in a different way; she or he can enhance family members' ability to interpret by clarifying unfamiliar terms and information.

In cases in which patients profess to want family members to interpret potentially because of subtle familial pressure, clinicians can discuss with patients various ways to support their preferences without creating more familial animosity, such as by having both professional and family interpreters available. Relationships between family members and patients are often far more complicated than traditional dichotomous notions of oppression and equality acknowledge. Since professionals are usually unfamiliar with patients' family dynamics, it is more important for professionals to follow their patients' own assessments and expressed wishes than to second-guess and paternalistically "free" them from their families.[42] Although some LEP patients do appreciate the opportunity to interact with professional interpreters rather than their family members, others who have spent all their lives in an oppressive relationship and have not been able to break free of such controlling influence may have even less courage or desire to do so when they are surrounded by strangers and plagued with illness or injuries. While the family may be exerting undue pressure on a patient, it may still be the patient's most important support system and part of his or her identity. As some have argued, targets of oppression rarely experience themselves solely as victims.[43] Moreover, it seems reasonable to assume that most families, including those that appear controlling, are not malicious toward their members or the patient; they do not usually use the clinical setting as the tool to exploit their members.[44] The family may be such an integral part of the patient's identity that denial of the family's opportunities to interpret may cause more dis-

tress, further isolate the patient, and increase the patient's powerlessness in an unfamiliar setting. Since some of these patients will return to their family upon discharge, and interpreters usually do not work with patients outside of the clinical setting, it may be counterproductive for well-meaning professionals to pit patients against their families.

There are other situations in which a patient clearly prefers using a family interpreter, but clinicians worry that the latter will intentionally omit relevant information on protective grounds. For example, a family member may refuse to allow a professional interpreter to be present due to the worry that the professional interpreter may use certain words (for example, cancer) that can affect the patient's psychological well-being or are considered taboo in the patient's culture. The family interpreter may also try to persuade a clinician not to use certain language in a consultation. In these cases, it may be helpful for clinicians to first use a professional interpreter to ask the patient about past interpreting experience and the familial decision-making model, and talk to the potential family interpreter to find out how she or he might deliver the information. It is important to distinguish cases in which the patient's family member simply does not want to use certain words, from cases when the interpreter refuses to convey particular ideas. As we considered earlier, family interpreters can sometimes deliver a message and facilitate understanding without using certain terminology.

After listening to both the patient and the family, clinicians can remind them of the benefits of having professional interpreters present to clarify, and to offer multiple opportunities and methods to disclose and interpret essential information. When professionals reframe the conflict as an opportunity to learn more about the patient's and the family's concerns, they can acquire better understanding of the patient's and family's priorities and negotiate a suitable approach to deliver information.[45] Such an approach may also help a family to be more receptive to accessing other supporting resources that can enhance the patient's care and also ease the family's burden. At the end of a consultation, clinicians can ask, again through printed materials or a professional interpreter, if patients *and* family interpreters would like any clarification. Clinicians can also provide translated materials and contact phone numbers in printed form in the patients' language to be given to patients upon discharge, and let them know that the team welcomes further discussion and clarification.

CONCLUSION

In closing, it is important to emphasize that I am not arguing against the use of professional interpreters or the careful presentation of clinical data. Family interpreters are not always available, and they should not replace other much-needed efforts to improve patients' cultural safety. More importantly, their potential ability and willingness to serve as the communication liaison should not be used as an excuse to not make professional interpreting services and other resources available. After all, there are likely different preferences among LEP patients and their family members regarding interpreting methods. It is also important to find out whether a desire on the part of patients or family members to not utilize a professional interpreter is the result of a perception that the offered professional services are inadequate or inappropriate.

I also acknowledge that further empirical evidence needs to confirm the ability of family members to enhance patients' understanding and to facilitate informed and voluntary decision making. To fully respect patients' agency and to promote their well-being, a case-by-case approach to determine the suitability of family interpreting is more helpful than a blanket policy prohibiting such communication methods. While professional interpreters can be a valuable resource for LEP patients who prefer such services, some LEP patients may be concerned not only about one particular consultation, but also the care situation after the visit. Since most interpreters are strangers who will not be able to assist in person after the consultation, family members who can offer continual language and care assistance may be particularly valuable to LEP patients.[46] When professionals deny family involvement in the name of protecting patients' safety, autonomy, and confidentiality, they may ironically be exacerbating

their vulnerability and perpetuating their marginalized status.

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NOTES

1. G. Flores et al., "Errors in Medical Interpretation and Their Potential Clinical Consequences in Pediatric Encounters," *Pediatrics* 111, no. 1 (2003): 6-14; E. Jacobs et al., "Impact of Interpreter Services on Delivery of Health Care to Limited-English-Proficient Patients," *Journal of General Internal Medicine* 16, no. 7 (2001): 468-74.

2. G. Rollins, "Translation, Por Favor," *Hospitals and Health Networks* 76, no. 12 (2002): 46-50; C. Blake, "Ethical Considerations in Working with Culturally Diverse Populations: The Essential Role of Professional Interpreters," *CPA Bulletin* 35, no. 3 (June 2003): 21-3; Flores et al., see note 1 above.

3. This article will focus on using competent *adult* family members as interpreters, not whether minors should serve as interpreters.

4. Flores et al., see note 1 above.

5. Jacobs et al., see note 1 above; Office of Minority Health, U.S. Department of Health and Social Services, *Ensuring Cultural Competence in Health Care: Recommendations for National Standards and an Outcome-Based Agenda* (Washington, D.C., 1999); R. Weech-Maldonado et al., "Race/Ethnicity, Language, and Patients' Assessments of Care in Medicaid Managed Care," *Health Services Research* 38, no. 3 (2003): 789-808.

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Special Section: Clinical Ethics and Prisons

Medical Ethics in Correctional Healthcare: An International Comparison of Guidelines

Bernice S. Elger

MEDICAL ETHICS IN CORRECTIONAL HEALTHCARE: INCREASED ATTENTION REQUIRED

Although a number of recent publications have addressed issues related to ethics in correctional healthcare that have led to public outcry, such as the documented participation of physicians in torture in U.S. prisons,[1] general articles on this subject are rare. This is particularly surprising, as medical ethics in correctional healthcare not only must confront dilemmas of the most serious kind, but must apply to a very large number of patients, especially in the U.S., where 1 percent of the adult population is incarcerated.[2]

Indeed, a search for correctional healthcare and ethics or prison and ethics in the abstract or title of publications recorded in MEDLINE during the past 10 years yields 170 articles, the principal focus of which is ethical problems related to prison medicine. They discuss single ethical issues related to the recent participation of doctors in torture,[3] the conduct of research with prisoners,[4] hunger strikes in prisons in Turkey[5] or Guantanamo,[6] healthcare for terminally ill inmates,[7] capital punishment,[8] mental health issues in prisons,[9] AIDS lawsuits and prisoners,[10] or addiction in prisons.[11] Older articles address psychological research[12] and the quality of healthcare in prisons,[13] and only some of them, most of them written in 1980 and before, are general articles on ethics in correctional healthcare.[14] The relative scarcity of recent general articles on ethical issues in places of detention is particularly surprising, as medical ethics in correctional healthcare applies to an important number of patients, especially in the U.S. where it concerns 2.3 million detainees; as stated above, this represents approximately 1 percent of the adult U.S. population.[15] While the U.S. accounts for 5 percent of the global population, it accounts for 25 percent of the world's prisoners in U.S. prisons and jails.[16] (Later in this article, the terms *prisoner* and *prison* are employed in the sense of *place of detention,* and are meant to include jails and other places of detention, as well as detainees in general.)

Several factors predispose the creation of ethical problems in healthcare in correctional institutions. Not only is the prevalence and impact of these problems currently rarely examined, but many of these problems are in need of conceptual clarification, especially since various courts have come to contradictory conclusions.[17] The requirements of security and the need for healthcare services[18] conflict and regularly cause ethical problems, due to the prevalence of ethically

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sensitive medical and social problems in the inmate population.

We will provide a brief description of these problems here, using U.S. statistics. In other countries inmates present similar problems, although the prevalence of prisoners with addictions and mental illness varies according to different penal strategies and the availability of community healthcare plans in other countries; for example, the prevalence of rape in prison seems to be much lower in most Western European places of detention, based on reports from routine private discussions with inmates in Europe.[19]

Socio-demographic characteristics of detainees in the U.S. indicate that inmates in the U.S. are overwhelmingly working class and poor; members of minority groups are disproportionately represented in the prison populations; racial minorities account for nearly 80 percent of all drug offenders at the state level; more than 80 percent of incarcerations in the U.S. are for nonviolent crimes; two-thirds of convicted jail inmates were actively involved with drugs prior to their admission to jail.[20]

The overwhelming prevalence of medical problems in places of detention is illustrated by statistics concerning HIV[21] and hepatitis. The prevalence of these diseases in prisoners has been found to be substantially higher than in the general population,[22] for example, in Maryland, 7 percent of prisoners have HIV, 30 percent have hepatitis C, and 25 percent have hepatitis B;[23] among all inmates in the U.S. the rates of hepatitis C infection are reported to be 30 to 40 percent.[24] In addition to the other serious harms it creates, rape is an important vector of infection.[25] According to leading prevalence studies, 7 to 12 percent of responding male inmates in the U.S. had been raped an average of nine times.[26] Sexual coercion has been reported by as many as 27 percent of some inmates of U.S. correctional facilities for women.[27]

The aim of this article is to fill an important gap in the existing ethical literature: to present the foundations of medical ethics in correctional healthcare. After a summary of general issues in medical ethics in the prison context, we will present recommendations from professional organizations outside the U.S., as well as the legal context created by international bodies such as the United Nations (U.N.) and the Council of Europe. Following this, recommendations and guidelines from the U.S. will be described. In the discussion section, European and international standards will be compared to the legal context and professional guidelines in the U.S., and, in addition, the U.S. recommendations will be critically evaluated in light of international ethical and human rights standards.

THE FOUNDATIONS OF MEDICAL ETHICS IN CORRECTIONAL HEALTHCARE

General Medical Ethics

The lack of recent general articles on ethics in correctional healthcare might be explained by an assumption that, seen from a broad ethical perspective, there seems nothing new to say. In places of detention, the same ethical principles apply as outside correctional institutions. To start with the most ancient tradition, one could refer to the Oath of Hippocrates, which states, "I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."[28] In the tradition of medical ethics, no distinction is made between patients who are prisoners and those who are not. To quote a more recent mainstream approach in medical ethics,[29] the famous *prima facie* principles of medical ethics — respect for autonomy, beneficence, nonmaleficence, and justice — are as valid to guide the decisions of healthcare personnel working in correctional institutions as they are for healthcare personnel working outside prison settings. In the U.S. it appears, however, that neither the healthcare provided nor the principles of medical ethics actually applied in correctional institutions are equivalent to those outside correctional institutions, and, beyond this, there is no unanimous agreement that they should be equivalent.[30] In this respect, the principle of justice gains a special meaning in places of detention: the principle of equivalence — that the healthcare services that are provided inside and outside correctional institutions should not differ — is derived from the principle of justice.[31] Applying the principle of equivalence in countries that have national health systems and the right to basic healthcare assured through obligatory health insurance seems straightforward. It is not surprising that the principle of equivalence,

as we will argue below, is the guiding principle in European "soft law," and that it is enforced by the European Court of Human Rights, but not in the U.S., where the courts and several professional organizations use different standards. International bodies such as the U.N. and the Council of Europe have adopted several recommendations that deal with prisoners' rights to healthcare and mention the principle of equivalence. These quasi-legal instruments are often called "soft law" because they are not legally binding, in contrast to international conventions that have been ratified by a country or state. However, it should be noted that the European Court of Human Rights refers to soft law standards in its judgments, and this represents a unique enforcement mechanism for soft law in Europe. Several judgments of that court concern medical care in prisons, because prisoners and former prisoners have complained about inadequate healthcare during incarceration,[32] as will be discussed below.

Recommendations from Professional Organizations Outside the U.S.

Since general medical ethics in and outside correctional institutions follow the same principles, existing recommendations in various areas concerning healthcare should apply to prison medicine as well.[33] Not surprisingly, therefore, recommendations from international and European professional organizations address mainly those issues that are specific, if not unique, to the prison environment. Examples are the *World Medical Association Declaration on Hunger Strikers;*[34] the *World Medical Association Declaration of Tokyo,* which contains guidelines for physicians concerning torture and other cruel, inhuman, or degrading treatment or punishment in relation to detention and imprisonment;[35] and the *World Medical Association Statement on Body Searches of Prisoners.*[36] Another ethical issue addressed by several professional organizations is the role of physicians in capital punishment. The World Medical Association (WMA) emphasizes that prescribing drugs for lethal injection is not ethically acceptable.[37] The British Medical Association (BMA) urges doctors to not become embroiled in speculation about whether an individual should be subject to capital punishment.[38] The WMA, the BMA, and the World Psychiatric Association agree that, in the context of capital punishment, giving evidence on future dangerousness contravenes the ethical standards expected of all doctors.[39] To do so contravenes the ethical standards expected of all doctors not only because it can lead to the death of an individual, but also because the science involved is so inexact that one can never safely and accurately say that an individual could not be dangerous in the future or would be dangerous in the future. Since "dangerousness" relies not only upon the mental state of the individual, but on the circumstances in which he or she may find him- or herself, such a judgment can never be exact, and the possibility of inaccuracy renders such judgments unethical, if the consequence could be the death penalty.

In addition to having responded to a need for guidelines in the past, the WMA has recently noted an urgent need for education concerning medical ethics in correctional healthcare. As a consequence, in 2004 the WMA made available a web-based course for healthcare personnel working in prisons.[40] The WMA states that physicians who work in prisons must be able to provide adequate healthcare in the special environments that exist in prisons: "The doctor's conduct must not be in conflict with international human rights and ethical standards. . . . In many countries education of prison doctors is not a priority. Many doctors do not even have access to international conventions and rules regulating healthcare services for prisoners. They encounter human rights violations, but do not know how to deal with them adequately. We hope this course will meet some of the needs many prison doctors have for more knowledge and skills in human rights and medical ethics." The stated objectives of the program are to "present relevant international statements regulating the medical treatment of prisoners and to raise prison doctors' awareness of their role in various areas of conflicting interests between the prisoner (patient) and the prison administration, for example, hunger strikes, the patient's right to confidentiality, certifying prisoners for special punishment, etc."

International and European Law

It is not without good reason that the WMA points to the importance of international law. Several documents from the U.N. establish standards for medical ethics in places of detention. A central issue in these documents that deals with medi-

cal ethics in correctional healthcare is the principle of equivalence of care, which includes the equivalence of medical ethics inside and outside correctional institutions. In its *Basic Principles for the Treatment of Prisoners,* the U.N. states, "Prisoners shall have access to the health services available in the country without discrimination on the grounds of their legal situation."[41] Another relevant document from the U.N. is the *Principles of Medical Ethics relevant to the Role of Health Personnel;* Principle 1 states that "physicians . . . have a duty to provide them [prisoners] with protection of their physical and mental health and treatment of disease of the same quality and standard as is afforded to those who are not imprisoned or detained. . . . There may be no derogation from the foregoing principles on any ground whatsoever, including public emergency."[42]

It is in Europe that these international documents have been further elaborated, legislated, and legally enforced by the European Court of Human Rights (ECHR). In 2004 the Council of Europe Committee of Ministers published "Recommendation No R (98)7 concerning the Ethical and Organisational Aspects of Healthcare in Prison," which describes the main characteristics of the right to health in prison. Equivalence of care is explained to include access to a doctor "at any time . . . day and night"; "medical, psychiatric and dental treatments equivalent to those enjoyed by the general public" of the same country; and the right to outside treatment if it is not available inside the prison. The patient's consent and confidentiality must be "guaranteed and respected with the same rigour as in the population as a whole." Professional independence is another key element: "Medical decisions should be governed only by medical criteria. Healthcare personnel should operate with complete independence. . . . " Professional independence in its most complete form means that a complete separation of power exists, as it has, for example, been realized in the prison medicine department of the University of Geneva. The prison administration and correctional officers are employed by the cantonal department of justice and police (which includes correctional institutions), but the prison healthcare system is part of the university, that is, it is under the cantonal department of health.[43]

The legal enforcement of the principle of equivalence of care in Europe through human rights law and the ECHR was created as a reaction to its own history. The aftermath of the Doctors' Trial at Nuremberg is keenly felt in Europe, where the violations, including the human rights of persons deprived of their liberty, took place. The human rights framework set up in Europe since 1950 (the "Convention for the Protection of Human Rights and Fundamental Freedoms"[44]) strongly emphasizes the protection of all detainees. The principle of equivalence of healthcare is legally enforced through the European Court of Human Rights, also known as the Strasbourg Court (it is physically located in that city). The current incarnation of the court was instituted on 1 November 1998, replacing the then-existing enforcement mechanisms that included the European Commission of Human Rights, created in 1954, and the previous, limited Court of Human Rights, created in 1959. The European Court of Human Rights responds to requests by individuals, and its judgments have binding force. The notion of equivalence in healthcare emerged in the case law of the ECHR in 1979 and is now part of a normative framework covering 47 countries, the members of the Council of Europe.

Inadequate medical care is considered inhuman treatment and is a violation of Article 3 of the "Convention for the Protection of Human Rights and Fundamental Freedoms": "No one shall be subjected to torture or to inhuman or degrading treatment or punishment."[45] Several cases have affirmed the principle of equivalence of healthcare for detainees (*Bonnechaux v. Switzerland,* 1979; *De Varga Hirsch v. France,* 1983; *Patanye v. Italy,* 1986; and most recently *Farbtuhs v. Lettonie*, 2004, and *Gelfmann v. France,* 2004).[46]

A further layer of protection is achieved through the Council of Europe Committee for the Prevention of Torture and Inhumane or Degrading Treatment or Punishment (or CPT). The mandate of the CPT is from the "European Convention for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment,"[47] which has been ratified by all 47 member states of the Council of Europe. Article 1 of the "Convention" states: "The Committee shall, by means of visits, examine the treatment of persons deprived of their liberty with a view to strengthening, if necessary, the protection of such persons from torture and from inhuman or degrading treatment or punishment."[48] The CPT is comprised of independent

experts. Under the "Convention," CPT delegations have unlimited access to places of detention and the right to move inside such places without restriction. They interview persons deprived of their liberty in private and communicate freely with anyone who can provide information. The recommendations that the CPT formulates, based on its visits, are included in a confidential report that is sent to the country concerned. This report becomes the starting point for an ongoing dialogue with this country. If the country fails to cooperate or refuses to improve the situation in the light of the committee's recommendations, the CPT may make a public statement.

Over its years of activity, the CPT has developed standards relating to the treatment of persons deprived of their liberty. In its judgments, the European Court of Human Rights quotes the existing European recommendations. Through this mechanism, the recommendations of the Council of Europe as well as the CPT standards are legally enforced.

It is therefore important to look in some more detail at the content of these recommendations. In the "3rd General Report on the CPT's activities covering the period 1 January to 31 December 1992," the CPT affirms the principle of equivalence of healthcare: "prisoners are entitled to the same level of medical care as persons living in the community at large. . . . "[49] In this report, the CPT emphasizes further that the provision of healthcare services to persons who have been deprived of their liberty is a subject of direct relevance to the CPT's mandate. An inadequate level of healthcare services may rapidly lead to situations that can be described as "inhuman and degrading treatment." Further, the healthcare services that are provided in a given establishment may play an important role in combating ill-treatment, both in that establishment and elsewhere, in particular in police establishments. The considerations that have guided the CPT during its visits to prison healthcare services include the following:

- Access to a doctor,
- Equivalence of care,
- Patients' consent and confidentiality,
- Preventive healthcare,
- Humanitarian assistance,
- Professional independence, and
- Professional competence.

The legal enforcement of patients' rights and professional independence in correctional healthcare protects healthcare providers' ability to act according to general standards of medical ethics, especially with respect to maintaining confidentiality, reporting violence, reporting torture, and conflicts of interest, that is, when the welfare of the detainee-patient is in conflict with administrative or security requirements.

The Legal Context in the U.S.

Not surprisingly, for a country such as the U.S., in which nearly 16 percent of the population does not have access to basic healthcare,[50] applying the principle of equivalence is difficult, and might even be used to justify the absence of healthcare services for poor prisoners. In the U.S., the courts have noted that prisoners cannot choose where they live,[51] and, likewise, prisoners cannot choose whether to enroll in a health insurance plan once they are incarcerated. In Europe the prevailing attitude is that punishment is limited to the deprivation of liberty and does not affect the right to equivalent healthcare; in the U.S., a prevailing principle used by the courts to determine whether the healthcare provided to prisoners is inadequate was described as "deliberate indifference to their serious health care needs" in a landmark case, *Estelle v. Gamble* (1976).[52] The question discussed in this Supreme Court decision was, "what must a plaintiff prove for a prison's medical action/inaction to constitute a violation of their 8th Amendment right to be free from cruel or unusual punishment?"[53] The Court answered, "Prisoners who claim an Eighth Amendment violation as to healthcare needs must demonstrate both an objective serious medical need as well as prison officials' subjective culpable state of mind in denying the prisoner medical care . . . . the crucial test for an Eighth Amendment claim has therefore been whether prison officials knew about a prisoner's . . . [serious health] condition and whether they disregarded the prisoner's need for health care."[54] The courts have subsequently given different characterizations to the concept of deliberate indifference.[55] Three categories are worth mentioning: "denied or unreasonably delayed access to a physician for diagnosis and treatment, failure to administer treatment prescribed by a physician, and the denial of professional medical judgment."[56]

Recommendations from Professional Organizations in the U.S.

Professional standards in the U.S. have been established and have evolved under the influence of legal cases. Among the most important of the professional organizations that have established ethical guidelines for correctional healthcare is the National Commission on Correctional Health Care (NCCHC). This not-for-profit organization began its activities in the early 1970s, when a study by the American Medical Association "found inadequate, disorganized health services and a lack of national standards" in U.S. jails.[57] The NCCHC evaluates and develops policy and sets standards for health services in correctional facilities that it publishes on its website and in separate volumes for prisons, jails, and juvenile confinement facilities.[58] Although many professional organizations refer to general medical ethics in their recommendations concerning correctional healthcare, one remarkable characteristic of professional guidelines in the U.S. is that professional organizations find ethics and clinical medicine in the prison context sufficiently different from practice outside correctional institutions that they have written separate guidelines for each. The reasons for these different recommendations are illustrated by the "NCCHC Clinical Guideline for Health Care in Correctional Settings: Asthma."[59] Although this clinical guideline is based on a national U.S. guideline ("Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma,"[60] issued by the National Heart, Lung, and Blood Institute of the National Institutes of Health), modifications were judged necessary for the prison and jail context: "Correctional settings tend to house large numbers of patients with asthma, and the phenomenon can lead to serious problems with morbidity and mortality. The modifications [in these guidelines] were designed to simplify the NAEPP [National Asthma Education and Prevention Program] guidelines and be more cautious due to the special challenges of providing care in the correctional setting. Our intent is for clinicians to focus on those patients whose disease is categorized as moderate or severe as well as any patient whose clinical status is unstable."[61] This quotation from the NCCHC "Clinical Guideline" clearly indicates that the standards recommended for prisoners are lower than those outside prisons because prison physicians do not have the time and resources to treat or diagnose mild asthma.

This example illustrates the dilemma that most professional organizations that have members who provide healthcare for prisoners face: like the NCCHC, the American College of Physicians (ACP) acknowledges in its "Ethics Manual": "Limited access to health care is one of the most significant characteristics of correctional systems in the United States."[62] The gap between the level of healthcare services that are available outside prisons and the conditions in correctional institutions is a great ethical burden, with which professional organizations, every prison physician, and prison directors[63] must struggle. In a report to the U.S. Congress, the NCCHC stated that it regrets the lack of available specific "guidance or advice on moral issues that are unique to correctional heath care settings. Correctional healthcare professionals function in a highly restrictive and unique environment. There is limited opportunity for peer review of medical policies and administrative actions in a correctional environment."[64] Therefore the NCCHC recommended that a national advisory panel be established on ethical decision making among correctional and health authorities, to assist it in addressing the ethical dilemmas encountered in correctional healthcare, especially issues such as confidentiality, informed consent, and access to care for infectious diseases.[65]

In the following sections, we will summarize the ethical recommendations from various U.S. professional organizations concerning the three most central issues in general medical care:

- Access to treatment,
- Consent of prisoner patients, and
- Confidentiality.

In addition, we will address briefly recent pressing issues:

- Participation in interrogation,
- Participation in execution, and
- Physicians' attitudes towards the abuse and torture of inmates.

We will focus here on a description of those aspects in which U.S. guidelines differ from international and European recommendations and evaluate these differences later in the discussion section.

Access to Treatment. Recommendations from U.S. professional organizations concerning access to treatment vary widely from a general requirement that healthcare should be "available," from the American Bar Association[66] and the American Public Health Association;[67] to statement invoking "unimpeded access to health care," from the American Correctional Association;[68] to the principle of equivalence, from the American Psychological Association: "The fundamental policy goal should be to provide the same level of mental health services to patients in the criminal justice process as are available in the community."[69]

In addition, the need to communicate information about access to healthcare services to inmates, orally and written in a form and language they can understand, upon arrival in a prison,[70] as well as a need "for a system of processing complaints regarding health care" by the ACC,[71] is stressed.

As the clinical guidelines from the NCCHC on asthma indicate, the requirement to make healthcare "available" is often acknowledged to be limited to the more severe forms of a disease. Similarly, the American College of Physicians (ACP), after stating that it has multiple reasons (scientific, ethical, and policy) to be involved in the politics and care of prisoners, notes "the future challenges posed to internal medicine," especially "the prioritization of funds and expenditures in a capitated setting." It also reminds readers, "if one accepts that societies may be judged by how they handle their most vulnerable populations, ensuring quality healthcare delivery in prisons clearly belongs among the College's missions."[72]

The ACP "Ethics Manual," after reminding readers that correctional systems in the U.S. are characterized by their "limited access to health care," adopts the vague standpoint that "physicians who treat prisoners as patients face special challenges in balancing the best interests of the patient with those of the correctional system." Despite these limitations, the ACP "Ethics Manual" states, "physicians should advocate for timely treatment and make independent medical judgments about what constitutes appropriate care for individual inmates."[73] No guidance is given regarding what this "advocacy" requires in terms of the personal obligations of prison physicians or the responsibility of professional organizations (for example, to eject members who do not refuse to comply with unethical health standards).

Consent. The "NCCHC Clinical Guidelines" refer to strict standards for informed consent to treatment, which include the requirement to obtain consent according to legal standards set by the states, documentation of consent, and exceptions specified by law.[74] In practice, however, treatment may be given to an inmate without his or her permission if refusal of treatment would place others at serious risk.[75] Guidelines are more explicit on consent for mental health treatment. For example, the APA "Draft Forensic Mental Health Standards and Guidelines" states, "The principles of informed consent as embodied in the ethical guidelines of the American Psychiatric Association remain applicable to patients in lock-ups, jails, and prisons. The patient should participate, to the extent possible, in decisions about evaluations and treatment. Psychiatrists should offer to discuss with their patients the nature, purposes, risks, and benefits of the potential types of treatment."[76] In a training manual, "HIV Mental Health and Prisons," the APA emphasizes that "refusing medical treatment or missing a therapy appointment is not generally an appropriate reason for a disciplinary infraction, as anyone, including inmates, has the right to refuse medical treatment. Refusing medical treatment or missing therapy sessions is generally best handled in the context of the therapeutic relationship and explaining to the inmate the consequences of the refusal (e.g., they may be discontinued from your caseload, their medical condition may not resolve, etc.) is a more appropriate way to handle this situation."[77] This statement is somewhat ambivalent because the term "generally" might be seen to imply that a disciplinary action could sometimes be justified when an inmate refuses treatment.

Confidentiality. Although the NCCHC guidelines refer to court cases that establish the constitutional right of inmates to privacy in their medical diagnoses and other healthcare records and information (*Doe v. Coughlin,* 1988; *Woods v. White,* 1988), B. Jaye Anno, one of the founders of NCCHC, states in the guidelines that this "right is not violated by the reporting of medical findings in the ordinary course of prison medical care operations or probably even to prison and jail executives with a reason to know."[78] What seems to be unconstitutional is only the "casual, unjusti-

fied dissemination of confidential medical information to nonmedical staff and other prisoners" (*Woods v. White,* 1988:874).[79]

The APA training module on HIV, mental health, and prisons contains explicit sections on the limitations on privacy and confidentiality within correctional systems: "As mental health professionals steeped in the ethics of confidentiality, working in a correctional system where little is confidential is challenging. Most correctional systems respect the importance of confidentiality for outside providers operating in the system; however, each system has explicit requirements for reporting. All professionals are accustomed to reporting requirements for credible threats of harm to the self or others or to children or vulnerable adults. However, in prisons, threats of harm can take the form of information concerning planned break outs — a source of harm that outside professionals may not consider. It is important to clarify your ethical reporting responsibilities and procedures. Similarly, you must plan how you will inform inmates clearly about the limitations of confidentiality in your work."[80] Of particular concern to the APA is the problem of confidentiality in the case of suicidal ideation: "In correctional settings, professionals must carefully balance the potential threat of self-harm with the potential harm caused by reporting. In prisons, threats of self-harm are generally not met simply with understanding and reassurance. Inmates who report thoughts or attempts at self-harm may be strip-searched and placed in segregation. Hence, your responsibility as a professional is increased to ensure that all potential harms are considered in reporting."[81] In light of the risks to confidentiality in the correctional setting, the APA goes so far as to suggest that, in the case of potentially damaging information collected in the course of HIV research, such as information on sexual behavior or substance abuse (which have potential legal and disciplinary consequences for inmates), researchers must not only ensure that sensitive information is protected, but also "that information that is potentially damaging is not collected."[82] Similarly, the APA recommends that some health information should not be put into the medical record of a detainee, but kept in locked separate files by the psychologist: "The psychological report may go in the medical packet, but the raw test data should be kept in a separate locked file in your office. This insures that individuals who do not understand the psychometric properties of the testing material or interpretation [assumed to be security personnel] are not given the raw data to falsely interpret."

The APA guidelines make clear that the ethical dilemmas that face health personnel around confidentiality in correctional institutions is caused by the conflict of some state laws with ethical values: "Inmates may divulge reportable offenses (substance use, sexual activity, possession of contraband) to you in the course of your counseling, education, or prevention interventions. While most prisons only require suicidal or homicidal intent or ideation, child/vulnerable adult abuse, and threats to security (such as, elopement or escape plans), be sure to check your specific requirements." Also, "Then, be sure to outline the limits of confidentiality to every patient that you work with at the prison. Understand that while confidentiality issues may be clear to you, some prison administrators may not abide by these limits and try to pressure you to violate confidentiality of your patient. Be polite but firm in stating your reporting obligations to administrators." It should finally be noted that the APA makes an effort to remind health personnel to send security officers out of the consultation room to ensure privacy: "When conducting an evaluation, be sure to get as private a space (within the constraints of security) as possible. This communicates respect to your patient, in addition to just being good ethical practice. Instead of having an officer in the room during the assessment, check to see if the officer could sit outside the room and look in through the window. This will be dictated entirely by security practices and if this is not possible, you will need to decide whether to conduct the assessment."[83]

The stance of the APA might be characterized as acknowledging that general professional ethics might need to be partly abandoned in the prison context, due to state law and individual prison policy, and as attempting to minimize limitations of confidentiality as much as possible. Some state government bodies, such as the New York State Office of Mental Health, more adamantly oppose restrictions to confidentiality in the correctional setting, especially in situations such as the involvement of physicians in capital cases: "The concerns raised by the CDO [Capital

Defender Office] are serious ones and not to be taken lightly. The CDO considers all statements made by capital defendants to be protected and confidential and that by participating in clinical interviews, inmates do not waive their statutory rights to confidentiality or their constitutional rights to freedom from self-incrimination. . . . The SCOC [State Commission of Correction] and the OMH [Office of Mental Health] have assured the CDO that mental health service providers zealously protect the confidentiality of their interactions with inmates according to strict codes of ethics under which the various treatment professions practice. Moreover, the provisions of Mental Hygiene Law §33.13 adequately protect the constitutional and confidentiality rights of capital defendants since all clinical information is presumptively confidential and barred from disclosure unless expressly authorized under the statute. Since there is no statutory exception for the disclosure of otherwise confidential clinical information to prosecutors of capital cases, the only applicable exceptions would be inmate consent or a court order requiring disclosure upon a finding that the 'interests of justice significantly outweigh the need for confidentiality' (for example, a judicial subpoena without this finding would be insufficient to release the information)."[84]

Participation in interrogation, participation in execution, physicians' attitudes towards abuse and torture. Finally, we think it important to mention briefly the publication of several recent professional guidelines in the U.S. triggered by the recent events in Guantanamo and with respect to the war on terror. Whereas some organizations in the U.S. are not unanimous in their defense of a standard that considers nonequivalent healthcare as inhuman and degrading treatment, some have adopted strict positions against the participation of physicians in torture and capital punishment,[85] which are in line with U.N. recommendations and European guidelines. An ACP statement, "Relation of the Physician to Government,"[86] is similar to a recent position paper from the NCCHC, "Correctional Health Care Professionals' Response to Inmate Abuse."[87] The ACP states, "Physicians must not be a party to and must speak out against torture or other abuses of human rights. Participation by physicians in the execution of prisoners except to certify death is unethical. Under no circumstances is it ethical for a physician to be used as an instrument of government to weaken the physical or mental resistance of a human being, nor should a physician participate in or tolerate cruel or unusual punishment or disciplinary activities beyond those permitted by the United Nations Standard Minimum Rules for the Treatment of Prisoners."

Discussion: Differences between the U.S. and International and European Regulations Concerning Ethics in Correctional Healthcare

The recommendations of U.S. professional organizations, as well as the U.S. legal framework, clearly differ in many respects from European and U.N. guidelines, especially concerning access to healthcare and confidentiality. While equivalent healthcare for detainees is required by human rights law in the European and U.N. guidelines, a large body of soft law, and specific enforcement mechanisms, in the U.S. the principle of equivalence is never mentioned in court cases and emerges only rarely in professional guidelines. As a consequence, U.S. professional organizations do not use the same guidelines for prisoners and nonprisoners, but struggle with the proposition of special guidance and its ethical justification.

From a strict human rights approach, in line with the recommendations of the Council of Europe, neither a lack of access to healthcare for a significant proportion of non-incarcerated individuals nor a similar (or worse) lack for detainees is acceptable. But even given the high priority that Americans assign to an individual's freedom to decide whether to purchase health insurance or to spend money on other goods, the lack of healthcare for prisoners is difficult to justify because incarcerated persons do not have the freedom to choose. They cannot choose between different health insurance plans, nor can they rely on family or other supportive resources (such as, for example, help from a charitable organization) when they encounter health problems. This situation is similar, if not worse, than the situation of limited choices available for other parts of the population, such as the poor and the uninsured elderly, for whom the U.S. provides federal insurance coverage. In the absence of a uniform standard of care in the U.S., the principle of equivalence should at least be interpreted as an obligation to assure healthcare access for prisoners that would be equivalent to Medicaid, as reported in Oregon.[88]

Professional organizations in the U.S. might be hesitant to do this because providing healthcare services for prisoners is a sensitive issue, and it may be difficult to admit that prison physicians are forced to constantly breach basic ethical principles when they agree to work in circumstances that are fraught with ethical problems. U.S. professional organizations would deal more appropriately with the ethical dilemmas of healthcare professionals who work in correctional institutions by stating clearly that a prisoner does not differ from any other patient with respect to deontological and ethical obligations within the patient-physician relationship. Such clarity would allow a consideration of the actual ethical dilemma: the unethical conditions under which many physicians work in correctional institutions.

Professional organizations can do more than acknowledge that the ethical dilemmas that healthcare professionals in prisons face justify an explicit discussion of triage or other models, and attempt to find an efficient and just way to distribute limited resources. Another solution has been, at least in theory, used in some European countries. If a physician in a particular situation can only act in an unethical way, for example, being forced to under treat a patient, professional organizations could — as they do for physicians who participate in capital punishment and torture — sanction members who engage in such practices. If professional organizations ban members from working in clearly unethical prison environments, correctional institutions will be exposed to increased pressure to change.

It is surprising how far, compared to international and European standards, the American College of Physicians departs from the general values of medical ethics. What does it mean, when it states in its "Ethics Manual," that physicians need to "balance . . . the best interests of the patient with those of the correctional system"?[89] From a European standpoint, decisions made in correctional healthcare must use the same ethical principles as those used outside prisons. What makes ethics in correctional healthcare different from ordinary medical ethics is not the reasoning process, but the context in which the balancing of ethical principles takes place. The obligation of a physician is not to balance the interests of a patient against the interests of the correctional system; rather, the principles of beneficence and nonmaleficence require a physician to consider what constitutes a good outcome for a patient, and also the possible outcomes that can be expected in the prison context, compared to the possible outcomes outside prison.

We will illustrate the difference between the approach of the ACP and a European approach, using the example of conflicts that healthcare personnel face regarding confidentiality as a result of interaction with third parties, such as the justice system and prison security personnel. Nonmedical personnel do not need to have access to confidential information to ensure security. Imagine a detainee who suffers from an acute medical condition that requires immediate transfer to an outside hospital. In U.S. prisons it is not rare that wardens must be informed about a detainee's medical condition before they will approve transport to the hospital. However, from a classical view of medical ethics, the principles of beneficence and nonmaleficence require that a physician decide to transfer on the grounds of medical necessity alone, and obtain the consent of the detainee before any information is divulged. Within the framework of the guidelines of the Council of Europe, the responsibility of the warden is to organize the transfer of the patient and assure security. Thus, a warden needs to be told only what is necessary for the medical transfer: *Will it require an ambulance or can another transportation modality be used? To which hospital should the detainee be transferred? Should accompanying personnel wear a mask to protect them from contracting a contagious respiratory disease?* There is no need to reveal a diagnosis for security reasons. Ethical principles require a physician to inform a warden that he or she is bound by medical confidentiality.

In Switzerland the confidentiality requirement is part of criminal law. If a physician breaches medical confidentiality without a valid reason, he or she risks prosecution, as well as the loss of his or her authorization to practice. Healthcare workers who transmit medical information to a warden in this situation will not only be sanctioned by the medical institution for which they work, they will also be subject to federal law if the detainee engages in a lawsuit.

We recommend, in the case of a non-urgent conflict with a warden, that a physician inform the medical hierarchy, which will then discuss

the matter with the warden. In an urgent case, should a warden refuse a transfer, requiring that he or she be given medical information that she or he does not have the right to know, a physician should explain his or her obligations to the warden, including an immediate report to the medical hierarchy, and that the medical institution will inform the warden's hierarchy about the incident and its medical consequences for the detainee.

Within the European human rights framework that regulates healthcare for detainees, the statement by the ACP that the right to confidentiality "is not violated by the reporting of medical findings in the ordinary course of prison medical care operations or probably even to prison and jail executives with a reason to know,"[90] is not acceptable unless, based on the same laws and guidelines that apply outside prison, an immediate danger to an identified person exists that can only be prevented by breaching confidentiality.

In addition, reporting suicidal ideation to non-health personnel, as discussed by the APA,[91] would not be justified within the approach recommended by the Council of Europe. Strip-searching and segregating inmates who report thoughts or attempts at self-harm would not be acceptable; instead, based on the probability of self-harm, inmates would be transferred to an in-patient psychiatric unit without any need to breach confidentiality. If the probability of self-harm is sufficiently low to justify allowing the prisoner to stay in the correctional institution, the prisoner should be asked whether security personnel may be informed that the prisoner is suicidal, the aim being to increase the vigilance of non-health personnel to meet the health needs of detainees.

CONCLUSIONS

The framework of medical ethics in correctional healthcare is outlined in international declarations. In contrast to ethical guidelines and legal regulation in the U.S., the U.N., the Council of Europe, and the WMA state unanimously that medical ethics in correctional healthcare should follow the same principles as those followed outside correctional institutions. U.S. professional organizations should make statements that are more clearly in line with international frameworks not only concerning issues of recent intensive media coverage, such as physicians' participation in torture and executions, but also access to healthcare and confidentiality. Ethical principles should be weighed in correctional healthcare using the same criteria used outside correctional institutions, taking into account the harm-benefit ratios related to the specific context as well as specific risks to decisional autonomy. The evaluation standard for the medical care of detainee patients should be: *How would I treat a patient who is not incarcerated?* Unless the situation involves immediate danger to an identified person that cannot otherwise be prevented, breaches of confidentiality and paternalism cannot be justified — the same standard used outside prisons. To remedy this disparity, efforts should be made to address the pressures created by the prison context during medical consultations, and to search for practical solutions to change or circumvent these factors.

Dual loyalty conflicts related to confidentiality should be evaluated using the same high threshold criteria as for patients at liberty; for example, confidentiality can be overridden to prevent serious, imminent harm to an identified person when it cannot be prevented in any other than by breaching confidentiality.

It should be noted that we report here basically on guidelines. A large gap may exist between what is expressed in guidelines and clinical reality. Numerous web sites and books written by former prisoners report a substantial number of ethical problems in correctional healthcare, and not only in the U.S. In spite of adequate ethical and legal standards, in Europe, the published reports of the CPT, as well as cases brought before the European Court of Human Rights, provide evidence of unmet ethical standards in many European countries. A clear need exists for empirical studies that address ethical problems and standards in correctional healthcare; these will help identify the issues and situations in which education and changes are urgently needed, and will provide the evidence needed to capture the attention of policy makers and the population at large to put the needed changes in practice.

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When Prisoners Are Patients

Sharon Douglas and Susan Dorr Goold

In "Medical Ethics in Correctional Healthcare,"[1] presenting and contrasting recommendations from professional organizations in and outside the U.S., with the goal to describe "the foundations of medical ethics in correctional healthcare," Bernice Elger begins with Hippocrates: "I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."[2] This same standard is affirmed by the American Medical Association (AMA) in its *Code of Medical Ethics*, as it states that the patient-physician relationship "gives rise to physicians' ethical obligation to place patients' welfare above their own self-interest and above obligations to other groups. . . ."[3]

Indeed, the AMA "Principles of Medical Ethics" also includes the physician's duty to provide "competent medical care," the physician's "respect for human dignity and rights," the physician's safeguarding "patient confidences and privacy," the physician's "responsibility to the patient as paramount," and the physician's supporting "access to care for all people."[4] Sections of the *Code of Medical Ethics* prohibit any physicians' involvement in executions, interrogations, or torture.[5] Outside the *Code of Medical Ethics*, AMA House of Delegates policy H-430.988, "Prevention and Control of HIV/AIDS and Tuberculosis in Correctional Facilities," clearly states that standards of care, consent, and confidentiality should be equivalent within and without of correctional facilities.[6] This philosophy is consistent with that of the World Medical Association (WMA),[7] and forms the ethical foundation for the patient-physician relationship, whether this relationship exists inside a correctional facility (or any place of detention), in a rural practice area, managed-care setting, academic center, government facility, or a free clinic.

It is thus surprising that Elger neither quotes nor cites the AMA *Code of Medical Ethics* in her article. Instead the author discusses ethical guidelines from the American College of Physicians, the American Psychiatric Association, the National Commission on Correctional Health Care,

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the British Medical Association, the WMA, and the Council of Europe. Other countries' codes, guidelines, and laws are nowhere to be found. Yet the ethics of treating prisoners has been commented upon in other countries,[8] to say nothing of the treatment of detainees and prisoners during World War II in Germany or during apartheid in South Africa. U.S. guidelines (as described by Elger) and practice are contrasted with "international" standards (although only the WMA codes could rightly be painted with those colors) and, not surprisingly, U.S. guidelines and practice are found to be inferior. Unfortunately, practices in other countries — even those in Europe — are not similarly examined.

In Elger's article, the spotty treatment of other countries, and the focus on criticizing the U.S. system (for there is no question that the U.S. system of incarceration disproportionately affects the poor, the mentally ill, the addicted, and minorities), detracts from what could otherwise be an important updating of the ethics of caring for prisoners. Other than the topics of capital punishment, torture, and psychiatric care (for psychiatrists have long recognized the problems of dual loyalty, confidentiality, and consent that pose special challenges for the incarcerated), correctional healthcare ethics has received little attention. We hope that Elger's article will inspire others, as it has us, to turn their attention to this important subset of patients.

In her article, Elger advocates the principle of equivalence of care proposed by the *European Committee for Prevention of Torture and Inhumane or Degrading Treatment,* applying it to issues of consent, confidentiality, and access, and this commentary will discuss these further.[9] Elger also briefly discusses physicians' participation in interrogation, physicians' participation in execution, and physicians' attitudes towards abuse and torture of inmates, which we will also address in this commentary. In conclusion, we will argue for American physicians' responsibility to treat all patients competently and humanely, including those in correctional facilities or detention. We will also argue that physicians should advocate, when needed, for consistent treatment, report deficiencies in standards of care, and promote medical education on appropriate treatment of patients in all settings.

Engaging autonomous patients in informed consent for medical care is ethically and legally required of physicians.[10] The practice of consent demonstrates respect for the patient's right to self-determination, and requires accurate medical facts and skilled communication of recommendations relative to treatments.[11] The patient is able to ask questions and the physician must be sure to discuss the nature of the condition, the objectives of treatment, any alternatives to treatment, possible outcomes, and the risks involved with proposed treatments.[12] However, even with the great value placed on patients' rights to informed consent to treatment in the U.S., respect for individual autonomy may be outweighed by other obligations to that patient or by other considerations, including the good of society. An inmate being treated for active tuberculosis who does not want such treatment, for instance, could be required to continue treatment, and this practice would be equivalent to what often happens outside correctional facilities. In another example, the World Health Organization vaccinated some individuals against their will in the campaign to eliminate smallpox, justifying that practice by appealing to the health of the public (although not without criticism).[13]

Correctional facilities that entail forced confinement of a population in close quarters inherently present a greater than average share of tensions between individual liberty and public health. Add a population *defined* by the loss of liberty in most domains of their daily lives, and it is not difficult to see how respect for autonomy could be threatened. Medical personnel need to critically consider exceptions to ethical standards (such as consent), and be especially sensitive to the influence that a context of restricted liberties, even a culture of "penal harm"[14] might have on such judgments (by the patient, physicians, or others).[15]

Similar to consent, confidentiality is a fundamental tenet of medicine but it is not absolute.[16] A patient should be able to disclose information to a physician knowing that the physician will respect the confidentiality of such information. The physician should not divulge confidential information without a patient's consent unless overriding ethical considerations justify exceptions. Overriding considerations should be rare, and in such cases the patient should generally be

notified and the minimal amount of information should be disclosed. The AMA, in its *Code of Medical Ethics*, states that physicians should advocate for protection of patients' confidential information and at times work toward changes in policy or law when needed.[17] Elger holds as a standard the risk of harm to identifiable others, while she discusses the "security concerns" in a correctional facility. Yet threats of violence or suicide *should* receive serious consideration, given the prevalence of mental illness (and violence) in prisons, and protection of the patient and fellow inmates may, if no alternatives exist, require breaching confidentiality.

According to the *Code of Medical Ethics* of the AMA, access to care includes "a basic right to have available adequate health care" as well as a right to continuity of care.[18] This concept applies to all patients, including prisoners. "Principle IX" of the AMA *Code of Medical Ethics,* "A physician shall support access to medical care for all people," speaks for itself.[19]

Elger points out that the American College of Physicians (ACP), in its "Ethics Manual," characterizes correctional systems as having "limited access to health care." She alludes to, but does not use, as a test of "equivalency" the (shameful) fact that some prisoners might have even worse access to care outside prison than they do while incarcerated.

While limited access to healthcare should never affect the ethics of the patient-physician relationship, it can certainly affect how a patient responds to a standard-of-care recommendation made by a physician: according to a recent report by the Commonwealth Fund, more than one-third (37 percent) of all U.S. adults reported going without needed care because of costs in 2007.[20]

We agree with the ACP that "physicians should advocate for timely treatment and make independent medical judgments about what constitutes appropriate care for individual inmates." Such advocacy will indeed vary with the circumstances. It may be as simple as providing a patient with contact information for a source of help, or as involved as multiple phone calls and letters or leadership in a community or organization to ensure access for vulnerable populations — again, including, but not limited to, prisoners. We would be hard-pressed to identify what specific behaviors would constitute sufficiently ethical advocacy, as might be suggested by Elger.

The AMA, like the ACP, proscribes physicians' participation in capital punishment, interrogation, and torture.[21] As stated in an AMA opinion on participation in interrogation, "physicians who engage in an activity that relies on their medical knowledge and skills must continue to uphold principles of medical ethics."[22] These very clear American ethical guidelines for physicians provide solid justification for doctors and medical organizations to refuse to participate in state-ordered executions and can provide military physicians with a similarly strong set of ethical guidelines.

All physicians should support ethics education relative to the patient-physician relationship, and the challenges and complexities of various settings, including correctional facilities. We agree with Elger that insufficient attention is paid to this marginalized, vulnerable population. Such education should start in medical school and should be available as continuing education for all physicians. As Elger notes, the WMA has developed a web-based course for healthcare personnel working in prisons, which should be applauded.

Codes and guidelines for physicians (and other medical personnel) are important to "get right," but not nearly as important as ethical practice. Unfortunately we know very little about correctional healthcare ethics in practice, in the U.S. or elsewhere. A few studies[23] paint a dim picture, and, as would be true in any practice setting, physicians have ethical obligations to report unethical colleagues, as stated in AMA policy H-275.952, "Reporting Impaired, Incompetent or Unethical Colleagues."[24] In its *Code of Medical Ethics,* "Principle II," the AMA also makes clear physicians' duty to expose physicians who are deficient in character.[25] The AMA and state licensing boards, for their part, should continue to sanction members who do not follow ethical guidelines. Physicians also have the responsibility, individually and through organizations such as the AMA, "to seek changes in those [legal] requirements which are contrary to the best interests of the patient."[26]

In conclusion, we applaud Elger for bringing attention to a too often neglected domain of ethics for healthcare professionals. The ethical obli-

gation to provide "equivalent" treatment, when applied to *any* vulnerable population, confronts challenges of limited resources, conflicts with the rights and interests of others, and exists in a context of restricted liberties and rights. Physicians working in such settings, like physicians working with the homeless or with refugees, must be especially vigilant to ensure that they remain "dedicated to providing competent medical care, with compassion and respect for human dignity and rights," "regard responsibility to the patient as paramount,"[27] and be mindful that "health and human rights are interrelated."[28]

NOTES

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Commentary on Elger's "Medical Ethics in Correctional Healthcare"

Robert W. Keisling

I agree with Bernice Elger that the same standards should apply in U.S. jails and prisons as are currently in place in Europe.[1] Unfortunately, we have the little problem of 48 million uninsured people in the U.S.[2] The fact of the matter is that many people now get better healthcare in jails than in the community.

The U.S. Department of Justice now estimates that 64 percent of the inmates in jails are mentally ill.[3] Many of these people are homeless. They are dying 20 years sooner than the general population. Studies report that the vast majority of inmates released from jails and prisons do not get care upon release.[4]

Some mentally ill persons have never received treatment outside of a jail. Jails and prisons have replaced the state mental hospitals of yesteryear.

So while Europeans wish for people to receive the same care in jails as they do in the community, it might be better for the reverse to be the case in the U.S. We have invested billions of dollars in providing health and mental healthcare in jails and prisons.[5] Courts have found that inmates have a constitutional right to this care.[6] No such rights exist in the community.

Therefore, many mentally ill persons are cycling in and out of jail and prisons due to the sad state of the health and mental health system in the U.S. Many people cannot afford their medications. Public mental health clinics have waiting lists. Many times, police officers will encourage family members to press charges against their relatives so they can get care. There is universal coverage on the inside, but not on the outside.

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NOTES

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Commentary on Elger's "Medical Ethics in Correctional Healthcare"

Joel A. Dvoskin

Bernice Elger has written a proposal for the ethical requirements, aimed largely at healthcare professionals in the United States, that she would apply to jails and prisons.[1] For the most part, Elger's suggestions are already well entrenched in various ethical codes, including one of which she is apparently unaware; that is, that of the Society for Correctional Physicians. The exception, her proposed principal of "equivalence," was considered and rejected by the American Psychiatric Association,[2] for reasons that are discussed below and in the commentary on Elger by Robert Kiesling, also in this issue of *JCE*,[3] because it could have meant a diminution in the care to which some inmates and detainees are entitled.

One important underlying premise of Elger's ethical proposals is a restatement and reification of an inaccurate myth; specifically, her allegation that "the requirements of security and the need for healthcare services conflict" could not be more wrong. It is not surprising that she has made this error, as her source for this claim, an analysis of military tribunals at Guantanamo Bay, has virtually nothing in common with American jails and prisons.[4]

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In contrast to the "security versus treatment" myth, it has been my consistent experience that correctional staff and officials are often vocal advocates for adequate health and mental healthcare, and the most strident critics when such care is not provided. In my own work as an expert witness for plaintiffs and defendants in conditions of confinement class actions, the data upon which findings of unconstitutional conditions are made were often provided by custody staff. This is not to suggest that all corrections staff and officials are equally strong advocates for treatment. However, the generalization that they are not is unsupported by data or experience.

Elger's allegation that security concerns trump the medical needs of captives is unsupported by any data whatsoever. She fails to give a single example of a physician who was prevented from providing care due to custody or security concerns. This is not to say that care is always adequate; often it is not. However, the reasons for inadequate care in jails and prisons are generally the same as the reasons for inadequate care in the free world, and those reasons almost always start with a lack of money. In order to meet miserly public budgets, managers of care in corrections, just like managers of care in the community, are forced to make difficult choices about how to spend money. In response, they may limit formularies, and both groups have difficulty paying high

enough salaries to recruit enough competent doctors and nurses.

The notion that security and treatment are not complementary is best refuted with several simple case examples. Suppose that an inmate receives six months of outstanding psychological treatment for post-traumatic stress disorder (PTSD), and a week later is raped by his cell mate. Does Elger really believe that prevention of the rape would be less beneficial to the inmate than provision of therapy? What she may not understand is that security means prevention of violence within the jail or prison, and, without it, inmates are the first to suffer. Equally important, safe jails and prisons are more likely to be able to retain competent healthcare professionals, who seldom want to work where they feel endangered. Simply put, not only can security and treatment coexist, they are interdependent.

Elger cites three overarching principals of adequate medical care; (1) access to treatment, (2) consent of prisoner patients, and (3) confidentiality. As noted elsewhere in this commentary, access to treatment is limited in a variety of healthcare settings in the U.S., especially those that serve communities of poverty and color, and this is especially problematic for the "working poor" who may be ineligible for Medicaid. Consent requirements in correctional settings tend to be similar to those in the free world; indeed, Elger cites no exceptions. The third criterion, confidentiality, is closely tied to clinical independence, and each has similar correctional exceptions.

To be sure, Elger is right when she calls for clinical independence for careproviders, but she is wrong when she alleges, without evidence, that such independence does not commonly exist in U.S. correctional facilities. In my experience, there are several circumstances in which confidentiality is violated and when medical decisions may be influenced by custodial concerns: (1) when the patient poses or expresses a risk of harm to self, (2) when the patient poses or expresses a risk of harm to others, (3) when the patient poses or expresses a risk of escape or disrupting the order of the institution.

Interestingly, the first two exceptions, danger to self and others, are applied as a matter of law and ethics in virtually all healthcare settings, in and out of corrections. In regard to mental healthcare, these are usually affirmative legal duties. The third, escape and institutional disorder, seems a fair subject for debate. Certainly, the concept of escape has little relevance without some form of captivity, and this would not apply to the community. Unfortunately, Elger does not tell us whether she would agree to violate confidentiality in the face of a planned escape attempt, but I am happy to argue that she should. Escaping prisoners pose *and* face great dangers, not the least of which is being shot when recaptured. Further, allowing them to escape has nothing whatsoever to do with their medical care. Similarly, any effort to disrupt the prison order, for example, by inciting a riot, poses great risk to everyone who lives and works in jails or prison.

Other than these exceptions, Elger provides no evidence to suggest that the ethical standards for medical and mental health confidentiality in jails and prisons are inferior to those in the free community. The notion of "security versus treatment" is frequently cited, almost always (as in this case) without any evidence to support it. While correctional staff are undoubtedly not immune to bias and stigma, in my experience they are often advocates for better treatment, especially for inmates with serious mental illnesses. In my experience, they often proclaim that jails and prisons are ill-suited for the treatment of persons with serious illnesses, and readily admit that their training for these tasks is inadequate.

There are other reasons for correctional advocacy of better healthcare for inmates. Put bluntly, inmates who receive inadequate care complain a lot, and they tend to be harder to get along with. Further, when inmates are sick and untreated for communicable diseases, the environment becomes dangerous for everyone who lives and works there, and for the communities in which staff members live and to which inmates will eventually return.

As noted above, using the word "security" in a pejorative manner is misleading. Security is not synonymous with punishment or mean-spirited treatment. To the contrary, security should be most synonymous with safety. When correction officers keep correctional facilities "under control," they are doing the inmates a favor. Correctional facilities that are inadequately controlled are even more dangerous for inmates than for staff.

Elger makes much of the fact that access to care in jails and prisons is limited. However, this

is not a criticism of American corrections, but of the American healthcare system. Care in the U.S. is limited for everyone, inmates and citizens alike, almost always by economics. The notion that inmates, if only they were not incarcerated, would be "free" to choose their health insurance, is yet another inaccurate assertion. It implies that healthcare is affordable for everyone; and clearly it is not. Ironically, the same communities from which many inmates hail are exactly the same communities in which adequate healthcare is unavailable.

As Robert Keisling notes, healthcare in prisons should not aspire to community equivalence, because, for many inmates raised in communities or poverty and color, the healthcare they receive in prison may be the best care they have ever received. This is not surprising in a country in which healthcare is not a right, but a privilege. In contrast to the community, American correctional facilities have an affirmative constitutional duty to provide healthcare, including psychiatric care, when there is a serious need.[5] The court in *Estelle v. Gamble* wisely declined equivalence as its standard, opting instead for need.

Consider the huge disparity between affluent communities and the communities from which the majority of inmates were raised. An "equivalence" standard would require more and better healthcare in rich communities than poor. A "need" standard, in contrast, places the constitutional "floor" of care at the same level for every community and every inmate.

Elger seems to implicitly understand the superiority of a needs-based ethical standard, when her argument moves from "equivalence" to inadequacy: "Inadequate medical care is considered inhumane treatment."[6] Unfortunately, she moves from there back to equivalence and (oddly) freedom from torture, thus conflating three very different ethical principles, each of which is deserving of disaggregation and careful discussion.

Elger seems offended by the concept that a whole prison might have healthcare needs, needs that might conflict with the wishes of a particular inmate. In response, I would cite the concept of public health. Medical and confidentiality decisions regarding *one* inmate might indeed conflict with public health decisions that serve the medical needs of *all* of the inmates, but this conflict is no less ethical than a decision to preclude someone with a serious, airborne infectious disease from coming to school.

Elger makes a much stronger point, and one that is deserving of serious consideration, when she calls for a right to preventive treatment. In U.S. jails and prisons, a right to treatment is occasioned by an existing "serious medical need," which would seem to preclude preventive care as a constitutional duty. Since money is always scarce and constitutional mandates always come first, it is not surprising to find that few resources are left over for preventive care.

However, Elger's suggestion is a good one, not only for its altruistic motives, but as a matter of public policy. Again pointing to a public health perspective, some diseases (for example, multiple-drug resistant Staphylococcus aureus — MRSA) can only be effectively treated by primary prevention. Finally, prevention of the most serious illnesses can save a great deal of very expensive tertiary care, thus making more medical care available for more people at the same cost.

Despite the considerable efforts of an active and competent plaintiff bar, armed with ethical standards and constitutional mandates, and coupled with advocacy from correctional administrators, it remains sadly true that correctional healthcare in America remains in great need of improvement. But to attribute these deficiencies to ethical shortcomings among American corrections and healthcare professionals is inaccurate and unfair. By far, the most important reason for inadequate healthcare in jails and prisons is the same reason that our healthcare system inadequately attends to adults and children who live in poverty: so far at least, Americans simply refuse to pay for it.

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NOTES

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Physicians, Mass Incarceration, and Medical Ethics

Scott A. Allen

Thousands of physicians work in United States prisons where ethical dilemmas are numerous. At the same time, ethics training for U.S. medical physicians is typically meager. A recent well-publicized survey of U.S. medical students found that fully one-third of the 1,756 that responded to the survey could not state when they would be required to disobey an unethical order. Further, 37 percent did not know that the Geneva Conventions prohibit ever threatening or demeaning prisoners or depriving them of food or water.[1] In an era of mass incarceration, a phenomenon made possible in part by the support of medical professionals, the need for a vigorous discussion of the ethical roles of physicians in prisons is pressing. Yet a review of the medical literature yields very few articles discussing the general ethics for health professionals working in correctional settings. In this issue of *The Journal of Clinical Ethics,* Bernice Elger makes a timely and important contribution with a review and discussion of the issue of medical ethics in correctional healthcare with reference to both U.S and international guidelines.[2]

The fundamental ethical dilemma in correctional medicine is established because physicians are ethically bound to act first in the interest of their patient while the institution engaging the physician's services often acts first in the interest of the state, and often against the interests of the patient. The physician's competing obligation to the patient and the institution can be described by the term *dual loyalty,* a "conflict between professional duties to a patient and obligations, express or implied, real or perceived, to the interests of a third party such as an employer, an insurer or the state."[3] Dual loyalty is an ethical conflict shared by physicians working in other settings including the military, occupational medicine, and even managed care. While the concept of dual loyalty is helpful in describing the inherent conflict that correctional physicians confront, it does not establish ethical parity of the competing loyalties. Even in the face of compelling competing values, the physician's primary loyalty remains to the patient. As cited by Elger in her review, the United Nations' *Principles of Medical Ethics relevant to the Role of Health Personnel*

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states that physicians have a duty to protect health and treat disease using the same standards applied in the community, and there may be no derogation from this obligation on any grounds "including public emergency."[4] *The World Medical Association Declaration of Tokyo* states, "The physician's fundamental role is to alleviate the distress of his or her fellow human beings, and no motive, whether personal, collective or political, shall prevail against this higher purpose."[5]

To many, the role of physicians in jails and prisons appears to be incidental. Individuals are detained; they have health needs, so the custodial institution seeks the services of physicians to address those needs. But the role of physicians in the establishment of correctional institutions is fundamental. Both legally and ethically, a prison or jail cannot exist without the support of physicians. In 1976 the United States Supreme Court ruled in *Estelle v. Gamble* that the failure to provide access to medical services is a violation of the Eighth Amendment's prohibition on cruel and unusual punishments.[6] At the same time, physicians who work in jails and prisons are often inattentive or unaware of the effect their presence has in conferring legitimacy to the correctional institution. As a profession, medicine has not adequately confronted or debated the role the healing profession has had in the support and development of mass incarceration in the U.S.

The United States has undertaken an expansive and unprecedented social experiment with a program of mass incarceration. During the past 20 years, the prison population in the United States has grown to more than 2.3 million, roughly 1 percent of the population, a remarkable accomplishment for a country founded on the principles of liberty.[7] No other country incarcerates anywhere near as large a percentage of their population.[8] The long-term effects of mass incarceration on the health of the incarcerated individuals, their families, and their communities are not yet fully known.

The ethical conflicts created by physicians' engagement in this system of mass incarceration in general are further complicated because mass incarceration has taken a punitive approach to medical illness. Addiction and mental illness are medical conditions. In combination, these two conditions affect the vast majority of inmates in U.S. jails and prisons.[9] However, access to adequate medical treatment for these conditions is often deficient or lacking in U.S. prisons.[10] Treatment for mental illness and addiction are often afterthoughts to the institutional mission, if they are addressed on an institutional level at all. The mass incarceration of the mentally ill and those suffering from addiction also represent a failure by the community. When criminal activity is a potential consequence of inadequately treated addiction and/or mental illness, the prison becomes the unintended consequence of an inadequate healthcare system. Should physicians be content with the status quo?

The American College of Physicians ethical code states, "Under no circumstances is it ethical for a physician to be used as an instrument of government to weaken the physical or mental resistance of a human being, nor should a physician participate in or tolerate cruel or unusual punishment or disciplinary activities beyond those permitted by the United Nations Standard Minimum Rules. . . ."[11] The phrase "to weaken the physical or mental resistance" in this guideline is likely meant to address the participation of physicians in interrogations, and in any event applies to the conduct of individual physicians. Yet it suggests the question: Should medicine, as a profession, silently and blindly support institutions such as prisons that, in their present form, may do more to weaken the physical and mental constitution of prisoners than they do to promote their health and well-being?

Prisons are not always inhospitable to the promotion of health. The relative stability of the prison setting, in combination with access to quality healthcare services may provide a window of opportunity to intervene in the treatment of illness that has proven difficult to manage or that has been neglected due to lack of healthcare coverage in community settings. The relative enforcement of sobriety may provide a window of opportunity for the engagement in addiction treatment. In reality, however, the opportunity to use the period of confinement as an opportunity to address chronic health needs is often not seen as a priority of correctional institutions, as it is not part of their stated mission, and perhaps more importantly, not a budgeted priority.

Beyond the lost opportunity to address unmet health needs is the simple fact that the modern U.S. prison is not the result of a thoughtful

evidence-based process designed to rehabilitate convicted criminals by means of effective programming aimed at reform and restoration of the prisoner as a person and as a member of society. The idea of reform of prisoners is all but dead in the United States. Prisons in the U.S., rather, are the result of a political process that has marginalized thoughtful discussion of potential solutions in favor of politically expedient remedies such as tough drug sentencing laws and rigid sentencing guidelines. Despite the enormous financial and human costs of mass incarceration, until recently few have asked: just what the tax paying public is getting for the money? At the same time, few physicians have asked about the health impact of prisons on the prisoners themselves, their families, and their communities. Conditions of confinement in many cases can be quite detrimental to the health and well-being of inmates. Elger cites disturbing statistics on rape and coercive sex. Use of prolonged isolation with the advent of so-called "super-max" facilities has expanded, despite consistent evidence that prolonged isolation is harmful to the mental health of prisoners, and may even constitute torture.[12]

As a result of high costs and poor outcomes, there is growing interest among public policy makers in considering alternatives to mass incarceration. Sorting out "best practices" from ineffective ones will require expertise, data, and ongoing study. Yet, ironically, research in prison settings is logistically difficult owing to strong human subjects protections that were established in reaction to past excesses and abuses. Still, humane study protocols with ample human subject protections aimed at helping to address specific problems of the prison population and affected communities are feasible, and should be a public priority.

Physicians also cannot ignore the fact that incarceration disproportionately affects communities of color and individuals who are socioeconomically disadvantaged.[13] It is worth noting that these communities are the same groups who are under served by the healthcare system as a whole.[14]

Inside the prison there is the issue of the standard of medical care. Elger links the "principle of equivalence" — the idea that prison health standards should not differ from those of the community — with the idea of "justice." In her discussion about the guidelines issued by the NCCH (National Commission on Correctional Healthcare) for asthma, Elger points out that these special guidelines, adapted from the widely accepted community standard, unavoidably create a separate and unequal medical standard for prisoners. The NCCH cited the logistical challenges of providing care in prisons as the justification for a modified standard. A similar discussion surrounded the development of the 2002 National Institutes of Health guidelines for the management of hepatitis C. Some participants at the consensus conference suggested that hepatitis C standards should not apply to prisoners, because correctional institutions might be overwhelmed by the challenge of implementing a community standard with limited financial and medical resources for a chronic disease that affects as many as one-third of the prison population. In the end, the NIH panel wisely rejected the plea for a separate but unequal standard, and instead called for more study on how the practical and logistical challenges of delivering hepatitis care in prisons could be addressed.[15] This is a more ethically sound approach. It is fair to acknowledge the challenges of meeting community standards in prisons, but the accepted community standard of treatment should not be compromised for prisoners.

Even with these profound ethical conflicts, physicians are duty bound to remain engaged with correctional institutions as long as they exist, because the widescale abandonment of patients is not a practical or morally acceptable option. However, physicians as individuals and as a profession need to reclaim leadership in the reform of sentencing laws that have led to the mass incarceration of their patients, and to advocate for improvements in the wider implementation of effective evidence-based treatments for medical illness, whether it be infectious diseases such as HIV, hepatitis, and TB, or mental illness or addiction, before during and after incarceration. In addition to supporting reforms, organized medicine should provide practical and clear guidelines for physicians who work in correctional settings, explicitly reaffirming the obligations of physicians to preserve and protect the health and human rights of their patients. Finally, health professionals who work in correctional settings must have legally enforceable professional independence and autonomy in both clinical management of their pa-

tients' medical conditions and in their efforts to protect their patients' basic health and human rights. Simply put, physicians must demand that the correctional institutions they support respect the human dignity of their patients. Further, as an ethical and public health matter, physicians must work to ensure that, at a minimum, the institutions they support do not undermine the physical and mental health of their patients.

NOTES

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Cruel and Unusual Punishment: Distinguishing Distributive and Retributive Justice

Felicia Cohn

The California prison healthcare system is currently in receivership of a size and scope unprecedented nationally. Attorneys representing California prisoners successfully brought two class action lawsuits against the state in 2001 demonstrating that the medical and mental healthcare in California's prisons are so inadequate that they violate the federal Constitution's Eighth Amendment ban on cruel and unusual punishment. *Plata v. Schwarzenegger*[1] addresses medical care and *Coleman v. Schwarzenegger*[2] focuses on mental healthcare. In establishing the receivership, U.S. District Court Judge Thelton E. Henderson wrote, "By all accounts, the California prison medical care system is broken beyond repair. The harm already done in this case to California's prison inmate population could not be more grave, and the threat of future injury and death is virtually guaranteed in the absence of drastic action."[3] At issue are billions of dollars to support the construction of thousands of new beds at existing prisons, re-entry centers, healthcare-related spaces, and local jails, for the 33-prison system.

To date the construction has not been completed — not even initiated. The state settled the suit in 2002 and agreed to a range of remedies that would bring prison medical care in line with constitutional standards. Failure to comply with the court's direction resulted in the establishment of a receivership. Judge Henderson wrote:

> The Court has given defendants (the State) every reasonable opportunity to bring its prison medical system up to constitutional standards, and it is beyond reasonable dispute that the State has failed. Indeed, it is an uncontested fact that, on average, an inmate in one of California's prisons needlessly dies every six to seven days due to constitutional deficiencies in the CDCR's [California Department of Corrections and Rehabilitation's] medical delivery system. It is clear to the Court that this unconscionable degree of suffering and death is sure to continue if the system is not dramatically overhauled.[4]

In August 2008, Federal Receiver J. Clark Kelso moved to seize $8 billion from the California Treasury for medical, mental health, and dental care by the end of the 2011-2012 fiscal year, and requested $2 million per day in fines for failure to fund the needed healthcare beds.

California, so often a leader on social issues, may once again be leading the way — although by court-ordered force — in providing substantive content to the prison healthcare standard established in *Estelle v. Gamble*.[5] The state, mired

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in a budget crisis with a deficit of $15 billion and extreme prison overcrowding, has not prioritized inmate healthcare. Certainly, this is understandable, if not justifiable, but must be considered against the larger backdrop. Even in times of budget surplus, prison healthcare has been under funded. This situation, indeed the bleak picture of prison healthcare nationally, suggests at least one fundamental ethical question: How do we define justice in healthcare?

In 1976 the U.S. Supreme Court issued its landmark ruling in *Estelle v. Gamble,* defining the basic constitutional standard of adequate prison healthcare. Justice Marshall wrote for the Court:

> Deliberate indifference to the serious medical needs of prisoners constitutes the unnecessary and wanton infliction of pain. . . . proscribed by the Eighth Amendment. This is true whether the indifference is manifested by prison doctors in their response to the prisoner's needs or by prison guards in intentionally denying or delaying access to medical care or intentionally interfering with treatment once proscribed.[6]

In effect, this decision grants prisoners a right to healthcare. Prisoners, unlike the majority of the American population, are guaranteed both access to healthcare and needed services. Subsequent court rulings and various healthcare organizations have defined inmates' right to healthcare, invoking a community standard or principle of equivalence,[7] that is, prison healthcare ought to mirror that which is available in the community. Such a standard reflects an international consensus on healthcare as a human right. Elger, in this issue of *The Journal of Clinical Ethics,* describes the ethical problems arising out of failure in the U.S. to embrace and operationalize such a standard in American prisons. She notes, "for a country such as the U.S., in which nearly 16 percent of the population does not have access to basic healthcare, applying the principle of equivalence is difficult, and might even be used to justify the absence of healthcare services for poor prisoners."[8] The obvious question: Why should inmates have a right to healthcare when even access to healthcare services has not yet risen to the level of a legal right for law-abiding American citizens? However, the question raised is backward, and its reversal suggests more promising directions for both clinical medicine and public health. Rather than asking why prisoners are guaranteed something the rest of us are not, we should question why all Americans do not have a right to healthcare.

Yet the focus continues to be prisoners' rights. In response to the California receiver's quest for adequate funds for prison healthcare, California Senator Jeff Denham (R-Atwater) said, "the idea of providing $8 billion for state-of-the-art healthcare for murderers like Charles Ng, Richard Allen Davis, and Scott Peterson is sheer lunacy."[9] The implication in these tight budget times is that prisoners do not deserve the healthcare that is constitutionally required, particularly when there are so many other competing needs. On the one hand, to fund prison healthcare when state programs for children, the disabled, the elderly, and other vulnerable populations are being cut or eliminated may be "sheer lunacy." On the other hand, the "lunacy" may be in Denham's response itself. The comment suggests that inmates do not deserve healthcare and appears to rely on a criterion of just desserts to frame a public policy issue. Should our status in society, or our contributions — positive or negative — determine whether we deserve healthcare services? A re-examination of definitions of justice at the societal level and their implications for policy development is needed.

When it comes to the American justice system, it is easy to confuse distributive and retributive justice. Retributive justice involves assessing wrongdoing to determine appropriate punishment. It may seem appropriate to punish the commission of a crime with a denial of healthcare. In committing and being convicted of a crime, one forfeits rights and access to societal goods. Among those goods, some might argue, is healthcare. This may seem especially appropriate for the violent offenders, those who take life or injure their victims. *Lex talionis* or "an eye for eye" thinking can be interpreted to mean that individuals who take life or cause injury deserve whatever ill effects they suffer while incarcerated for their crimes. One who causes harms should suffer harms. However, our criminal justice system has long rejected such a literal interpretation of punishment, preferring to withhold freedom in amounts commensurate with the crime (except for capital cases).

Other rights, both legal and human, are preserved. Further, some rights are reserved specifically for those determined to be criminal, such as the right to be free from cruel and unusual punishment. Inmates do have rights, and it is the responsibility of the justice system to assure maintenance of those rights, despite the limited freedom of imprisonment, and despite however heinous their crimes may be.

Even if retributive and distributive notions of justice are not confused, creating conditions in which prisoners cannot access necessary healthcare services is inappropriate and unfairly distributes healthcare resources. First, it defines distributive justice by merit, which in this situation essentially disguises retributive justice. Second, such a conception of justice is generally soundly rejected as unfair in American political philosophy, in public policy, and certainly in healthcare practice. While we have far from achieved anything close to egalitarianism in healthcare, the distribution of healthcare resources is most often guided by other criteria including need, likelihood of benefit, lottery, and even the ability to pay, rather than merit or societal contribution.[10] Third, any distributive scheme that purposefully leaves out a portion of the population ignores the effect of that population on the whole: "Because prisoners constantly come in contact with other prisoners, staff, guards, healthcare professionals, and the general public through visits, the rampant spread of communicable diseases throughout the nation's prisons affects society as a whole."[11] And inmates are released into the greater community without leaving their illnesses behind. If for no other reason then a utilitarian self-protection, it is imperative that inmates receive adequate healthcare. American prisons have become incubators for infections diseases such as HIV, hepatitis, and tuberculosis. In one survey of prisoners, 44 percent of state inmates and 39 percent of federal inmates reported a current medical problem other than a cold or virus.[12]

Elger suggests that "the actual ethical dilemma" is "the unethical conditions under which many physicians work in correctional institutions."[13] True, but this conceives of the problem narrowly. This is not just an issue for prison physicians. The prison healthcare dilemma represents a larger conflict facing American healthcare in sorting out ethical principles, policy requirements, and reality. Certainly physicians should embrace their ethical obligation to the principle of social justice, "to work actively to eliminate discrimination in healthcare, whether based on race, gender, socioeconomic status, ethnicity, religion, or any other social category."[14] However, without a clear definition or criteria for justice in healthcare that addresses both public policy requirements and realistic constraints, it is impossible to determine what ethical working conditions are and to what goal(s) healthcare professionals should work.

The World Health Organization has called for a right to health, defined as the right of all to enjoy the highest possible level of health.[15] This right of health suggests that all have access to the services needed to strive for the degree of health experienced by the most privileged group in society.[16] Equity in health or healthcare services may not be an achievable political standard, but the pursuit of equity should not get lost in prejudice and discrimination. The true test of a just society may well lie in how it treats those perceived to be its most undeserving. Imagine a society in which prisoners truly have a right to healthcare. We could then begin to lay claim to such a right for all. California, willingly or unwillingly, may lead efforts to define justice in healthcare for inmates, and ultimately for all Americans.

NOTES

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Medical Ethics and Competence for Execution

David M. Adams

Bernice Elger mounts a powerful critique of the ethical standards for delivering healthcare at most U.S. correctional facilities.[1] According to Elger, these standards are rooted in a basic proposition of *accommodation to penological interests*: balancing the rights of incarcerated patients to confidentiality or informed consent against the alleged needs of penal institutions to restrict or altogether eliminate such rights. Elger points up the bland and morally weak pronouncements of many U.S. professional organizations regarding the provision of care to prisoners, and rightly denounces the scandalous policy of "deliberate indifference."

In sharp contrast to the U.S. position is the stance of many European and international professional and judicial bodies, broadly endorsing a particular conception of justice — the *principle of equivalence of care* — as the proper basis for correctional medical ethics. According to equivalence, "no distinction is made between patients who are prisoners and those who are not"; "healthcare services that are provided inside and outside correctional institutions should not differ." In short, the standards of ethical practice of medicine should be blind to the patient's correctional status. Elger summarizes her thesis this way:

> The obligation of a physician is not to balance the interests of a patient against the interests of the correctional system; rather, the principles of beneficence and nonmaleficence require a physician to consider what constitutes a good outcome for a patient, and also the possible outcomes that can be expected in the prison context, compared to the possible outcomes outside prison.

And, I would suggest, where a correctional procedure has no comparable outcome outside the prison, a corollary of the principle of equivalence says that such a procedure should immediately be suspect as a product of accommodation. While I agree with Elger that violations of equivalence are the most salient moral errors committed in correctional medicine, I am somewhat less certain that the way to rectify such mistakes is always clear. I briefly mention here one puzzling area of correctional practice where this is apparent: the treatment of death-row inmates, and more particularly still, the requirement that condemned prisoners be "competent" to die before they can be killed.

As Elger indicates, the World Medical Association, the American Medical Association, and other bodies forbid physicians' involvement in executions. Can such a ban be grounded in the principle of equivalence? This is difficult to say. After all, the obvious medical procedures typically called for in an execution — prescribing or ad-

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ministering medications, selecting injection sites, placing intravenous (IV) lines, monitoring vital signs, pronouncing death — are in some sense the precise equivalent of procedures routinely and appropriately afforded persons outside prison walls. Thus, an argument could be made that physicians' involvement in executions calls in this way for equivalent treatment of the incarcerated and the non-incarcerated alike. Of course, the problem is here disguised by the phrase "in some sense": for in the death-chamber, these actions are in the service of directly causing death, and for most physicians that makes all the difference.

Still, there are some points at least worth considering on the side of the "equivalence" argument. As the briefs submitted to the U.S. Supreme Court in the recent lethal injection case revealed,[2] evidence continues to accumulate that the process of lethal injection in U.S. prisons is intolerably marred by botched procedures and incompetent personnel: repeatedly clumsy and painful efforts to obtain venous access, IV infiltrations, inadequate assessment of sedation levels by untrained personnel, and incompetent monitoring of vital signs. If the principle of beneficence requires an equivalent concern for the physical and mental pain and suffering of a condemned prisoner as for a non-incarcerated patient undergoing treatment, then shouldn't healthcare professionals participate even in executions (albeit reluctantly) precisely in order to ameliorate such suffering?[3] (It is worth noting that the AMA policy E-2.06 "Capitol Punishment" permits physicians to provide the condemned with "tranquilizers" to relieve the anticipatory dread of impending execution.[4])

Equally perplexing questions arise about the determination of "competence" to die. Under the Court's decision in *Ford v. Wainright*,[5] a condemned inmate may not be put to death if he fails to comprehend that he is scheduled to die and the reasons for his execution. The "competence-for-execution" (CFE) requirement generates wrenching dilemmas, both for prisoners and for healthcare professionals.[6] While the AMA enjoins what amount to direct forms of physicians' participation in the death-chamber, its policy on capital punishment reasons that "testifying as to medical diagnoses as they relate to the legal assessment of competence for execution" is not forbidden.[7] In a brief submitted in the *Panetti* case, the American Psychiatric Association saw no problems with such evaluations, confidently asserting that "mental health professionals can reliably identify the nature and extent of an individual's rational understanding of an impending execution," and calling this an "uncontroversial aspect of forensic mental health assessment."[8]

Testimony and assessments about competence to die are suspect forms of involvement in execution, according to the corollary of equivalence: for they cannot be performed in a way that is independent of penological considerations — there is no analogue to such procedures outside the penitentiary. Healthcare professionals routinely assess competence, of course — most commonly, the competence or capacity to consent for treatment. Competence-for-execution has nothing to do with decision-making capacity, however, since there is nothing for the condemned to decide. CFE is about awareness of facts pertaining to one's death. That this is so is clear from the key measures mental health professionals use to assess it. Condemned inmates are asked to relate their "beliefs about what it actually means to receive a sentence of death. . . about what it would mean for him/her to be dead . . . about transformations or changes that will happen to him/her after execution." The prisoner is prompted to explain the "procedure for execution that he/she will undergo: what happens, how it works," and is pressed to say "why s/he should be executed."[9] There is no conceivable medical need to elicit answers to such questions from anyone outside death-row. Therefore, physicians and other health professionals who evaluate an inmate's readiness to die are performing a task inextricably connected with — and in furtherance of — an exclusively penological objective; namely, to kill. This is a violation of nonmaleficence.

Yet what if physicians refuse to participate in such assessments of competence? Will these evaluations then be conducted by unqualified personnel — or worse, by correctional officials themselves, producing a patent conflict of interest? Once more, a satisfying solution is elusive. Short of abandoning CFE altogether,[10] courts, correctional officials, and medical ethicists will continue to grapple with this and the many other issues Elger has so thoroughly canvassed.

NOTES

1. B. Elger, "Medical Ethics in Correctional Healthcare: An International Comparison of Guidelines," in this issue of *JCE*.

2. *Baze, et al. v. Rees* (07-5439) (2007), *http://www.supremecourtus.gov/opinions/07pdf/07-5439.pdf,* accessed 25 August 2008.

3. Some physicians who do participate in capital punishment appear motivated by just these concerns. See A. Gawande, "When Law and Ethics Collide — Why Physicians Participate in Executions," *New England Journal of Medicine* 354, no. 12 (2006): 1221-9.

4. American Medical Association policy E-2.06, "Capital Punishment," *Code of Medical Ethics*, 2008-2009 ed. (Chicago: AMA, 2008), available at *www.ama-assn.org/ama1/pub/upload/mm/369/e206capital punish.pdf,* accessed 2 September 2008.

5. *Ford v. Wainwright* 477 U.S. 399 (1986).

6. See J. Spring, "Singleton's Story: Choosing Between Psychosis and Execution," *Hastings Center Report* 35, no. 3 (2005): 30-3.

7. See note 4 above.

8. *Brief for* Amici Curiae *American Psychological Association, American Psychiatric Association, and National Alliance on Mental Illness in Support of Petitioner*, *Baze, et al., v. Rees* (07-4539) (2007), p. 22, *http://www.psych.org/MainMenu/EducationCareerDevelopment/Library/AmicusCuriae_1.aspx,* accessed 25 August 2008.

9. See P. Zapf et al., "Assessment of Competency for Execution: professional Guidelines and an Evalution Checklist," *Behavioral Sciences and Law* 21 (2003): 103-20.

10. I have argued for just this claim in "*Doxa* and Death: Belief, Capital Punishment, and the Competence-for-Execution Requirement," an unpublished manuscript — interested readers may contact the author for further information.

Response to Douglas and Goold

Bernice S. Elger

First of all, I thank Sharon Douglas and Susan Dorr Goold for supporting my claim that the neglected domain of ethics for healthcare professionals who work in prisons needs more attention, and for acknowledging that "studies paint a dim picture"[1] about the ethics of correctional healthcare in practice, in the U.S. and elsewhere.

I am glad to have the opportunity to discuss briefly some aspects of the statements by the AMA concerning medical ethics in prisons because these statements help to illustrate the points I made in my article. Because of the limited space, I will present a few examples. A more detailed comparison of AMA policy concerning healthcare ethics with recommendations from the Council of Europe[2] and the World Medical Association (WMA) will follow in a future separate publication.

THE PRINCIPLE OF EQUIVALENCE

In the three bodies of AMA policy available on the internet (health ethics, including the AMA *Code of Medical Ethics,* AMA directives, and AMA governance),[3] the *principle of equivalence* or the term *equivalent care* for detainees are not mentioned. Instead, policy D-430.998 (entitled "Health Care Standards in U.S. Correctional Facilities")[4] states only that standards in correctional settings are under evaluation and that AMA is consulting "appropriate medical specialty societies and the National Commission on Correctional Health Care (NCCHC)." As Douglas and Goold acknowledge, standards that meet those of persons "in the outside community at large" are mentioned in a specific context only, namely concerning HIV treatment for detainees ("Correctional medical care must, as a minimum, meet the prevailing standards of care for HIV-infected persons in the outside community at large. Prisoners should have access to all approved therapeutic drugs and generally employed treatment strategies," H-430.988 "Prevention and Control of HIV/AIDS and Tuberculosis in Correctional Facilities").[5]

Furthermore, the same policy departs from the equivalence principle when it recommends mandatory HIV testing ("Federal and state correctional systems should provide comprehensive medical management for all entrants, which includes mandatory testing for HIV infection and tuberculosis followed by appropriate treatment for those infected"). The position of the AMA is in contrast with European soft law, which clearly allows only voluntary testing based on respect for the principle of equivalence: "Epidemiological HIV/AIDS monitoring including anonymous, non-correlated

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screening could be considered only if such methods are used in the general population and if their application to prison populations appears likely to yield results useful to prisoners themselves."[6]

No one questions that, as Douglas and Goold argue, "respect for individual autonomy may be outweighed by other obligations to that patient or by other considerations, including the good of society."[7] Rather, as shown by the example of mandatory versus voluntary testing of prisoners, the point is that the cut-off thresholds in the balance between individual rights and public health must be the same inside and outside prisons.

BODY SEARCHES

Another interesting example is AMA policy on body searches. The Council of Europe states clearly that "prison doctors should not become involved in such procedures."[8] The WMA allows physicians to participate in exceptional and emergency circumstances: "This non-medical act may be performed by a physician to protect the prisoner from the harm that might result from a search by a non-medically trained examiner."[9] In contrast, the AMA endorses physicians' participation in body searches in a routine manner, outside urgent and exceptional situations: "(1) Since searches of body orifices are conducted for security and not medical reasons, there is usually no need for them to be performed by medical personnel and, as a general rule, it is preferable that they be performed by correctional personnel who have been given special training. (2) Where state laws or agency regulations require that body cavity searches be conducted only by physicians or other medical personnel such as physician assistants, nurses or nurse practitioners, such searches should be performed by healthcare personnel other than those employed to provide care to inmates" (H-430.999, "Searches of Body Orifices").[10] This example of AMA policy reinforces a point made in my article, that professional organizations should go beyond acknowledging the ethical dilemmas that face healthcare professionals in prisons when legal or prison practices require unethical conduct: "If a physician in a particular situation can only act in an unethical way. . . professional organizations could — as they do for physicians who participate in capital punishment and torture — sanction members who engage in such practices."[11] This may force the states to change their policies and laws (especially if the sanctions involve loss of professional licenses). Rather than adapting AMA policy to accommodate state laws, the AMA could set clearer ethical limits for physicians.

A BASIC RIGHT

As Douglas and Goold state, under the AMA *Code of Medical Ethics,* access to care includes "a basic right to have available adequate healthcare," as well as a right to continuity of care, which applies to all patients, including prisoners. Douglas and Goold note, " 'Principle IX' of the AMA *Code of Medical Ethics,* 'A physician shall support access to medical care for all people,' speaks for itself."[12] Yet in fact, the voice of the AMA *Code* is rather muffled. The principles in question need to be applied to the correctional context more clearly and openly — and more often. Of the eight articles published since 2004 in the *Journal of the American Medical Association* that include the key word *prison,* only one (by Linder and colleague, published after the final redaction of my article),[13] refers to the AMA *Code of Medical Ethics.*

Indeed, physicians do not possess magic wands to make "access to care" and "confidentiality" a reality. How should a physician, faced with an AMA recommendation that is in favor of mandatory HIV testing, respond to the following text from the same recommendation: "Correctional institutions should assure that informed consent, counseling, and confidentiality procedures are in place to protect the patient, when HIV testing is appropriate" (H-430.988), if, as is often the case, confidentiality is not respected in the facility where the physician works?[14] Although Douglas and Goold are right that "Unfortunately we know very little about correctional healthcare ethics in practice,"[15] some things *are* widely known, such as the lack of confidentiality and the great variation among correctional facilities concerning access to healthcare services in the U.S. The interesting question that needs more attention is: *What should an individual physician do in an unethical context?* This dilemma is not resolved by Douglas and Goold's reminder that the

AMA requires physicians to denunciate unethical colleagues. Most prison physicians are willing to respect medical ethics, but many have few alternatives — accept unethical compromises, quit their job, or lose their job because they do not comply with prison directives.

I appreciate the opportunity provided by the commentary from CEJA to restate my conclusion that "U.S. professional organizations should make statements that are more clearly in line with international frameworks not only concerning issues of recent intensive media coverage, such as physicians' participation in torture and executions, but also access to healthcare and confidentiality."[16]

ACKNOWLEDGMENT

I thank Alex M. Capron, LLB, for his comments and encouragement.

NOTES

1. S. Douglas and S.D. Goold, "Commentary on "Medical Ethics in Correctional Healthcare," in this issue of *JCE.*

2. It is worth mentioning that the Australian Medical Association (also abbreviated as AMA) defends positions that repeat those of the Council of Europe concerning the principle of equivalence as well as body searches. Australian Medical Association, "Health Care of Prisoners and Detainees—1998," *http://www.ama.com.au/web.nsf/doc/SHED-5G4V6U,* accessed 30 August 2008.

3. To access the AMA *Code of Ethics, Policies of the AMA House of Delegates,* and the *AMA Constitution and Bylaws* online, use the AMA Policy Finder: *http://www.ama-assn.org/ama/noindex/category/11760.html,* accessed 30 August 2008.

4. American Medical Association policy D-430.998, "Health Care Standards in U.S. Correctional Facilities," *Policies of the AMA House of Delegates,* use the AMA Policy Finder, *http://www.ama-assn.org/ama/noindex/category/11760.html,* accept the terms of use, and search on D-430.998.

5. Ibid.

6. Council of Europe, "Recommendation No. R (93)6 of the Committee of Ministers to Member States concerning prison and criminological aspects of the control of transmissible diseases including AIDS and related health problems in prison," *http://www.legislationline.org/legislation.php?tid=160&lid=4908&less=false,* accessed 30 August 2008. The same recommendation states, "In the present state of knowledge, compulsory testing of prisoners should be prohibited since it would be ineffective and discriminatory and therefore unethical."

See also "Council of Europe Committee of Ministers Rec(1998)7 on the ethical and organisational aspects of healthcare in prison, explanatory memorandum," *http://www.unav.es/cdb/ccoerec98-7exp.html,* accessed 30 August 2008, which states, "28. Opportunity should be made available to all incoming prisoners to receive, in private, advice concerning infectious ailments which may have been acquired prior to entry into the prison. In this perspective voluntary screenings for such diseases as hepatitis, sexually transmitted diseases, tuberculosis or infection with HIV are required."

7. Douglas and Goold, see note 1 above.

8. "Council of Europe Committee of Ministers Rec(1998)7 on the ethical and organisational aspects of healthcare in prison," *http://www.coe.int/t/e/legal_affairs/legal_co-operation/prisons_and_ alternatives/legal_instruments/ Rec.R(98)7%20.asp,* accessed September 2007.

9. WMA. World Medical Association Statement on Body Searches of Prisoners. Adopted in Budapest, Hungary, October 1993.

10. American Medical Association policy H-430.999, "Searches of Body Orifices," *Policies of the AMA House of Delegates,* use the AMA Policy Finder, *http://www.ama-assn.org/ama/noindex/category/11760.html,* accept the terms of use, and search on H-430.999.

11. Elger, "Medical Ethics in Correctional Healthcare: An International Comparison of Guidelines," in this issue of *JCE.*

12. Douglas and Goold, see note 1 above.

13. J. F. Linder and F. J. Meyers, "Palliative Care for Prison Inmates: 'Don't Let Me Die in Prison'," *Journal of the American Medical Association* 298, no. 8 (2007): 894-901.

14. AMA policy D-430.998, see note 4 above.

15. Douglas and Goold, see note 1 above.

16. Elger, see note 11 above.

Law

Legal Trends in Bioethics

Sigrid Fry-Revere, Nathaniel B. Revere, Deborah Chen, and Sheeba Koshy

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 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

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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 "Legal Trends" 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" FALL 2008

This "Legal Trends" highlights an array of emerging bioethics issues, but most notable is the manipulation of informed consent to further a political agenda. It is one thing to require informed consent based on a reasonable standard of disclosure, with allowances for the specific needs of individual patients for additional information; it is quite another matter to try to legislate the smallest details of what is disclosed and when. The spring 2007 issue of "Legal Trends" included a report of legislation introduced in South Carolina that required a woman to view an ultrasound of her fetus before consenting to an abortion. As enacted in May 2008, the bill was revised so that a woman would be offered the opportunity to view her ultrasound before consenting to an abortion, but not required to do so. Also in the spring 2007 issue, we discussed South Dakota and Ohio legislative efforts that would force physicians to use specific language in describing the abortion process to patients. Similar attempts to legislate the specific details of what is communicated during the informed consent process have been reported in every issue of "Legal Trends" since. None of these efforts was successful until the Oklahoma legislature overrode the governor's veto of the Freedom of Conscience Act. The new Oklahoma law comes very close to achieving the original intent of the South Carolina ultrasound law (see "The Rights of Maturing Individuals and their Parents"). For the first time, similar tactics involving informed consent are being employed by advocates of choice at the end of life at the state legislative level (see "Life-and-Death Decisions").

Since the principles of informed consent are crucial to all medical decision making, it is with mixed feelings that, beginning with this "Legal Trends" there no longer is a specific section devoted to informed consent. Over the last decade, the general standards for informed consent have become ingrained in the law, and the actual principles are rarely in dispute any more. There is no doubt that the process of informed consent is regularly abused and observed more as a legal precaution than as a genuine attempt to help patients and their surrogates make informed healthcare decisions; nonetheless, the principles are so ubiquitous among the issues covered in "Legal Trends" that an already long column would become unwieldy if every entry that dealt with informed consent, from abortion to genetic testing and medical marijuana, were given separate treatment in a section devoted to informed consent. If ever there is a ground-breaking legal development that directly affects the underlying principles of informed consent *per se*, be assured that a section devoted to informed consent will reappear.

Many entries in this "Legal Trends" are a good illustration of the inherent tension built into the U.S. constitutional system of government. One of James Madison's primary goals in writing the U.S. Constitution was to maintain a balance of power between the three branches of government and the state and federal governments to prevent the accumulation of too much power in any one governmental entity. Several possible shifts in power appear to be underway that have implications for laws of importance in the field of bioethics. A discussion of federal control over state activities continues with the FDA's preemption of state regulations and Congress's preemption of state marijuana laws (See "FDA" and "Unconventional Treatments"). We report on efforst by the FDA to extend its regulatory authority abroad.

While Madison tried to prevent federal agencies from preempting state authority, there is no constitutional mechanism to prevent the FDA from setting up regulatory offices on foreign soil, not because Madison felt such expansion of power was acceptable, but because he never considered the possibility, other than perhaps in a military or diplomatic context.

Finally, "Legal Trends" revisits some issues repeatedly discussed here. Healthcare professionals continue to be threatened with prosecution and prison for helping their patients either with unwanted pregnancies (see "The Rights of Maturing Individuals and their Parents") or intractable pain (see "Unconventional Treatment") and the shortage of suitable organs for an increasing population of transplantation patients presents new bioethical dilemmas (see "Organ and Tissue Procurement").

FDA

The U.S. Supreme Court decided two federal preemption cases last term and is set to consider a third, *Wyeth v. Levine,* S. Ct. Docket No. 06-1249, this fall. The Court split its decisions on FDA preemption of state law last term; in *Riegel v. Medtronic, Inc.,* 552 U.S. ___ (2008), the Court ruled that federal regulations preempted state law, but in *Warner-Lambert*, the Court upheld state regulations (see "Legal Trends," *JCE* summer 2008, pp. 170-171). Given the Court's decision in *Riegel v. Medtronic* and the similarity in the facts between the *Riegel* and *Wyeth* cases, it is puzzling the Court granted *certiorari* in both cases unless at least some of the Justices intend to draw distinctions between the two cases. *Riegel* involved a medical device approved under the Medical Device Amendments of 1976, which specifically include preemption language barring states from imposing their own requirements on FDA pre-market approved devices. The *Wyeth* case involves a drug, not a device, and no such explicit preemption language exists in the laws governing drug approvals. The push and pull dynamics that sustain the balance of power among the states, the federal government, and the various branches of the federal government may prompt the Supreme Court to push back and tell the FDA, "Not so fast. Congress did not expressly grant the FDA preemptive authority for drugs under certain circumstances, as it did for devices. Unless and until Congress expressly grants the executive branch such authority, it does not exist."

New FDA regulatory efforts in China and India are listed under the heading of "Interesting Developments in Other Countries." These actions mark an expansion of FDA's oversight, moving beyond its inspection authority over products coming into the U.S. once they reach the U.S., to regulating products even before they leave foreign soil.

Recent Judicial Cases and Regulatory Actions April - June 2008

Federal. On 8 April 2008, the U.S. Court of Appeals for the Third Circuit, in *Colacicco v. Apotex, Inc. et al.* (decided together with *McNellis v. Pfizer Inc.*), found that the federal Food, Drug, and Cosmetic Act preempted the filing of claims under state law. The issue was whether actions taken by the FDA pursuant to the act and the FDA's implementation of regulations preempted plaintiffs' ability to sue under state failure-to-warn laws. Plaintiffs alleged the defendant companies violated state common law by selling products with labeling that failed to warn consumers of the increased risk of suicide and depression. Both cases were dismissed. *Colacicco v. Apotex, Inc. et al.,* 521 F.3d 253 (3rd Cir., 2008).

Public Citizen, a consumer advocacy group, filed suit in U.S. District Court in Washington, arguing the FDA violated the law by not ruling on a two-year-old petition to ban prescription painkillers Darvon and Darvocet within the required six months. At issue is propoxyphene, a narcotic sold by numerous generic manufacturers, as well as under the brand names Darvon and Darvocet. Public Citizen cited the accidental deaths of more than 2,000 while using the drug. AP, "FDA sued for failure to act on risky painkiller," 19 June 2008, *http://www.msnbc.msn.com/id/25269705/* accessed 8 August 2008.

The FDA issued warnings to 23 companies selling supplements and products that fraudulently claim to prevent, treat, or cure cancers. Most of the products are not FDA approved and can be purchased on the internet. Officials warn that the products may cause harmful interactions with common cancer treatments. U.S. DHHS, "United FDA Warns Individuals and Firms to Stop Selling Fake Cancer 'Cures'," *FDA News,* 17 June 2008, *http://www.fda.gov/bbs/topics/NEWS/2008/NEW01852.html*, accessed 21 August 2008.

Recent Developments in Law and Regulation April - June 2008

Federal. On 17 April 2008, the Safeguarding America's Pharmaceuticals Act was introduced in the House. If enacted, the bill would substantially expand federal drug pedigree requirements. The legislation allows for the destruction of counterfeit

drugs at ports-of-entry and revises federal drug pedigree standards and preempts state requirements. H.R. 5839, 110th Cong. 2nd Reg. Sess. (2008).

On 2 April 2008, Lawmakers urged the FDA to require that all TV ads for prescription medicines display the FDA's contact information to help consumers report serious side-effects. Reps. Rosa DeLauro, D-Conn., and Jan Schakowsky, D-Ill., cited a *Consumer Reports* poll that found that only one-third of respondents who had experienced an adverse reaction after taking a prescription drug knew they could inform the agency about such events. B. Dubose, "Lawmakers recommend inclusion of FDA hot line in TV drug ads," *Los Angeles Times*, 3 April 2008, *http://articles.latimes.com/2008/apr/03/nation/na-drugs3*, accessed 8 August 2008.

On 9 June 2008, Congress initiated an inquiry into the management and priorities of the FDA's Office of Criminal Investigations. The office doubled its budget from fiscal year 2000 to fiscal year 2009. This has allowed for a 50 percent increase in the number of investigators during the years 2000 to 2006. However, there has been a 20 percent drop in arrests and convictions during the same period. A. Mundy, "Congress Presses FDA on Investigations," 11 June 2008, *http://online.wsj.com/article/SB121314729048063047.html?mod=dist_smartbrief*, accessed 8 August 2008.

On 17 April 2008, U.S. House of Representatives Committee on Energy and Commerce released a Discussion Draft of the FDA Globalization Act. The bill allows the FDA to recall contaminated foods and unsafe medications and medical devices. It establishes a group of inspectors to monitor companies manufacturing food, medications, medical devices, and cosmetics abroad. Currently the FDA can only recommend recalls, not mandate them. Kaiser Family Foundation, "Draft Legislation Aimed at Overhauling FDA Would Require More Inspections, Change User Fees," *Kaiser Daily Health Policy Reports*, 18 April 2008, *http://www.kaisernetwork.org/DAILY_REPORTS/rep_hpolicy_recent_rep.cfm?dr_cat=3&show= yes&dr_DateTime=04-18-08#51620*, accessed 8 August 2008.

On 31 March 2008, the FDA unveiled a five-year $30 million program intended to increase drug safety. Under the "Prescription Drug User Fee Act (PDUFA) IV Drug Safety Five-Year Plan," the FDA would employ more safety reviewers and risk-management and medication-error experts to improve drug security. FDA, 7 April 2008, vol. 5, no. 68, *http://fdanews.com/ newsletter/ article?issueId=11468&articleId=105577*.

On 16 June 2008, the FDA announced a new requirement for manufacturers of "conventional" antipsychotic drugs to add label information about the increased risk of death associated with off-label use for behavioral problems in elderly people with dementia. Similar labeling requirements were announced in 2005 for newer "atypical" antipsychotic drugs. Atypical and conventional antipsychotics work similarly, as both are dopamine receptor antagonists, but atypical antipsychotics have a lower incidence of neurological side-effects. The recently-passed Food and Drug Administration Amendments Act of 2007 gives the FDA the authority to mandate drug warnings; previously, it could only request warnings. DHHS, "FDA Requests Boxed Warnings on Older Class of Antipsychotic Drugs," *FDA News*, 16 June 2008, *http://www.fda.gov/bbs/topics/NEWS/2008/NEW 01851.html,* accessed 28 July 2008.

On 28 May 2008, the FDA announced a plan to strengthen drug labels to give patients and healthcare professionals more precise information about how drugs affect women during pregnancy and breast-feeding. The proposed rule is subject to a 90-day public-comment period. U.S. Department of Health and Human Services, "FDA Proposes New Rule to Provide Updated Information on the Use of Prescription Drugs and Biological Products during Pregnancy and Breast-feeding," *FDA News*, 28 May 2008, *http://www.fda.gov/bbs/topics/NEWS/2008/NEW01841.html*, accessed 8 August 2008.

On 13 February 2008, the FDA issued new draft guidelines that allow pharmaceutical and medical device companies to send physicians studies on "off-label," or non-FDA-approved uses. Under current guidelines, physicians can prescribe medications for off-label uses, but drug companies are prohibited from marketing the drugs for unapproved purposes. Under the draft guidelines, drug companies can send physicians unabridged reprints of studies on off-label uses published in peer-reviewed medical journals, as long as those studies are not significantly supported by the drug company. FDA, "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," (,February 2008, *http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0053-gdl.pdf*.

On 22 May 2008, the FDA introduced an initiative called the "Sentinel Initiative," a system that would use information on Medicare claims to assess the risks of drugs already on the market. The system will allow the FDA to monitor almost immediately how drugs affect health. This would be a formidable departure from the current system, under

which regulators may not learn about the adverse effects of a drug until years after the fact. G. Harris, "F.D.A. to Expand Scrutiny of Risks From Drugs After They're Approved for Sale," *New York Times*, 23 May 2008, *http://www.nytimes.com/2008/05/23/washington/23fda.html*, accessed 8 August 2008.

The States. Of the 50 U.S. states, 36 states have implemented laws to enable or study programs that redistribute unused prescription medications to uninsured or low-income individuals. Some states allow the drugs to be donated in sealed containers by individuals (**Arizona, Colorado, Florida, Georgia, Hawaii, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Utah, Wyoming**), while others only allow institutions to make donations (**Arkansas, California, Connecticut, Indiana, Kentucky, Maine, Minnesota, Mississippi, Montana, Nevada, New Jersey, New York, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Wisconsin**). The drugs typically are examined by pharmacists for consumer safety and then are distributed. R. Cauchi and K. Hanson, "State Prescription Drug Return, Reuse and Recycling Laws," *National Council of State Legislatures Website*, 29 July 2008, *http://www.ncsl.org/programs/health/Rx-Reuse. htm*, accessed 21 August 2008.

Interesting Developments in the Private Sector, April - June 2008

The Joint Commission on Accreditation of Healthcare Organizations issued safety recommendations to hospitals to prevent drug errors or adverse reactions in children. The recommendations ask hospitals to do the following: (1) weigh pediatric patients in kilograms on admission, because weighing children in pounds raises the risk of improper dosage; (2) clearly indicate adult medications that have been repackaged to suit pediatric patients; (3) store medications for adults away from pediatric care units. Kaiser Family Foundation, "Joint Commission Issues Alert Calling on Hospitals To Do More To Prevent Medication Errors in Children," *Kaiser Daily Health Report*, 11 April 2008, *http://www.kaiser network.org/Daily_Reports/rep_index.cfm?DR_ID=51477,* accessed 8 August 2008.

Interesting Developments in Other Countries, April - June 2008

China. On 17 June 2008, the U.S. Health and Human Services Secretary Michael Leavitt announced that the FDA has received diplomatic approval to set up three inspections offices in the Peoples' Republic of China to help ensure the safety of food, drugs, and medical devices imported into the U.S. The offices are expected to be open by the end of the year. Office of Health and Human Services, "United States and China Outline Progress on Agreement on Food and Feed Safety," 18 June 2008, *http://www.hhs.gov/news/press/2008pres/06/20080618a. html*, accessed 21 August 2008.

India. The FDA hopes to establish operations in India to better regulate the growing volume of food, medicines, medical devices, and animal feed exported to the U.S. FDA Deputy Commissioner Murray Lumpkin said that the FDA would first like to set up operations in China and then in Mumbai by the end of the year. He also stated that the FDA has interest in expanding the placement of staff in Amman, Jordan, to serve as a Middle East base, as well as in Central or South America and Europe. L. Richwine and S. Heavey, "U.S. FDA Seeks India Post for Food, Drug Checks," *Reuters*, 21 June 2008, *http://www.reuters.com/article/latestCrisis/idUSN20430434*, accessed 8 August 2008.

THE RIGHTS OF MATURING INDIVIDUALS AND THEIR PARENTS

In *Gonzales v. Carhart*, 550 U.S. ___, 127 S. Ct. 1610 (2007), the U.S. Supreme Court allowed Congress to put restrictions on first-trimester abortions in a way it had never done before (see "Legal Trends," *JCE* summer 2007, pp. 163, 164-166), but at least one circuit court is interpreting the Court's *Carhart* ruling as narrowly as possible (see the Fourth Circuit's decision below). Michigan's Governor Jennifer Granholm (D) and Arizona's Governor Janet Napolitano (D) also took contrarian positions when they vetoed bills that would ban "partial-birth abortions," even though the bill included an exception to save the life of the mother.

On the other side of the political aisle, the Oklahoma legislature overrode Governor Brad Henry's (D) veto of the "Freedom of Conscience Act," which would have required a woman to undergo an ultrasound prior to having an abortion.

A dozen or more laws have been introduced in the past year to require women to view ultrasounds before consenting to an abortion. A federal bill with the same type of requirements was introduced, but seems to be stalled in committee. Most of the state bills have failed or are stalled, and up until August 2008, the few that passed (**Georgia, Louisiana, South Carolina, South Dakota**) only require that a woman be offered the opportunity to take or view an ultra-

sound. Oklahoma's law is the first to *require* that an ultrasound be done and shared with the patient. While the new law allows the woman to "avert her eyes," it also *requires* the healthcare professional conducting the ultrasound to describe the images, including the dimensions of the embryo or fetus, cardiac activity the presence of external members, and internal organs.

Judicial Cases and Regulatory Actions April - June 2008

***Federal**. On 20 May 2008, the Fourth U.S. Circuit Court of Appeals in *Richmond Medical Ctr. v. Herring* reconsidered the constitutionality of a Virginia statute that outlaws what is termed "partial birth infanticide," Va. Code Ann. § 18.2- 71.1 and found the statute unconstitutional under *Gonzales v. Carhart*, 550 U.S. ___, 127 S. Ct. 1610 (2007). The U.S. Supreme Court in *Carhart* placed significance on the fact that the federal law imposed criminal liability only on physicians who had the intention of performing the disfavored intact dilation and evacuation (D&E), also called a "partial birth abortion." A simple or standard D&E that accidentally lead to an intact D&E would not result in criminal liability. The Fourth Circuit held that the Virginia statute, unlike the federal statute upheld in *Carhart*, would place undue burden a woman's right to abortion by discouraging all D&E procedures for fear they may accidentally result in the illegal intact D&E, instead of only prohibiting those D&Es intended by the physician from the outset to result in an intact D&E. *Richmond Medical Ctr. v. Herring*, ___F.2d___ (4th Cir. 2008), Case No. 03-1821. Opinion, *http://pacer.ca4.uscourts.gov/opinion.pdf/031821A.P.pdf*.

***Kansas.** On 4 April 2008, the Kansas Supreme Court extended by three months the grand jury investigation of George Tiller, MD, for supposedly performing illegal late-term abortions. The grand jury was originally scheduled to expire 8 April 2008. The court held that no further extension would be allowed. The Kansas Supreme Court also ruled that the citizen-called grand jury was constitutional, and its subpoenas for medical records of Tiller's patients seeking late-term abortion were relevant and not harassing as long as the privacy of patients was protected. On 20 May 2008, 35 records were provided. Tiller, citing privacy concerns, had refused to honor the subpoenas issued by the grand jury on 25 January 2008. *George R. Tiller, MD, et al. v. Hon. Michael Corrigan, et al.* (Kas. Sup. Ct. Case No. 99,951). Tiller is also charged with 19 misdemeanors for failing to receive second opinions on abortions from doctors with whom he was not financially affiliated. On 11 June 2008, Tiller's criminal trial was rescheduled for 28 July 2008. *State of Kansas v. George R. Tiller* (18th Judicial District court of Sedgwick County Case No. 07 CR 2112).

Kentucky. On 18 August 2008, the jury trial of Hamid Hussain Sheikh, MD, was scheduled to begin. Sheikh was indicted in November 2007 on charges of defrauding Medicaid by illegally billing for abortions disguised as routine fetal ultrasounds and charging both Medicaid and his patients for treatment. Sheikh has denied all allegations. *Commonwealth of Kentucky v. Hamid Hussain Sheikh* (Franklin Cir. Ct. No. 07-CR-00236).

On 5 June 2008 the Kentucky Board of Medical Licensure suspended Sheikh's license to practice medicine. A hearing before the Board of Medical Licensure is scheduled for November 2008. Sheikh does not intend to renew his license and retired in June. V. Honeycutt Spears, "Gynecologist's Medical License Suspended," *Lexington Herald-Leader*, 26 June 2008, *http://www. kentucky.com/148/story/444141.html*, accessed 22 July 2008.

Recent Developments in Law and Regulation April - June 2008

Federal. There has been no action on a bill introduced 20 September 2007 and referred to the Committee on Health, Education, Labor, and Pensions that would require all abortion providers to perform ultrasounds before performing abortions, explain the results, and provide medical descriptions of the images. The bill would allow for exceptions in cases of medical emergency and would permit women to look away from the images. S. 2075, 110th Leg., 1st Reg. Sess. (2007).

There has been no action on a concurrent resolution introduced 27 September 2007 and referred to the House Committee on Foreign Affairs that would declare that Congress strongly condemned human rights violations in the People's Republic of China, including its strict birth limitations and the resultant coerced abortions and sterilizations. H. Con. Res. 220, 110th Leg., 1st Reg. Sess. (2007).

*There has been no action on a bill that would prevent the Indian Health Service from paying for abortion except in the case of rape, incest against a minor, or to save the life of the mother. The bill passed the Senate on 26 February 2008, and an identical bill was referred to the House Ways and Means Committee on 28 February 2008. S. 1200, 110th Leg., 1st Reg. Sess. (2007).

***Arizona**. On 4 April 2008, the governor vetoed

a bill that would have prohibited minors from obtaining abortions unless they had parental consent, could prove to a judge with "clear and convincing evidence" that they were "sufficiently mature and capable of giving informed consent" without a guardian's consultation, or if the judge determined an abortion was in the mother's best interest without a guardian's consent. The governor stated the bill was unnecessary and that current law already set forth the "clear and convincing" standard of proof for a judicial bypass. H.B. 2263, 48th Leg., 2nd Reg. Sess. (Ariz. 2007).

*On 4 April 2008, the governor vetoed a bill that would have banned partial birth abortion, allowing doctors who performed the procedure to be prosecuted on both a state and federal level. The bill included an exemption to save the life of the mother if no other medical procedure would save the mother's life. The governor stated that instead of "introducing more criminal penalties into the relationship between a woman and her physician," efforts should be directed to the root issues of unwanted pregnancy, focusing on family planning and the prevention of sexual violence. H.B. 2769, 48th Leg., 2nd Reg. Sess. (Ariz. 2007).

Alaska. On 11 April 2008, a bill died in the state senate that would have required parental consent prior to a minor's obtaining an abortion. H.B. 364, 25th Leg., Reg. Sess. (Alas. 2008).

California. On 18 June 2008, the California Institute for Regenerative Medicine (CIRM) and Canada announced a three-year collaborative agreement that will explore approaches to evaluate, fund, and monitor stem cell research projects. Canada will contribute $100 million Canadian dollars to the Cancer Stem Cell Consortium (CSCC), which has partnered with CIRM. CIRM, "Minister Clement, Governor Schwarzenegger Join Forces to Fight Cancer Through Stem Cell Research," *State of California*, 18 June 2008, *http://www.cirm.ca. gov/press/pdf/2008/06-18-08_b.pdf*, accessed 23 July 2008. On the same day, CIRM also announced a partnership with the Australian state of Victoria. CIRM and Victoria will jointly seek and evaluate grant applications and make recommendations for funding research. CIRM, CSCC, and Victoria will initially collaborate on the CIRM Disease Team grants, which will fund multi-disciplinary teams of scientists seeking therapies for specific diseases. CIRM, "Victoria and California Announce International Collaboration to Advance Stem Cell Research toward Cures," 18 June 2008, *http://www.cirm.ca.gov/press/pdf/2008/06-18-08.pdf*, accessed 23 July 2008.

*An initiative has been placed on the California ballot for November 2008 that would require parental notification and a 48-hour waiting period before a minor can obtain an abortion, with exemptions for medical emergencies and parental waivers. Proposition 4 represents the third time in four years California voters have considered a requirement for parental notification and a waiting period. "Waiting Period and Parental Notification Before Termination of Minor's Pregnancy," Initiative 07-0053, California Secretary of State website, *http://www.sos.ca.gov/elections/elections j.htm.*

***Florida**. A bill has died that would have required all women to undergo ultrasound testing prior to obtaining an abortion. S.B. 2400, 2008 Reg. Sess. (Fla. 2008).

***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 for 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**. On 13 June 2008, the governor vetoed a bill that would ban "partial-birth abortions" with an exception to save the life of the mother but none to protect her health. The governor refused to support any late-term abortion ban that did not provide an exception to protect both the life and health of the mother. S.B. 776, 94th Leg., Reg. Sess. (Mich. 2007).

Minnesota. On 23 May 2008, a bill was pocket vetoed that would have allowed scientists to conduct limited research on embryonic stem cells. The governor stated the bill was both unethical and immoral and that adult-derived stem cells were superior to embryonic stem cells. He indicated he would be willing to support research using "induced" pluripotent stem cells derived from adult cells, since such a technique would not use human eggs or embryos. The bill would have allowed research on embryos donated with written consent after infertility treatment and prohibited the sale or cloning of embryonic tissue. The bill would also have allowed the University of Minnesota to use state funds for stem cell research. S.F. 0100, 85th Leg. Sess. (Minn. 2008).

***Missouri.** There has been no action on a bill that would modify the informed consent requirement for an abortion by adding new requirements to be fulfilled at least 24 hours prior to obtaining the abortion. Specifically, the bill requires that the

woman be presented with printed materials and videos detailing the risks of an abortion and the physiological characteristics of an unborn child, and the opportunity to view an active ultrasound of the unborn child and hear the heartbeat of the unborn child. 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).

***New Jersey**. The construction of a new stem cell research facility has been put on hold indefinitely. Officials are re-evaluating the project. The governor remains open to other plans for the continued funding of stem cell research, but did not have a time line for restarting construction. J. Margolin and T. Sherman, "State Pulls Back on Stem Cell Funding," *Star-Ledger*, 22 June 2008, *http://www.nj.com/newark/index.ssf/2008/06/state_ pulls_back_on_stem_cell.html*, accessed 23 July 2008.

***Ohio**. On 20 June 2008, a law went into effect that requires abortion providers to give patients an opportunity to view an ultrasound image of the embryo or fetus and to offer to provide a physical copy of the image, both at no extra charge, as long as the ultrasound is performed before the abortion. The bill was signed into law on 21 March 2008. H.B. 314, 127th Gen. Assem., Reg. Sess. (Oh. 2007).

Oklahoma. On 17 April 2008, the state legislature overrode the governor's veto of the Freedom of Conscience Act. The omnibus bill includes a requirement that all women undergo an ultrasound prior to an abortion. Doctors must provide medical descriptions of ultrasound images as well as explain what ultrasounds depict while displaying the images, although women may avert their eyes. The bill also protects doctors and workers with moral objections to performing abortions, allows healthcare providers to refuse to perform abortions or refuse to admit patients seeking abortions, and requires abortion providers to post a notice informing women it is illegal for anyone to force them to have an abortion. S.B. 1878, 51st Leg. Sess. (Okla. 2008).

***Pennsylvania**. On 3 April 2008, the governor signed into law a bill that provides for an umbilical cord blood bank and requires healthcare practitioners to give pregnant patients information regarding umbilical cord donation. 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**. Measure 11, an initiative to ban abortions, has been placed on the November ballot. The measure would allow for exceptions in cases of rape or incest, to save a woman's life, or in cases of a "substantial and irreversible health risk" or impairment to "a major bodily organ or system." "An Act to Protect the Lives of Unborn Children, and the Interests and Health of Pregnant Mothers, by Prohibiting Abortions Except in Cases Where the Mother's Life or Health is at Risk, and in Cases of Rape and Incest," *http://www.sdsos.gov/electionsvoteregistration/electvoterpdfs/2008/2008regulateperformanceofabortions.pdf,* accessed 23 July 2008.

Tennessee. In May 2008 an abortion-related bill died in the Senate Judiciary Committee. The bill would have required informed consent and a 24-hour waiting period prior to obtaining an abortion. SB 3512, 105th Gen. Assem., Reg. Sess. (Tenn. 2008).

Interesting Developments in Other Countries

Australia. The New South Wales government planned to introduce legislation in July requiring teenagers under age 18 seeking cosmetic surgery to observe a three-month cooling-off period in an effort to reduce unnecessary surgeries. The NSW government has taken its cue from Queensland, which banned appearance-centered cosmetic surgery for teens under 18 earlier this year. Doctors from the NSW branch of the Australian Medical Association are calling for a ban on all teen cosmetic surgery, claiming teenagers with poor body image are attempting to raise their self-esteem by resorting to cosmetic surgery. Under current laws, teenagers under 18 may only undergo cosmetic surgery in private hospitals, and those under 16 need parental consent. The new laws would also include better regulation of plastic surgery advertisements. A. Bennett, "Teen Celeb Surgery Bann Call," *Adelaide Now*, 21 April 2008, *http://www.news.com.au/story/0,23599,23575293-29277,00.html*, accessed 22 July 2008.

Stephen Peter Morrow, an Australian teacher found guilty of getting a teenage student pregnant and then paying for her abortion, was sentenced to six years in prison. S. Ertelt, "Australia Teacher Who Got Student Pregnant, Bought Abortion Gets Six Years," *Life News*, 17 April 2008, *http://www.lifenews.com/int703. html*, accessed 21 August 2008.

Brazil. On 29 May 2008, the Brazil Supreme Court decided that scientists can conduct embryonic stem cell research. A slim majority comprised of

six of the court's 11 justices upheld a 2005 law allowing embryonic stem cell research, which was challenged in that same year by former Attorney General Claudio Fontelles, who argued the law was unconstitutional because it violated the right to life. The Court's ruling was immediately criticized by conservatives in the world's largest Roman Catholic country. M. Sibaja, "Brazil's Top Court approves Stem Cell Research," *AP,* 29 May 2008, *http://ap.google.com/article/ALeqM5il SQD5t_pO3YCyS_IdsF2jLzEX2QD90VMFDOC*, accessed 21 August 2008.

Europe. The Council of Europe, an intergovernmental organization, passed a nonbinding resolution calling for member states to legalize abortion. Although abortion is legal throughout most of Europe, it is either severely restricted or illegal in Ireland, Andorra, Poland, Monaco, and Malta. "Council of Europe Pressures Member States to Legalize Abortion," *Feminist Wire*, 21 April 2008, *http://feminist.org/news/newsbyte/uswirestory.asp?id=10953*, accessed 21 August 2008.

Norway. On 17 April 2008, the Christian Democratic Party of Norway proposed a new abortion law that would require counseling for all women considering abortion as well as free contraception for persons under the age of 24. Although the party's constituency is only 7 percent of the population, it holds considerable influence. C. Stein, "Christian Party Proposes New Abortion Law," *Aftenposten*, 17 April 2008, *http://www.aftenposten.no/english/article 2375148.ece,* accessed 21 August 2008.

Romania. On 26 June 2008, a government commission of doctors and health officials allowed 11-year-old Florina Vranceanu to have an abortion due to the exceptional circumstances of her case. The girl claimed to be raped by a 19-year-old uncle who has since disappeared, although the rape has not been proven. The girl was 21 weeks pregnant at the time of the ruling, and Romania does not allow abortions after 14 weeks unless the mother's life is at risk. The committee determined that the girl's mental health was at risk if she did not terminate the pregnancy and decided that she could have an abortion in Romania. Despite the ruling, the girl's parents still plan to travel to Britain, where the abortion limit is 24 weeks, for the procedure. BBC News, "Romanian Girl Permitted Abortion," *BBC News*, 27 June 2008, *http://news.bbc.co.uk/2/hi/europe/7477448.stm*, accessed 23 July 2008.

United Kingdom. New guidelines from the National Health Services released in June 2008 expect IVF clinics in the UK to lower rates of multiple births to the national average of 24 percent by January 2009 and 10 percent by 2010. Clinics would have to increase the numbers of single embryos transferred back into women's wombs; opponents are concerned that patients would have to spend more on fertility treatments to receive multiple IVF cycles instead of implanting multiple embryos in a single cycle. Although the National Institute of Clinical and Health Excellence recommends women receive three cycles of IVF, only 5 percent of clinics in England offer three cycles, and most only offer one. Since the average success rate per cycle of IVF is only 25 percent, women feel pressured to implant more embryos. However, this tactic also increases the risks of multiple births, which are more dangerous for the mother and babies than singleton births. The chair of the British Fertility Society believes that NHS first needs to address IVF funding issues, since women who must fund their own treatments are less willing to undergo multiple cycles to successfully become pregnant. BBC News, " 'One Egg' IVF Strategy Launched," *BBC News*, 26 June 2008, *http://news.bbc.co.uk/2/hi/health/7475392.stm,* accessed 22 July 2008.

*A bill to update the 1990 Human Fertilisation and Embryology Bill is making its way through Parliament committees. The bill would allow the creation of "saviour siblings," created when parents use IVF to selectively implant an embryo that genetically matches a child with a serious illness; allow the creation of hybrid embryos for stem cell research; and remove a requirement for doctors to consider the need for a father before offering fertility treatment, allowing lesbian couples and single mothers to receive IVF treatment. A proposed amendment attempting to lower the current abortion limit of 24 weeks was tabled. Human Fertilisation and Embryology Bill, HL 2007-08, *http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html,* accessed 22 July 2008.

LIFE-AND-DEATH DECISIONS

Most noteworthy is a bill introduced by Compassion & Choices, a national end-of-life care advocacy organization, called the "California End-of-Life Options Act." Compassion & Choices has repeatedly tried to get an Oregon-style aid-in-dying bill passed in California, with little success. This bill reveals a new strategy for Compassion & Choices, one that has been employed for several years by pro-life advocates — and just as worthy of criticism when used by advocates on the left as when used by advocates on the right, because of its political manipulation of the informed-consent process. If the act is passed, it

will make almost no difference what it mandates, as the list of legal end-of-life options that physicians must offer to discuss with patients. The mere mandate of any list presumes that legislators can predict exactly what is appropriate to share, and when, with patients who come to their prognoses from very individual experiences and emotional states. How can it be medically indicated or morally justified to give a patient aged 40 who has pancreatic cancer the same information at the same point of prognosis as an 85-year-old patient whose cancer has returned after 10 years and two successful efforts to put her or his cancer into remission? Medicine is an art. Specific communications between physicians and patients is a very real part of that art, and should not be legislated.

Political persuasion aside, both the Oklahoma ultrasound law (described above in the "Rights of Maturing Individuals and their Parents" section) and the California end-of-life options law (described below) reduce doctors and patients to puppets in a politically scripted play that unacceptably restricts their professional and personal autonomy in medical decision making. Patients need accurate information to make fully informed decisions, but patients need that information at a time when they are emotionally ready and willing to analyze and put that information to good use.

Judicial Cases and Regulatory Actions
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Florida. On 2 April 2008, the Okeechobee Circuit Court issued an injunction to block the removal of a stroke victim's feeding tube. The woman, Karen Weber, is able to breathe on her own but can neither swallow nor speak. Weber's husband wants her feeding tube removed and his wife transferred to hospice, while Weber's mother claims she is alert and responsive and has expressed a wish not to go to hospice. The judge appointed a three-member committee to evaluate the woman's competence, but a competency hearing has not been scheduled. *Martha Tatro v. Raymond Weber* (Okeechobee Cir. Ct. No. 2008GA064 & 2008OS063). A signed copy of the court order for the appointment of the evaluation committee is included in *In re: Karen Weber* is *http://www.telladf .org/UserDocs/Weber CourtOrder.pdf*.

***Montana**. There have been no further developments on a suit filed in the state First Judicial District Court on seeking to allow mentally competent terminally ill patients to obtain medication from their physicians to help them achieve a peaceful death. The suit references Montanans' right to privacy and dignity guaranteed by the state constitution. *Baxter et al. v. Montana*, (Mt. 1st Dist. DV 2007 787), *http://www.compassionandchoices.org/localgroups/mt/documents/BaxtervMTComplaint 10-17-07.pdf*.

Recent Developments in Law and Regulation
April - June 2008

***California**. The bill reintroducing the California Compassionate Choices Act has died due to lack of activity. A.B. 374, 2007-2008 Leg., Reg. Sess. (Cal. 2007). It failed 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." That bill, introduced on 22 February 2008, called the "California End-of-Life Options Act," is working its way through the state legislature. It has undergone many changes as it is reviewed by various legislative committees, but, as originally introduced, the act requires physicians who make a diagnosis that a patient has a terminal illness or a prognosis of less than one year to live to provide the patient with the opportunity for information and counseling on all legal end-of-life choices, including hospice, a prognosis with and without continuation of curative treatment, refusal or withdrawal from life-sustaining treatment, voluntary stopping of eating and drinking, and palliative sedation. A.B. 2747, 2007-2008 Leg., Reg. Sess. (Cal. 2008).

***Georgia.** A bill to facilitate informed consumer health insurance choices is working its way through the state legislature. The Georgia Health Marketplace Act, which passed the senate 6 March 2008, would establish a website that provides consumers with a forum to easily access comparisons of deductibles, copayments, benefits, and premiums for a wide variety of different healthcare plans; would allow purchases with pre-tax dollars; and would enable Georgians to set up personal health savings accounts. S.B. 404, 149th Gen. Assem., Reg. Sess. (Ga. 2008).

***Illinois**. No action has been taken on 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 Hampshire. A bill dealing with advance directives died in committee. The bill, originally introduced on 4 January 2007, 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. H.B. 40, 2007-2008 Leg., Reg. Sess. (N.H. 2008).

Virginia. The governor 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

Australia. An Australian Supreme Court jury found Shirley Justins guilty of manslaughter on 19 July 2008. Justins assisted the suicide of her 19-year partner, Graeme Wylie, who overdosed on a veterinary drug, Nembutal, in 2006, three years after a diagnosis of Alzheimer's. Justins was found to have given him the drug and told him he would die if he drank it. The court found Wylie was not mentally capable enough to make an informed decision to end his life, that Justins negligently breached her duty of care, and allegedly had a financial motive for Wylie's death — he recently changed his will to leave her most of his estate. A family friend who illegally brought the drug from Mexico is charged with accessory to manslaughter; she and Justins face up to 25 years in prison. K. Arlington, "Graeme Wylie's Partner Shirley Justins Guilty of Manslaughter," *Daily Telegraph*, 20 June 2008, *http://www. news. com.au/dailytelegraph/story/0,22049,23892081-5007132,00.html,* accessed 13 August 2008.

Mexico. On 22 April 2008, the Senate legalized passive euthanasia, allowing doctors to withdraw life-sustaining medication if the patient is in palliative care and has less than six months to live. Doctors are not able to euthanize patients or assist in suicide, and consent from the patient or patient's family is required. Euthanasia Research & Guidance Organization, "World Laws on Assisted Suicide," 9 May 2008, *http://www. finalexit.org/lawsnamerica. html*, accessed 13 August 2008.

ORGAN AND TISSUE PROCUREMENT

In a system that is dependent on altruistic motivation, it is important to minimize even the appearance of impropriety, let alone actual criminal activity. Confidence in organ procurement organizations, tissue banks, and transplant professionals will plummet if events like those reported in this issue of "Legal Trends" continue to dominate the news. It is tragic that a surgeon in California, whether well-meaning or not, was so careless as to actually hasten, or give the impression he was hastening, the death of a patient in order to harvest his organs. Similarly, the conviction of a former oral surgeon for secretly harvesting and selling bone and tissue from cadavers creates widespread public suspicions of the whole organ procurement process. The potential for public misunderstanding is also great when well-meaning policies like the New York City pilot program using "rapid-organ-recovery ambulances" are implemented. Another potential public-relations nightmare is looming as more transplant programs endorse donation after cardiac death (DCD). The practice of transplanting a heart after cardiac arrest may actually be illegal, but even if other forms of DCD are legal and medically sound, they undercut and, in many people's eyes, even contradict the definition of death as a cessation of brain function. Half a century has been spent changing cultural attitudes toward death and organ donation. Medical advances have transformed heart disease from a killer to a chronic condition. Citizens have been trained to initiate CPR when a person's heart stops. Automated external defibrillators, rescue devices for persons suffering cardiac arrest, are now common in most public facilities, including schools and shopping malls. In light of these very successful educational efforts, it is not going to be easy to simply turn around and say, but now it is acceptable to treat a person whose heart has stopped for just seconds or a minute or two as dead. Efforts to facilitate paired kidney donation and develop an ethically acceptable way to compensate living donors for at least the costs associated with donation may create less public mistrust and be more productive solutions in the long run.

Judicial Cases and Regulatory Actions April - June 2008

***California**. On 16 May 2008, the California medical board filed a complaint against a transplant surgeon, accusing him of unprofessional conduct while attempting to procure organs from a patient. If found guilty under the Medical Practice Act, his license could be revoked or suspended or he could be placed on probation. L. Parrilla, "Medical Board Files Complaint Against Transplant Surgeon," San Luis Obispo, 7 June 2008, *http://www.sanluis obispo.com/news/local/story/381047.html*, accessed 18 August 2008. The surgeon has also been accused of dependent adult abuse during an attempted organ donation, allegedly hastening the patient's death with excessive painkillers and sedatives in order to harvest his organs. The defendant has asked for this charge to be dismissed, but the judge has not indi-

cated when a decision might be made. If the charge is not dropped, the surgeon will go to trial on 2 October 2008. *People of California v. Hootan Roozrokh* (San Luis Obispo Superior Court Case No. 405885).

***New York**. On 27 June 2008, the New York Supreme Court sentenced Michael Mastromarino, a former oral surgeon illegally harvesting and selling bone and tissue from cadavers for transplants, to 18 to 54 years of imprisonment after making a plea bargain. Mastromarino will also have to forfeit $4.68 million made from selling body parts. The body parts, which were not properly screened and tested, have caused diseases in many transplant recipients. Three accomplices are also charged: Joseph Nicelli, a former embalmer, has been removed from the case until he recovers from a head injury sustained last year; Lee Cruceta, who headed the "cutting crew," has pleaded guilty for an 8 to 25 years in prison; and Christopher Aldorasi, a "cutter," was given a 27-year prison sentence. C. Kearney, "Boss of Body Parts Ring Gets 18-54 Years," *Reuters*, 28 June 2008, *http://www.reuters.com/article/sphereNews/idUSN2744659520080628? sp=true&view=sphere*, accessed 30 July 2008.

Recent Developments in Law and Regulation April - June 2008

On 20 June 2008, the board of the Organ Procurement and Transplantation Network (OPTN), run by the United Network for Organ Sharing (UNOS), approved elements of a pilot national system to facilitate kidney pair donation, which involves "two or more living donor transplants where the initially intended donor/recipient pairs are medically incompatible." The plan prioritizes giving patients the most possible opportunities to get transplants. UNOS News Bureau, "OPTN/UNOS Board Approves Measures to Broaden Access for Living Donation, Pediatric Transplantation, Highly Sensitized Kidney Transplant Candidates," *OPTN*, 20 June 2008, *http://www.optn.org/news/newsDetail. asp?id=1098*, accessed 13 August 2008.

***District of Columbia**. On 15 April 2008, the Uniform Anatomical Gift Revision Act of 2008 became effective. Among other things, the bill, signed 25 February 2008, protects a donor's decision from interference after death and re-establishes D.C.'s donor registry. D.C. Council, B17-58 (2007).

***Georgia**. On 12 May 2008, a bill was signed into law that would allow organ procurement agencies to harvest organs without further permission from family members if the donor's intent were 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. The bill became effective 1 July 2008. S.B. 405, 149th Gen. Assem., Reg. Sess. (Ga. 2007).

Kansas. On 14 May 2008, the governor signed into law a bill designating organ procurement groups as one of the places to which a corpse may be sent after someone's death. State law had previously limited those locations to a hospital, a cemetery, a coroner's lab, a funeral home, a crematory, or the University of Kansas Medical Center. Before being sent, the body would have to be released by someone appointed by the deceased or his or her family. H.B. 2700, 82nd Leg., Reg. Sess. (Kan. 2008).

*****There has been no action on a bill 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. H.B. 2362, 82nd Leg., Reg. Sess. (Kan. 2008).

***Maine**. On 8 August 2008, a bill passed that would adopt the 2006 Uniform Anatomical Gift Act without changes, since the bill was carried over to the 2008 session. 123rd Leg. Sess. L.D. 1505, 123rd Leg., Reg. Sess. (Me. 2007).

New York. New York City officials are planning a pilot program using "rapid-organ-recovery ambulances" after receiving a three-year $1.5 million grant from the federal Health Resources and Services Administration. Ambulances would set out after EMTs give up on resuscitation, to attempt to preserve a victim's organs until his/her organ donor status or family had been located, so the family could have time to consider organ donation. Organs would not be taken without consent; the measure seeks to address complaints from families of would-be organ donors not eligible for donation because they did not die in a hospital. R. Stein, "N.Y. Planning Special Ambulance To Recover Organs," *Washington Post*, 24 May 2008, *http://www. washingtonpost. com/wp-dyn/content/article/2008/05/23/AR2008052303006.html*, accessed 14 August 2008.

Interesting Developments in the Private Sector

On 16 June 2008, the AMA called for legislators to modify current law and allow pilot studies on financial incentives for cadaveric organ donations. The National Organ Transplantation Act prohibits financial incentives, stating that altruism is the only ethical motivation for organ donation. An AMA

Board member stated that motivational incentives should be studied to decrease the number of patients waiting for organ transplants. M. Turner, "Financial Incentives Could Improve Organ Donation and Reduce Donor-Recipient Gap," *AMA*, 16 June 2008, *http://www.ama-assn.org/ama/pub/category/18674.html*, accessed 13 August 2008.

Interesting Developments in Other Countries

European Union. On 22 April 2008, members of the European Parliament voted to create a voluntary EU-wide donor card and a 24-hour transplant hotline as well as to increase public awareness about the importance of organ donation. Members of the European Parliament (MEPs) believe that expanding and speeding up the organ donation system will help decrease the demand for illegal organs. BBC News, "MEPs Back Europe Organ Donor Card," *BBC News*, 22 April 2008, *http://news.bbc. co.uk/2/hi/europe/7358789.stm*, accessed 13 August 2008.

Philippines. The Philippine Department of Health banned kidney transplants for foreigners, with an exception for those related by blood to Filipino citizens. "Foreigner" was defined as someone without a Filipino citizenship. While organ sales are illegal, the black market is thriving due to so-called transplant tourism. While hospitals are only permitted to perform 10 percent of transplant procedures on foreigners, many facilities exceed this limit. C. Conde, "Philippines Bans Kidney Transplants for Foreigners," *New York Times*, 30 April 2008, *http://www. nytimes.com/ 2008/04/30/world/asia/30phils.html*, accessed 13 August 2008.

UNCONVENTIONAL TREATMENT

Although the heading "unconventional treatment" was introduced in the spring 2007 "Legal Trends," what was meant by "unconventional treatment" was first discussed in the summer 2008 column. The phrase "unconventional" is meant to apply to treatments that are outside mainstream medicine, not as a derogatory or judgmental term describing the merit of those specific treatments. This is to some extent an unsatisfactory compromise, because the term "unconventional" clearly has negative connotations, albeit in the context used here those connotations are unintentional. We have struggled to find a more appropriate heading for the types of treatments included in this section. Some entries involve innovative treatments, such as those tested in clinical trials. Others discuss treatments as old as or older than medicine itself, such as midwifery. Some discuss treatments of questionable legality, such as medical marijuana, but most of the treatment options discussed are perfectly legal — just not part of mainstream medicine. As diverse as they are, these treatments have several points of commonality — society is struggling with how to regulate them and is debating whether such treatments should be permitted alongside mainstream medical treatments. At this point the only nomenclature that fits seems to be "unconventional," but alternative suggestions are welcome.

The medical marijuana issue may come to a head soon. The victims in the power struggle between states and the U.S. Drug Enforcement Administration (DEA) are adding up, and most are far from what one might call "pot-heads." For example, below we discuss a case against a former software developer who first used medical marijuana for his own migraines. Since he had to drive hours to get to a dispensary, and being a businessman always on the lookout for new business opportunities, Charles Lynch opened a medical marijuana dispensary closer to home and operated it with scrupulous care. He kept meticulous records, double-checked medical marijuana prescriptions by calling the doctors who wrote them to assure their validity, and complied with all state and local laws in establishing his dispensary. Lynch even claims to have had phone conversations in which DEA officials told him the enforcement of medical marijuana laws was a local matter. Friends of Charles C. Lynch, "About Charles C. Lynch," *Friends of Charles C. Lynch Fund,* at *http://www=.friendsofccl.com,* accessed 23 August 2008. Despite all his precautions, Lynch's dispensary was closed and his marijuana burned. He was arrested, tried, and convicted (5 August 2008) for violation of federal drug laws and faces a minimum sentence of five years in prison and as many as 85 years.

At the federal level, in the U.S. it is legal to take the active ingredient in marijuana in pill form but not to smoke marijuana. The FDA approved two cannabinoids for use as medical therapies: dronabinol (Marinol) and nabilone (Cesamet). These synthetic THC medications are not smoked but administered orally in pill form. The FDA issued an advisory against smoking marijuana for medical purposes, based on a finding that smoking marijuana for medical purposes has a high potential for abuse and evidence that smoked marijuana is actually harmful. (FDA Press Release, 20 April 2006, *http://www.fda.gov/bb/topics/news/2006/new01362.html,* accessed 19 September 2007.) Some noteworthy private organizations that have repeatedly considered and refused to endorse medical marijuana include

the National Multiple Sclerosis Society, the American Cancer Society, and the American Academy of Ophthalmology. Medical marijuana laws at the state level allow prescriptions for leaf marijuana for smoking, which many advocates say is more effective than ingesting THC in other forms. In addition to the 13 states **(Alaska, Colorado, Hawaii, Maine, Maryland, Montana, Nevada, New Mexico, Oregon, Rhode Island, Washington, Vermont)** where legislatures or the citizenry (through ballot initiatives) have approved medical marijuana, nine prominent organizations have endorsed the use of medical marijuana (the American College of Physicians, the Leukemia and Lymphoma Society, the American Academy of Family Physicians, the American Public Health Association, the American Psychiatric Association, the American Nurses Association, AIDS Action, the American Academy of HIV Medicine, and the Lymphoma Foundation of America).

Judicial Cases and Regulatory Actions April - June 2008

Federal. The trial of a state licensed medical marijuana dispensary in Morro Bay, California, was set for 22 July 2008 in the U.S. District Court of Los Angeles. The dispensing of medical marijuana to patients with a doctor's prescription has been legal under California law since 1996. Charles Lynch opened his dispensary in April 2006 and operated with the blessings of the mayor, who was present at the ribbon cutting ceremony. On 17 July 2007, federal agents arrested Lynch for selling marijuana in violation of federal law. Friends of Charles C. Lynch, "About Charles C. Lynch," *Friends of Charles C. Lynch Fund, http://www.friends ofccl.com,* accessed 23 August 2008. Currently, all sale and use of marijuana, even medical marijuana, which is legal in 13 states, is a violation of federal law. The U.S. Supreme Court's ruled in *Gonzales v. Raich*, 545 U.S. 1 (20005), that Congress has the authority to ban the use and sale of cannabis even if approved for medical purposes at the state level.

On 17 April 2008, a bill recognizing the medical value of marijuana was introduced in the House; it would reclassify marijuana under the Controlled Substances Act (CSA) from a Schedule I drug to a Schedule II drug, allowing it to be medically prescribed. The bill would prevent federal interference in local or state-run medical marijuana programs and protect qualified patients and caregivers and physicians from the CSA and Food, Drug, and Cosmetic Act. H.R. 5842, 110th Cong. 2nd Reg. Sess. (2008).

On 12 May 2008, the U.S. District Court for Eastern Missouri denied the Drug Enforcement Administration (DEA) its attempt to use an injunction to suspend the DEA registration of Seth Paskon, MD, before trial, stating the government did not provide sufficient evidence showing why an injunction should be issued before trial. The judge also noted that the DEA could have used administrative procedures of the Controlled Substances Act (CSA) to suspend Paskon's registration and failed to explain why it chose not to. The government alleges that Paskon issued prescriptions for narcotics beyond medical necessity, leading to overdoses and death for many patients. The judge also denied the government's motion for a partial summary judgment, stating that while expert opinion was provided, there was no evidence from patients or undercover agents with proof of the alleged CSA violations. The government's civil case against Paskon alleging Medicaid and Medicare fraud went to trial in July. *United States v. Seth Paskon* ____ F. Sup9. ____ (U.S. Dist. Ct., Eastern District of Mo. Case No. 4:2007cv01161). Opinion, *http://www.fdalawblog.net/fda_law_blog_hyman_phelps/files/paskon_opinion.pdf*.

California. On 18 April 2008, Jeffre Sanderson and his wife Alice Wiegand were given prison sentences for growing marijuana. Although Sanderson and Wiegand alleged the marijuana was for medicinal and spiritual purposes, federal law does not recognize California's medical marijuana laws. Sanderson received a 24-month sentence and Wiegand received a six-month sentence; Wiegand was allowed to remain free until 1 December to make arrangements for a caretaker for the couple's children. The couple is considering an appeal. D. Walsh, "Federal Judge Sentences Plumas Pot Growers," *Sacramento Bee*, 19 April 2008, *http://www.sacbee.com/101/story/874091.html*, accessed 30 July 2008.

***Colorado.** There have been no developments on a case in which a couple, whose medical marijuana plants were destroyed after being seized by local police, filed a motion seeking $202,800 in 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 sum is the highest ever sought for the destruction of a drug, the result of a requested estimate of the plants' value from the U.S. Drug Enforcement Administration (DEA). The request put the agency in an awkward position, since it has long been criticized for inflating the value of seized marijuana to aid the prosecution of drug cases. The suit was filed 17 January 2008. 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**. On 24 June 2008, the Missouri Supreme Court upheld a 2007 law legalizing midwifery without the presence of a physician. Doctors' groups had complained that physicians practicing medicine with unlicensed midwives could be at risk for professional discipline, but the court said the law exempted certified midwives from prohibitions on practicing medicine. *Missouri St. Med. Health Assoc. v. State of Missouri and Missouri Midwives Assoc.* (Mo. Sup. Ct. Case No. SC88783).

Vermont. In April a Vermont Supreme Court disciplinary counsel recommended that Martha Davis, a lawyer on trial for growing and smoking marijuana, have her law license suspended for two months. Her case proceeds to the Vermont Professional Responsibility Board, which could choose to accept or reject the recommendation. Davis said she smoked the marijuana to relieve pain from migraine headaches and chronic arm and leg pain from an inflammatory disease. Davis was charged with felony marijuana possession after game wardens found 2.5 pounds of marijuana at her home. The county prosecutor amended the charges to misdemeanors and allowed her to enter the Court Diversion Program, so records of the charges will be deleted after she completes community service. S. Smallheer, "Panel: Judge Should Lose License for 60 Days," *Times-Argus*, 19 April 2008, *http://www.mpp.org/ states/ vermont/news/panel-judge-should-lose-licen.html*, accessed 30 July 2008.

Recent Developments in Law and Regulation April - June 2008

Michigan. On 12 April 2008, lawmakers voted to include on the November ballot a measure to legalize medical marijuana for treatment of "debilitating medical conditions." Secretary of State T. Land, "Statewide Ballot Proposal Status," *Michigan Department of State website*, 9 July 2008, *http://www.michigan.gov/documents/sos/Statewide_Bal_Prop_Status_180489_7.pdf,* accessed 30 July 2008.

Interesting Developments in the Private Sector

On 16 June 2008, the American Medical Association (AMA) released its first guidelines regarding medical tourism. The nine-point guidelines address informed consent, financial incentives, and follow-up treatment. AMA, "New AMA Guidelines on Medical Tourism," 16 June 2008, *http://www.ama-assn.org/ama1 /pub/upload/mm/31/medicaltourism.pdf*, accessed 30 July 2008.

Interesting Developments in Other Countries

Canada. On 14 April 2008, Health Canada announced it would soon be seeking bids on a seven-year contract to cultivate and distribute medical marijuana, with options for two one-year extensions. The government will accept bids until 15 September 2008. Health Canada plans to eventually cease allowing patients to grow their own medical marijuana, potentially giving the contract-winning firm a monopoly on medical marijuana. Opponents of such a monopoly are concerned that the government would only supply one strain of marijuana, noting that different symptoms are better treated by different strains of marijuana. Currently, fewer than 20 percent of medical marijuana users buy the drug from the government. Canadian Press, "Health Canada Looking for Marijuana Grower," *CBCnews.ca*, 15 April 2008, *http://www.cbc.ca/health/story/2008/04/15/healthcanada-marijuana.html*, accessed 31 July 2008.

United Kingdom. On 24 June 2008, Health Secretary Alan Johnson announced plans to ensure all patients in the U.K. are made aware of relevant research and clinical trials and may participate in clinical trials if they meet the criteria. Johnson announced plans to establish five to 10 Academic Health Science Centres, bringing together university research departments and teaching hospitals by partnering the education, research, and clinical functions of the institutions. Department of Health, "More Involvement and Choice for Patients," *News Distribution Service*, 24 June 2008, *http://nds.coi.gov.uk/Content/Detail.asp? ReleaseID=371664&NewsAreaID=2*, accessed 24 July 2008.

HEALTHCARE COVERAGE

In the current economic downturn, states are facing rising healthcare costs as well as increasing financial pressure on general budgetary expenses, raising new bioethics issues. One ethical question being debated in almost every state legislature is whether increasing cigarette taxes is an acceptable form of funding existing or expanded coverage for healthcare costs. According to the Campaign for Tobacco-Free Kids, since 2002, 43 states and the District of Columbia have enacted 76 tobacco tax increases, raising the average state tax from 61 cents to $1.13. The R. J. Reynolds Tobacco Company esti-

mates that the federal excise tax of $.39 per pack could raise $7.3 billion a year, in addition to state tobacco taxes generating annual revenues of approximately $14.5 billion. In April, the New York Legislature approved a $1.25 increase in the $1.50 per pack tax, making cigarettes sold in the state the most expensive in the nation. Massachusetts is looking to follow New York with an increase of $1 per pack, bringing the total tax to $2.51. In 2008, 22 state legislatures were considering or had enacted bills to raise tobacco taxes. K. Sack, "States Look to Tobacco Tax for Budget Holes," *New York Times*, 21 April 2008*, http://www.nytimes.com/ 2008/04/21/us/ 21tobacco.html?_r=1&ref=us&oref=slogin*, accessed 21 April 2008.

Recent Judicial Cases and Regulatory Actions, April - June 2008

Federal. On 30 June 2008, U.S. District Court for the District of Columbia denied the American Association for Homecare's motion for an injunction against national competitive bidding, scheduled to start 1 July 2008. The injunction was denied because "the court concluded that the plaintiffs are unable to demonstrate an irreparable injury." Mobility Management, "AAHomecare NCB Injunction Motion Denied," Mobility Management, 30 June 2008, *http://www.mobilitymgmt.com/articles/64899*, accessed 24 July 2008. Currently, there are three other cases filed against the Centers for Medicare and Medicaid Services (CMS), the current administrator of the national competitive bidding program. The companies filing suit are King and Spalding, Washington, D.C.; Amarillo, a Texas-based Brown and Fortunato company; and VGM Group's Last Chance for Patient Choice, based in Iowa. Penton Media, "AAHomecare Lawsuit to Stop Competitive Bidding Makes Four," *HomeCare*, 2008, *http:// homecare mag.com/news/aahomcare-lawsuit-stop-competitve-0806/,* accessed 24 July 2008.

***Federal**. 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, a cancer patient, argues that the Department of Health and Human Services (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*, at *NY12525-#412881-v13-JL_SDNY_complaint_11_26_07.Doc.* Complaint, *http://www.medicarerights.org/off_label _complaint _Nov 2007.pdf*.

California. On 05 May 2008, a coalition of healthcare providers filed suit against the state of California to prevent a 10 percent cut in Medi-Cal payments scheduled for 1 July 2008. The plaintiffs claim that such cuts are in violation of state and federal law 42 C.F.R. §447.204.*http://www.cmanet.org/ publicdoc.cfm/2/1/press section2/425\http:// dockets.justia.com/docket/court-cacdce/case_no-2:2008cv03363/case_id-416402/.*

*On 11 June 2008, the California Supreme Court declined to review an appeals court ruling that cancelling an individual's health insurance policy for an omission or mistake on an application after a claim is submitted is prohibited under state law. The court also held that an insurer cannot cancel a member's policy if the insurer does not attach a copy of the application to the policy when it is issued. *Ticconi v. Blue Shield of California* (Ca. S. Ct. No. S162434). Opinion, *http://appellatecases.courtinfo. ca.gov/search/case/mainCaseScreen. cfm?dist=0&doc_id=530594&doc_no=S162434.*

***Illinois**. On 15 April, the Cook County Circuit Court issued a temporary injunction against Governor Rod Blagojevich's efforts to expand the state's FamilyCare program. The court found the expansion an unauthorized and an unlawful use of tax dollars. The part of the expansion proposal dealing with breast and cervical cancer screenings for the uninsured, however, was deemed to be within the law. The injunction is part of a lawsuit challenging the constitutionality of the governor's ordered expansion of the FamilyCare program. Plaintiffs claim the expansion is unconstitutional, since it would cost $43 million in its first year without receiving legislative approval. *Richard Caro, et al. v. Rod Blagojevich, et al.* (Cook County Circuit Ct. Case No. 07 CH 34353), *http://news blogs.chicagotribune.com/ clout_st/files/healthruling.pdf*. A previous lawsuit, *Gidwitz, et al. v. Maram*, has been dismissed and combined with the current lawsuit. *Gidwitz, et al. v. Maram*, No. 2007 MR ____.

Recent Developments in Law and Regulation, April - June 2008

Federal. On 15 July, Congress overrode the President's veto of H.R. 6331, a bill that would prevent a scheduled 10 percent decrease in Medicare reimbursements to physicians. Public Law No. 110-275.

On 2 April 2008, a bill was introduced that would expand title 38 of the U.S. Code to expand healthcare services available to female veterans, including counseling for sexual assault. The Women Veterans Health Care Improvement Act of 2008 is currently under review by the Committee on Veteran's Affairs. S. 2799, 110th Cong., 2nd Reg. Sess. (2008).

*There has been no action on the Indian Health Care Improvement Act. The Senate version passed on 26 February 2008; an identical bill was referred to House Ways and Means Committee on 28 February 2008. The bill provides $35 billion to the Indian Health Service to allow 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).

*There has been no movement on the Healthy Americans Act, first introduced in the Senate in January 2008. The bill would create incentives for private health insurers to provide coverage directly to individuals, while employers' contributions would be shifted to wages, and eventually a health insurance contribution to the federal government. S. 334, 110th Cong., 2nd Reg. Sess. (2008).

On 2 April 2008, the U.S. Securities and Exchange Commission, in a reversal of its previous position, has declared that companies must allow shareholders to vote on a proposal for universal health insurance coverage. The SEC has told companies such as Boeing, General Motors, and Wendy's International that they may not omit a healthcare proposal from their proxy materials. R. Pear, "S.E.C. Backs Health Care Balloting," *New York Times*, 27 May *http://www.nytimes.com/ 2008/05/27/business/27health.html*, accessed 28 July 2008.

Alabama. There has been no action on a bill proposed by the state house that would increase the state cigarette tax from $.26 to $.75 per pack. Funds collected through the proposed cigarette tax would go to the State General Fund, which can also used to cover state healthcare programs. HB 361, 2008 Leg., Reg. Sess. (Ala. 2008).

***Alaska**. There has been no action on a universal healthcare proposal. The bill, 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. The bill was originally introduced in the Senate on 10 September 2007 and was sent to the finance committee 14 March 2008. S.B. 160, 24th Leg., Spec. Sess. (Alaska 2007).

California. A bill passed the state house but failed in the state senate that would have imposed a $1.50 per pack increase to fund universal health reform. A.B. 1a, A.B. x7, 2007-2008 Leg., Reg. Sess. (Cal. 2007).

Connecticut. On 27 May 2008, the governor signed into law a bill that eliminates the requirement that patients receiving treatment in residential facilities stay in the hospital three days before insurance will cover their costs and extends the benefits to adults. The bill takes effect on 1 January 2009. S.B. 167, 2008 Gen. Assem., Reg. Sess. (Conn. 2008).

District of Columbia. On 1 April 2008, a bill was introduced to create universal healthcare for D.C. residents. The bill, called the Healthy DC Act, among other provisions, would create competition between insurance companies for individual customers (as opposed to their workplaces), and subsidize insurance premiums for the 25,000 uninsured residents who are ineligible for Medicaid. The bill would also raise the cigarette tax from $.05 to $.10 for each cigarette to increase revenue for the Healthy DC fund. D.C. Council, B17-700 (2008).

Florida. Two similar bills that would have increase the cigarette tax to help pay for state healthcare programs died in committee. The state house bill would have increased the cigarette tax by $.661 per pack, and funds would go to the General Revenue Fund that can be used for healthcare programs. The state senate bill would have increased the tax by $1.00 per pack and would increase enrollment in the Florida KidCare program. H.B. 299, S.B. 2790, 2008 Reg. Sess. (Fla. 2008).

Georgia. Two bills, introduced in February 2008, to increase the cigarette tax to cover general state expenses, including state healthcare programs, died in committee. Both would have increased the cigarette tax from $.37 per pack to $1.37 per pack. H.B.

1197, H.B. 1264, 149th Gen. Assem. Reg. Sess. (Ga. 2008).

On 7 May 2008, the governor signed into law two bills intended to make health insurance plans more affordable. Under the first bill, HB 977, insurers are exempt from a 2.5 percent tax that previously covered premiums for high-deductible plans that included health savings accounts. H.B. 977 also provides a $250 tax credit to small businesses that spend at least that much to enroll their workers in health savings accounts. The second bill, S.B. 383, would only classify health reimbursement accounts — accounts set up to allow for the use of pre-tax dollars for health-related expenses — as insurance if they are packaged with individual insurance policies. H.B. 977, S.B. 383, 149th Gen. Assem. Reg. Sess. (Ga. 2008).

Hawaii. On 2 May 2008, the legislature overrode the governor's veto of a bill that enrolls the state in the state I-SaveRX program, allowing residents to purchase lower-cost drugs from overseas. Hawaii is the sixth state to enroll in the program, and it is expected to see savings of up to 55 percent. H.B. 7, 24th Leg., Reg. Sess. (Haw. 2008).

Illinois. The state legislature is considering two bills introduced to increase the cigarette tax by $.90 per pack; revenue from the tax increase proceeds of the additional taxes be paid into the Tax Compliance and Enforcement Fund, the Healthcare Provider Relief Fund, and the Pension Stabilization Fund. One, H.B. 556, was introduced on 10 January 2008 and the other, S.B 2545, was introduced on 15 February 2008. Both bills are currently under consideration in the Rules Committee. H.B. 556, S.B. 2545, 95th Gen. Assem. Reg. Sess. (Ill. 2008).

***Iowa**. On 13 May 2008, the governor signed into law a bill increasing the income eligibility threshold for hawk=i, the state's version of the state Children's Health Insurance Program (SCHIP), from 200 percent of the federal poverty level to 300 percent. The bill lays out plans to reach universal coverage for children by 2011 and all adults by 2013. The bill also allows children between 18 and 25 to remain on their parents' health insurance plans unless they marry or move out of state. The bill does not mandate coverage for children and encourages the use of electronic health records. The bill became effective immediately upon signing. H.F. 2539, 82nd Gen. Assem., 2nd Sess. (Iowa 2008).

Kansas. On 18 May 2008, the governor signed into law a bill implementing several new healthcare initiatives. The bill expands eligibility for enrollment in the state Children's Health Insurance Program (SCHIP) and sets aside $2.5 million for "safety net clinics" and $460,000 to expand Medicare coverage for pregnant women. The bill became effective 1 July 2008. S.B. 81, 82nd Leg., Reg. Sess. (Kan. 2008).

The state legislature is considering a bill to increase the cigarette tax in order to help pay for state healthcare programs. The bill, originally introduced on 1 February 2008, would increase the cigarette tax by $.50 per pack and earmark a four cent increases in later years for health reform. The bill is under consideration in the Taxation Committee. H.B. 2737, S.B. 542 82nd Leg., Reg. Sess. (Kan. 2008).

Kentucky. A bill died in committee on that would have increased the cigarette tax by $.40 up to $0.70 per pack, to help pay for state healthcare expenditures. H.B. 443, 2008 Reg. Sess. (Ky. 2008).

Maine. On 16 April 2008, the governor signed into law a bill that would increase excise taxes on beer and wine and create a new tax on soda to fund Dirigo Health, which oversees the state's subsidized health insurance program. The beverage taxes replaced a proposed $.50 per pack increase in the cigarette tax previously supported by the governor (123rd Legislative Session, L.D. 790, L.D. 1608, 123rd Leg., Reg. Sess. (Me. 2007)). L.D. 2247, 123rd Leg., Reg. Sess. (Me. 2007). A People's Veto for the new beverage taxes has been placed on the November ballot. N. Augur,"Fed Up with Taxes Files More Than 90,000 Signatures for People's Veto," *Fed Up with Taxes*, 15 July 2008, *http://www.fedupwithtaxes.org/index.php/Press-Releases/Fed-Up-With-Taxes-Files-More-Than-90000-Signa-tures*, accessed 18 August 2008.

Massachusetts. On 1 July 2008, Governor Deval Patrick signed into law a bill raising the tax on Massachusetts cigarettes by $1 per pack, bringing the total to $2.51. The revenue generated from this tax is supposed to help offset the cost of Massachusetts' new health insurance law. Chapter 64C section 7A.

On 15 July 2008, the Massachusetts House Joint Committee on Health Care Financing revised portions of a bill that would prevent pharmaceutical companies from providing gifts and meals to physicians. It also removed provisions that would require drug and medical device manufacturers to disclose consulting and speaking payments to physicians. The provision, which would have made each violation punishable by a $5,000 fine, was also removed. S.B. 2526, 185th Gen. Court., Reg. Sess. (Mass. 2008).

***Minnesota**. On 13 May 2008, the governor vetoed a bill that would have established a statewide health improvement program. The governor stated that the bill increased healthcare access at the cost of quality improvement and "meaningful cost con-

tainment." H.F. 3390, 85th Gen. Assem., Reg. Sess. (Minn. 2008).

Montana. On 18 June 2008, an initiative, No.155, the Healthy Montana Kids Plan Act, received enough signatures to be included on the November 2008 ballot. The act would establish a children's health insurance coverage plan by raising the minimum income level that qualifies for Medicaid. Currently, 16 percent of the children in Montana are uninsured. Text of the initiative is available on Ballotpedia at *http://www.ballotpedia.org/wiki/index. php?title= The_Healthy_Montana_Kids_Plan_Act_ %282008 %29*, accessed 21 July 2008.

Nebraska. On 21 February 2008, a bill to increase cigarette taxes that would have used a portion of the revenue for behavioral health funding was withdrawn. The bill, originally introduced on 23 January 2008, would have increased the cigarette tax by $.10 to $.74 per pack. L.B. 1149, 100th Leg. Sess. (Ne. 2008).

New Jersey. On 8 July 2008, New Jersey Governor Jon Corzine signed into law S1557, a bill which, as well as nearly doubling the previous annual income threshold for FamilyCare coverage (from $27,645 to $42,400), would mandate healthcare coverage for all New Jersey residents under the age of 19. This is the first part of a three-step plan to achieve universal healthcare within the state. S. 1557, 2008 Gen. Assem., Reg. Sess. (NJ. 2008).

New York. On 19 April 2008, the governor signed into law a bill that would increase the state cigarette tax by $1.25, from $1.50 per pack, making it the highest in the nation at $2.75 per pack. The state budget office projected the tax would raise $265 million annually. Much of the revenue would be used for health programs including those to help smokers quit and to keep youths from starting. Ch. 57, S.B. 6807, 230th Gen. Reg. Sess. (N.Y. 2007).

Senator Jeffrey Klein (D-NY) released a report that alleges that some of the HMOs in New York State are restricting patients' access to "single-source drugs," brand-name medications that do not have low-cost generic versions. The report involved a survey of 15 HMOs that have drug plans in New York. It suggests that HMOs block brandname drugs to make larger profits. W. Sherman, "HMOs Block Key Brand-Name Medicines to Make Big Bucks, Report Says," *New York Daily News*, 18 May 2008, *http://www.nydailynews.com/news/2008/05/18/2008-05-18_hmos_block_key_brandname_medicines_to_ma.html*, accessed 20 August 2008.

North Carolina. Recently, three bills were introduced that would increase the state cigarette tax to help fund state healthcare programs. H.B. 1026, introduced 26 March 2008, would fund a cancer hospital at the University of North Carolina at Chapel Hill. H.B. 1565, introduced 17 April 2008, would raise the cigarette tax by $.02 per cigarette to $.0375, and H.B. 2034, introduced 9 May 2008, would levy an excise tax on tobacco products other than cigarettes at 20 percent of the product's price. Both the latter bills would create revenue for the state general fund, which in turn could be used for healthcare programs. H.B. 1026, H.B. 1565, H.B. 2034, Gen. Assem. 2007-2008 Sess. (N.C. 2008).

Rhode Island. On 13 March 2008, a bill was introduced that would increase the cigarette tax to fund a tobacco control program. S.B. 2860, 2008 Gen. Assem., Reg. Sess. (R.I. 2008).

South Carolina. On 27 May 2008, the governor vetoed a bill that would raise the cigarette tax by $.50 per pack in order to help pay for healthcare programs. On the same day, an attempt to override the veto in the state legislature failed. H.B. 3567, 117th Gen. Assem., 2nd Reg. Sess. (S.C. 2008).

Utah. On 5 March 2008, a bill was voted down in the state house that would have raised the cigarette tax by $.50 per pack of 20 to $1.195, appropriating $3.1 million, or the total amount of the revenue, whichever was less, for the Cigarette Tax Restricted Account, and any extra funds for the Department of Health for cancer screening and the Gold Medal Schools Program. H.B. 355, 2008 Gen. Sess. (Utah, 2008).On 17 March 2008, the governor signed into law a bill that would levy a tax on moist snuff, of $.75 per ounce, that would generate revenue for the general fund, which, in turn, would help cover state healthcare programs. H.B. 356, 2008 Gen. Sess. (Utah, 2008).

Washington. On 1 April 2008, the governor signed into law a bill that empowers the state insurance commissioner to monitor individual health plan premium rate changes, reject "unreasonable" proposals, and order the return of excess profits to the state. S.B. 5261, 60th Leg., 2008 Reg. Sess. (Wash. 2008). The full text of Chapter 303 as signed by the governor can be found at *http://apps.leg.wa.gov/documents/billdocs/2007-08/Pdf/Bills/Session%20Law %202008/5261-S.SL.pdf.*

West Virginia. A bill died in committee that would have increased the cigarette tax to $1.35 per pack to help pay for state healthcare reforms. H.B. 3123, 80th Leg., Reg. Sess. (W. Va. 2008).

Wyoming On 4 March 2008, a bill was voted down in the state house that would have lowered the discount on cigarette stamps sold to wholesalers from 6 percent to 1.2 percent. The general funds raised would have in part been available to cover

the cost of state healthcare programs. H.B. 41, 59th Leg., Reg. Sess. (Wyom. 2008).

VACCINES

A recurring theme in "Legal Trends" is: Who should bear the burden of healthcare costs, both preventative and curative? One of the costs of preventative medicine in the form of vaccines is the cost in quality of life, and sometimes in life itself, caused by the physical adverse reactions that vaccinations can cause in some patients. It is well-established health policy and legal doctrine that when a population is protected from a deadly, highly contagious and otherwise untreatable disease, the cost of an occasional adverse reaction is a small price to pay for protecting the entire community from a tragedy of epic proportions (See the U.S. Supreme Court Decision in *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905) involving a smallpox epidemic). However, who should bear the cost of the care of those who suffer adverse reactions? In the U.S., the federal government pays claims for injury caused by vaccines recommended by the Centers for Disease Control and Prevention (CDC) that are mandated at the state level. While this seems like a fair scheme in general, many vaccines are mandated today that fall far below the original requirements set out by *Jacobson,.* and arguably should be voluntary, particularly those vaccines intended to protect an individual rather than the community at large (for example, the HepB and HPV are vaccines that arguably fall into this category). Even if someone disagrees that any of the vaccines on the CDC's recommended list that states now mandate should be voluntary, there are other questions worth asking: Is the cost-benefit analysis done by policy makers when they mandate a vaccine accurate? How many lives are expected to be saved by mandating the vaccine versus the number of adverse events, including those causing death, that can be expected? Could an unintended consequence of relieving vaccine manufacturers of liability for adverse reactions, as is the case when a vaccine is mandated by law, be that the incentive to produce the safest vaccine possible is diminished?

Judicial Cases and Regulatory Actions April - June 2008

Federal. A decision by the U.S. Court of Federal Claims in November 2008, conceding that childhood vaccines contributed to a nine-year-old girl's autistic symptoms, recently became public on an autism advocacy website. The court statement indicates that five vaccines received on a well-baby checkup in 2000 aggravated a rare underlying mitochondrial disorder that manifested with features of autism spectrum disorder. A Portuguese study suggests the disorder, caused by a point mutation in a gene for the 16S ribosomal RNA, is more common in autistic children, with incidence rates of about 7 percent compared to 0.02 percent in the general population. The concession did not specify whether thimerosal, a mercury-based preservative now only used in certain flu shots, or something else in the vaccine was at fault. Public health officials state this decision is an exceptional case rather than a landmark ruling linking vaccines and autism. The Poling family will be paid from a federal vaccine-injury fund (on 1 October 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Inury Compensation Program), although the exact amount has not been determined. Two other cases alleging that vaccination caused children's autism went to trial in May 2008. *Poling, et al. v. Secretary of Health and Human Services* (U.S. Fed. Ct. of Claims, Case No. 02-1466 V).

Recent Developments in Law and Regulation, April - June 2008

Federal. On 25 June, the Advisory Committee on Immunization Practices (ACIP) voted to add the rotavirus vaccine Rotarix to the list of recommended infant inoculations. Rotarix, created by GlaxoSmith Kline Plc, is in competition with another vaccine, RotaTeq, created by Merck and Co., approved by the FDA two years ago. The FDA approved Rotarix on 3 April0. The CDC did not express a preference for either vaccine. ACIP, "ACIP Provisional Recommendations for the Prevention of Rotavirus Gastroenteritis among Infants and Children," 1 July 2008, *http://www.cdc.gov/vaccines /recs/provisional/downloads/roto-7-1-08-508.pdf*, accessed 30 July 2008.

The FDA is still considering whether or not to approve Merck's human papillomavirus vaccine (HPV), Gardasil, for women 27 to 45, stating there are "issues" preventing approval. Merck discussed the FDA's questions with the agency and was expected to respond to the FDA in July. Merck will also seek approval to use Gardasil for males by the end of 2008. L. Krauskopf, "Merck's Gardasil Not Cleared for Older Women," *Reuters*, 25 June 2008, *http://www.reuters.com/article/rbss Pharmaceuticals%20-%20Diversified/idUSN254263042008 0625?sp=true*, accessed 30 July 2008.

Missouri. On 3 April 2008, the Health Care Foun-

dation of Greater Kansas City announced that it would provide the HPV vaccine Gardasil to uninsured and underinsured girls and women free of charge at 139 participating clinics and health centers. Gardasil's usual commercial cost of about $360 limits access for girls and women with inadequate insurance who do not qualify for Missouri's free Vaccines for Children program. Missouri Foundation for Health, "Free HPV Vaccine Available at 139 Missouri Sites," 3 April 2008, *http://www.mffh.org/press_release1408.htm*, accessed 24 July 2008.

West Virginia. On 4 June 2008, a bill went into effect that would allow pharmacists to vaccinate those 18 or older. The bill, signed into law 31 March 2008, initially allows pharmacists to administer vaccines for influenza and pneumonia, but once the state Boards of Pharmacy, Medicine, and Osteopathy propose rulings for legislation, vaccinations for hepatitis A and B, tetanus, and shingles may be administered. Pharmacists must first complete a board-approved immunization administration course and maintain American Red Cross or American Heart Association certification for basic medical training. H. B. 3056, 78th Leg., Reg. Sess. (W. Va. 2008).

Interesting Developments in Other Countries

***Canada**. Quebec has joined other Canadian provinces in establishing an HPV vaccination plan for schoolgirls. Girls in fourth and ninth grades will receive Gardasil for free if their parents request it. Health Canada has approved Gardasil for girls aged nine and up, and most vaccinations will take place in schools. C. Nordqvist, "Quebec to Offer Schoolgirls Free HPV Vaccine," *Medical News Today*, 14 April 2008, *http://www.medical newstoday.com/articles/103936.php*, accessed 24 July 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 April - June 2008

Federal. On 21 May 2008, the President signed into law the Genetic Information Nondiscrimination Act (GINA), which protects Americans from genetic discrimination when seeking health insurance or employment. H. R. 493, 110th Cong. 2nd Reg. Sess. (2008).

On 24 April 2008, the President signed into law a bill amending the Public Health Service Act to set up guidelines standardizing newborn screening tests. It would establish grants to set up programs that screen newborns, educate healthcare professionals and families about newborn screening, and set up a system to assess and coordinate treatment of congenital, genetic, or metabolic disorders. S. 1858, 110th Cong. 2nd Reg. Sess. (2008).

Federal. On 15 April 2008, the New Democrat Coalition announced a proposal to pattern a federal healthcare information technology (IT) program after one in New York City as the city transitions to electronic health records. The long-term goal is 75 percent participation in a fully interoperable health information exchange by 2018. New Democrat Coalition, "New Dems Offer Roadmap Forward on Health IT," 15 April 2008, *http://www.house.gov/apps/list/press/ca10_ tauscher/healthIT.html*, accessed 13 August 2008.

On 27 June 2008, the U.S. Drug Enforcement Administration (DEA) published proposed regulations that would permit authorized medical providers to use electronic prescriptions for restricted drugs, including the sleep medications Lunesta and Ambien. Pharmacies would be able to receive, dispense, and archive the e-prescriptions. DEA, "DEA Issues Proposed Regulations to Allow Electronic Prescriptions for Controlled Substances," 27 June 2008, *http://www.usdoj.gov/dea/pubs/pressrel/pr062708.html*, accessed 13 August 2008.

New York. On 28 March 2008, the governor announced $105 million in grants were awarded to 19 community-based health information technology projects. The grants would help develop a unified statewide electronic medical record system, and are part of a plan to overhaul New York's healthcare system. "New York Awards $105 Million In Health Information Technology Grants," 28 March 2008, *http://www.state.ny.us/governor/press/press_0328081.html*, accessed 13 August 2008.

Interesting Developments in the Private Sector

On 19 May 2008, Google opened public access to Google Health, which allows users to store health records online. Users can import records from hospitals and pharmacies partnered with Google Health, search for doctors and hospitals, and enter data on health conditions, medications, allergies, and lab test results. Users decide which medical organizations can view or send updates to their profile. In response

to concerns on users' privacy, Google's vice president of search products and user experience said there would be extra security on the servers holding the records. J. Vascellaro, "Google Helps Organize Medical Records," *Wall Street Journal*, 20 May 2008, *http://online.wsj.com/article/SB121123806355705263*.html, accessed 12 August 2008.

MEDICAL TOURISM

Interesting Developments in the Private Sector

On 16 June 2008, the American Medical Association (AMA) released its first guidelines regarding medical tourism. The nine-point guidelines address informed consent, financial incentives, and follow-up treatment. AMA, "New AMA Guidelines on Medical Tourism," 16 June 2008, *http://www.ama-assn.org/ama1/pub/upload/mm/31/medicaltourism.pdf*, accessed 30 July 2008.

Interesting Developments in Other Countries

Philippines. The Philippine Department of Health banned kidney transplant for foreigners, with an exception for those related by blood to Filipino citizens. *Foreigner* is defined those who are not Filipino citizens. While organ sales are illegal, the black market is thriving due to so-called transplant tourism. While hospitals are only permitted to perform 10 percent of transplant procedures on foreigners, many facilities exceed this limit. C. Conde, "Philippines Bans Kidney Transplants for Foreigners," *New York Times*, 30 April 2008, *http://www.nytimes.com/2008/04/30/world/asia/30phils.html*, accessed 13 August 2008.

HIV/AIDS

Judicial Cases and Regulatory Actions April - June 2008

Texas. On 14 May 2008, an HIV-positive man was convicted of harassing a public official with a deadly weapon: he spat into the open eye and mouth of a police officer and was sentenced to 35 years in prison. The man, indicted under a habitual-offender statute resulting in a minimum of 25 years imprisonment, will not be eligible for parole until he has served half of his sentence due to the deadly weapon finding. The CDC has stated that contraction of HIV from saliva is extremely rare. The police officer has not contracted HIV. G. Kovach, "Prison for Man With H.I.V. Who Spit on a Police Officer," *New York Times*, 16 May 2008, *http://www.nytimes.com /2008/05/16/us/16spit.html*, accessed 8 August 2008.

Recent Developments in Law and Regulation April - June 2008

Minnesota. On 20 May 2008, a bill was pocket vetoed that would have created an exemption in the informed consent policy of Minnesota's 2006 Genetic Privacy Law for the collection, analysis, and indefinite storage of infant blood and DNA. The bill would have allowed parents to object to the taking, analyzing, sharing, and storing of infant blood; however, persons collecting blood samples would not be required to advise parents of this right. Prior to collecting the blood samples, it would have been required to provide parents with a document with information about how the blood would be used, and that parents could sign a written exemption to the blood testing, use, and storage. S. F. 3138, 85th Leg. Sess. (Minn. 2008).

New York. In June 2008, New York City Department of Health and Mental Hygiene clinics discontinued use of a rapid oral fluid HIV test, the OraQuick Advance Rapid HIV-1/2 Antibody Test, after it delivered an unusual number of false positive results. Use of the test was previously suspended in December 2005 after a spike of false-positives, but was reinstated after three weeks with the stipulation that all positive results had to be confirmed with a finger-stick test. The more recent increase in false positives began in late 2007. The reason for the false-positive spikes has not been determined. NYC hospitals began using the tests widely in April 2008; the tests use a gum swab and return a result after 20 minutes. CDC, "False-Positive Oral Fluid Rapid HIV Tests — New York City, 2005—2008," *Morbidity and Mortality Weekly Report*, 18 June 2008, *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm57e618a1.htm,* accessed 4 August 2008.

South Carolina. On 11 June 2008, the governor vetoed a bill that would eliminate a current requirement that school district superintendents and school nurses must be given the names of any students who test positive for HIV/AIDS at any of the state's clinics or private doctor's offices. The bill would have given the students' names only to the Department of Health and Environmental Control (DHEC). School nurses would have to contact the DHEC in the event a student came into contact with another student's blood, and the DHEC would inform the nurse of any blood-borne diseases and any neces-

sary medical treatment. The governor stated a personal belief that the bill was moving in the wrong direction and that he felt more "highly contagious diseases," like Hepatitis B and Hepatitis C, should be added to the list. S. 970, 117th Gen. Assem., 2nd Reg. Sess. (S.C. 2008).

In May, the legislature passed a $2.4 million budget for the state's AIDS Drug Assistance Program. The money will help prevent long waiting lists; after federal funding was cut last year, 567 people were on a waiting list. Kaiser Family Foundation, "South Carolina Legislature Approves $2.4M for State ADAP," *Kaiser Daily HIV/AIDS Report*, 9 May 2008, *http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID =52042*, accessed 8 August 2008.

Interesting Developments in the Private Sector

On 24 April 2008, five groups of Atlanta students produced several public service announcements designed to be viewed and shared via cell phone, called Personal Public Service Announcements, encouraging young adults to be tested for HIV. The student groups received funding, information, and donated equipment from the CDC and Verizon. Verizon aired the PPSAs from 20 June - 20 July 2008 on a VCast mobile video network channel, and the CDC created a channel on the popular video-sharing site YouTube. University of Georgia New Media Institute, "The AIDS Personal Public Service Announcement Project," 23 April 2008, *http://www.mynmi.net/aids_ppsa/*, accessed 4 August 2008.

Interesting Developments in Other Countries

***International**. On 24-26 June 2008, the International Task Team on HIV-related Travel Restrictions concluded its third meeting after drafting recommendations to remove HIV-specific restrictions on entry, stay, or residence in a country, noting that such recommendations are discriminatory. The final recommendations will be presented in December 2008 at the next meeting of the UNAIDS Programme Coordinating Board. UNAIDS, "Third meeting of the International Task Team on HIV-related Travel Restrictions," 18 July 2008, *http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2008/20080718_travel_restrictions.asp*, accessed 5 August 2008.

Brazil. On 7 April 2008, Brazil opened its first government-run condom factory. The factory will produce 100 million condoms annually with rubber from trees in the Amazon. The factory will generate 2.2 million reais (about $1.3 million) annually for workers and will reduce pressure to cut down rain forest trees as well as reduce Brazil's current dependence on imported condoms, which it distributes at no cost. Brazil's government says it is the largest purchaser of condoms in the world. Reuters, Inc., "Brazil says Condoms to Stem Amazon Losses, AIDS," *Reuters*, 7 April 2008, *http://www.reuters.comarticle/environmentNews/idUSN0721438020080407*, accessed 4 August 2008.

Egypt. On 29 May 2008, an appeals court upheld three-year prison terms given to five men with HIV/AIDS. The men were charged with "habitual practice of debauchery," which in Egyptian law includes homosexual sex acts. Before conviction, the men were forcibly submitted to HIV tests and abusive anal examinations to "prove" they had engaged in sex acts with other men, and men who tested HIV-positive were chained to hospital beds. Human Rights Watch, "Egypt: Court Upholds HIV Sentences, Reinforces Intolerance," *Human Rights News*, 29 May 2008, *http://www.hrw.org/english/docs/2008/05/29/egypt18959.htm*, accessed 5 August 2008.

Ireland. On 16 June 2008, the Minister for Health Promotion and Food Safety announced the HIV and AIDS Education and Prevention Plan 2008-2012. The plan prioritized encouraging HIV tests for at-risk groups and educating the public. The plan includes providing condoms to at-risk groups in targeted health settings for no cost. Department of Health and Children, "Minister Wallace Launches the HIV and AIDS Education and Prevention Plan 2008 – 2012," 17 June 2008, *http://www.dohc.ie/press/releases/2008/20080617b.html*, accessed 8 August 2008.

Jamaica. In April, the National Family Planning Board announced plans to unveil the FC2, a new female condom, in an effort to provide women with more control over HIV/AIDS prevention measures. The board also planned to conduct workshops to promote use of the condoms and address negative stigma and myths about the condoms. Kaiser Family Foundation, "Jamaica to Launch New Female Condom as Part of HIV/AIDS Prevention Efforts," *Kaiser Daily HIV/AIDS Report*, 22 April 2008, *http://www.kaisernetwork.org/Daily_reports/print_category.cfm?dr_cat=1&dr_DateTime=04-22-08*, accessed 8 August 2008.

Kenya. On 10 April 2008, the Kenyan government announced a plan to fasttrack a national rollout of male circumcision by mid-2008 to help prevent HIV. Several trials in 2006 report that circumcision decreased new HIV infections in men by more than half. National AIDS Control Council, "Govern-

ment to Roll out Male Circumcision," 10 April 2008, http*://www.nacc.or.ke/2007/default2. php?active _page_id=272&id=279*, accessed 9 August 2008.

Singapore. On 22 April 2008, the parliament approved a bill making it illegal people who think they might be HIV-positive to have sex without first informing their partners of the risks. Violations could be punished with up to 10 years of imprisonment and a $50,000 fine. A 1992 law makes it illegal for people knowing they have HIV to choose not to tell their partners; punishment for a violation would be increased to the same amount. The government said it would only act if a victim filed a complaint and only after a through investigation. The bill also encourages people to get tested for HIV and avoid risky behaviors. Kaiser Family Foundation, "Singapore's Parliament Approves Measure That Addresses Spread of HIV Through Unsafe Sex," *Kaiser Daily HIV/AIDS Report*, 24 April 2008, *http://www.kaiser network.org/Daily_reports/rep_index. cfm?DR_ID=51720*, accessed 9 August 2008.

CONSCIENTIOUS OBJECTIONS (HEALTHCARE PROVIDERS AND RELATED PROFESSIONS)

Recent Judicial Cases and Regulatory Actions April - June 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**. There have been no developments in a case filed by 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. The Illinois Supreme Court heard arguments on 18 March 2008 but have not yet published an opinion. *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 April - June 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. (N.Y. 2007).

MENTAL HEALTH

Recent Developments in Law and Regulation April - June 2008

***Federal**. On 3 June 2008, the Senate unanimously passed Mental Health Improvements Act of 2007. The bill, originally introduced on 15 October 2007, would provide for improved treatment of veterans with posttraumatic stress and/or substance abuse disorders. The bill was referred to the House Veterans' Affairs Committee on 4 June 2008. S.B. 2162, 110th Leg., Reg. Sess. (2007).

*There has been no action on a bill 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).

*There has been no recent activity on the Paul Wellstone Mental Health and Addiction Equity Act of 2008. The act passed the House 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).

*There has been no action 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).

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 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).

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

Artificial embryonic stem cells made from adult skin cells were just as effective as real embryonic stem cells, according to scientists attending the Biotechnology Industry Organization conference 16 through 20 June 2008. The use of these artificial stem cells, created by adding genes coding for transcription factors to skin cells, would relieve ethical pressures involving embryonic cells and relieve the bottleneck created by the limited supply of embryonic cells. Although the technique currently used to create artificial stem cells has a low success rate, scientists believe the process can be rapidly improved. B. Fikes, "Artificial Embryonic Cells Fuel Research 'Explosion'," *North County Times*, 23 June 2008, *http://www.nctimes.com/articles/2008/06/23/business/doc485fda4aca 79b142165416.txt*, accessed 29 July 2008.

Concerns have recently been raised about the safety of nanoparticles in consumer products like cosmetics and sunscreen. Some believe the FDA should require cosmetic manufacturers to note the presence of nanoscale materials in their products, but the FDA's 2007 Nanotechnology Task Force found no evidence to suggest that nanoscale materials were inherently more hazardous than non-nanoscale materials. R. Carvajal, "Why FDA Currently Can't Require 'Nanotech' Labeling on Cosmetics," *FDA Law Blog*, 17 April 2008, *http://www.fdalawblog.net/ fda_law_ blog_hyman_ phelps/2008/04/why-fda-current.html,* accessed 29 July 2008.

Judicial Cases and Regulatory Actions April - June 2008

Missouri. On 30 June 2008, a suit was filed to delay the state from providing $21 million in funding to the Life Science Research Board. The lawsuit questions whether limits on spending from the state life-sciences research fund blocking spending for abortion and human cloning are overridden by a 2006 amendment supporting stem cell research. Opponents are concerned that money from the fund may be used to support embryonic stem cell research. *Missouri Roundtable for Life vs. Sarah Steelman et al.*, (Cole County Cir. Ct. Case No. 08AC-CC00517).

Recent Developments in Law and Regulation April - June 2008

California. On 6 June 2008, a bill was unanimously approved by the assembly that would allow biotech companies to claim tax deductions based on net operating losses over 20 years instead of the current 10. Since biotech companies take, on average, 14 years to develop their first products and sev-

eral more years to reach profitability, the current 10-year carry-forward usually expires before companies begin to make profits. The bill would match the current 20-year carry-forward of the federal government. The bill would take immediate effect but have no fiscal impact until 2019. A.B. 1370, 2007-2008 Leg., Reg. Sess. (Calif. 2007).

Maryland. On 16 June 2008, the governor announced the BIO 2020 Initiative, a plan to invest $1.1 billion in biotechnology research over the next decade. The initiative includes directing at least $20 million annually to stem cell research, expanding the technology incubator network, and doubling the Biotech Investment Tax Credit once in fiscal year 2010 and again in 2013. M. O'Malley, "Announcement of the Bio 2020 Initiative" (speech transcript), 16 June 2008, *http://www.gov.state.md.us/speeches/080616.asp*, accessed 29 July 2008.

***Massachusetts**. On 16 June 2008, the governor signed into law a bill that would provide $1 billion over 10 years to strengthen the state's life sciences industry. The bill will create the Massachusetts Life Sciences Center (MLSC), which is responsible for overseeing the initiative. The $1 billion initiative provides $300 million for targeted infrastructure projects, including building a stem cell bank at the University of Massachusetts Medical School; $200 million for public infrastructure project investments at the discretion of the MLSC; $25 million annually for ten years in tax credits for life sciences projects; and $25 million annually for ten years for the Massachusetts Life Sciences Investment Fund held by the MLSC for loans, fellowships, grants, and investments in the life sciences sector. H. 4829, 185th General Court, Reg. Sess. (Mass. 2007).

Interesting Developments in Other Countries

International. On 12 June 2008, the International Society for Stem Cell Research (ISSCR) announced a draft set of stem cell research guidelines for both researchers and the public to fight back against misleading websites claiming to have new stem cell treatments for any number of diseases. The guidelines address stem cell creation, studies, and research; make specific recommendations for oversight, accountability, and informed consent; and address social justice issues such as fair access. The ISSCR hopes to release final guidelines by the end of the year. ISSCR, "International Committee Recommends Stringent Guidelines for Translating Stem Cell Therapies from the Lab Bench to the Bedside," 12 June 2008, *http://www.isscr.org/press_releases/clin_guidelines.html,* accessed 28 July 2008.

European Union. On 1 June 2008, the European Union's new law on chemical standards, the Registration, Evaluation and Authorization of Chemicals (REACH), came into effect. It included no regulations on nanotechnology, but new scientific evidence suggesting nanoparticles could cause health risks is pressuring officials to create regulations on nanomaterials. The study, published in *Nature Nanotechnology* on 20 May 2008, reveals that long, straight carbon nanotubes can cause cancerous lesions when injected into the lungs, much like asbestos. Researchers have not yet studied the effects of environmental exposure or inhalation, and one scientist suggests that these problems may be avoided by using only short, curly nanotubes or mixing nanotubes with liquids instead of powders so they cannot be accidentally inhaled. The EU's decisions about nanotechnology will likely affect nanotechnology regulation worldwide. M. Dalton, "EU to Pace Nanotechnology," *Wall Street Journal*, 29 May 2008, *http://online.wsj.com/article/SB121201044102027389.html?mod=MKTW,* accessed 29 July 2008.

South Korea. On 16 May 2008, the South Korean Parliament passed a law that banned cross-species cloning, the process of inserting human cells into animal eggs, and allowed the use of stem cells to treat "general" diseases instead of only "rare and incurable" diseases or infertility. The cross-species cloning ban is punishable by three years of imprisonment. Opponents say the ban will hinder stem cell research, since human eggs are difficult to obtain and many eggs are needed for research. Agence France-Presse, "South Korean Parliament Passes Law Banning Type of Cloning, Broadening Embryonic Stem Cell Research," *Daily Women's Health Policy Report,* 19 May 2008, *http://www.nationalpartnership.org/site/News2?abbr=daily2_&page=NewsArticle&id= 11349*, accessed 28 July 2008.

***United Kingdom**. A bill to update the 1990 Human Fertilisation and Embryology Bill is making its way through Parliament. The bill will allow:

- The creation of "saviour siblings," whereby parents use IVF to selectively implant an embryo that genetically matches another child with a serious illness;
- Allow the creation of hybrid embryos for stem cell research; and
- Remove a requirement for doctors to consider the need for a father before offering fertility treatment, which would allow lesbian couples and single mothers to receive IVF treatment.

A proposed amendment attempting to lower the current abortion limit of 24 weeks was tabled. Human Fertilisation and Embryology Bill, HL 2007-08, *http://services.parliament.uk/bills/2007-08/humanfertilisation andembryology.html*.

On 30 June 2008, the Human Fertilisation and Embryo Authority (HFEA) approved an application from the Clinical Sciences Research Institute at the University of Warwick to create human-pig hybrid embryos to study cardiomyopathy. The license lasts for 12 months and comes into effect 1 July 2008. HFEA, "HFEA Statement on Warwick University hybrid embryo research," 30 June 2008, *http://www.hfea.gov.uk/en/1698.html,* accessed 30 July 2008.

TRUST / ACCOUNTABILITY

The federal government has not established adequate guidelines to prevent hospital-acquired infections nor has it pushed hospitals to follow standards to reduce infections, according to a Government Accountability Office (GAO) report released 18 April 2008. C. Bascetta, "Health-Care-Associated Health Risks in Hospitals," *Government Accountability Office,* April 16, 2008, *http://www.gao.gov/docsearch /abstract.php?rptno=GAO-08-673T*, accessed 21 August 2008.

Judicial Cases and Regulatory Actions April - June 2008

Federal. On 25 June, the California Northern District Court denied requests from two veterans groups for a permanent injunction to prevent the Department of Veteran Affairs (VA) from "continuing certain widespread practices and policies." Such policies included failing or refusing to provide timely medical treatment and tampering with records and claim files. The veterans groups claimed that the VA was not fulfilling its obligation to provide care for veterans with posttraumatic stress disorder (PTSD), citing extensive processing delays and backlogs. The court stated the requested injunctions would require an overhaul of the VA, which would be outside the scope of the court's jurisdiction. *Veterans for Common Sense et al. v. James B. Peake, Secretary of Veterans Affairs, U.S. Department of Veterans Affairs, et al.* (Northern CA District Ct. Case No. 3:2007cv03758). The case is on appeal in the Ninth Circuit U.S. Ct. of Appeals (Case No. 08-16728).

On 4 June 2008, the U.S. Department of Justice announced the settlement of a legal action against Walgreens. The company has agreed to pay $35 million to settle claims filed against it from 2001 to 2005. The Department of Justice alleged that Walgreens switched prescriptions for Medicaid patients who were prescribed Ranitidine, Fluoxetine, and Eldepryl to more expensive capsules, to substantially increase its reimbursement from Medicaid while providing no additional medical benefit to patients. U.S. Department of Justice, "Walgreens to Pay $35 Million to U.S., 46 States & Puerto Rico to Settle Medicaid Prescription Drug Fraud Allegations," 4 June 2008, *http://www.usdoj.gov/opa/pr/2008/June/08-civ-496.html*, accessed 21 August 2008.

Alabama. On 19 June 2008, in the case of *State of Alabama v. AstraZeneca, LP,* the Montgomery County Circuit Court upheld the fraud conviction and $40 million in compensatory damages that Alabama won against AstraZeneca Pharmaceuticals, LP, in a Medicaid drug-pricing suit, but ruled the $175 million punitive damages awarded were unlawfully excessive. The court ruled that state law limits punitive damages to three times compensatory damages and cut the amount down to $120 million. J. Lewis, "Punitive Damages Reduced," 22 June 2008, *http://www.injuryboard.com.aspx?id=242338*, accessed 23 August 2008.

California. On 9 June 2008, the state health department sent cease and desist letters to 13 companies, including 23andMe, deCODEme Genetics, and Navigenics, that offered genetic testing online. The businesses were operating without clinical laboratory licenses, and the genetic tests offered were not clinically validated for accuracy or medical utility. California law requires that all lab tests, including genetic testing, must be ordered by a license physician, but many of the labs were doing testing without a doctor's prescription. Critics believe consumers should not require a doctor's permission to investigate their own genetic information. K. Ravn, "DNA Testing Industry Wrestles with California Law," *Los Angeles Times*, 14 July 2008, *http://www.latimes. com/features/health/la-he-closer14-2008jul14, 1,1444195.story*, accessed 31 July 2008.

The City of Los Angeles filed suit on 16 April 2008 alleging that Anthem Blue Cross engaged in a widespread pattern of false advertising and fraud. The complaint alleges that the insurer's coverage is largely illusory and sold to consumers based on false promises, and accuses Anthem Blue Cross of concealing a scheme to renege on policies for those diagnosed with serious medical conditions, including cancer and congestive heart failure. The City of Los Angeles is seeking damages totaling $1 billion. L. Girion "Anthem Blue Cross sued over rescissions,"

Los Angeles Times, 17 April 2008, *http://www.latimes.com/business/la-fi-insure17apr17,0,3901131.story*, accessed 8 August 2008.

Massachusetts. Blue Cross and Blue Shield of Massachusetts and MassHealth, the state Medicaid program, announced that hospitals and doctors who operate on the wrong limb or give a dangerous dose of medication will no longer be able to bill them for costs related to fixing the error. Health policy analysts said the move represents the boldest attempt by any state to use payments to reduce preventable life-threatening errors. S. Smith, "Medical Mistakes No Longer Billable," *Boston Globe*, 19 June 2008, *http://www.boston.com/news/local/ articles/2008/06/19/medical _mistakes_no_longer_billable*, accessed 8 August 2008.

Michigan. On 14 May 2008, a Michigan administrative law Judge David Lick ruled that Blue Cross Blue Shield (BCBS) of Michigan would not be justified in increasing premiums by 24 percent to 42 percent for individual health insurance plans. BCBS of Michigan is a not-for-profit company and the state's insurer of last resort. As such, is and must seek state approval for all premium rate increases. Kaiser Family Foundation, "Michigan Judge Rules Against Blue Cross Blue Shield Rate Hikes, Cites Large Surplus," 16 May 2008, *Kaiser Daily Health Policy Report*, *http://www.kaisernetwork.org/Daily_Reports/rep_index.cfm?DR_ID=52196*, accessed 8 August 2008.

Recent Developments in Law and Regulation
April - June 2008

Federal. On 20 May 2008, the Senate issued a new version of the Physicians Payments Sunshine Act of 2007. The revised bill would require drug and medical device manufacturers to publicly report payments and gifts to physicians. The previous bill required all gifts valued at $25 or more to be disclosed, but that amount has been revised to $500. The legislation would require companies to begin disclosing payments on 31 March 2011. S. 2029, 110th Cong. (1st Sess. 2007). A companion bill was introduced in the House on 13 March 2008. The House bill would not only fine companies that knowingly fail to report these payments and gifts with a penalty of $10,000 to $100,000 for each infraction but would also bar the companies from taking tax deductions on advertising for that year. H.B. 5605, 110th Cong. (2nd Sess. 2008).

*There has been no action on a bill introduced in the Senate on 6 September 2007 that would require drug, medical device, 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).

On 2 April 2008, a bill was introduced that would require the VA to make several changes to improve care for female veterans. The VA would be required to have a women's health expert on staff at each facility, and VA mental health professionals would have to be trained to treat sexually assaulted women. The bill authorizes several studies, including one that would focus on the physical, mental and reproductive health of women returning from Iraq and Afghanistan, and another which would examine women's barriers to healthcare access at VA clinics. S. 2799, 110th Cong. 2nd Reg. Sess. (2008).

On 3 April 2008, the Center for Medical Standards, a branch of the U.S. Department of Health and Human Services, released a final rule that updates requirements and standards of care for Medicare-approved dialysis facilities nationwide. The current requirements were first published in 1976. The revised requirements will reflect the clinical and scientific advances since then and focus on patients' rights, safety and participation. Dialysis centers will have up to 180 days to comply with the new requirements. Kaiser Family Foundation, "CMS Issues Final Rule To Update Dialysis Center Standards," 4 April 2008, *Kaiser Daily Health Policy Report*, *http://www.kaisernetwork.org/DAILY_REPORTS/rep_index.cfm?DR_ID=51361*, accessed 8 August 2008.

On 18 June 2008, the Center for Medical Standards, a branch of the U.S. Department of Health and Human Services, announced plans for a five-star rating system to help consumers make more informed decisions when selecting a nursing home. CMS will seek comments from the nursing home

industry and consumers to decide the specific criteria for the ratings. Ratings will be available on the Medicare website by the end of the year. Kaiser Family Foundation, "Bush Administration Announces Quality Rating System for Nursing Homes," 19 June 2008, Kaiser Daily Health Policy Report, *http://www.kaisernetwork.org/DAILY_REPORTS/rep_index.cfm? DR_ID=52839*, accessed 8 August 2008.

On 21 May 2008, the Disabled American Veterans (DAV) proposed a bill to ensure predictable funding for the VA at a hearing in the Senate Veterans' Affairs Committee. Under this proposal, lawmakers would approve funds for medical care in the VA's budget one year in advance. The proposal was presented as an alternative to S. 2639, introduced in February, which would make VA healthcare funds mandatory. R. Tiron, "Veterans' Groups Pushing for More Predictable VA Funding," *The Hill*, 19 May 2008, *http://thehill.com/business—lobby/veterans-groups-pushing-for-more-predictable-va-funding-2008-05-19.html*, accessed 16 August 2008.

Colorado. Colorado Springs-based Coast Independent Review board had its right to grant expedited approval revoked after allegations it violated FDA regulations to protect patients in medical research. 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 appointed to review the ad approved it without any change, 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.

***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 the Private Sector

According to a report released by the Association of American Medical Colleges, medical schools should not allow pharmaceutical or medical device companies to provide food, gifts, or travel to physicians, faculty members, or students. Such "forms of industry involvement tend to establish reciprocal relationships that can inject bias, distort decision-making and create the perception among colleagues, students, trainees and the public that practitioners are being 'bought' or 'bribed' by industry." Most medical schools follow AAMC recommendations, but they may decline to adhere to them. Kaiser Family Foundation, "Association of American Medical Colleges Proposes Ban on Pharmaceutical Company Gifts to Physicians, Staff, Medical Students," 28 April 2008, *Kaiser Daily Health Policy Report*, *http://www.kaisernetwork.org/dailyreports repindex.cfm?DR_ID=51788*, accessed August 8 2008.

Interesting Developments in Other Countries

Britain. The pharmaceutical company Reckitt Benckiser is accused of cheating the National Health Service. Internal memos leaked by a whistle-blower within the company 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 (about U.S.$78 million), but a generic version of the drug was never developed, even though Gaviscon was out of patent for 10 years. Reckitt's accusers say that the leaked memos reveal this is due to deliberate manipulation of the patent process by Reckitt, via "evergreening," a method by which a company repeatedly files for revised patents on existing products that extend the 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.

Letters

Response to Stump, Klugman, and Thornton, "Last Hours of Life: Encouraging End-of-Life Conversations"

To the Editor. — The article by Stump and colleagues proposes an interesting approach to end-of-life conversations based on the Last Hours of Life worksheet.[1] Topics covered in this worksheet include the tasks the patient still wants to accomplish in life, the patient's fears about death, the setting where the patient wants to die, the patient's preferred state of mind for the moment of death, and those people the patient wants at the bedside at that moment. The authors report data from piloting the worksheet at seminars and lectures for health professionals from Nevada, California, and Oregon.

As intriguing as this worksheet is, we were surprised that the study design and data analysis did not consider culture. Health professionals in the western U.S. surely constitute a particular culture with specific values, beliefs, and behaviors by which they interpret life experiences. Perhaps some of our prior research can add a helpful, cross-cultural perspective on end-of-life conversations.

We studied seriously ill inpatients' beliefs about important considerations for end-of-life decisions. We recruited subjects by ethnic group and gender. Striking differences in beliefs occurred by both kinds of culture. For ethnic culture, African Americans (AAs) distinguished themselves in three ways from Mexican Americans (MAs) and Euroamericans (EAs).[2] First, unlike the other two ethnic groups, AAs preferred not to talk about end-of-life matters before imminent death. (Of course, the risk of honoring this preference is that imminently dying patients may no longer be able to discuss those matters.) Second, unlike MAs and EAs, AAs virtually never refused life support even when functional outcomes would likely be poor. And third, unlike the other groups, AAs did not spontaneously acknowledge organ donation as an important benefit to others or express a willingness to donate.

Other differences characterized the gender cultures across ethnic groups.[3] For example, men focused almost completely on predicted, acceptable functional capacities. Yet women took into account not only predicted, acceptable functional capacities but also factors such as meaningful times or places to die and the psychological or economic burdens their deaths might place on their families.

Our results highlight certain parts of the Last Hours of Life worksheet for further research. Specifically, it should elaborate the impact on terminal care wishes of subjects' views about specific functional capacities, family dynamics, or beliefs about the body. More importantly, future research with the worksheet should focus more on patients than health professionals, and take explicit account of ethnic and gender cultures. We await with interest the results of this additional research.

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NOTES

1. B.F. Stump, C.M. Klugman, and B. Thornton, "Last Hours of Life: Encouraging End-of-Life Conversations," *The Journal of Clinical Ethics* 19, no. 2 (Summer 2008): 150-9.

2. H.S. Perkins et al., "Cross-Cultural Similarities and Differences in Attitudes about Advance Care Planning," *Journal of General Internal Medicine* 17 (2002): 48-57; H.S. Perkins et al., "Exploring Chronically Ill Seniors' Attitudes about Discussing Death and Postmortem Medical Procedures," *Journal of the American Geriatrics Society* 53 (2005): 895-900.

3. H.S. Perkins, J.D. Cortez, and H.P. Hazuda, "Advance Care Planning: Does Patient Gender Make a Difference?" *American Journal of the Medical Sciences* 327, no. 1 (2004): 25-32.

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